SCOPE Collaborative Clinical Charter

S*tandardizing* ***C****are to improve* ***O****utcomes in* ***P****ediatric* ***E****SRD*

A National Quality Improvement Initiative

In, June 2009 the Pediatric Nephrology Quality Assurance Performance Improvement Workgroup and the Children's Hospital Association (CHA) (then known as the National Association of Children's Hospitals and Related Institutions (NACHRI)) held a Pediatric Nephrology Quality Improvement Webinar. The purpose of the webinar was to identify several areas for quality improvement within Pediatric Nephrology including reducing infection rates in dialysis patients, growth in chronic kidney disease, immunization rates in chronic kidney disease, anemia management in end-stage kidney disease and bone and mineral metabolism management in end-stage kidney disease. Because of the current emphasis within our healthcare system on reducing infection, this group developed a quality improvement project focused on reducing exit-site infection and peritonitis rates (peritoneal dialysis-associated infections/PDI's) in pediatric chronic peritoneal dialysis patients. It is hoped that this will be the first of many collaborative quality improvement initiatives for pediatric nephrology centers across the country.

Chronic peritoneal dialysis (CPD) is the most common dialysis modality utilized for children with end-stage kidney disease worldwide (1). Although rates of peritoneal dialysis related infections (PDI's), including exit site infection and peritonitis, have decreased over the last two decades, the rates for these infections in children typically exceed those seen in adult CPD patients (2, 3, 4), and peritonitis remains the most significant complication of CPD in pediatric patients (3,5). Peritonitis is the leading cause for hospitalization among pediatric CPD patients world-wide, and data from the United States Renal Data Systems (USRDS) reveal that the cumulative incidence of hospitalization increased from 19.3% over the 36 month period between 1995-1998 to 34.3% in the period between 1999-2002 (5). Data from the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS) reveal that peritonitis is the leading reason for modality change among children on CPD (6). Finally infection is a leading cause of death among pediatric CPD patients (5). Although internationally developed guidelines for the treatment of PDI's include recommendations for peritoneal dialysis catheter placement, training and exit site and catheter care practices to reduce PDI's, most of these recommendations are not evidence-based, and it is unknown how uniformly these recommendations are followed (7, 8, 9). According to data from the NAPRTCS and the International Pediatric Peritoneal Dialysis Network (IPPN), there is significant variability in peritonitis rates among centers caring for pediatric peritoneal dialysis patients (6, 10). A recent 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 NAPRTCS registry, revealed a mean peritonitis rate of 1 episode every 28.1 patient months (95% CI 25.8-30.9), with an annualized rate of 0.43. However, the peritonitis rates in these highly active pediatric CPD centers ranged widely from 1 episode every 9.7 patient-months to 1 episode every 90.1 patient-months (personal communication, K Martz, EMMES). These data suggest practice variability in care and the potential standardize best practices and improve PDI rates in pediatric CPD patients by evaluating and implementing a more uniform approach to PDI prevention.

The SCOPE project has been approved by the American Board of Pediatrics (ABP) to serve as a model for practitioner involvement in collaborative performance improvement activities which can be used as part of the ABP's Maintenance of Certification (MOC) requirements.

This project is being offered to pediatric nephrology centers that seek to improve the health care of children by reducing exit site infection and peritonitis rates. This project serves as starting point for building collegial network of pediatric nephrology centers skilled in successful quality improvement efforts that in the future can be expanded to topics in addition to PDI prevention.

PDI Initiative Aim

The aim of the project is to minimize exit site infection and peritonitis rates among pediatric CPD patients. The project is part of a broader effort to assist Pediatric Nephrology teams in 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-associated infections, will also serve as a model for future Pediatric Nephrology projects that could improve the quality of pediatric care and facilitate physician maintenance of board certification.

Project Goals

The long-term goal of the project is to build the foundation of a sustainable collaborative network to improve the outcomes of children cared for in the more than 100 Pediatric Nephrology centers in the United States. The shorter-term goals of the project are to:

1. Engage Pediatric Nephrology physicians, infection control practitioners, and other physicians and clinicians currently implementing quality improvement efforts in their own institutions and involve them in collaborative activities focused on minimizing PDI especially as this project is expanded across the country.

