Chapter 28
The Peritoneal Dialysis Outcomes and Practice Patterns Study

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Introduction

Kidney failure is a leading contributor to the global public health burden with over 2.6 million people requiring kidney replacement therapy (KRT) or kidney transplantation [1]. Peritoneal dialysis (PD) is a form of KRT that is currently utilized by approximately 11% of maintenance dialysis patients worldwide [2] with an average of 20.8 people per million population (pmp) initiating PD each year treated by approximately 1.3 PD centers pmp [3]. PD is a cost-effective treatment [4, 5] which is associated with an initial survival advantage [6, 7] and offers patients a flexible, home-based therapy with increased treatment autonomy [8, 9]. Since the mid-1990s, there have been progressive improvements in patient survival on PD, which have outstripped those observed on HD [10, 11]. Over the same period, there have been concomitant improvements in PD technique survival, with progressively fewer patients transferring to hemodialysis [10]. However, technique survival varies widely both within and between countries, with 3-year rates ranging from 29%

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in Malaysia to 91% in China [2, 12]. This variation is not fully explained by case-mix, suggesting that other factors, such as center practices, may play a role [13–15]. Technique failure has a major disruptive impact on the lives of patients and their caregivers, results in appreciable morbidity and mortality, and has been identified by clinicians and patients as a top research priority [16–18]. Technique failure also incurs considerable cost to healthcare systems, as evidenced by a Canadian study which showed that PD technique failure within the first 3 years resulted in a similar cost burden to patients treated with HD alone, thereby obviating the overall financial benefits that PD provides compared with HD [19]. As technique failure still remains one of the major factors limiting both the utility and utilization of PD as a therapy around the world [2, 12, 20–22], it is imperative that the factors underpinning technique failure are comprehensively identified and, where possible, mitigated.

This chapter will examine the importance of the problem of PD technique failure and provide an overview of the current status and early findings of the Peritoneal Dialysis Outcomes and Practice Patterns Study (PDOPPS), the prime objective of which is to identify modifiable practices associated with superior PD technique survival.

The Problem of Technique Failure

One of the key difficulties with technique failure is that there is significant variation in how it is defined in the published literature [23]. In particular, there is marked variation regarding when PD is considered to start and when it is considered to end. Although not often defined at all, some groups define PD to have started with the first exchange (e.g., the *Registre de Dialyse Péritonéale de Langue Française*), while others define it as the end of PD training (Brazilian PD study, BrazPD) [23]. A number of groups, such as USRDS, do not count PD at all unless patients were on that modality at 90 days following dialysis initiation, despite the fact that the first 90 days are a high-risk period for technique failure [24, 25]. Most studies also do not define how long a patient has to be off PD to qualify as a technique failure [23]. A recent Australia and New Zealand Dialysis and Transplant (ANZDATA) registry study explored a range of definitions used to describe PD technique failure and ultimately recommended that PD technique failure be standardly defined as a composite end point of transfer to hemodialysis for at least 30 days or death (either on PD or within 30 days of ceasing PD) [26]. They also recommended a secondary definition using a time window of 180 days, which provides additional information on the likelihood of return to PD [26]. Additional time windows, e.g., 60 days, may be reported. Having a standardized definition of technique failure is critical to benchmarking between centers and countries and to properly elucidating patient-level and center-level characteristics associated with technique failure.

The most commonly recognized patient-related risk factors for technique failure include younger age, higher body mass index, Indigenous race, lower socioeconomic status, and comorbidities (such as diabetes) [15, 27–33]. However, recent studies

have demonstrated that center-level characteristics may play an even more significant role in PD technique failure variability [34]. Schaubel et al. collated data from the Canadian Organ Replacement Register and observed that a dialysis unit's experience in treating PD patients had a significant impact on PD outcomes [35]. Overall, as the cumulative number of patients treated with PD increased and as the percentage of patients initiated on PD increased, mortality and technique failure rates both decreased [35]. Other registry-based studies completed in France, Netherlands, Brazil, Canada, and the United States have similarly shown a correlation between smaller PD center size and higher technique failure rates [35–39]. These findings were further distinguished in a systematic review by Pieper et al. which concluded that larger center volume was associated with an improved technique survival [40]. In an ANZDATA registry study of 9362 patients from 51 centers in Australia, Htay et al. observed sevenfold variation in technique failure across centers which was predominantly accounted for by modifiable, center-level factors (such as PD unit size and proportion of patients treated with PD) rather than patient characteristics [34]. Indeed, center variation in PD technique failure was reduced by 28% after adjusting for patient-specific factors and by a further 53% after adjusting for center-specific factors [34]. Similar findings were observed for rates [27] and outcomes [41] of peritonitis, which is the major cause of PD technique failure after death. These findings suggest the possibility that PD technique failure is strongly influenced by modifiable center characteristics relating to their practice and/or organization.

