

# Design of the standardizing care to improve outcomes in pediatric end stage renal disease collaborative

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**Abstract** The Standardizing Care to Improve Outcomes in Pediatric End Stage Renal Disease (SCOPE) Collaborative is a North American multi-center quality transformation effort whose primary aim is to minimize exit-site infection and peritonitis rates among pediatric chronic peritoneal dialysis patients. The project, developed by the quality improvement faculty and staff at the Children’s Hospital Association’s Quality Transformation Network (QTN) and content experts in pediatric nephrology and pediatric infectious diseases, is modeled after the QTN’s highly successful Pediatric Intensive Care Unit and Hematology-Oncology central line-associated blood-stream infection (CLABSI) Collaboratives. Like the Association’s other QTN efforts, the SCOPE Collaborative

is part of a broader effort to assist pediatric nephrology teams in learning about and using quality improvement methods to develop and implement evidence-based practices. In addition, the design of this project allows for targeted research that builds on high-quality, ongoing data collection. Finally, the project, while focused on reducing peritoneal dialysis catheter-associated infections, will also serve as a model for future pediatric nephrology projects that could further improve the quality of care provided to children with end stage renal disease.

**Keywords** Pediatric · Dialysis · Peritonitis · Infection · Improvement

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## Introduction

Chronic peritoneal dialysis (CPD) is the most common dialysis modality utilized for children with end stage renal disease (ESRD) worldwide [1, 2]. Peritoneal dialysis (PD) catheter-related infections, including exit-site infection and peritonitis, are the most significant complications of CPD, and peritonitis is a leading cause of hospitalization, termination of CPD, and death among pediatric CPD patients [3–6]. Although internationally developed guidelines for the prevention and treatment of PD catheter-related infections include recommendations for best-care practices for PD catheter insertion, patient and family training, and long-term PD catheter care, variation in the application of these and other PD-related guidelines likely exists [7]. In turn, data from national and international registries reveal significant variability in peritonitis rates among centers caring for pediatric CPD patients [3, 8]. An analysis of center-specific peritonitis rates between 2003 and 2008 in 35 centers with more than 10 years of follow-up data submitted to the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) registry revealed a mean peritonitis rate

of one episode every 28.1 patient-months (95 % confidence interval 25.8–30.9). However, the peritonitis rates in these pediatric CPD centers ranged from one episode every 9.7 patient-months to one episode every 90.1 patient-months (K. Martz, EMMES, personal communication 2014). These data suggest practice variability in care and the potential to improve peritonitis and catheter exit site infection rates by implementing a more uniform approach to PDA items to be included at each monthly visit catheter management.

We therefore developed a quality transformation collaborative effort to standardize PD catheter care and labeled it the Standardizing Care to Improve Outcomes in Pediatric End Stage Renal Disease (SCOPE) Collaborative. It was developed under the guidance of the quality improvement experts at the National Association of Children's Hospitals and Related Institutions (NACHRI), now part of the Children's Hospital Association (hereafter referred to as the Association). The SCOPE Collaborative is one of several projects operated through the Association's Quality Transformation Network (QTN). Using a model characterized by collaboration combined with rigorous methodologies, tightly coordinated implementation, and large data sets of process and outcome metrics with monthly reporting cycles, QTN's participating centers are achieving healthcare improvements at a lower cost, more efficiently, and faster than any single hospital can achieve working independently. (9–11)

The primary hypothesis of the SCOPE Collaborative is that the rate of PD catheter-related infections can be reduced in participating centers by increasing the implementation of best practices for PD catheter care. The specific aims of the SCOPE Collaborative project are to minimize exit-site infection and peritonitis among children on CPD. In this article, we describe the design and structure of the SCOPE Collaborative.

## Design and methods

### Overview of study design and collaborative structure

#### *Best-care "Bundles"*

Central to the specific aim of this project is the standardization of PD catheter care. The collaborative has focused on three areas of catheter care: catheter insertion, training of patients and their care-givers, and maintenance care or follow-up. The specific practices included in each of the care "Bundles" were developed by a team of pediatric dialysis, pediatric quality improvement, and pediatric infectious diseases experts using published registry data, consensus guidelines, and the expert opinion of the faculty involved, with significant feedback from the pediatric nephrology community via webinars, conference calls, and presentations at national and international meetings [7, 12–23]. The specific care elements included in

the Peritoneal Dialysis Catheter Insertion Bundle, the Peritoneal Dialysis Patient and Care Giver Training Bundle, and the Peritoneal Dialysis Catheter/Exit-Site Follow-up Care Bundle are shown in Tables 1, 2, 3 and Fig. 1. A key driver diagram, detailing the relationship between the interventions, key drivers, and outcomes, is shown in Fig. 2.