2. Build on existing collaborative groups of Pediatric Nephrology centers currently engaged in registry activities to foster the groups' ability to systematically test and implement changes that can significantly reduce exit site infection and peritonitis rates among pediatric CPD patients.

3. Develop and sustain a program that enables physicians involved in reducing exit site infection and peritonitis rates to develop competencies in performance improvement and systems-based thinking, thereby enabling them to meet the ABP Part IV MOC requirements and become quality improvement leaders and resources within their institution. What is learned in this project about

methods of ensuring that physicians become competent in performance improvement and systems-based thinking may be applied to other pediatric sub-specialties.

4. Generate new knowledge and evidence-based clinical practices in the Pediatric Nephrology population by involving Nephrology physicians, physicians and clinicians in related specialties and disciplines, and their teams and families in a performance improvement collaborative that brings together clinical research and improvement methods.
    - Build upon the data generated from previous observational databases to further refine and define, test and spread best care practices using improvement science methodologies to clearly codify an evidence-based catheter insertion, post-operative care, training and catheter and exit site care bundles. These bundles will serve as evidence-based "best peritoneal dialysis care practices" for children maintained on chronic peritoneal dialysis. These bundles can also serve as a platform for future evidence-based research in our subspecialty.
    - Gather data about all exit site infections and peritonitis episodes in pediatric CPD patients in order to develop a framework for future quality improvement collaboratives.

5. Rely on and improve physician and nurse team functionality to implement changes needed to eradicate PDI's and improve overall Pediatric Nephrology team's safety culture and team function.

6. Identify strategies and methods to spread the new and most efficacious best practice changes to all physicians and nurses involved in reducing exit site and peritonitis rates in US Pediatric Nephrology centers.

Specific Goals for Participating Organizations

1. Minimize exit site infection and peritonitis among children on chronic peritoneal dialysis.
2. Reduce mortality and morbidity of patients on peritoneal dialysis
3. By July 2021, accomplish the following secondary aims:
    - Reduce peritonitis rates among PD patients in SCOPE by 5%
4. By July 2021, accomplish the following:
    - Maintain/Increase % follow up compliance:
        i. Teams with 2 or more years' experience in SCOPE maintain >80% compliance with f/up bundles through July 2021
        ii. Teams with less than 2 years' experience in SCOPE achieve >75% compliance by July 2021
    - Insertion compliance:
        i. Maintain compliance with all insertion bundle elements except use of catheter within 14-days at >90% by July 2021.
    - Training Compliance:
        i. Increase compliance with post-training bundle from 52% to 80% by July 2021.
5. By July 2021:
    - Maintain culture negative rate compliance at <10%

To accomplish these goals this project has engaged the resources of:

- CHA, in assistance in developing and running a quality transformation collaborative
- The American Board of Pediatrics, to certify that the project meets MOC requirements
- EMMES/NAPRTCS to provide a pre-established collaborative network of Pediatric Nephrology Centers currently engaged in data collection and dissemination for the purpose of quality assurance

PDI Initiative Change Package/Bundle

The collaborative improvement effort will have three areas of emphasis for peritoneal dialysis catheter care and maintenance. These areas of focus further codify and define best care approaches which may lead to infection rate reduction.

BUNDLE #1:Peritoneal Dialysis Catheter Insertion Bundle:

1. Standardize CPD catheter exit-site orientation to the lateral or downward position
2. Standardize use of a single dose of a first generation cephalosporin at the time of CPD catheter placement
3. Standardize post-operative exit-site care to include standard duration without dressing change, use of sterile dressing changes until exit-site is healed, and immobilization of the CPD catheter during healing phase

