

Managing and implementing protocols

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Objectives

1. Differentiate between protocols and practice guidelines
2. Discuss how to establish protocols
3. Review how to evaluate protocols

What is a medical protocol?

- a detailed written set of instructions to guide the care of a patient or to assist the practitioner in the performance of a procedure.

Similarities between clinical practice guidelines and protocols

- Guidelines:
 - Guide decisions
 - Based on current evidence-based management strategies
- Protocols:
 - Guide decisions
 - Based on current evidence-based management strategies

Kohr, L. & Hravnak, M. (2001). Clinical practice guidelines and protocols guide decisions. *AACN News*, 18(3).

Differences between clinical practice guidelines and protocols

- Guidelines:
 - Are flexible
 - Are easily modified to patient needs
 - Can be adapted within a large variety of settings
- Protocols:
 - Are more rigid
 - Define a specific management plan
 - Leave little room for adjustment
 - Reflect regional or institutional practices

Kohr, L. & Hravnak, M. (2001). Clinical practice guidelines and protocols guide decisions. *AACN News*, 18(3).

Treatment protocol

- For treating (**or preventing**) a particular ailment
 - Peritonitis
 - PD catheter exit-site infection

More on the topic... a caveat

- Evidence-based clinical guidance documents are heterogeneous, as is the terminology utilized to describe and/or label them.
- The phrases "guideline," "protocol," "practice parameter," "pathway," "standard," etc., are used in many different contexts by different guideline developers.

(National Guideline Clearinghouse www.guideline.gov/faq.aspx)

How to establish a protocol

- e.g. Insertion of a PD catheter
 - Form a multi-disciplinary group
 - Review the literature:
 - published clinical guidelines
 - published best practices
 - Write up a protocol
 - Obtain approval
 - Implement the protocol
 - Evaluate the protocol
 - Plan for updating

Brunier, G. et al. (2010). A change to radiological peritoneal dialysis catheter insertion: Three-month outcomes. *PDI*, 30, 528-533.

Resources

Organization	Latest update	Title	Website
University Health Network, Division of Nephrology (Toronto, Canada)	2012	UHN Division of nephrology: Housestaff/NP guidebook	www.nephrology.utoronto.ca www.ukidney.com/
Canadian Society of Nephrology (CSN)	2011	CSN Clinical Practice Guidelines	www.csnsn.ca
International Society of Peritoneal Dialysis (ISPD)	2010	1. Peritoneal dialysis related infections 2. Peritoneal access	www.pdconnect.com/cgi/reprint/30/4/393
The Renal Association (UK)	2009/10	1. Peritoneal dialysis 2. Peritoneal access	www.renal.org/clinical/GuidelinesSection/Guidelines.aspx
NKF KDOQI (US)	2006	Peritoneal dialysis adequacy	www.kidney.org/professionals/kdoqi/guideline/

Grading of evidence

Ia	systematic review or meta-analysis of RCTs*
Ib	at least one RCT*
IIa	at least one well-designed controlled study without randomisation
IIb	at least one well-designed quasi-experimental study, such as a cohort study
III	well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, case-control studies and case series.
IV	expert committee reports, opinions and/or clinical experience of respected authorities

* RCT = Randomized Controlled Trial

From: www.patient.co.uk/doctor/Different-Levels-of-Evidence-%28Critical-Reading%29.htm

Grading of recommendations

A	requires at least one RCT* as part of the body of evidence
B	requires availability of well-conducted clinical studies but no RCTs in the body of evidence.
C	requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality.

* RCT = Randomized Controlled Trial

From: www.patient.co.uk/doctor/Different-Levels-of-Evidence-%28Critical_Reading%29.htm

GRADE system: Newer system

	Expert recommendations
Strong (Grade 1) Weak (Grade 2)	Based on balance between the benefits and risks, burden, and cost.
	Quality of level of evidence
High (Grade A) Moderate (Grade B) Low (Grade C)	Based on factors such as study design, directness of evidence, and consistency of results

Figueiredo, A. et al. (2010). Clinical practice guidelines for peritoneal access, *PDI*, 30, 424-429.