Another piece of evidence suggesting that PD technique failure is driven by modifiable center characteristics is the evidence that implementation of national quality initiatives has been associated with substantial improvements in technique survival rates. The best example of this is the Australian and New Zealand peritonitis continuous quality improvement (CQI) initiative, which involved generating better evidence to inform peritonitis guidelines, facilitating better translation of evidence and guidelines into clinical practice, and establishing CQI processes at local, state, and national levels through improved outcomes monitoring with quarterly audit and feedback, identification of barriers and enablers through implementation research, improved education targeting early career nephrologists, development of standardized peritonitis pathways, and incentivizing performance improvement [42]. These initiatives were quickly followed by a one-third reduction in peritonitis rates, a one-half reduction in between-center peritonitis rate variation, and a significant improvement in PD technique survival [42].

Due to the cumulative evidence that center-level characteristics are a significant driver for PD technique failure, a better understanding of the modifiable causes of PD technique failure is required. A limitation of the aforementioned studies is that they largely relied on information collected by registries, which lacked sufficient granularity of data (particularly in relation to center organization and practices) to comprehensively address this issue. With this in mind, PDOPPS was established as a global collaboration between the Arbor Research Collaborative for Health and the International Society for Peritoneal Dialysis (ISPD) to understand variation in PD practices and outcomes, identify optimal practices, and ultimately improve outcomes for patients treated with chronic PD [23].

PDOPPS: Design and Rationale

Rationale

Based on the findings of the aforementioned studies, the basic tenet of PDOPPS is that variable (and often poor) PD technique survival rates are driven by variable (and often poor) PD center practices, such that identifying those modifiable practices associated with superior PD outcomes (including PD peritonitis-free survival and technique survival) will help to better inform clinical practice and ultimately patient outcomes.

PDOPPS builds on the successful methodology established by Dialysis Outcomes and Practice Patterns Study (DOPPS), which was originally formed in 1996 to study in-center HD patients and practices [43]. The primary objective of DOPPS was to improve HD patients' morbidity and mortality outcomes, inform policy changes, as well as influence patients' health-related quality of life [43]. DOPPS has helped shape HD practices on a global scale and still remains a leading resource for the nephrology community worldwide with comprehensive data that have influenced clinical practice guidelines for HD [43–49]. DOPPS initially started with 308 HD units from 7 different countries [44] at initiation and then expanded to 21 countries, 580 facilities, and over 30,000 census patients by 2015 [50]. This large prospective cohort study has led to important practice policy changes such as the fistula first policy and strategies for improved management of anemia [51–53], mineral and bone disorders [54, 55], and quality of life among HD patients [56–58]. The program has now been expanded to include patients with chronic kidney disease (CKDopps) [59] and patients receiving peritoneal dialysis (PDOPPS) [23]. All three of these major projects share the common goal of identifying measurable differences in facility practices that will help inform strategies to improve patient outcomes.

Design

The PDOPPS is an international prospective cohort study of PD patients over the age of 18, which began recruitment in 2013. The primary outcome is all-cause PD technique failure, and the secondary outcomes include all-cause mortality, hospitalization rates, PD-related complications, patient-reported outcomes, and cause-specific technique failure [23]. The overall objective is to identify differences in clinical practice between centers to improve PD outcomes as well as to generate scientific hypotheses for the variations found in the study [23].

