# The Use of Registry-based Data in Guideline Development

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# Disclosures and Conflicts of Interest

- No disclosure
- No conflicts of interest

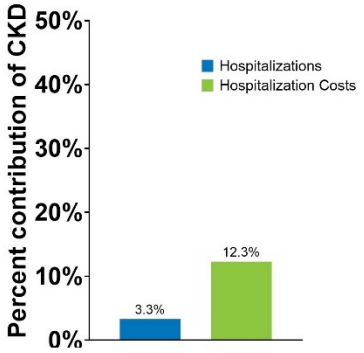
# Learning Objectives

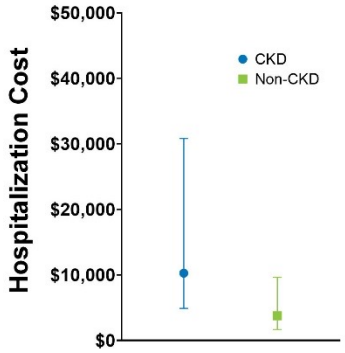
- Understand the importance of registry data in pediatric nephrology
- Describe the use of data in Population/Intervention/Comparison/Outcomes (PICO) process
- Provide specific examples using IPPN and SCOPE data

# Children's Hospitals Working Together

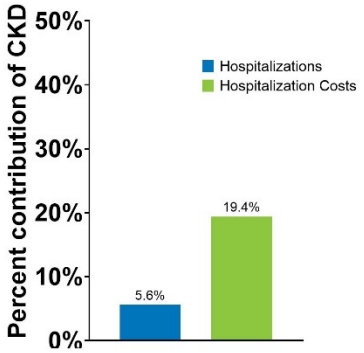
# Hospitalization Burden of Chronic Kidney Disease

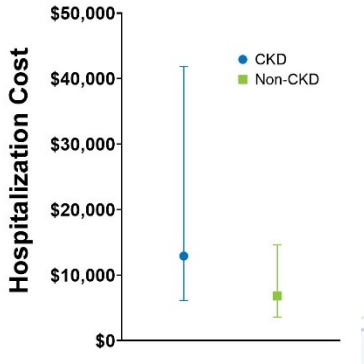
**HCUP KID**




**PHIS**




HCUP KID=Healthcare Cost & Utilization Project Kids' Inpatient Database (AHRQ)
PHIS=Pediatric Health Information System (Children's Hospital Association)

# 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

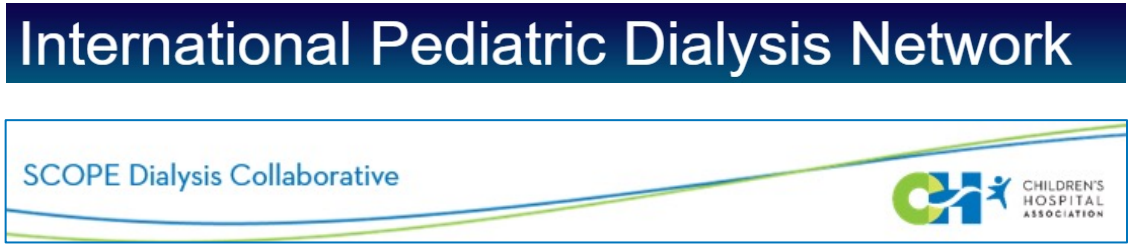
# PICO Process: Evaluating existing evidence

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

# PICO Process: Generating new evidence




- 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 Process: Generating new evidence

| PICO Question | N, Total | 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

# PICO Process: Generating new evidence

*Training characteristics: IPPN*

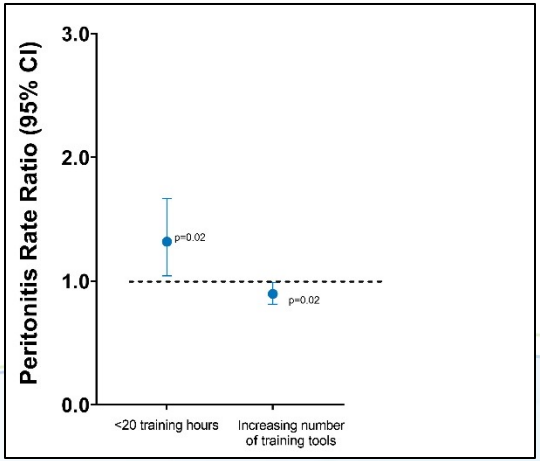
**Research question:** *Is there an association between training practices and infection rates (peritonitis, exit site)?*