How to evaluate (assess the quality) of clinical practice guidelines

- AGREE tool
 - Scope and purpose
 - Stakeholder involvement
 - Rigour of development
 - Clarity of presentation
 - Applicability
 - Editorial independence

www.agreecollaboration.org/instrument/

The Agree Collaboration. (2003). Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: The AGREE project. *BMJ Quality & Safety*, 12, 18-23.

Peritoneal Access Guidelines

- Implantation protocol (1A)
 - “Administration of prophylactic antibiotics is recommended to reduce the risk of catheter-site infection, peritonitis, and wound sepsis.”

Figueiredo, A. et al. (2010). Clinical practice guidelines for peritoneal access. *PDI*, 30, 424-429.

Am J Kidney Dis. 2000 Nov;36(5):1014-9.

Role of preoperative antibiotic prophylaxis in preventing postoperative peritonitis in newly placed peritoneal dialysis catheters.

Gadallah MF, Ramdeen G, Mignone J, Patel D, Mitchell L, Tatro S.

Department of Medicine, Division of Nephrology, and Department of Surgery, University of Florida Medical Center, Jacksonville, FL, USA. merit.gadallah@jax.ufl.edu

Trends in PD Catheter Exit-site Care (*Prowant, 2006, ADC*)

Issue	Adult (125)	Pediatric (22)
Pre-op antibiotics	66.4%	76.2%
Cleansing agent post-op		
•Povidone-iodine	28.0%	
•Chlorhexidine	12.0%	
•Hydrogen peroxide	4.8%	
Chronic use of prophylactic antibiotics (<i>Staph aureus</i> carriers)		
•Systemic	25.0%	19.1%
•Local	42.7%	50.0%

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Protocol for PD catheter insertion

- All PD units must establish a protocol for PD catheter insertion
 - Administer a single dose of prophylactic antibiotic at the time of catheter insertion
- “Less than half of PD units in ANZ have a protocol for use of prophylactic antibiotic at the time of PD catheter insertion”

Jose, M. D. et al. (2011). Peritoneal dialysis practice in Australia and New Zealand: A call to action. *Nephrology*, 16, 19-29.

How many of you have a protocol for pre-operative prophylactic antibiotics before PD catheter insertion?

Colonoscopy: Antibiotic prophylaxis - Guidelines

- Patients undergoing colonoscopy with polypectomy are at risk for enteric peritonitis
 - presumably from movement of bacteria across the bowel wall into the peritoneal cavity:

Piraino, B. et al. (2005). ISPD guidelines: Peritoneal dialysis-related infections, *PDI*, 25.

Piraino, B. et al. (2011). ISPD position statement on reducing risks of peritoneal dialysis-related infections. *PDI*, 31(6), 614-630.

**RISKS AND OUTCOMES OF PERITONITIS AFTER FLEXIBLE
COLONOSCOPY IN CAPD PATIENTS**

Terence Yip, Kai Chung Tse, Man Fai Lam, Suk Wai Cheng, Sing Leung Lui, Sydney Tang,
Matthew Ng, Tak Mao Chan, Kar Neng Lai, and Wai Kei Lo

Department of Medicine, Tung Wah Hospital, University of Hong Kong, Hong Kong

How many of you have a protocol for antibiotic prophylaxis pre colonoscopy for your patients on PD?

Protocol for antibiotic prophylaxis before a colonoscopy

- Antibiotic prophylaxis is necessary for colonoscopy:
 - Ampicillin 1 gm IP in night bag/long dwell prior to procedure
 - Tobramycin 120 mg IP in night bag/long dwell prior to procedure
 - Flagyl 500 mg PO 1 hour pre procedure and 500 mg PO 12 hours post procedure
 - Patient should be drained (“empty”) prior to procedure

Watson, D. (Ed.). (2012). UHN Division of Nephrology Housestaff/NP Guidebook. Available at www.nephrology.utoronto.ca/

Discuss your own experiences

Thank you!