During the initial phase (Phase 1) that extended from 2013 to 2016, PDOPPS randomly selected at least 20 different PD centers with at least 20 prevalent PD patients from each of the 7 different countries (Australia, New Zealand, Canada, Japan, Thailand, the United Kingdom, the United States) (Fig. 28.1). At study initiation, all centers completed a census of their PD patients from which 20–30 prevalent patients were randomly selected independent of the dialysis unit's size. A maximum

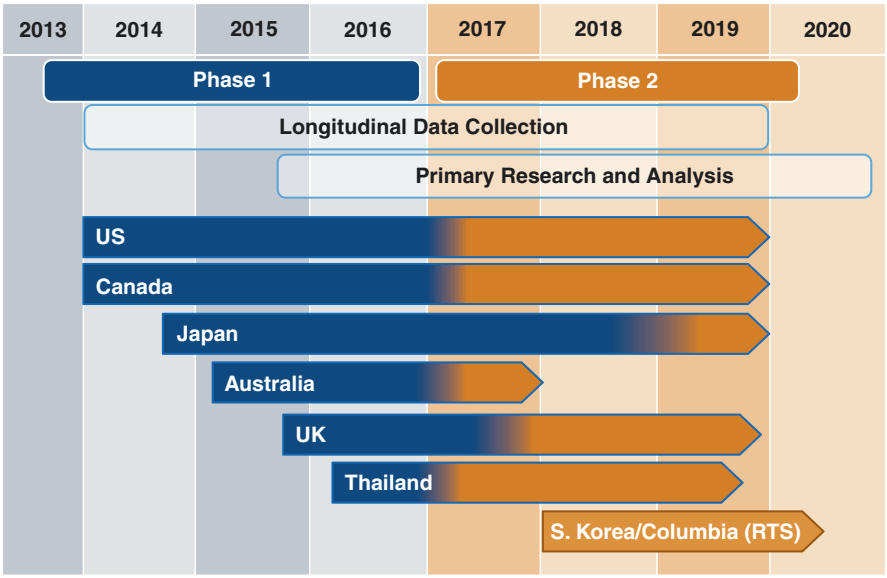

Fig. 28.1 Country participation and timelines for PDOPPS

of 25 incident patients (defined as patients initiating PD within 30 days of the PDOPPS census date and receiving at least one PD treatment at home or a nursing home) were also included. Patients continued to be followed up until kidney transplantation, transfer to a different dialysis unit, permanent hemodialysis transfer (>4 months), kidney function recovery, death, or PDOPPS ends. If patients left the study, they were replaced by randomly chosen patients (on an annual basis) who had entered the dialysis center since the last sampling period [23]. Within each country, national funding was utilized for data collection [23, 60]. All of the original seven countries, except for Australia and New Zealand, and two new countries (South Korea and Colombia) have participated in extended follow-up during phase 2 (2017–2020), during which the cohort has been enriched with incident patients (Fig. 28.1).

Study Data and Collection Instruments

The data collected by PDOPPS using patient and facility questionnaires have been developed by six workgroups in the areas of infection prevention and management, patient support, PD catheter access and function, PD training and education, dialysis prescription and fluid management, and clinical application of PD therapy (Fig. 28.2). These workgroups consist of key international content experts who were carefully selected by the ISPD and Arbor Research Collaborative for Health to ensure diverse representation of disciplines, gender, ethnicity, and geographic regions.