**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*



# PICO Process: Generating new evidence

*Compliance with ISPD Training recommendations: SCOPE*

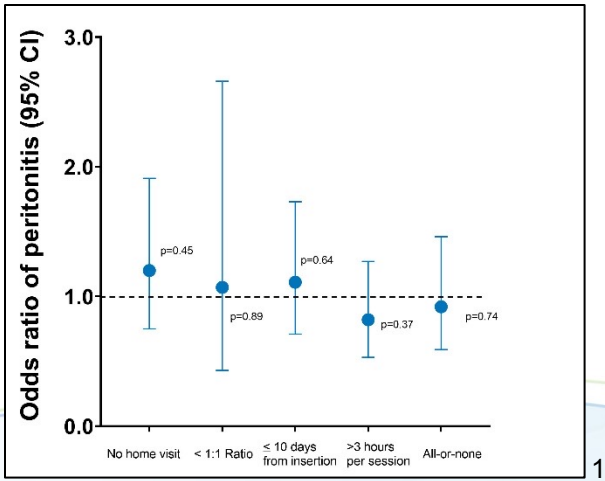
**Research question:** *Is there an association between 4 ISPD training recommendations and peritonitis infection?*

**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*



# PICO Process: Generating new evidence

*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)*

# PICO Process: Generating new evidence

*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)*

# PICO Process: Generating new evidence

*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*

# PICO Process: Generating new evidence

*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?*

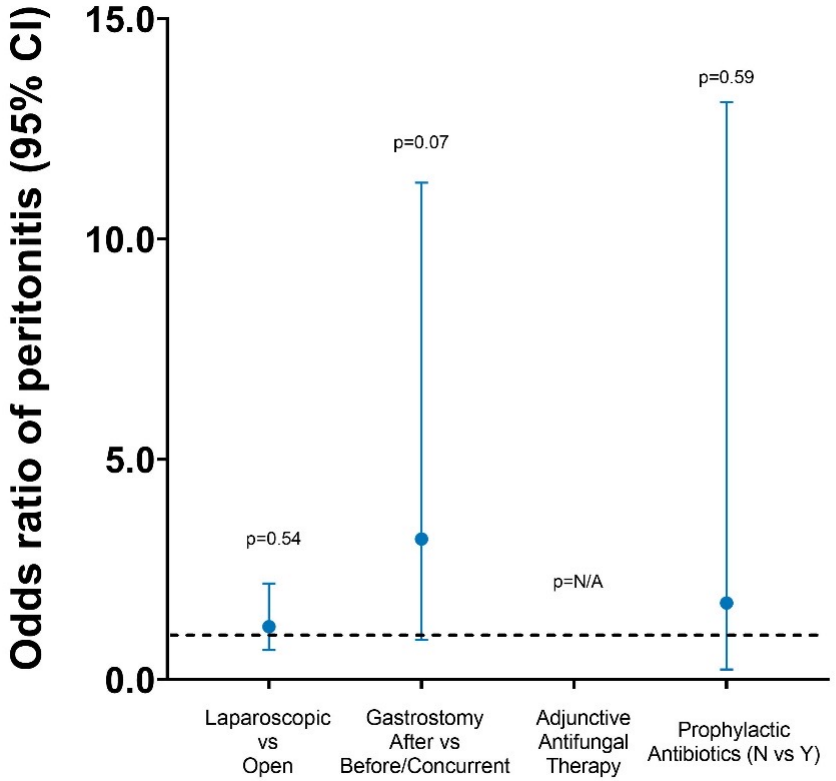
**Intervention:** *Use of prophylactic antibiotics at the time of invasive dental or GI/GU procedures (No vs Yes)*

