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CADTH RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS

Point-of-Care Urine Pregnancy Screening in the Emergency Department: Diagnostic Accuracy, Clinical Utility, and Guidelines

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Authors: Wendy Pejic, Charlene Argáez

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Acknowledgments:

Research Questions

1. What is the diagnostic accuracy of point-of-care urine pregnancy screens for patients presenting to the emergency department?
2. What is the clinical utility of point-of-care urine pregnancy screens for patients presenting to the emergency department?
3. What are the evidence-based guidelines associated with the use of point-of-care urine pregnancy screens for patients presenting to the emergency department?

Key Findings

Three non-randomized studies were identified regarding the diagnostic accuracy or clinical utility of point-of-care urine pregnancy screens for patients presenting to the emergency department.

Methods

A limited literature search was conducted on key resources PubMed, CINAHL database, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases and a focused Internet search. No methodological filters were applied to limit retrieval by publication type. The search was limited to English language documents published between January 1, 2007 and November 29, 2017. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Female patients in emergency departments
Intervention	Point-of-care urine pregnancy screens
Comparators	Q1-2: Blood/serum pregnancy tests (human chorionic gonadotropin laboratory results); Urine pregnancy tests (human chorionic gonadotropin laboratory results) Q3: No comparator
Outcomes	Q1: Diagnostic accuracy Q2: Clinical utility of POC test (e.g., length of stay in emergency department, turnaround time for results, time to diagnostic imaging when comparing two methods) Q3: Guidelines (in the emergency department)
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, evidence-based guidelines

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and evidence-based guidelines.

Three non-randomized studies were identified regarding the diagnostic accuracy or clinical utility of point-of-care urine pregnancy screens for patients presenting to the emergency department. No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, or evidence-based guidelines were identified.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

Three non-randomized studies[1-3] were identified regarding the diagnostic accuracy or clinical utility of point-of-care (POC) urine pregnancy screens for patients presenting to the emergency department.

The authors of one study determined that the performance of nine of 11 commonly used urine POC human chorionic gonadotropin (hCG) devices that they assessed (in a prior study) were susceptible to false-negative results (thought to be due to the hCG β core fragment [hCGβcf]).[1] They then went on to search the FDA's Manufacturer and User Facility Device Experience (MAUDE) database in order to ascertain whether these false results were experienced in clinical practice. A total of 707 false-negatives were reported in the MAUDE database due to either the hCGβcf hook effect or the limit of detection of the test itself. These false-negative results were observed in many of the currently available devices and the authors concluded that the false-negatives represent a larger public health issue that needs to be addressed.[1]

Using a prospective observational cohort, investigators in another study sought to examine the performance of a commercial urinary test (neither the test name nor manufacturer were provided in the abstract) for the detection of abnormal first trimester pregnancies in women presenting to the emergency department.[2] Testing in 803 patients occurred; however, the investigators were unable to confirm the accuracy of the test for the detection or exclusion of abnormal first-trimester pregnancies.[2]

The investigators of another study sought to quantify the false-negative rate of POC urine pregnancy test (using OSOM hCG Combo, Sekisui Diagnostics, San Diego, CA) in women presenting to an academic, large volume, urban emergency department.[3] One hundred and fifty-four false-negative POC urine pregnancy results were identified over 146 visits for 137 patients (in a one-year period), accounting for a false-negative rate of 10.8% (95% confidence interval [CI] of 9.3 to 12.6) per result (or 10.5% of visits [95% CI of 8.9 to 12.2]). The authors also noted that 61% (80/131) incidences of the false-negative results occurred at < 200 mIU/ml when same-day serum hCG results were available. They concluded that their institution's false-negative rate was unacceptably high using the OSOM hCG Combo test.[3]