#### *Collaborative structure*

The collaborative structure used by the Association and Collaborative participants is characterized by a partnership between the quality improvement coaches and staff at the Association, a multi-disciplinary, multi-institutional core faculty comprised of two pediatric nephrologists, a pediatric infectious diseases specialist, and two pediatric dialysis nurses/educators, and the healthcare providers and staff at 29 participating pediatric dialysis centers throughout the USA (Table 4). These centers provide a diverse pediatric (aged birth through to 22 years) dialysis population from both urban and rural locations. Center size ranges from 3 to 50 patients. Each of these centers has the committed participation of a multi-disciplinary team, consisting of at least one pediatric nephrologist and one pediatric dialysis nurse/educator. Other team members may include infectious diseases specialists, infection control faculty or staff, surgeons, quality improvement staff, and unit administrators.

The process used to assist teams to reliably implement best-care practices is centered on extensive coaching, real time and transparent performance data shared among all participants, and the application of quality improvement principles. Two face-to-face "Learning Sessions" are held per year, where teams are educated about best-care practices, and quality improvement tactics such as small tests of change (Plan-Do-Study-Act cycles) to address barriers to the implementation and sustainability of these practices. This education is reinforced with monthly webinars and conference calls, eGroups, one-on-one coaching of teams by the core faculty, monthly data feedback at both the aggregate level and specific PD unit level on process measures (Insertion, Training and Follow up Bundle compliance) and outcome measures (peritonitis and exit-site infection rates), and ongoing sharing of best ideas and barriers/issues among teams using all of the above mentioned forums. Each participating center has agreed to provide support for the travel and time of its team, the hotel/catering costs for the twice-a-year 2-day face-to-face Learning Sessions, data maintenance and analysis, and salary for the SCOPE Collaborative staff and faculty.

The SCOPE Collaborative also includes a partnership between the Association and NAPRTCS. NAPRTCS includes a voluntary registry containing data on >19,000 children with chronic kidney disease from over 100 participating institutions in North America [3]. The Data Coordinating Center of NAPRTCS, the EMMES Corporation, manages the web-

**Table 1** Peritoneal Dialysis Catheter Insertion Bundle

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Intra-operative care

- PD catheter exit-site orientation is in the lateral or downward position
- A single dose of a first generation cephalosporin is given prior to incision
- No sutures are placed at catheter exit site

Post-operative care

- Exit-site dressing is not changed for the first 7 post-operative days, unless soiled, loose or damp and if changed, conducted by a healthcare professional
- Sterile procedure is used for all exit-site dressing changes until the exit-site is healed
- PD catheter is immobilized until exit-site is healed
- PD catheter is not used for peritoneal dialysis for at least 14 post-operative days

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PD, peritoneal dialysis

based data collection and maintenance, data analysis, and reporting for the SCOPE Collaborative. This partnership allows SCOPE to build on the long-standing collaboration between pediatric CPD centers and NAPRTCS and to benefit from nearly 30 years’ experience of data collection and analysis in pediatric kidney disease patients.

*Measures and data*

Compliance with the care practices included in the three Bundles are collected as process measures for the Collaborative. Each dialysis center’s team self-monitors PD catheter insertions, patient/caregiver training sessions, and monthly follow-up visits for pediatric CPD patients followed

**Table 2** Peritoneal Dialysis Patient and Care Giver Training Bundle<sup>a</sup>

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- Training performed by a qualified registered nurse
- Trainer to trainee (or family) ratio 1:1
- Appropriate teaching aides such as photographs, mannequin or apron used during training
- Training should cover all elements specified in ISPD guidelines [7, 12]
- Training should include specific procedures for:
  - hand hygiene according to the world health organization guidelines [24]
  - exit-site care
  - aseptic connection technique
- Post-training concept and demonstration test administered at completion of training and again at one-month post-training visit
- Home visit performed

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ISPD, International Society of Peritoneal Dialysis

<sup>a</sup> The initial patient and caregiver training will include the items as listed here, with details on the training checklist provided in Fig. 1

