

**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. Citation: 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

**SECTION 2: Critical Appraisal of Validity**  
**[to be completed by the Potential PURL Reviewer]**

- 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
- 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 [http://www.uptodate.com/home/help/faq/using\\_UTD/index.html#cite](http://www.uptodate.com/home/help/faq/using_UTD/index.html#cite) & 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: <http://www.uptodate.com>. {Insert date modified if given.} Accessed 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 <http://www.DynamicMedical.com>. 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  $\geq$  38 degrees C (100.4 degrees F), infants and children 3-36 months old with unexplained fever  $\geq$  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  $\geq$  3 years old with signs and symptoms of UTI should have a urine sample tested for infection<sup>(2, 5)</sup>
  - 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 ([Ann Emerg Med 2016 May;67\(5\):625 full-text](#))
  - *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  $\geq$  38 degrees C (100.4 degrees F) in infants < 3 months old, and  $\geq$  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  $\geq$  39 degrees C (102.2 degrees F), one should consider further evaluation of the fever with urinalysis and culture to rule out UTI.
  - see [Fever without apparent source in infants aged < 3 months](#) and [aged 3-36 months](#) for details
- urine collection<sup>(1, 3, 4, 5)</sup>
  - clean catch urine sample is recommended method in toilet-trained children ([National Institute for Health and Care Excellence \(NICE\) 2007 Aug:CG54 PDF](#), [ESPU/EAU Grade B Level 2a](#))
  - if high-quality clean-catch midstream urine sample cannot be obtained
    - collect urine by catheter or suprapubic aspiration ([AAP Strong recommendation, Evidence Quality A](#), [ESPU/EAU Grade B Level 2a](#); [NICE 2007 Aug:CG54 PDF](#))

- 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<sup>(5)</sup>
  - diagnosis of acute pyelonephritis/upper UTI is suspected
  - infant or child at high or intermediate risk of serious illness
  - 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<sup>(3)</sup>
- in febrile children aged 2-24 months<sup>(2)</sup>
  - 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 ([AAP Strong recommendation, Evidence Quality A](#))
  - if no apparent source of fever and immediate antibiotics not required
    - clinical follow-up without testing sufficient if child has low likelihood of UTI ([AAP Strong recommendation, Evidence Quality A](#))
    - 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](http://www.DynamicMedical.com) Last Updated: May 12, 2017. Accessed May 30, 2017.

#### C. Bottom line recommendation or summary 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: <http://www.uptodate.com>. 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 [Pediatrics 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: <https://www.nice.org.uk/guidance/cg54/chapter/1-guidance> . 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, or 4, 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?

3

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.
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.