



Priority Updates from the Research Literature

PURLs Journal Club Family Physicians Inquiries Network

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Overview of the PURLs Journal Club

The PURLs Journal Club is a plug-and-play toolkit created from published Priority Updates to the Research Literature (PURLs) publications published in *The Journal of Family Practice*. Each month PURL authors take the research used to write the PURL publication and create speaker notes for journal club facilitators. The PURLs Journal Club provides a structured method for helping faculty (even those who may not feel comfortable with biostatistics or evidence-based medicine concepts) prepare for a journal club in less time. In addition, the toolkit assists in faculty development while at the same time keeping faculty and residents up-to-date with the medical literature.

What is included in the PURLs Journal Club?

PURLs Journal Club Instructions

Comprehensive instructions for facilitators to assist with materials needed for journal club participants, learning standards, objectives, components, and format of journal club.

Published PURL Manuscript

Copy of PURLs manuscript published in *The Journal of Family Practice*.

Review Form

Document that shows background information completed by faculty authors prior to discussion session to determine if nominated article meets the six PURL criteria.

Speaker Notes

Speaker notes help facilitators walk journal club participants through the published article step-by-step with completed answers to the questions participants need to answer to critically appraise and understand the article.

Blank Worksheet

The blank worksheet provides the format of the journal club for the participants to follow along as well as complete.

Journal Club Rationale

I. Learning Standards

- 1. RRC Requirements
 - a. Residents must gain practical experience in data searching and grading, statistical methods, and application to practice
 - b. The training environment must be in compliance with evidence based medicine practice
- II. Objectives of Journal Club

1. By the end of the residency, all residents will be able to perform the five basic components of Evidence Based Medicine and critical appraisal. These components include;

- Ask answerable questions
- Assessing validity and relevance of the article
- Synthesizing data
- Applying the evidence to their practice

2. By the end of residency, all residents will know how to use these EBM skills in making clinical decisions.

- 3. All residents will be able to conduct a critical appraisal of original research.
- III. Components of Journal Club

1. Journal Club (JC) is a longitudinal experience. Repeat exposure to EBM concepts over the 3 year residency to achieve the goals of the Journal Club curriculum. Recommend to conduct JC monthly.

2. Utilize FPIN's **PURLs** Toolkit.

Download PURLs Journal Club Toolkit from www.fpin.org

- Obtain the original research article to critically appraise during JC
- Utilize worksheets during JC to guide the critical appraisal
- Utilize the faculty speaker notes to help guide the critical appraisal

- Utilize the PURLs article to assist leading your discussion, then review at the end of JC and decide if you agree with the PURL summary

Journal Club Format

I. Format of Journal Club

- 1. Resident learners read the **background** information from the research article.
 - From the background, define the clinical question using PICO
 - P patient or population
 - I intervention being investigated
 - C Comparison
 - O Outcomes being measured
- 2. Discuss the **relevance** of the article use the appropriate worksheet as a tool.
- 3. Review the **methods** section. Discuss the **validity** of the study using the worksheet as a tool
- 4. Review the **result** section

- Utilize the appropriate worksheet as a tool to synthesize the results (and the faculty speaker notes)

- Look for statistical significance with the results, utilizing the data provided
 - How large was the treatment effect
 - How precise was the treatment effect
 - convert data to user friendly data if possible (Number Needed to Treat)
- Are the results clinically significant?
- Are there other factors that could affect the outcome?
- 5. Discuss how to **apply** the evidence
 - Are the results clinically significance?
 - Can the results be applied to your patients?
 - Will the results change your practice?

6. Using the CEBM table, assign a Level of Evidence to the article (the PURLs article will have done this as well)

II. Tools available for the critical appraisal;

- Worksheets on RCT studies, cohort trials, systematic reviews, diagnosis studies
- Faculty speaker notes
- PURLs article
- EBM glossary of terms
- CEBM table for assigning a LoE

PURLs Journal Club Instructions

- 1. Obtain Journal Club Toolkit from <u>www.fpin.org</u> which will include:
 - a. Journal Club Instructions (this form)
 - b. Review form (background from faculty discussion and published PURL)
 - c. Published PURL
 - d. Speaker Notes (Completed study template)
 - e. Blank Study Template Form (based on type of study)
- 2. Obtain the Original Article PDF (citation in the speaker notes) from your library.
- 3. Send Original Article PDF along with blank study template form to journal club participants
- 4. Review speaker notes, read original article and published PURL
- 5. Identify your journal club presenter and ensure they are prepared to lead participants through the study template form
- 6. Assist your presenter as needed through the journal club
- 7. Pass out the published PURL and compare result





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An easy approach to obtaining clean-catch urine from infants

Current collection methods leave much to be desired. But a new method may provide a quick alternative.

