The Use of Registry-based Data in Guideline Development

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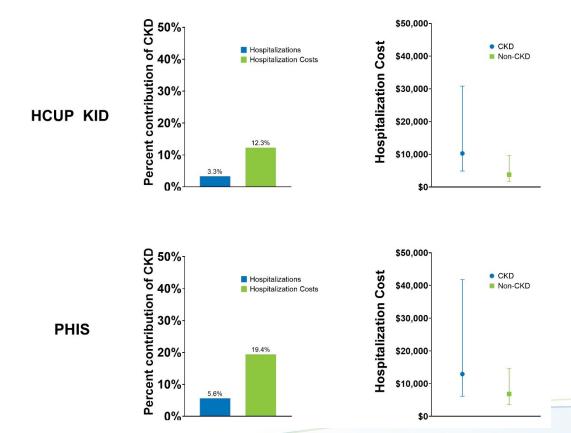
Disclosures and Conflicts of Interest

- No disclosure
- No conflicts of interest

Learning Objectives

- Understand the importance of registry data in pediatric nephrology
- Describe the use of data in Population/Intervention/Comparison/Outcomes (PICO) process
- Provide specific examples using IPPN and SCOPE data

Hospitalization Burden of Chronic Kidney Disease



Registry data in pediatric nephrology

Benefits

- Clinically applicable outcomes
- Continuum of care settings
- Sample size/power to answer questions single centers can't

Difficulties

- Resource intensive: require people-hours to manually enter
- Specificity of data collection results in numerous unstandardized registries

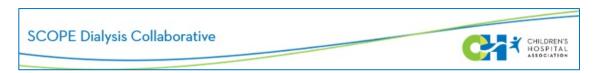
PICO Process: Evaluating existing evidence

- 54 questions in the following areas:
 - Training
 - Catheter type/placement
 - Exit site care
 - Connectology
 - Adjunctive prophylactic abx therapy
 - Ostomy patients
 - Empiric abx therapy
 - Modification of therapies (based on culture results)
 - Relapsing peritonitis
 - Adjunctive therapy
 - Removal/replacement
 - Diagnosis/treatment of catheter-related infection
 - Modification of APD

List of PICO Questions that were planned to be addressed as recommendations

Group	#	Population	Intervention	Comparison	Outcome	Considerations
						Comments
1. Training	1.	Pediatric patients	Longer	Shorter	The risk for	Potential Study from Asia
		and/or caregivers	duration of	duration of	peritonitis and	IPPN Training Survey
		who are trained to	training	training	exit-site/tunnel	
		perform home PD			infections	SCOPE data available on duration of training
	2.	Pediatric patients	Home visits	No home visits	The risk for	IPPN training survey
		and/or caregivers			peritonitis and	
		who are trained to			exit-site/tunnel	
		perform home PD			infections	
	3.	Pediatric patients	Frequency of	Another	The risk for	IPPN training survey
		and/or caregivers	retraining	frequency of	peritonitis and	
		who are trained to		retraining	exit-site/tunnel	
		perform home PD			infections	
	4.	Pediatric patients	Post-training	Informal	The risk for	SCOPE Registry
		and/or caregivers	written and	assessment of	peritonitis and	IPPN, Training Survey
		who are trained to	demonstrati	understanding	exit-site/tunnel	Triv, Training Survey
		perform home PD	on		infections	
			competency			
			testing			
	5.	Pediatric patients	Repeated	No repeat	The risk for	SCOPE Registry
		and/or caregivers	testing every	competency	peritonitis and	

International Pediatric Dialysis Network



- For questions without good pediatric evidence:
 - What data are available in each registry?
 - How much? Can the PICO question be answered with a reasonable amount of certainty?
 - Which data align best with PICO questions?
 - Which questions had insufficient data to answer?