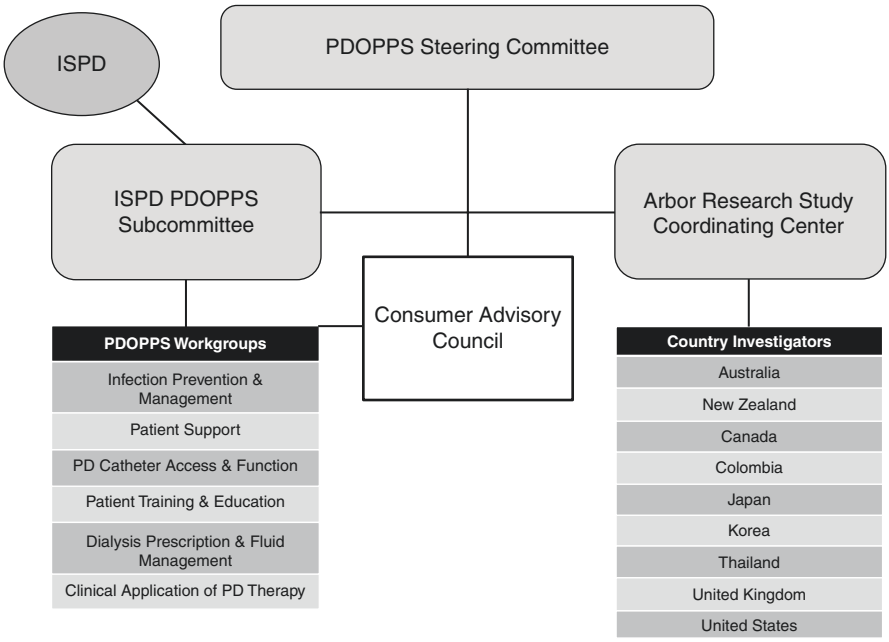

Fig. 28.2 PDOPPS organizational structure

Data collected by PDOPPS are depicted in Fig. 28.3. Demographic data, medical comorbidities and history, PD treatment, PD-related infections, and hospitalizations were collected at study enrolment. PD-related events or treatment changes were collected during follow-up by an interval summary questionnaire which was completed for each patient every 4 months. Furthermore, a standardized questionnaire was completed by patients, which focused on their quality of life and treatment satisfaction and was updated annually. From a center-level perspective, data collection forms were completed by the nurse unit manager and medical director to capture specific unit practices and clinical outcomes. All data were collected using standardized data collection procedures and tools, entered into an online data entry system (PDOPPSLink), and electronically submitted to the data management center at Arbor Research Collaborative for Health [23].

Analysis

Analytic methods used in PDOPPS have been described in detail previously [23]. Associations between practices and outcomes will be analyzed at both patient and center levels. In order to address possible bias introduced by unmeasured patient-level confounders, an instrumental variable analysis will also be applied, as has been done in other published DOPPS research [46]. Facility-based instrument variable

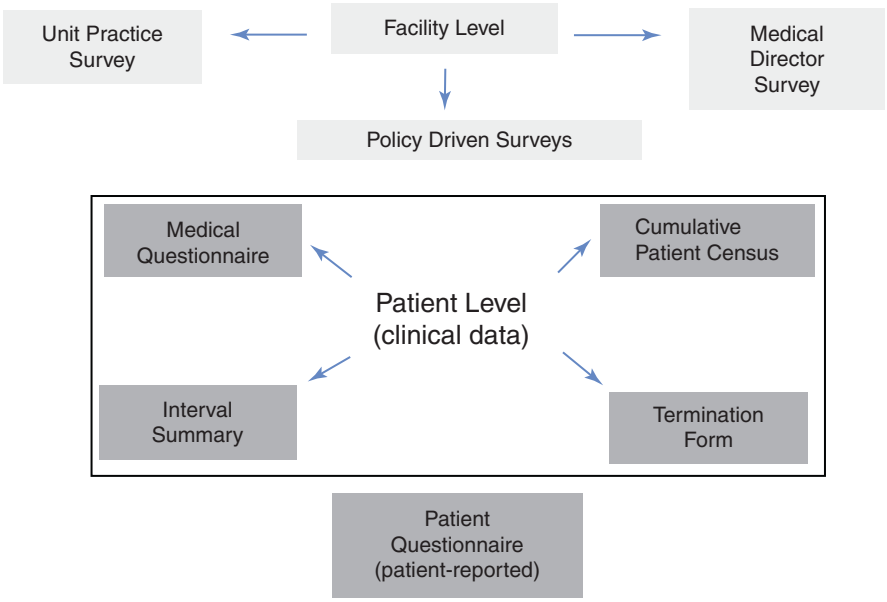

Fig. 28.3 Data collected by PDOPPS

analysis relies on the fact that patients are assigned to the facility's treatment preferences in a "quasi-random" fashion, which is independent of unmeasured patient-level confounders and therefore allows more valid estimates of treatment effects.

Ancillary Studies

PDOPPS provides an important opportunity for investigator-initiated ancillary studies to be conducted. Groups are able submit proposals for analysis of existing PDOPPS data or new data collection in collaboration with PDOPPS. These proposals are reviewed and approved by the PDOPPS Steering Committee. To date, four ancillary studies have been approved:

(a) The "Empowering Patients on Choices for Renal Replacement Therapy Study" (EPOCH-RRT), which aims to compare the effectiveness of hemodialysis and PD with respect to patient-centered outcomes and to develop a decision aid to assist patients with dialysis modality selection
(b) "Biological Determinants of Peritoneal Dialysis Outcomes" (BIO-PD), which aims to identify and validate genetic variants that explain the interindividual variability in peritoneal membrane function in patients undergoing PD
(c) "Optimizing Early Dialysis Catheter Function" (UKCath Study), which aims to establish the determinants of early PD access function, in particular "medical"

versus "surgical" insertion methods and their associated treatment pathways, with the intention of improving PD access outcomes