PRACTICE CHANGER

Apply gauze soaked in cold sterile saline to the suprapubic area to stimulate infants ages 1 to 12 months to provide a clean-catch urine sample. Doing so produces significantly more clean-catch urine samples within 5 minutes than simply waiting for the patient to void, with no difference in contamination and with increased parental and provider satisfaction.¹

STRENGTH OF RECOMMENDATION

B: Based on a single good-quality, randomized controlled trial.

Kaufman J, Fitzpatrick P, Tosif S, et al. Faster clean catch urine collection (Quick-Wee method) from infants: randomised controlled trial. *BMJ*. 2017;357:j1341.

ILLUSTRATIVE CASE

A fussy 6-month-old infant is brought into the emergency department (ED) with a rectal temperature of 101.5° F. She is consolable, breathing normally, and appears well hydrated. You find no clear etiology for her fever and suspect that a urinary tract infection (UTI) may be the source of her illness. How do you proceed with obtaining a urine sample?

febrile infant in the family physician's office or ED is a familiar clinical situation that may require an invasive diagnostic work-up. Up to 7% of infants ages 2 to 24 months with fever of unknown origin may have a UTI.² Collecting a urine sample from pre-toilet-trained children can be time consuming. In fact, obtaining a clean-catch urine sample in this age group took an aver-

age of more than one hour in one randomized controlled trial (RCT).³ More convenient methods of urine collection, such as placing a cotton ball in the diaper or using a perineal collection bag, have contamination rates of up to 63%.⁴

The American Academy of Pediatrics (AAP) guidelines for evaluating possible UTI in a febrile child <2 years of age recommend obtaining a sample for urinalysis "through the most convenient means."⁵ If urinalysis is positive, only urine obtained by catheterization or suprapubic aspiration should be cultured. Guidelines from the National Institute for Health and Care Excellence in the United Kingdom are similar, but allow for culture of clean-catch urine samples.⁶

A recent prospective cohort study examined a noninvasive alternating lumbarbladder tapping method to stimulate voiding in infants ages 0 to 6 months.⁷ Within 5 minutes, 49% of the infants provided a clean-catch sample, with contamination rates similar to those of samples obtained using invasive methods.⁷ Younger infants were more likely to void within the time allotted. Another trial of bladder tapping conducted in hospitalized infants <30 days old showed similar results.⁸

There are, however, no previously reported randomized trials demonstrating the efficacy of a noninvasive urine collection technique in the outpatient setting.

Use of invasive collection methods requires skilled personnel and may cause significant discomfort for patients (and parents). Noninvasive methods, such as bag urine collection, have unacceptable contamination rates. In addition, waiting to catch a potentially cleaner urine sample is timeconsuming, so better strategies to collect urine from infants are needed. This RCT is the first to examine the efficacy of a unique stimulation technique to obtain a cleancatch urine sample from infants ages 1 to 12 months.

STUDY SUMMARY

Noninvasive stimulation method triggers faster clean urine samples

A nonblinded, single-center RCT conducted in Australia compared 2 methods for obtaining a clean-catch urine sample within 5 minutes: the Quick-Wee method (suprapubic stimulation with gauze soaked in cold fluid) or usual care (waiting for spontaneous voiding with no stimulation).¹ Three hundred fifty-four infants (ages 1-12 months) who required urine sample collection were randomized in a 1:1 ratio; allocation was concealed. Infants with anatomic or neurologic abnormalities and those needing immediate antibiotic therapy were excluded.

The most common reasons for obtaining the urine sample were fever of unknown origin and "unsettled baby," followed by poor feeding and suspected UTI. The primary outcome was voiding within 5 minutes; secondary outcomes included time to void, whether urine was successfully caught, contamination rate, and parent/clinician satisfaction.

Study personnel removed the diaper, then cleaned the genitals of all patients with room temperature sterile water. A caregiver or clinician was ready and waiting to catch urine when the patient voided. In the Quick-Wee group, a clinician rubbed the patient's suprapubic area in a circular fashion with gauze soaked in refrigerated saline (2.8° C). At 5 minutes, clinicians recorded the voiding status and decided how to proceed.

Using intention-to-treat analysis, 31% of the patients in the Quick-Wee group voided within 5 minutes, compared with 12% of the usual-care patients. Similarly, 30% of patients in the Quick-Wee group provided a successful clean-catch sample within 5 minutes compared with 9% in the usual-care group (P<.001; number needed to treat=4.7; 95% CI, 3.4-7.7). Contamination rates were no different between the Quick-Wee and usual-care samples. Both parents and clinicians were more satisfied with the Quick-Wee method than with usual care (median score of 2 vs 3 on a 5-point Likert scale, in which 1 is most satisfied; P<.001). There was no difference when results were adjusted for age or sex. No adverse events occurred.