PICO Question			N, Intervention	N, Comparison	N, Missing
1.	Duration of training longer vs shorter	1,450	750	700	
2.	Home visits vs no home visits	1,450	1,078	372	
3.	Retraining frequency vs another	34,290	31,479	2,811	
5.	Repeat competency testing vs. none	34,290	29,654	4,388	248
8.	Laparoscopic vs open catheter placement	1,838	1,416	409	13
9.	Prophylaxis Antibiotic therapy vs none	1,838	1,741	97	
12.	Daily exit site care vs 3 times a week	34,290	9,217	3,142	21,931
13.	Topical antibiotic prophylaxis vs not	34,290	10,741	1,342	22,207
15.	Gastrostomy Before/After PD	1,838	204	406	1,228
17.	Using prophylactic antibiotics and antifungals for gastrostomy placement	610	???	???	
18.	Adjunctive antifungal with antibiotics	588	452	134	2
19.	Prophylactic antibiotic for invasive procedures (dental or GI/GU)	320	248	67	5
31.	Fungal peritonitis, catheter removal vs treatment and removal	65	62	3	
33.	Fungal peritonitis, catheter removal time X vs Y	62			
34.	Fungal peritonitis, catheter replacement time X vs Y	23			



6 questions we wanted to try and answer

Training characteristics: IPPN

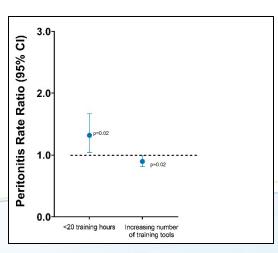
Research question: Is there an association between training practices and infection rates (peritonitis, exit site)?

Intervention: Questionnaire (44 questions) was used to assess PD training practices from January 2019 to December 2020

Outcome: Peritonitis and exit site infection rates (per patient year)

Results:

- <20 training hours associated with increased peritonitis rates
- Increased number of training tools associated with lower peritonitis rates
- No association with exit site infection rates



Compliance with ISPD Training recommendations: SCOPE

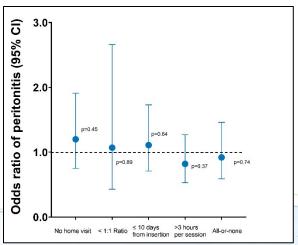
Research question: Is there an association between 4 ISPD training recommendations and peritonitis infection?

Intervention: Compliance with 4 ISPD training recommendations (home visit, 1:1 training, delay training for >10 days post insertion, training sessions < 3 hours)

Outcome: Peritonitis within 90 days of insertion

Results:

- No association between compliance with any of the 4 recommendations and infection within 90 days
- No association between all-or-none compliance with all 4 recommendations and infection within 90 days



Laparoscopic vs Open Catheter Placement: SCOPE

Research question: Is there an association between the surgical technique for PD catheter placement and peritonitis infections?

Intervention: Laparoscopic vs open placement

Outcome: Probability of peritonitis within 7 days of insertion

Results:

 No association between surgical technique and peritonitis within 7 days of insertion (p=0.54)

Gastrostomy before/after PD catheter placement: SCOPE

Research question: Is there an association between the timing of gastric tube placement in relation to PD catheter placement and peritonitis infections?

Intervention: Gastrostomy after PD catheter placement vs before/concurrent placement

Outcome: Probability of peritonitis within 7 days of placement or insertion

Results:

 No association (??) between the timing of gastric tube placement and peritonitis within 7 days of insertion (p=0.07)

Adjunctive antifungal therapy with antibiotic: SCOPE

Research question: Is there an association between the adjunctive use of oral nystatin or fluconazole vs no antifungal and fungal peritonitis?

Intervention: Use of oral nystatin or fluconazole vs no antifungal among patients receiving antibiotics for another infection

Outcome: Probability of a fungal infection following antibiotic administration

Results:

- Null findings
- 1 fungal infection following antibiotic administration in each exposure group

Prophylactic antibiotic therapy with invasive procedure: SCOPE

Research question: Is there an association between the use of prophylactic antibiotics at the time of invasive procedures (dental, GI/GU) and peritonitis infections?

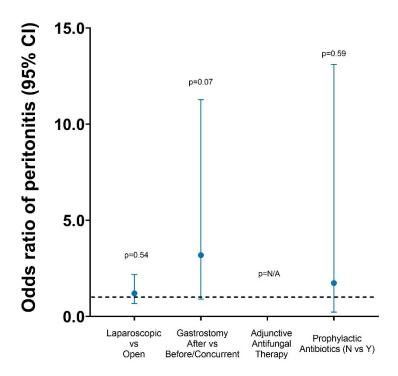
Intervention: Use of prophylactic antibiotics at the time of invasive dental or GI/GU procedures (No vs Yes)

Outcome: Probability of peritonitis within 7 days of invasive procedure

Results:

• No association between use of prophylactic antibiotics and peritonitis within 7 days of procedure (p=0.59)

PICO Process: Next Steps



Next Steps: Evidence to Decision



Questions?

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