**Table 3** Peritoneal Dialysis Catheter/Exit-Site Follow-up Care Bundle<sup>a</sup>

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- Objective score of exit-site using International Pediatric Peritoneal Dialysis Network (IPPN) scoring tool (Table 5) (7, 25)
- Review key aspects of each of the following:
  - hand hygiene
  - exit-site care
  - aseptic technique
- Query for touch contaminations or other break in aseptic technique and whether they were treated according to ISPD guidelines [7]
- Repeat concept and demonstration test administered every 6 months
- Patient/care giver receives training after a peritonitis episode

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<sup>a</sup> Items to be included at each monthly visit

in their unit. In addition, catheter care provided to hospitalized CPD patients, including those who have not yet established care in the outpatient setting (e.g., neonates/infants), is monitored. Data on compliance with each of the respective Bundle elements are submitted monthly via a web-based data collection system. Compliance for all three Bundles is assessed as all or none, meaning that each patient’s insertion, training session or follow-up event has to comply with all of the elements of the respective Bundle to be considered compliant.

The outcome measures for the SCOPE Collaborative are the monthly exit-site infection rate and the monthly peritonitis rate. As per the International Society of Peritoneal Dialysis (ISPD) guidelines, an empiric diagnosis of peritonitis is made if the peritoneal effluent is cloudy, the effluent white blood cell (WBC) count is >100/mm<sup>3</sup>, and at least 50 % of the WBCs are polymorphonuclear leukocytes [7, 12]. Relapsing peritonitis, defined as a recurrence of peritonitis with the same organism as in the immediately preceding episode based on antibiotic susceptibilities, or a second culture-negative infection within 4 weeks of completion of antibiotic treatment are not counted as a new infection [7, 12]. A catheter exit-site infection is diagnosed in the presence of a purulent discharge from the sinus tract or as a score of ≥4 using an objective scoring tool to characterize pericatheter erythema, swelling, crust, secretion, and tenderness, with or without a pathogenic organism cultured from the exit site (Table 5) [7, 25]. Infection rates are calculated as per the ISPD guidelines as an annualized rate (number of infections for a time period, divided by peritoneal dialysis-years at risk during that time period, and expressed as episodes per year) and as the interval between infections (peritoneal dialysis-months at risk, divided by number of infections) [7, 12]. Data on number of patients and peritonitis and exit-site episodes (numerators and denominators) and details of the infection events (e.g., causative organism, response to treatment) are also submitted monthly via the web-based data collection tool. For comparative purposes, each team submitted its ‘baseline’ monthly peritonitis and exit-site

	Yes	No
<b>Training Overview</b>		
Teaching aids (photos, hands-on equipment, mannequin or training apron with PD catheter) used?		
Did training cover recommended elements in ISPD Guideline?		
<b>Training Protocol – Hand Washing Procedure</b>		
Include review of WHO alcohol-based handrub procedure?		
Include review of WHO handwash procedure?		
<b>Training Protocol – Exit-Site Care Procedure</b>		
Include washing hands with soap and water according to WHO guidelines?		
Include collecting unopened supplies (cleansing solution, sterile gauze, sterile cotton swab, antibiotic cream, dressing if used), and prepare the work area by cleaning with bleach wipe and/or laying down clean paper towel or clean towel?		
Include performing hand hygiene using WHO alcohol-based handrub procedure?		
Include after hand hygiene, opening supplies onto a clean field to avoid contamination from removing soiled or old dressing?		
Include repeating hand hygiene using WHO alcohol-based handrub procedure if anything other than PD supplies & equipment is touched?		
Include washing exit-site with sterile gauze and antiseptic solution according to manufacturer's instructions and PD center teaching ( <i>circular motion for iodine products or scrubbing motion for others</i> ), and air dry?		
Include placing mupirocin or gentamicin cream on sterile cotton swab and applying to exit-site?		
Include performing exit-site care regularly and whenever exit-site wet or dirty?		
<b>Training Protocol – Aseptic Connection Technique</b>		
Include instructions on washing hands with soap and water according to WHO guidelines?		
Patient instructed to place mask if used.		
Include instructions on performing hand hygiene using WHO alcohol-based handrub procedure?		
Include instructions on after handrub, touching only PD supplies and equipment?		
Include instructions on repeating hand hygiene using WHO alcohol-based handrub procedure if anything other than PD supplies & equipment is touched?		
Include reviewing of "accidental contamination" procedure to be followed if aseptic technique is broken?		
<b>Post-Training Protocol (respond whether this is initial or one-month post-training repeat)</b>		
Post-training concept test administered?		
Post-training concept test passes?		
Post-training demo test administered?		
Post-training demo test passed?		

