

NACB Laboratory Medicine Practice Guidelines (LMPG)

Evidence-Based Practice for
Point of Care Testing
Renal Focus Group

2004



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Introduction

- Dipstick urinalysis is a fixture in POCT since introduction of Clinistix
 - Screening of general population
 - Screening of inpatients
- Dipstick testing widespread because:
 - relatively inexpensive
 - easy to perform
 - painless to the patient
- DUA has been a staple for community health and preoperative screening, and in the work-up of urinary tract and systemic diseases



Introduction

- The real clinical utility of DUA is more often assumed than proven
- More recently other tests of renal function have become available at the point of care
- The value of these tests at the point of care needs to be established as well



Introduction

- Our group focused on renal function testing (BUN, creat, electrolytes) and dipstick urinalysis
- Excluded tests:
 - Glucose, microalbumin (diabetes)
 - Leukocyte esterase, nitrite (ID)
- 5 project phases: clinical question formulation, literature search, abstract review, full-text review, grading and recommendations



More Exclusions

- Excluded all studies that were analytical comparisons or evaluations that did not address patient outcomes
- Excluded all studies that focused on outcomes but did not address POCT versus another method



Approach to Guidelines

- Recommendations graded A,B,C,D,I using system from the U.S. Preventive Services Task Force
- Literature graded:
 - I: properly randomized controlled trial
 - II-1: well-designed controlled trials without randomization
 - II-2: well-designed cohort or case-control analytic studies, preferably from more than one center or research group
 - II-3: multiple time series with or without intervention. Dramatic results in uncontrolled experiments.
 - III: Opinions of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees.



Sample Literature Search

#	Search History	Results
1	point-of-care testing	465
2	point of care testing	1343
3	ancillary testing	318
4	satellite testing	213
5	bedside testing	1119
6	near-patient testing	107
7	near patient testing	542
8	remote testing	545
9	Physician's Office Laboratories	91
10	1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9	3722
11	BUN	5196
12	blood urea nitrogen	5820
13	urea	57069
14	creatinine	38113
15	10 AND (11 OR 12 OR 13 OR 14)	<u>77</u>



Clinical Question #1

- Does measurement of BUN and/creatinine at the point of care (versus the core lab) result in quicker time to treatment, decreased wait time, or decreased length of stay for inpatient, ED, dialysis, CVDL, or chemotherapy patients?



Clinical Question #1

- Abstracts for review: 77
- Papers for full-text review: 13
- Papers accepted for grading: 3
- 2 Recommendations
 - ED
 - CVDL



Clinical Question #1

- Does POCT for creatinine/BUN in the ED result in decreased LOS?
 - Recommendation: D
 - Grade of evidence: II-3
 - (Tsai et al, 1994; Parvin et al, 1996)
- Does POCT for creatinine/BUN in the CVDL result in decreased wait time?
 - Recommendation: B
 - Grade of evidence: II-3
 - (Nichols et al, 2000)



Clinical Question #2

- Does screening for renal insufficiency by urine pH dipstick at the point of care result in earlier diagnosis of renal insufficiency and fewer adverse events or decreased length of stay for patients compared to screening by core lab urine pH testing?

Clinical Question #2

- Abstracts for review: 310
- Papers for full-text review: 3
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #3

- Does screening for metabolic disorders using urine dipstick pH at the point of care result in earlier diagnosis of metabolic disorders, along with fewer adverse events and more rapid time to treatment for patients in outpatient clinics or the NICU/nursery when compared to screening by core lab urine pH testing?



Clinical Question #3

- Abstracts for review: 310
- Papers for full-text review: 6
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #4

- Does measurement of urine specific gravity via dipstick testing at the point of care to evaluate renal function result in decreased patient wait time, quicker time to treatment, fewer adverse events, or decreased length of stay for inpatient, ED, or outpatient clinic patients when compared to measurement of urine specific gravity in the core lab?



Clinical Question #4

- Abstracts for review: 21
- Papers for full-text review: 6
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #5

- Does assessment of specimen integrity by measurement of urine specific gravity by dipstick testing at the point of care result in fewer repeat patient visits due to invalid urine specimens in the ED, physician's office lab, or workplace drug testing setting?



Clinical Question #5

- Abstracts for review: 2
- Papers for full-text review: 1
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #6

- Does determination of hydration status by measurement of plasma, serum, whole blood, or urine osmolality at the point of care result in decreased patient wait time, quicker time to treatment, decreased length of stay, or fewer adverse events for inpatient, ED, or outpatient clinic patients compared to measurement of osmolality in the core lab?