WHAT'S NEW

New method could reduce the need for invasive sampling

A simple suprapubic stimulation technique increased the number of infants who provided a clean-catch voided urine sample within 5 minutes—a clinically relevant and satisfying outcome. In appropriate patients, use of the Quick-Wee method to obtain a cleancatch voided sample for initial urinalysis, rather than attempting methods with known high contamination rates, may potentially reduce the need for invasive sampling using catheterization or suprapubic aspiration.

CAVEATS

Complete age range and ideal storage temperature are unknown

Neonates and pre-continent children older than 12 months were not included in this trial, so these conclusions do not apply to those groups of patients. The intervention period lasted only 5 minutes, but other published studies suggest that this amount of time is adequate for voiding to occur.^{6,7} Although this study used soaking fluid stored at 2.8° C, the ideal storage temperature is unknown.

CHALLENGES TO IMPLEMENTATION

AAP doesn't endorse clean-catch urine samples for culture

The Quick-Wee method is simple and easy to implement, and requires no specialized training or equipment. AAP guidelines do not endorse the use of clean-catch voided urine for culture, which may be a barrier to changing urine collection practices in some settings. JFP

Almost one-third of patients provided successful cleancatch samples within 5 minutes.

ACKNOWLEDGEMENT

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- Al-Orifi F, McGillivray D, Tange S, et al. Urine culture from bag specimens in young children: are the risks too high? J Pediatr. 2000;137:221-226.
- Reaffirmation of AAP clinical practice guideline: the diagnosis and management of the initial urinary tract infection in febrile infants and young children 2-24 months of age. *Pediatrics*. 2016;138:e20163026.
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COPD in Primary Care: Key Considerations for Optimized Madagement

This supplement is sponsored by AstraZeneca.

COPD in Primary Care: Key Considerations for Optimized Management

This supplement to *The Journal of Family Practice* provides an overview of 4 key topics critical to the effective management of COPD in primary care.

- Dyspnea and hyperinflation
- Anxiety and depression
- Inhaler device selection
- Treatment options



RCT Potential PURL Review Form PURL Jam Version

PURLs Surveillance System Family Physicians Inquiries Network

SECTION 1: Identifying Information for Nominated Potential PURL [to be completed by PURLs Project Manager]

- A. Citiation: Kaufman J, Fitzpatrick P, Tosif S, Hopper SM, Donath SM, Bryant PA, Babl FE. Faster clean catch urine collection (Quick-Wee method) from infants: randomised controlled trial. BMJ. 2017 Apr 7;357:j1341. doi: 10.1136/bmj.j1341.
- B. Link to PDF of full article: https://www.ncbi.nlm.nih.gov/pubmed/?term=28389435
- C. First date published study available to readers: 4/7/2017
- D. PubMed ID: 28389435
- E. Nominated By: Anne Mounsey
- F. Institutional Affiliation of Nominator: University of North Carolina Chapel Hill
- G. Date Nominated: 4/10/2017
- H. Identified Through: JAMA
- I. PURLs Editor Reviewing Nominated Potential PURL: Corey Lyon
- J. Nomination Decision Date: 5/12/2017
- K. Potential PURL Review Form (PPRF) Type: RCT
- L. Assigned Potential PURL Reviewer: Laura Morris
- M. Reviewer Affiliation: University of Missouri
- N. Abstract: Objective To determine if a simple stimulation method increases the rate of infant voiding for clean catch urine within five minutes. Design Randomised controlled trial. Setting Emergency department of a tertiary paediatric hospital, Australia.Participants 354 infants (aged 1-12 months) requiring urine sample collection as determined by the treating clinician. 10 infants were subsequently excluded. Interventions Infants were randomised to either gentle suprapubic cutaneous stimulation (n=174) using gauze soaked in cold fluid (the Quick-Wee method) or standard clean catch urine with no additional stimulation (n=170), for five minutes. Main outcome measures The primary outcome was voiding of urine within five minutes. Secondary outcomes were successful collection of a urine sample, contamination rate, and parental and clinician satisfaction with the method. Results The Quick-Wee method resulted in a significantly higher rate of voiding within five minutes compared with standard clean catch urine (31% v 12%, P<0.001), difference in proportions 19% favouring Quick-Wee (95% confidence interval for difference 11% to 28%). Quick-Wee had a higher rate of successful urine sample collection (30% v 9%, P<0.001) and greater parental and clinician satisfaction (median 2 v 3 on a 5 point Likert scale, P<0.001). The difference in contamination between Quick-Wee and standard clean catch urine was not significant (27% v 45%, P=0.29). The number needed to treat was 4.7 (95% confidence interval 3.4 to 7.7) to successfully collect one additional urine sample within five minutes using Quick-Wee compared with standard clean catch urine. Conclusions Quick-Wee is a simple cutaneous stimulation method that significantly increases the five minute voiding and success rate of clean catch urine collection. Trial registration Australian New Zealand Clinical Trials Registry ACTRN12615000754549.
- O. Pending PURL Review Date: 5/31/2017