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

1. Nerenz RD, Gronowski AN. Qualitative point-of-care human chorionic gonadotropin testing: can we defuse this ticking time bomb? [Internet] Clin Chem. 2015 Feb [cited 2017 Dec 06].
   Available from: http://clinchem.aaccjnls.org/content/61/3/483
2. Teixeira JL, Rabaioli P, Savaris RF. Sensitivity and specificity of a urinary screening test used in an emergency setting to detect abnormal first trimester pregnancies. Am J Obstet Gynecol. 2015 Jan;212(1):58.e1-5.
   PubMed: PM24983677
3. Woo KM, Director T, Sweeney C, Cristales D, Deguia J, Baumlin K. False negative point-of-care urine pregnancy results in the emergency department: quantifying a needle in the haystack in the clinical setting (Research Forum Abstracts) [Internet]. Annals of Emerg Med (Research Forum – Abstracts). 2015 [cited 2017 Dec 06].
   Available from: http://www.annemergmed.com/article/S0196-0644(15)01044-6/pdf
   see 417

Guidelines and Recommendations

No literature identified.

Appendix — Further Information

Non-Randomized Studies

Alternative Population

4. Curtis CM, Louie RF, Vy JH, Ferguson WJ, Lam M, Truong AT, et al. Innovations in point-of-care testing for enhanced United States disaster caches. Am J Disaster Med. 2013;8(3):181-204.
PubMed: PM24352993

Alternative Intervention

5. Wilgen U, Pretorius CJ, Gous RS, Martin C, Hale VJ, Ungerer JP. Hook effect in Abbott i-STAT beta-human chorionic gonadotropin (beta-hcg) point of care assay. Clin Biochem. 2014 Sep;47(13-14):1320-2.
PubMed: PM24836692

6. Fromm C, Likourezos A, Haines L, Khan AN, Williams J, Berezow J. Substituting whole blood for urine in a bedside pregnancy test. J Emerg Med. 2012 Sep;43(3):478-82.
PubMed: PM21875776

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Abstract available from: http://www.jksem.org/journal/view.php?number=445

Case Reports

8. Taylor N. Transient false-positive urine human chorionic gonadotropin in septic shock. Am J Emerg Med; 2015 Jun;33(6):864.e1-2.
PubMed: PM25616588

9. Yadav YK, Fatima U, Dogra S, Kaushik A. Beware of "hook effect" giving false negative pregnancy test on point-of-care kits. J Postgrad Med. 2013 Apr;59(2):153-4.
PubMed: PM23793322

10. Er TK, Chiang CH, Cheng BH, Hong FJ, Lee CP, Gines MA. False-positive urine pregnanc test in a woman with adenomysosis. Am J Emerg Med. 2009 Oct;27(8):1019-7.
PubMed: PM19857433

Review Articles

11. Abushouk AI, Taheri MS, Pooransari P, Mirbaha S, Rouhipour A, Baratloo A. Pregnancy screening before diagnostic radiography in emergency department: an educational review [Internet]. Emergency. 2017 [cited 2017 Dec 06];5(1).
Available from: http://journals.sbmu.ac.ir/emergency/article/view/15243

12. Best J, Kitlowski AD, Ou D, Bedolla J. Diagnosis and management of urinary tract infections in the emergency department. Emerg Med Pract. 2014 Jul;16(7):1-23.
PubMed: PM25379602

13. Rooney KD, Schilling UM. Point-of-care testing in the overcrowded emergency department – can it make a difference? [Internet]. Crit Care. 2014 [cited 2017 Dec 06]18;692.
Available from: https://ccforum.biomedcentral.com/articles/10.1186/s13054-014-0692-9

14. Griffey RT, Trent CJ, Bavolek RA, Keeperman JB, Sampson C, Poirier RF. "Hook-like effect" causes false-negative point-of-care urine pregnancy testing in emergency patients. J Emerg Med. 2013 Jan;44(1):155-60.
PubMed: PM21835572

15. Haarburger D, Pillay TS. Historical perspectives in diagnostic clinical pathology: development of the pregnancy test. J Clin Pathol. 2011 Jun;64(6):546-8.
PubMed: PM21460391

Additional References

16. Lin M. Stat pregnancy test…without urine? [Internet]. EP Monthly.2012 [cited 2017 Dec 06].
Available from: http://epmonthly.com/article/stat-pregnancy-test-without-urine/