(d) "Optimizing Prevention of PD-Associated Peritonitis in the US" (OPPUS), which aims to identify patient and PD facility characteristics that are associated with PD peritonitis risk in PD patients and to foster the development and implementation of a standardized peritonitis definition and evidence-based best practice guidelines into dialysis provider organization clinical care pathways and national quality improvement initiatives with the aim of better preventing peritonitis

Current Status of PDOPPS

The initial countries participating in PDOPPS included Australia, New Zealand, Japan, the United Kingdom, Thailand, Canada, and the United States. During phase 1, 7629 patients were recruited from 215 dialysis units across the 7 countries. The study has evolved over time, and now a total of 11,688 patients have been consented for the study. The number of patients enrolled in PDOPPS from each country and the overall facility enrolment summary are summarized in Table 28.1. Additional countries joining PDOPPS in phase 2 include South Korea and Columbia.

Having multiple countries participate in PDOPPS provides a diversity of patients, PD practices, and cultures that can be evaluated throughout the study. In particular, PDOPPS contains a mix of high-income countries (Australia, New Zealand, Canada, Japan, South Korea, the United Kingdom, the United States) and low- and middle-income countries (Colombia, Thailand) from the major regions of the world (North America, South America, Europe, Asia, and Oceania). It also contains a mix of countries with different PD policies including PD-first (Thailand), PD-favored (Canada, the United States), home-based dialysis-first (Australia, New Zealand), and hemodialysis-favored (Japan) approaches [61, 62]. This greatly enhances the

Table 28.1 PDOPPS center and patient enrolments (as of 31 October 2018)

Country	Centers enrolled	Patient enrolment status	
		Census patients	Consented
Australia	19	2097	520
New Zealand	2	341	73
United States	100	8787	3981
Canada	20	3286	925
Japan	32	1664	923
Thailand	22	4644	820
United Kingdom	20	2266	387
Colombia	56	4059	4059
PDOPPS total	271	27,144	11,688

South Korea has not commenced enrolment yet

generalizability of PDOPPS' findings and facilitates comprehensive evaluation of the impact of different practices and policies on PD outcomes. It also allows the examination of unique country practices, such as hybrid dialysis (a combination of PD and HD), which is utilized in approximately one-fifth of patients on PD in Japan but almost not at all in other countries [23, 63]. Moreover, the impact of any policy changes, for example, arising out of the OPPUS project, will be comprehensively evaluated via the PDOPPS platform.

Early Findings from PDOPPS

The findings collated in phase 1 of PDOPPS have thus far resulted in 19 abstracts presented at multiple international conferences and symposia, 15 published studies, and manuscripts in preparation [23, 60, 64, 65]. Some early findings from PDOPPS have been detailed below according to clinical workgroup.

Infection Prevention and Management

The infection prevention and management workgroup recently examined variations in prevention and treatment of PD-related infections in 170 centers caring for more than 11,000 patients in 7 countries [64]. The practices of each PDOPPS country were further compared against practices recommended by the ISPD guidelines, particularly with respect to monitoring the incidence of peritonitis and using prophylactic antimicrobials in the prevention of PD-related infections and empirical treatment of suspected peritonitis. Units consistently recorded and tracked peritonitis episodes in only five countries (Australia, New Zealand, Canada, the United Kingdom, and the United States), while Australia and New Zealand were the only countries in which 100% of PD units recorded and tracked exit site infections. Substantial practice variation was also observed in the use of daily topical antimicrobial prophylaxis (mupirocin or aminoglycoside) by PD units across Australia and New Zealand (ANZ, 94% of units), the United States (88%), Canada (80%), the United Kingdom (71%), Thailand (27%), and Japan (4%). This variation is difficult to understand given the strength of the practice recommendation by the ISPD guidelines (level 1B). Another key finding established was the suboptimal co-prescription of antifungal prophylaxis when PD patients received antibiotic courses to prevent fungal peritonitis, despite this being a level 1B ISPD guideline recommendation. No antifungal prophylaxis was prescribed at all in appreciable proportions of PD centers in ANZ (11%), Canada (45%), the United States (46%), Thailand (77%), the United Kingdom (88%), and Japan (93%). There was also variable administration of prophylactic antibiotics prior to PD catheter insertion despite this having a level 1A ISPD guideline recommendation. The lowest uptake of this guideline was in the

United States (63%), and highest adherence was observed in the United Kingdom and Canada (100%). Considerable differences in facility adherence were also observed in the administration of prophylactic antibiotics prior to other invasive procedures, although these variable uptakes may have been explained by the limited quality and strength of the evidence in this area (levels 2C and 2D). Overall, this study highlighted the significant variations in PD peritonitis prevention and treatment practices among the participating countries, which often deviated from ISPD guideline recommendations.