- A. Number of patients starting each arm of the study?
 179 in Quick Wee; 175 in standard care
- B. Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.) Infants aged 1-12 mos presenting to pediatric ER in need of urine sample. Clinician determined that clean catch was ok—presumably this excluded sicker infants. Mean age 5.4 mos, 50% male.
- C. Intervention(s) being investigated? Quick-Wee method (stimulation of suprapubic region with gauze soaked in refrigerated saline)
- D. Comparison treatment(s), placebo, or nothing? standard care (no stimulation, wait for infant to spontaneously void)
- E. Length of follow-up? (Note specified end points, e.g., death, cure, etc.) Intervention lasted 5 min in ER, or until voided
- F. What outcome measures are used? List all that assess effectiveness. Primary outcome was void yes/no Secondary outcomes were successful collection of urine (some were missed even though voiding occurred), contamination rates, parent/clinician satisfaction
- G. What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CU, p-values, etc.

Quick Wee method was more effective way to make an infant void within 5 min: 31% vs 12%; NNT ~5, P<.001. Also more effective for collecting a clean catch sample within 5 min: 30% vs 9%; NNT ~5, P<.001.

Contamination similar between groups: Quick Wee 27% (95% CI, 15-45%) vs standard care 45% (95% CI, 17-77%)

Quick Wee method had higher parent satisfaction than standard care (median score 2 vs 3 on a 5 point Likert scale, P<.001) and clinician satisfaction (median score 2 vs 3 on a 5 point Likert scale, P<.001)

H. What are the adverse effects of intervention compared with no intervention?
 N/A
 All infants cried in both groups

All infants cried in both groups

I. The study addresses an appropriate and clearly focused question. (select one) Well covered

Comments:

J. Random allocation to comparison groups: (select one) Well covered

Comments: computer generated sequence 1:1, consecutive pt enrolled

K. Concealed allocation to comparison groups: (select one)

Well covered

Comments: opaque envelopes

L. Subjects and investigators kept "blind" to comparison group allocation: (select one) Not applicable

Comments:

- M. Comparison groups are similar at the start of the trial: (select one) Well covered Comments: groups were similar
- N. Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential sources of bias. (select one)
 Not applicable
 Comments: all had same genital cleaning with room temp water prior to collection
- O. Were all relevant outcomes measured in a standardized, valid, and reliable way? (select one) Adequately addressed
 Comments: definitions given for contamination
 ** the Likert scale is not well defined, though, and it is not clear when this was administered, by whom, or exactly what defined the scale. Odd that the scores were whole numbers for both groups and exactly the same for both parents and clinicians...
- P. Are patient oriented outcomes included? If yes, what are they? We think that eliciting a clean catch void from an infant is patient oriented, because this can avoid the need for an invasive sample such as suprapubic aspiration or catheterization (although this study doesn't directly address that)
- Q. What percent dropped out, and were lost to follow up? Could this bias the results? How? 10 total withdrew after randomization, not concerning
- R. Was there an intention-to-treat analysis? If not, could this bias the results? How? yes
- S. If a multi-site study, are results comparable for all sites? N/A
- T. Is the funding for the trial a potential source of bias? If yes, what measures were taken to ensure scientific integrity? No issues
- U. To which patients might the finding apply? Include patients in the study and other patients to whom the findings may be generalized.
 Infants age 1-12 months with fever of unknown origin, excess fussiness, vomiting, etc
- V. In what care settings might the finding apply, or not apply?

ER, although reasonably this could work in clinic or urgent care, wherever urine sampling needed

W. To which clinicians or policy makers might the finding be relevant? ER, urgent care, outpatient physicians

SECTION 3: Review of Secondary Literature [to be completed by the Potential PURL Reviewer] [to be revised by the Pending PURL Reviewer as needed]

 Citation Instructions:
 For up-to-date citations, use style modified from

 <u>http://www.uptodate.com/home/help/faq/using_UTD/index.html#cite</u> &

 AMA style.
 Always use Basow DS on editor & current year as publication year.