BUNDLE #2: Peritoneal Dialysis Training Bundle

1. Standardize Registered Nurse as training personnel
2. Standardize trainer to trainee (or family) ratio to 1:1
3. Standardize that at least one primary provider and alternate provider receive training for each patient
4. Standardize use of teaching aides such as photographs, mannequin or apron during training.
5. Standardize use of a pediatric-specific training manual.
6. Standardize inclusion of key aspects of training in the areas of hand washing, exit-site care and aseptic technique.
7. Standardize that post-training concept and demonstration tests be administered at the completion of training and one month following completion of training
8. Standardize that a home visit be performed during the training period

BUNDLE #3: Peritoneal Dialysis Catheter/Exit Site Follow up Care Bundle

1. Standardize inclusion of objective score of exit-site, evaluation for immobilization of catheter and review of key aspects of training in monthly follow-up evaluation
2. Standardize that post-training concept and demonstration test be administered every 6 months
3. Standardize that re-training be performed after a peritonitis episode
4. Standardize use of prophylactic antibiotics after touch contamination or other break in aseptic technique according to the ISPD guidelines

PDI Initiative Core measures:

Patient Outcome Measures

- Exit-site infection rates defined as:
  - Number of infections for a time period, divided by dialysis-years time at risk and expressed as episodes per year (e.g. 0.43 episodes per year)

- Months of peritoneal dialysis at risk, divided by number of episodes, and expressed as interval between episodes, as defined by the ISPD guidelines (e.g. 1 episode every 28.1 patient months)
- For the purposes of the project, an exit site infection will be defined as treatment for exit site infection. As per the ISPD guidelines, The diagnosis of a catheter exit-site infection should be made in the presence of a purulent discharge from the sinus tract, or marked pericatheter swelling, redness, and/or tenderness, with or without a pathogenic organism cultured from the exit site. Infectious symptoms should be rated according to an objective scoring system (see table below) and an infection should be assumed with a cumulative exit-site score of 4 or greater.

Exit-Site Scoring System

	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

[a] Infection should be assumed with a cumulative exit-site score of 4 or greater.

- Peritonitis rates defined as:
  - Number of infections for a time period, divided by dialysis-years time at risk and expressed as episodes per year
  - Months of peritoneal dialysis at risk, divided by number of episodes, and expressed as interval between episodes, as defined by the ISPD guidelines
  - For the purposes of the project, a peritonitis episode will be defined as treatment for peritonitis. As per the ISPD guidelines, an empiric diagnosis of peritonitis should be made if the peritoneal effluent is cloudy, the effluent white blood cell (WBC) count is greater than 100/mm3, and at least 50% of the WBCs are polymorphonuclear leukocytes.
  - Relapsing peritonitis, defined as a recurrence of peritonitis with the same organism as in the immediately preceding episode, according to antibiotic susceptibilities, or a second culture negative infection within 4 weeks of completion of antibiotic treatment will be tracked, not be counted as a new infection.
- Median infection rates for the program will be determined by calculating the infection rate for each patient, and then obtaining the median of these rates

Process Measures

- Percent of patients for which all required catheter insertion, training and maintenance bundle components were implemented across dialysis unit
- Percent compliance with each bundle component in the dialysis unit
- Safety culture score at beginning of collaborative and annually thereafter

Additional Measures: Clinical and Demographic Data

For risk stratification exploration, the following additional variables will be captured for all patients experiencing an exit-site infection or peritonitis episode: Also capture data (with exceptions noted below) on all patients at time of catheter placement.

- Age
- Cause of ESRD
- Date of dialysis initiation
- History of previous kidney transplant
- Presence of gastrostomy tube/button
- Presence of urinary stoma (continent or incontinent)
- History of touch contamination, catheter leak or other break in aseptic technique within one week of infection (only after infection)
- Characteristics of peritoneal dialysis catheter (Exit site orientation (up/down/lateral), tunnel configuration (swan neck, straight, single cuff, dual cuff)
- Type of adapter (titanium/other)
- History of screening for and/or treatment of S. aureus carriage in patient and/or caregiver
- Identity of provider performing dialysis at time of infection and whether that provider received training (only after infection)
- Type of immobilization device used
- For exit site infection: Exit site score at time of infection/Culture obtained (Y/N), if yes, organism recovered (Y/N) if yes, specify. (only after infection)
- For peritonitis: Culture results (include negative)/ Was this episode a relapse (ie same organism within 4 weeks?/ Outcome of episode (resolution/removal of catheter/reduction in membrane function) (only after infection)

Participants

All hospital Pediatric Nephrology teams who perform chronic peritoneal dialysis are invited to participate in this project. Participants will include clinicians specializing in Pediatric Nephrology and quality improvement, and infection control professionals from across the country. Teams of all sizes are encouraged to participate. Institutional membership in CHA is not required.