**Outcome:** *Probability of peritonitis within 7 days of invasive procedure*

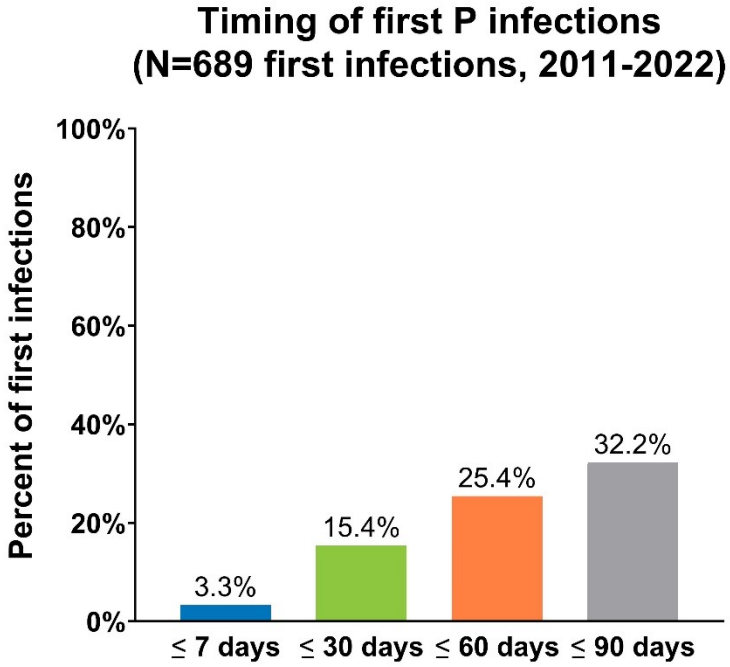
**Results:**

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

# PICO Process:  Next Steps



# What we know about early on-set infections




**Median (IQR) days to first infection : 183 (58, 440) days**

# What we know about preventing infection

**Table 4. Rate ratio models for peritonitis**

| Variables | Crude Rate Ratio (95% CI) | *P* Value | Adjusted Rate Ratio[a] (95% CI) | *P* Value |
|---|---|---|---|---|
| **Age group, yr** | | <0.001 | | 0.15 |
| <2 | Reference | | Reference | |
| 2–5 | 0.81 (0.62 to 1.06) | 0.12 | 0.59 (0.22 to 1.59) | 0.28 |
| 6–12 | 0.61 (0.51 to 0.73) | <0.001 | 0.66 (0.27 to 1.61) | 0.35 |
| 13–17 | 0.59 (0.49 to 0.71) | <0.001 | 0.68 (0.25 to 1.85) | 0.44 |
| ≥18 | 0.96 (0.65 to 1.44) | 0.85 | 1.06 (0.23 to 4.95) | 0.94 |
| **Race** | | <0.001 | | 0.09 |
| Nonblack | Reference | | Reference | |
| Black | 1.66 (1.42 to 1.95) | | 1.61 (0.93 to 2.80) | |
| Gastrostomy tube | 1.49 (1.29 to 1.72) | <0.001 | 1.30 (0.69 to 2.45) | 0.37 |
| Vesicostomy or stoma | 1.36 (1.10 to 1.69) | <0.01 | 1.04 (0.52 to 2.06) | 0.92 |
| Incontinence | 1.53 (1.32 to 1.77) | <0.001 | 1.29 (0.56 to 3.01) | 0.54 |
| Touch contamination | 1.75 (1.51 to 2.02) | <0.001 | 2.22 (1.44 to 3.43) | <0.001 |
| Patient performs PD themselves | 0.70 (0.59 to 0.81) | <0.001 | 1.17 (0.63 to 2.17) | 0.60 |
| Upward orientation | 3.14 (2.42 to 4.08) | <0.001 | 4.20 (1.49 to 11.89) | <0.001 |
| Plastic adapter | 1.33 (1.15 to 1.54) | <0.001 | 1.38 (0.86 to 2.22) | 0.18 |
| **Insertion compliance** | | 0.001 | | 0.67 |
| No | Reference | | Reference | |
| Yes | 0.62 (0.47 to 0.82) | | 0.91 (0.57 to 1.44) | |
| **Training compliance** | | 0.43 | | NA |
| No | Reference | | NA | |
| Yes | 0.88 (0.64 to 1.21) | | NA | |
| **Follow-up compliance** | | <0.001 | | <0.001 |
| No | Reference | | Reference | |
| Yes | 0.50 (0.40 to 0.62) | | 0.49 (0.30 to 0.80) | <0.01 |

95% CI, 95% confidence interval; PD, peritoneal dialysis; NA, not applicable.
[a]All significant variables in crude model were included in addition to sex and patient clustering.

Sethna et al (2016). *Clin J Am Soc Nephrol.* 11(9):1590-6.

# Conclusion

- Pediatric nephrology registry data is an integral part of establishing best-practice care recommendations
- For small patient populations (with big impact), it requires a collaborative effort.

Next Steps: Evidence to Decision