Example: Auth I. Title of article. {insert author name if given, & search terms or title.} In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2009. Available at: <u>http://www.uptodate.com</u>. {Insert date modified if given.} Accesses February 12, 2009. [whatever date PPRF reviewer did their search.}

For DynaMed, use the following style:

Depression: treatment {insert search terms or title}. In: DynaMed [database online]. Available at <u>http://www.DynamicMedical.com</u>. Last updated February 4, 2009. {Insert date modified if given.} Accessed June 5, 2009. {search date}

A. DynaMed excerpts

Urine studies:

General information:

- infants < 3 months old presenting with unexplained fever ≥ 38 degrees C (100.4 degrees F), infants and children 3-36 months old with unexplained fever ≥ 39 degrees C (102.2 degrees F) with other associated risk factor related to gender, ethnicity, circumcision status and/or prior history of UTI, and children ≥ 3 years old with signs and symptoms of UTI should have a urine sample tested for infection(2 5)
 - although symptoms like cough and rhinorrhea produced by a suspected viral respiratory infection may often be the explanation for an associated fever, when evaluating a child < 36 months old, if the fever is high enough (depending on the age of the child), one cannot exclude the possibility of a UTI (<u>Ann Emerg Med 2016 May;67(5):625 full-text</u>)
 - O DynaMed commentary -- When assessing fever as a risk factor for UTI in children < 24-36 months old, it is important to consider the height of the fever relative to the age of the patient. Temperature ≥ 38 degrees C (100.4 degrees F) in infants < 3 months old, and ≥ 39 degrees C (102.2 degrees F) in infants 3-36 months old associated with increased risk of occult serious bacterial infection, including UTI. If a child < 3 months old with upper respiratory symptoms presents with fever > 38 degrees C (100.4 degrees F), or a child 3-36 months old with upper respiratory symptoms presents with fever ≥ 39 degrees C (102.2 degrees F), one should consider further evaluation of the fever with urinalysis and culture to rule out UTI.
- see <u>Fever without apparent source in infants aged < 3 months</u> and <u>aged 3-36 months</u> for details
- urine collection $(\underline{1}, \underline{3}, \underline{4}, \underline{5})$
 - clean catch urine sample is recommended method in toilet-trained children (<u>National Institute for Health and Care</u> <u>Excellence (NICE) 2007 Aug:CG54 PDF</u>, <u>ESPU/EAU Grade B Level 2a</u>)
 - o if high-quality clean-catch midstream urine sample cannot be obtained
 - collect urine by catheter or suprapubic aspiration (<u>AAP Strong recommendation</u>, <u>Evidence Quality A</u>, <u>ESPU/EAU</u> <u>Grade B Level 2a</u>; <u>NICE 2007 Aug:CG54 PDE</u>)

- if low clinical suspicion of UTI, then dipstick or urinalysis may be done on more convenient urine specimen with catheterization done if urinalysis suggests UTI
- urine samples should be sent for culture if(5)
 - o diagnosis of acute pyelonephritis/upper UTI is suspected
 - o infant or child at high or intermediate risk of serious illness
 - o infant or child < 3 years old
 - *DynaMed commentary* -- sending for urine culture may be best approach if there is limited volume of urine specimen, especially in infants
- consider testing infants < 8 weeks old with asymptomatic jaundice(3)
- in febrile children aged 2-24 months⁽²⁾
 - if antibiotics required because of ill appearance or other pressing reason, obtain urine specimen by catheterization or suprapubic aspiration (not bag urine) for both culture and urinalysis before antibiotics (<u>AAP Strong recommendation</u>, <u>Evidence Quality A</u>)
 - o if no apparent source of fever and immediate antibiotics not required
 - clinical follow-up without testing sufficient if child has low likelihood of UTI (<u>AAP Strong recommendation</u>, <u>Evidence Quality A</u>)
 - options for children not at low risk for UTI include (AAP Strong recommendation, Evidence Quality A)
 - collect specimen by catheterization or suprapubic aspiration for culture and urinalysis
 - collect specimen by more convenient means and perform urinalysis
 - if urinalysis of fresh (< 1 hour since void) sample is negative for leukocyte esterase and nitrites, it is reasonable to monitor patient without antibiotics even though negative urinalysis cannot rule out UTI
 - if urinalysis suggestive of UTI (positive leukocyte esterase or nitrites or microscopic analysis reveals positive leukocytes or bacteria), then obtain urine specimen by catheterization or suprapubic aspiration for culture

B. DynaMed citation

Urinary Tract Infection (UTI) in Children. Miner DS. In: DynaMed [database online]. Available at: www.DynamicMedical.com Last Updated: May 12, 2017. Accessed May 30, 2017.