Clinical Question #6

- Abstracts for review: 6
- Papers for full-text review: 3
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #7

- Does screening for proteinuria using urine dipstick testing at the point of care to evaluate renal function result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay for inpatient, ED, or outpatient clinic patients when compared to urine protein screening using a core laboratory method?



Clinical Question #7

- Abstracts for review: 260
- Papers for full-text review: 33
- Papers accepted for grading: 6
 - 2 papers address cost-effectiveness (Craig et al, 2002; Hermansen et al, 1981)
 - 4 papers address accuracy for diagnosis of nephropathy compared to central lab (Agarwal et al, 2002; Abitbol et al, 1990; Ralston et al, 1988; Shaw et al, 1985)
- Recommendation: D
- Grade of evidence: II-3



Clinical Question #8

- Does detection of glomerular dysfunction by evaluation of hematuria using dipstick testing at the point of care result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay for inpatient, ED, or outpatient clinic patients when compared to evaluation of hematuria using core lab urinalysis?



Clinical Question #8

- Abstracts for review: 215
- Papers for full-text review: 16
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #9

- Does analysis of urine or serum electrolytes at the point of care result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay for inpatient, ED, or outpatient clinic patients when compared to analysis of electrolytes using the core laboratory?



Clinical Question #9

- Abstracts for review: 20
- Papers for full-text review: 6
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #10

- Does evaluation for pregnancy-induced hypertension or pre-eclampsia using urine protein dipstick testing at the point of care result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay for ED, outpatient clinic, or labor and delivery patients when compared to urine protein measurement using core laboratory methods?



Clinical Question #10

- Abstracts for review: 260
- Papers for full-text review: 17
- Papers accepted for grading: 3
 - (Murray et al, 2002; Waugh et al, 2001; Uttendorfsky et al, 1988)
- Does POCT for proteinuria result in fewer adverse events and reduced time to treatment during antenatal care?
 - Recommendation: D
 - Grade of evidence: II-3



Clinical Question #11

- Does the use of urine dipstick protein measurements at the point of care for diagnosis or recurrence monitoring of renal cancer result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay for inpatient, ED, or outpatient clinic patients compared to urine protein measurement using core lab methods?



Clinical Question #11

- Abstracts for review: 260
- Papers for full-text review: 1
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #12

- Does the use of urine dipstick pH testing at the point of care to predict renal stone recurrence result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay for inpatient, ED, or outpatient clinic patients compared to core lab urine pH testing?



Clinical Question #12

- Abstracts for review: 310
- Papers for full-text review: 4
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #13

- Does dipstick hematuria testing at the point of care to detect intra-abdominal trauma result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay for ED patients compared to evaluation of hematuria using core lab urinalysis?



Clinical Question #13

- Abstracts for review: 215
- Papers for full-text review: 16
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #14

- Does measurement of lactate at the point of care to assess or correct lactate buffer replacement in hemodialysis patients result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay?



Clinical Question #14

- Abstracts for review: 9
- Papers for full-text review: 3
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #15

- Does detection of myoglobinuria using urine dipstick testing at the point of care as an indicator for possible renal complications of muscle injury result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay for inpatient, ED, and outpatient clinic patients when compared to evaluation of myoglobinuria using core lab urinalysis?



Clinical Question #15

- Abstracts for review: 7
- Papers for full-text review: 4
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Clinical Question #16

- Does measurement of microalbuminuria using dipstick testing at the point of care to assess non-diabetic nephropathy result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased length of stay for inpatient, ED, and outpatient clinic patients when compared to evaluation of microalbuminuria using core lab methods?



Clinical Question #16

- Abstracts for review: 38
- Papers for full-text review: 11
- Papers accepted for grading: 0
- Recommendation: I - We conclude that the evidence is insufficient to recommend for or against routinely providing POCT
- Grade of evidence: N/A



Summary of Evidence

- With respect to most of the clinical questions presented, there is insufficient evidence in the literature to recommend for or against POCT
- In the few cases where there is evidence that addresses patient outcomes, it does not support the use of POCT for renal function or dipstick UA testing
- One specific case (Nichols et al.) demonstrates the utility of renal POCT if clinical systems are designed to capitalize on advantages of POCT



Recommendations for Future Studies

- Studies are needed that not only address comparison of POCT methods to core lab methods, but that address the impact of POCT on specific patient outcomes
- Studies are needed to address a variety of setting in which renal POCT is performed
- Studies should be controlled to address a specific patient population (e.g. ED, outpatient)
- Ideally, studies will be performed in a randomized control format with groups treated based on POCT or core lab methods (when practical)



Questions and Discussion

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