Clinicians who participate will:

- Receive the most current pediatric recommendations for the management of exit site infections and peritonitis in children (pediatric specific vs. extrapolated from adult data)
- Receive materials for use in clinical practice
- Learn early the results of collaborative studies and quality improvement projects
- Establish and implement best practices
- Contribute to the advancement of science and clinical practice
- Learn improvement science methods that can be applied to other topics
- Become a member of an esteemed collaborative
- Satisfy a requirement for Part IV maintenance of certification by the American Board of Pediatrics

The project requires Pediatric Nephrology clinical leadership and principal investigator roles that will gain experience in PDI reduction and elimination; a passion for achieving results; the ability to communicate with and engage physicians across the country; and the willingness to be visible and/or vocal at project related workshops and meetings. The Planning Committee was crucial in the development of the proposal and charter and includes key leaders in moving this national collaborative forward.

Planning Committee

- Mike Aldridge, MSN, RN, CCRN
- Paul Kurtin, MD
- Nancy McAfee, MSN, RN, CCN
- Marlene Miller, MD, MSc
- Alicia M Neu, MD
- Bradley A Warady, MD

SCOPE Faculty

SCOPE is now led by a national faculty including clinical leaders, infectious disease specialists, and quality improvement experts.

- Brandy Begin, RN
- Rebecca Same, MD
- Jennifer Ehrlich, RN
- Alicia M Neu MD
- Bradley A Warady MD

Expectations and Boundaries

For the length of time of this project, the PDI Clinical Faculty Steering committee and CHA will:

1. Provide an opportunity to participate in a collaborative that we believe can substantially reduce exit site infection and peritonitis rates in your patients
2. Provide evidence-based information on PDI
3. Teach participating centers how to apply a care model for reducing PDI
4. Teach the Model for Improvement
5. Offer coaching to Pediatric Nephrology teams on implementing and evaluating changes
6. Coordinate communication activities to keep participants connected to the steering committee and to colleagues during the improvement collaborative
7. Develop a framework for testing changes in care delivery
8. Provide tools, forms, and other aids to help with implementation of key areas of care for reducing PDI
9. Commit to writing multiple peer-review manuscripts with rigorous data analysis on collaborative efforts.

Participating organizations and teams are expected to:

1. Commit a senior leader – this may be the same person as the physician champion – to support and promote the team working on the collaborative improvement project
2. Send one (required) or two(recommended) team members who have the authority to drive change, including the physician champion and, ideally, a nurse and/or infection control professional, to two 2-day learning workshops per year (travel costs to be covered by participating hospital)
3. Provide resources and support to the hospital's team (includes attending workshops, devoting time to data entry, testing and implementing changes, and promoting active senior leadership)

4. Collect and submit data every month to the collaborative database
5. Provide staff to accommodate the approximately 40 hours of data collection required per month
6. Implement the standardized database collection tool to track patients and their care and submit monthly data
7. Commit to be transparent with all data to all other teams within the collaborative group
8. Work to involve all hospital staff as appropriate with the aim of helping the multidisciplinary clinical team become competent in safety and quality improvement
9. Perform pre-work activities to prepare for workshops
10. Connect project goals to the broader patient safety work in the hospital
11. Participate in collaborative group webinars and conference calls and a collaborative discussion listserv to share with and learn from others
12. Make well-defined measurements at least monthly, plot them over time for the duration of the collaborative improvement project and share them with the other teams in the collaborative
13. Maintain responsibility for IRB requirements for a quality improvement project (with option to publish aggregate data)

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