- C. Bottom line recommendation orsummary of evidence from DynaMed (1-2 sentences) Can obtain clean catch urine first, then invasive if unable to do so. If antibiotics required, use SPA or catheter and culture urine.
- D. UpToDate excerpts
 - UpToDate

We and the American Academy of Pediatrics recommend that infants and children with a suspected urinary tract infection (UTI), who are not toilet trained and who are ill enough to merit antimicrobial therapy, have urine cultures obtained by TUBC or SPA rather than by clean catch or clean urine bag specimen

a. Already incorporated this technique in section on clean voided samples!

Bajaj L and Boathner J. Urine collection techniques in infants and children with suspected UTI. In: Wiley JF, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2017. Available at: <u>http://www.uptodate.com</u>. Accessed May 28, 2017.

E. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences) Recommend catheterization or suprapubic aspiration when culture needed

F. Other excerpts (USPSTF; other guidelines; etc.) American Academy of Pediatrics:

- a. If a clinician assesses a febrile infant with no apparent source for the fever as not being so ill as to require immediate antimicrobial therapy, then the clinician should assess the likelihood of UTI.
- b. Action Statement 2a. If the clinician determines the febrile infant to have a low likelihood of UTI (see text), then clinical follow-up monitoring without testing is sufficient (evidence quality: A; strong recommendation).
- c. Action Statement 2b. If the clinician determines that the febrile infant is not in a low-risk group (see below), then there are 2 choices (evidence quality: A; strong recommendation).
- d. Option 1 is to obtain a urine specimen through catheterization or SPA for culture and urinalysis.
- e. Option 2 is to obtain a urine specimen through the most convenient means and to perform a urinalysis. If the urinalysis results suggest a UTI (positive leukocyte esterase test results or nitrite test or microscopic analysis results for leukocytes or bacteria), then a urine specimen should be obtained through catheterization or SPA and cultured; if urinalysis of fresh (less than 1 hour since void) urine yields negative leukocyte esterase and nitrite results, then it is reasonable to monitor the clinical course without initiating antimicrobial therapy, recognizing that a negative urinalysis does not rule out a UTI with certainty.

NICE is much more succinct:

A clean catch urine sample is the recommended method for urine collection.

G. Citations for other excerpts

AAP clinical practice guideline on diagnosis and management of initial urinary tract infection (UTI) in febrile infants and children aged 2-24 months reaffirmation can be found in <u>Pediatrics</u> 2016 Dec;138(6)

National Institute for Health and Care Excellence. Urinary tract infection in under 16s: diagnosis and management. Clinical guideline [CG54] Published date: August 2007. Available at: <u>https://www.nice.org.uk/guidance/cg54/chapter/1-guidance</u>. Accessed May 30, 2017.

H. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences) Use clean catch first to obtain urine for UA, use SPA or catheter if need culture (AAP, but not NICE—they are ok with using the clean catch for culture).

SECTION 4: Conclusions

[to be completed by the Potential PURL Reviewer] [to be revised by the Pending PURL Reviewer as needed]

- A. **Validity**: How well does the study minimize sources of internal bias and maximize internal validity? 2
- B. If **A** was coded 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?

- C. **Relevance**: Are the results of study generalizable to and relevant to the health care needs of patients cared for by "full scope" family physicians? 2
- D. If C was coded 4, 5, 6, or 7, please provide an explanation.
- E. Practice changing potential: If the findings of the study are both valid and relevant, does the practice that would be based on these findings represent a change from current practice? 3
- F. If E was coded as 1, 2, 3, or4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit. Use Quick Wee method to attempt clean catch urine collection rather than waiting for spontaneous voiding. There is an extrapolation here, where providers should attempt a clean catch in cases where a negative UA would "rule out" or avoid need for invasive sample. We were also unsure how many providers are using clean catch in this way, or if stimulation like this is already in use?

None of this compares to a bag or cotton ball, for example, but the practice changer would likely be using the Quick Wee method rather than a dirty method—instead of using Quick Wee rather than waiting for a clean catch spontaneous void.

G. Applicability to a Family Medical Care Setting:

Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc.), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, education or counseling a patient; or creating a system for implementing an intervention? 1 (definitely could be done in a medical care setting)

H. If **G** was coded as a 4, 5, 6, or 7, please explain.

I. Immediacy of Implementation:

Are there major barriers to immediate implementation? Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug, or other essentials available on the market? 1 (definitely could be immediately applied)

J. If I was coded 4, 5, 6, or 7, please explain why.

K. Clinically meaningful outcomes or patient oriented outcomes:

Are the outcomes measured in the study clinically meaningful or patient oriented? 4 (uncertain)

L. If **K** was coded 4, 5, 6, or 7 please explain why. Again, we don't doubt that this method works to obtain urine. But, the question is whether this could be applied in a way that changes the practice to avoid invasive sampling.