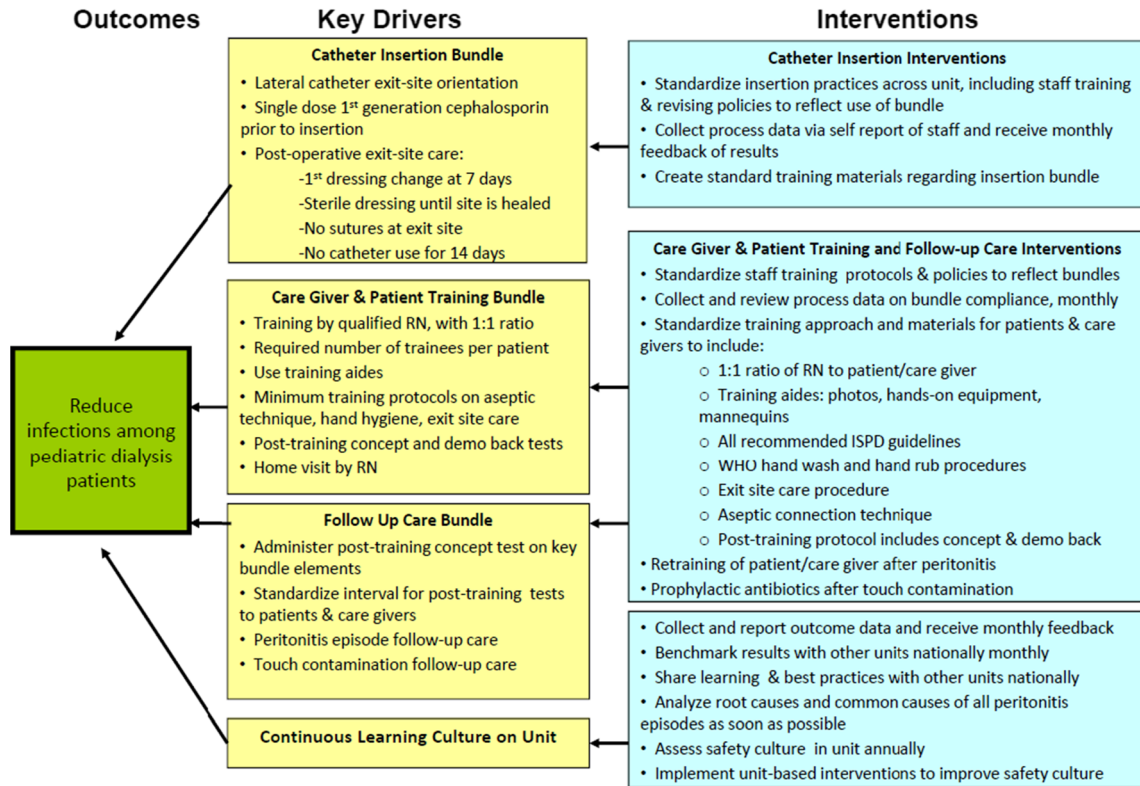
**Fig. 1** Peritoneal dialysis training checklist. WHO, World Health Organization

infection rates for the calendar year prior to the launch of the Collaborative.

For risk stratification exploration, the following additional variables are captured on all patients at the time of enrollment: age, race (white, black, Hispanic, or other), gender, cause of ESRD, and history of previous kidney transplant. The following data are collected at the time of

each catheter insertion: history of screening for and/or treatment of *Staphylococcus aureus* carriage in the patient, characteristics of the PD catheter [exit site orientation (upward/downward/lateral), tunnel configuration (swan neck or straight), intra-abdominal configuration (curled vs. straight), number of cuffs (one vs. two), type of insertion (laparoscopic vs. open) and adapter (plastic or