The group has gone on to examine the association between selected facility practices and peritonitis rates. While the overall peritonitis rate averaged across the seven PDOPPS countries was 0.28 episodes per patient-year, country-specific rates ranged from 0.24 episodes per patient-year in the United States to 0.40 episodes per patient-year in the United Kingdom. Preliminary findings suggest that peritonitis risk is generally not associated with facility size, is lower with APD use, and is higher with failure to use preoperative prophylactic antibiotics prior to PD catheter insertion and possibly failure to use either topical exit site mupirocin or aminoglycoside ointment. These early observations suggest that poor adherence to specific clinical practice guideline recommendations was associated with a higher peritonitis risk.

Patient Support

The PDOPPS patient support workgroup has developed research questions that highlight patient-reported issues. A key focus of the group was functional impairment among PD patients, aiming to identify if there was variation between countries and if this is associated with permanent transfer to hemodialysis or higher mortality rates. Tennankore et al. assessed patient's functional status via two self-reported questionnaires which were combined to create an overall score [65]. The study observed that functional impairment was highly prevalent among patients on PD, with significant differences between the participating PDOPPS countries. Patients in Thailand were shown to have the highest functional impairment, and Japan had the lowest. The study also established that impaired functional status was strongly associated with higher mortality rates; however, functionally impaired patients did not have an increased risk of permanent transfer to HD [65].

In a separate investigation, the workgroup has identified that patients reported a generally favorable perception of PD, with the most commonly reported advantages being home-based treatment and the lack of vascular cannulation, while the most commonly reported disadvantages were a feeling of abdominal fullness and PD fluid storage space requirements. Those patients seeing PD as more disadvantageous were more likely to be depressed, have a lower quality of life, and experience a transition to hemodialysis.

PD Training and Education

Significant variability has been found between countries in the delivery of training to PD patients. Striking differences were seen in the duration of PD training sessions with the majority of patients from Japan (88%) being trained for less than 2 hours and for 2–3 days (39%). In contrast, in Australia, 64% of patients received training sessions lasting up to 6 hours and typically over a 4–5-day period (69%). Interestingly, Japan also appeared to differ in the timing of training with 62% of patients having their training prior to PD catheter insertion, while most other countries confined training to after PD catheter insertion, typically following a period of 2–3 weeks. Canada (84%) and Japan (100%) predominantly trained patients in facilities, while Australia (57%) and the United Kingdom (50%) trained patients using a combination of home and facility. Future studies will evaluate the relationship between PD training practices and outcomes.

Dialysis Prescription and Fluid Management

Early findings from this workgroup have similarly shown that both PD prescriptions and the types of PD utilized were highly variable between the different PDOPPS countries. Most countries had a predominance of automated peritoneal dialysis (APD) use over continuous ambulatory peritoneal dialysis (CAPD) with utilization rates in the United States and Canada being 81% and 71%, respectively. However, in Thailand, the majority of PD patients were treated with CAPD (96%). Among the patients receiving APD, there were a broad number of exchanges that were prescribed to patients such that almost half of the PD patients in the United States and the United Kingdom were prescribed five or more exchanges overnight compared with 39% of patients receiving less than three exchanges in Japan. Similar degrees of national variation in practices were observed in the total dialysis volume prescribed, use of biocompatible solutions (including icodextrin), and the average concentrations of glucose employed.

Conclusion

PDOPPS is the largest and most comprehensive PD study to date. This multinational study has collected data and produced research, which will be extremely valuable to the PD community and help to provide strong evidence for improvements in PD practices. The formation of PDOPPS is unique in that it collaborates with multiple countries to create a diverse body of data for clinical research. Phase 1 has already documented wide variations in clinical practice that cannot be accounted for

by patient factors as well as variation in important outcomes such as infection. The next step (Phase 2) will establish how these variations in practice associate with the primary outcome, technique failure. Future directions for PDOPPS remain vast, and the potential for further research opportunities, protocol establishment, and improvement of national and international guidelines are ongoing, providing an invaluable resource for clinicians, patients, and their caregivers.

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