- M. In your opinion, is this a pending PURL?
 - 1. Valid: Strong internal scientific validity; the findings appear to be true.
 - 2. Relevant: Relevant to the practice of family medicine.
 - 3. Practice Changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different than current practice.

3

- 4. Applicability in medical setting.
- 5. Immediacy of implementation
- N. Comments on your response for question M. Same as above. Based on this individual trial, it is clear that using a stimulation method produces more clean catch urine samples in an ER setting. Is it valid to extrapolate this to reducing the invasive samples? Not as clear.

FPIN Journal Club RANDOMIZED CONTROLLED TRIAL SPEAKER NOTES

Title: "An easy approach to obtaining clean-catch urine from infants" Author: Laura Morris, MD, MSPH PURL Citation: Morris, LE. An easy approach to obtaining clean-catch urine from infants J Fam Pract. 2018 March;67(3):166,168-169

Original Article: Kaufman J, Fitzpatrick P, Tosif S, Hopper SM, Donath SM, Bryant PA, Babl FE. Faster clean catch urine collection (Quick-Wee method) from infants: randomized controlled trial. BMJ. 2017 Apr 7;357:j1341. doi: 10.1136/bmj.j1341.

1. What question did the study attempt to answer?

Patients – infants age 1-12 mos presenting to ER in need of urinalysis Intervention – Quick Wee method for obtaining urine sample (suprapubic stimulation with gauze soaked in cold fluid)

Comparison – standard clean catch urine without further stimulation

Outcome – voiding urine within 5 minutes. Secondary outcomes included successful collection of a sample, contamination rate, and parent/provider satisfaction

Di	id the study address an appropriate and clearly focused question	🛛 Yes 🗌 No
2.	 Determining Relevance: a. Did the authors study a clinically meaningful and/or a patient oriented outcome? b. The patients covered by the review similar to your population 	⊠ Yes □ No on ⊠ Yes □ No
3.	. Determining Validity: Study design; a. Was it a controlled trial?	🖂 Yes 🗌 No
	b. Were patients randomly allocated to Comparison groups?	es 🗌 No 🗌 Unclear
	c. Were groups similar at the start of a trial? Xe no <i>P</i> values given, but Table 1	es 🔄 No 🔄 Unclear generally appears similar
	d. Were patients and study personnel "blind" to treatment?	es 🔀 No 🗌 Unclear
	e. Aside from allocated treatment, were groups treated equall \widecheck Ye	y? es 🗌 No 🗌 Unclear
	f. Were all patients who entered the trial properly accounted f $$ Ye	for at its conclusion?

4. What are the results?

a. What are the overall results of the study?

Quick Wee method was more effective way to make an infant void within 5 min: 31% vs 12%; NNT ~5, P<.001. Also more effective for collecting a clean catch sample within 5 min: 30% vs 9%; NNT ~5, P<.001.

Contamination similar between groups: Quick Wee 27% (95% CI, 15-45%) vs standard care 45% (95% CI, 17-77%)

Quick Wee method had higher parent satisfaction than standard care (median score 2 vs 3 on a 5 point Likert scale, P<.001) and clinician satisfaction (median score 2 vs 3 on a 5 point Likert scale, P<.001)

- b. Are the results statistically significant?
- c. Are the results clinically significant?
- d. Were there other factors that might have affected the outcome?

🔀 Yes		No
🔀 Yes		No
_		
Yes	\times	No

🛛 Yes 🗌 No

No

No

Yes 🖂 No

imes Yes

Yes

5. Applying the evidence:

- a. If the findings are valid and relevant, will this change your current practice?
- b. Is the change in practice something that can be done in a medical care setting of a family physician?
- c. Can the results be implemented?



Potentially push back from ER doctors. AAP guidelines recommend only using cath/SP samples for culture

e. How was this study funded? Philanthropic research grant, other Australian government research funding grants.

6. Teaching Points

Absolute Risk Reduction (ARR) and Calculating a NNT– is the difference between the control event rate and the experimental event rate.

Successful clean catch urine within 5 min: ARR= 0.30 - 0.09 = 0.21 (21%)

The NNT is the inverse of the ARR – 1/ARR = 1/0.21 = 4.8

Therefore, you will need to attempt the Quick Wee method with 5 patients to collect 1 clean catch urine compared to waiting for the patient to void.