## SCOPE Collaborative Key Driver Diagram



**Fig. 2** Standardizing Care to Improve Outcomes in Pediatric End Stage Renal Disease (SCOPE) Collaborative key driver diagram

titanium)], and whether other procedures (placement of gastrostomy tube or hemodialysis catheter or other procedure) were performed at the time of catheter placement. The following data are collected at the time of each training session: duration of training session (number of encounters and total time dedicated to training) and the number of individuals trained and their relationship(s) to the patient. The following data are collected at the time of each follow-up visit: type of PD catheter adapter (titanium vs. plastic), presence of gastrostomy tube/button, presence of urinary stoma (continent or incontinent), history of touch contamination, catheter leak or other break in aseptic technique, identity of provider performing dialysis, and type of immobilization device, if used. The following data are collected at the time of each infection: identity of provider performing dialysis and whether that provider was trained to perform PD, dialysis effluent WBC count (for peritonitis) and culture results, history of touch contamination, catheter leak or other break in aseptic technique, and outcome of episode (resolution/removal of catheter/reduction in membrane function/transfer to hemodialysis/death). Finally, prospective data on the cost of treating infections, including hospitalization, are collected in order to provide a health economic assessment.

### Statistical considerations

Monthly annualized peritonitis and exit-site infection rates and compliance with the Bundles will be displayed graphically as a function of calendar time. The primary analysis will estimate the difference between the average baseline infection rates and the average post-intervention (e.g., Bundle implementation) infection rates. Exploratory data analysis will include summarizing (using rates, means, and proportions) and graphically displaying the peritonitis and exit-site infection rate and Bundle compliance over time for each PD center and then as an aggregate across all centers. The distribution of the number of peritonitis episodes will be assessed using descriptive statistics; peritonitis and exit-site infection rates will be summarized as annualized rates with 95 % confidence intervals. Differences between the baseline infection rates and the post-intervention infection rates will be modeled using generalized linear mixed models (GLMMs) and will include a random effect for PD center to accommodate PD center-specific variability in peritonitis rates.

Infection rates at baseline and during the post-intervention will be compared using a generalized Poisson model. A likelihood ratio test will be performed to test the assumption of an equal mean and variance under the standard Poisson

**Table 4** Standardizing Care to Improve Outcomes in Pediatric End Stage Renal Disease (SCOPE) Collaborative participating centers and team leaders (31 December 2013)

Center	Location	Team leaders
American Family Children's Hospital	Madison, WI	Allison Redpath Mahon, Dawn Foster
Lurie Children's Hospital of Chicago	Chicago, IL	Gal Finer, Nancy Majkowski
Arkansas Children's Hospital	Little Rock, AK	Richard Blaszak, Christine Blaszak
Boston Children's Hospital	Boston, MA	Michael Somers, Theresa Pak
Children's Hospital New Orleans	New Orleans, LA	Diego Aviles, Evie Jenkins
Children's Hospital Los Angeles	Los Angeles, CA	Rachel Lestz, Alice Sanchez
Children's Hospital of Wisconsin	Milwaukee, WI	Cynthia Pan, Jackie Dake
Children's Medical Center Dallas	Dallas, TX	Raymond Quigley, Haridas Thankappan
Children's Mercy Hospital	Kansas City, MO	Bradley Warady, JoLyn Grimes
Children's National Medical Center	Washington, DC	Kirtida Mistry, Jennifer Wilcox
Cincinnati Children's Hospital Medical Center	Cincinnati, OH	Rene Van De Voorde, Ellen Irvin
Driscoll Children's Hospital	Corpus Christi, TX	Samhar Al-Akash, Britt Stone
Johns Hopkins Children's Center	Baltimore, MD	Alicia Neu, Barbara Case
Kosair Children's Hospital	Louisville, KY	David Kenagy, Andrea Baker
Lucile Packard Children's Hospital at Stanford	Palo Alto, CA	Cynthia Wong, Brandy Begin
Mattel Children's Hospital UCLA	Los Angeles, CA	Joshua Zaritsky, Barbara Gales
Nationwide Children's Hospital	Columbus, OH	Hiren Patel, Beth Smith
Phoenix Children's Hospital	Phoenix, AZ	Mark Joseph, Deb Haskins
Seattle Children's	Seattle, WA	Coral Hanevold, Nancy McAfee
St. Louis Children's Hospital	St. Louis, MO	Ann Beck, Meg Shea
Cohen Children's Medical Center of New York	New Hyde Park, NY	Christine Sethna, Myung Cho
Texas Children's Hospital	Houston, TX	Sarah Swartz, Helen Currier
The Children's Hospital at Montefiore	Bronx, NY	Amy Skversky, Maureen Eisele
The Children's Hospital of Philadelphia	Philadelphia, PA	Madhura Pradhan, Christine Breen
UCSF Benioff Children's Hospital	San Francisco, CA	Paul Brakeman, Lina Campopiano
University of Iowa Children's Hospital	Iowa City, IA	Patrick Brophy, Jennifer Ehrlich
Upstate Golisano Children's Hospital	Syracuse, NY	Lawrence Shoemaker, Nancy Zacharek
Vidant Children's Hospital	Greenville, NC	Guillermo Hidalgo, Malinda Harrington