Internal validity

Internal validity refers to the accuracy or truth of the study results which depends on how well the design, implementation, and statistical analysis have minimized or eliminated bias. The factors that can effect internal validity are randomization, groups being equal at baseline, each group having the same treatment aside from the treatment under study, good follow up with a low dropout rate (typically less than 15%), blinding of participants and investigators (when possible) and intention to treat analysis.

This study had moderate to high internal validity. Researchers attempted to mitigate selection bias by including all infants regardless of hydration status or how recently fed.

External validity

External validity of a study is the degree to which the findings are able to be generalized to other groups or populations. This study has high external validity as over 100 providers in the ER participated (a more "real world" application of a protocol) and not just research staff who may have interacted differently with patients.

FPIN Journal Club RANDOMIZED CONTROLLED TRIAL

1. What question did the study attempt to answer? Patients -Intervention -Comparison -Outcome -Did the study address an appropriate and clearly focused question \Box Yes \Box No 2. Determining Relevance: a. Did the authors study a clinically meaningful \square Yes \square No and/or a patient oriented outcome? b. The patients covered by the review similar to your population \Box Yes \Box No 3. Determining Validity: Study design; a. Was it a controlled trial? \Box Yes \Box No b. Were patients randomly allocated to comparison groups? \Box Yes \Box No \Box Unclear c. Were groups similar at the start of a trial? \Box Yes \Box No \Box Unclear d. Were patients and study personnel "blind" to treatment? \Box Yes \Box No \Box Unclear e. Aside from allocated treatment, were groups treated equally? \Box Yes \Box No \Box Unclear f. Were all patients who entered the trial properly accounted for at it's conclusion

 \Box Yes \Box No \Box Unclear

4. What are the results?

a. What are the overall results of the study?

b. Are the results statistically significant?	🗆 Yes 🗆 No
c. Are the results clinically significant?	🗆 Yes 🗆 No
d. Were there other factors that might have	
affected the outcome?	🗆 Yes 🗆 No

5. Applying the evidence:

🗆 Yes 🗆 No
🗆 Yes 🗆 No
🗆 Yes 🗆 No
🗆 Yes 🗆 No

Teaching Points Spreadsheet

Purpose

Provide a searchable document in which journal club facilitators can identify specific lessons for journal club participants.

Example

Instructions: The PURL Journal Clubs and a conprehensive list of teaching points are listed below. If you are looking for a specific teaching point, please simply search for that point and navigate to that PURL Journal Club toolkit. For any questions, contact purls@fpin.org.			
Month/Year Title	Study Type	Teaching Point 1	Teaching Point 2
19-May Should you switch the DAPT agent one month after ACS?	RCT	Hazard Ratio	Confidence Interval
Apr-19 How do these 3 diabetes agents compare in reducing mortality?	Systematic Review	Hazard Ratio	
Mar-19 Bariatric survey + medical therapy: Effective TX for T2DM	RCT	Intention to Treat (ITT)	
Feb-19 Less is more when it comes to ketorolac for pain	RCT	Mean Difference	Confidence Interval
Jan-19 What's the best treatment setting for stable PE patients?	Cohort	Propensity matched scoring	Confidence Interval
Dec-18 Asthma diagnosis	Cohort	Confidence Interval	
Nov-18 Repeat PAP in 6 months for ASCUS	Cohort	Internal Validity	External Validity
Oct-18 Glucosamine for OA	RCT	Intention to Treat (ITT)	
Sep-18 Nonsterile gloves for minor procedures	Systematic Review	Heterogeneity	Forest Plots
Aug-18 First-time, mild diverticulitis: Antibiotics or watchful waiting?	RCT	Hazard Ratio	Noninferiority Studies
Jul-18 Let low-risk moms eat during labor?	Systematic Review	When it is appropriate to conduct a meta-analysis	
Jun-18 Antenatal fetal Rh screening	Cohort	Understanding sensitivity/specificity	Likelihood ratios
May-18 Pediatric migraines	RCT	Applicability	Futility Analysis
Apr-18 Clean-catch urine method	RCT	Absolute Risk Reduction (ARR) and Calculating a N	N Internal validity
Mar-18 Fish oil in pregnancy	RCT	External validity	Absolute Risk Reduction (
Feb-18 Tamsulosin for patients with ureteral stones?	Systematic Review	Heterogeneity	Forest Plots
Jan-18 Azithromycin for C-Sections	RCT	Putting an NNT or NNH into Perspective	Intention to treat
Dec-17 PPIs and UGI Bleeds	Cohort	Putting an NNT or NNH into Perspective	Misclassification Bias