distribution, and additional candidate distributions, including the generalized Poisson and the negative binomial distribution, will be considered as appropriate. The choice of the final model from candidate models will be based on the Akaike Information Criteria corrected for finite sample sizes (AICC), and the final model will be assessed for over-dispersion.

All analyses will be conducted using SAS, version 9.3 (SAS Institute, Inc., Cary, NC). Tests with a  $p$  value of  $\leq 0.05$  are considered to be statistically significant.

All participating centers received approval from their respective institutional review boards for participation in the SCOPE Collaborative.

**Table 5** Exit-site scoring tool [7, 25]

Exit-site scoring tool	0 points	1 point	2 points
Swelling	No	Exit only (<0.5 cm)	Including part of or entire tunnel
Crust	No	<0.5 cm	>0.5 cm
Redness	No	<0.5 cm	>0.5 cm
Pain on pressure	No	Slight	Severe
Secretion	No	Serous	Purulent

## Discussion

End stage renal disease is a rare condition in childhood, with an average annual incidence of between 7 and 16 per million age-related population and a prevalent pediatric dialysis population in the USA of slightly more than 2,000 patients [1, 2, 4]. Collaborative efforts are therefore required to define and improve the care provided to pediatric ESRD patients. Fortunately, several regional, national, and international pediatric nephrology collaborative organizations and registries have been providing robust and important information on the care of children with ESRD for decades. Data from these efforts have supported the development of national and international treatment guidelines and provided preliminary data for collaborative prospective clinical trials.

The SCOPE Collaborative has harnessed the power of these collaborative networks to extend the Association's highly successful Quality Transformation Network to pediatric ESRD. In its first QTN effort, SCOPE seeks to increase implementation of current best-care practices targeted to the PD catheter and thereby reduce PD catheter-associated infections. If successful, the SCOPE Collaborative will dramatically improve the care of pediatric CPD patients by reducing not only infection, but also the sequelae of those infections, including hospitalization, membrane failure, and death. The potential of this effort to improve the lives of pediatric CPD patients is paramount; however, as with the Association's other QTN efforts, the SCOPE Collaborative also has the potential to significantly reduce healthcare cost. It is currently estimated that the QTN's Pediatric Intensive Care Unit central line-associated blood-stream infection (CLABSI) Collaborative and its Hematology/Oncology CLABSI Collaborative have saved more than 600 lives and over \$170 million [9].

Although other collaborative efforts to improve the care of ESRD patients exist, the SCOPE Collaborative is uniquely based in rigorous quality improvement methodology. Real-time transparent data entry allows for an ongoing review of progress and sharing of experiences among collaborative participants. The participating center teams are multi-disciplinary, which allows a comprehensive approach that can identify barriers to successful implementation of best-care practices at the patient, provider, clinic, and system level. Another strength of the Collaborative structure is its adaptability. Although the best-care practices included in the Bundles are based on evidence-based guidelines where those data exist, many are based on expert opinion. The SCOPE Collaborative provides a platform to test whether these practices, when implemented consistently, can impact infection rates. That is, do they truly reflect best-care practices? In addition, through the collection of data on care practices that are

not included in the Bundles, patient-specific data, and detailed data on the infection episodes, the SCOPE Collaborative will allow the identification of other potentially modifiable factors or practices that may impact the risk for PD catheter-related infection. Because current best practices will be standardly implemented across the collaborative, the SCOPE Collaborative will also provide an ideal platform for testing new interventions aimed at reducing infections in a randomized, controlled fashion. Thus, although the primary aim of SCOPE is to reduce PD catheter-associated infection rates among the children cared for at participating centers, the Collaborative structure allows for the refinement of current practices and the development of truly evidence-based best-care practices. Finally, while SCOPE's initial focus is the reduction of PD catheter-associated infections, a broader aim is to develop a platform that can test and define best-care practices in all aspects of pediatric ESRD care.

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