



Canadian Agency for
Drugs and Technologies
in Health

RAPID RESPONSE REPORT: SUMMARY OF ABSTRACTS



TITLE: Point of Care Testing Technologies for Routine Clinical Chemistry Compared to Standard Laboratory Testing Methods: Clinical Effectiveness, Diagnostic Precision and Accuracy, Cost-Effectiveness, and Guidelines

DATE: 26 September 2013

RESEARCH QUESTIONS

1. What is the clinical effectiveness of the point of care testing (POCT) technologies versus standard laboratory tests in emergency and critical care situations?
2. What is the diagnostic accuracy and precision of the POCT technologies when compared to standard laboratory testing methods?
3. What is the cost-effectiveness of using POCT when compared to standard laboratory testing methods?
4. What are the guidelines associated with the use of POCT for patients in rural centers?

KEY MESSAGE

Two randomized controlled trials and 25 non-randomized studies were identified regarding point of care testing (POCT) technologies versus standard laboratory test methods in emergency and critical care situations. Two of the clinical studies contained cost information. No relevant evidence-based guidelines were identified.

METHODS

A limited literature search was conducted on key resources including PubMed, ECRI (Health Devices Gold), The Cochrane Library (2013, Issue 9), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic studies and guidelines. Where possible,

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retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2008, and September 18, 2013. The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

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, economic evaluations, and evidence-based guidelines.

Two randomized controlled trials and 25 non-randomized studies were identified regarding point of care testing (POCT) technologies versus standard laboratory test methods in emergency and critical care situations. Six of the identified studies pertained to pediatric patients and the remaining 21 to adult patients. No relevant health technology assessment reports, systematic reviews, meta-analyses, or evidence-based guidelines were identified. Additional references of potential interest are provided in the appendix.

OVERALL SUMMARY OF FINDINGS

Adult Patients

Cardiac Markers, Creatinine kinase

Four studies, one randomized trial with economic evaluation¹ and three non-randomized studies^{5,9,21} were identified that examined POCTs for creatinine kinase⁵ or cardiac markers that included creatinine kinase.^{1,9,21} Overall, the POCTs increased the proportion of patients discharged from the hospital,¹ were deemed to have the potential for an important impact on patient care,⁹ were deemed acceptable for use in critical care settings,⁵ and were considered superior to laboratory troponin-only testing in triaging patients with chest pain.²¹ The economic evaluation found that the POCT was unlikely to meet the cost-effectiveness threshold in the United Kingdom.¹ Further detail is provided in Table 1.

Table 1: Summary of Studies Examining Cardiac Markers and Creatinine Kinase				
Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness; Cost-effectiveness	Author Conclusions
<i>Goodacre et al., 2011¹ – RCT and Economic Evaluation</i>				
To evaluate the use of a POCT for cardiac markers on patient and healthcare outcomes	ED; POCT cardiac biomarkers (including creatinine kinase) vs. standard care	2263 participants, mean age 54.5 years, 58% male, 12% with known CHD. 1125 in POCT group	Successful discharge: 32% in POCT; 12% in standard care No statistically significant differences in mean length of	The POCT increased the proportion of patients successfully discharged with no change in mean hospital stay or inpatient days,

Table 1: Summary of Studies Examining Cardiac Markers and Creatinine Kinase

Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness; Cost-effectiveness	Author Conclusions
			<p>stay</p> <p>No statistically significant differences in EQ-5D scores after 1 and 3 months.</p> <p>3% of POCT and 2% of standard care patients had major adverse events (P = 0.313)</p> <p>Mean cost per patient: £1217 for POCT, £1006 for standard care (P = 0.056)</p> <p>Mean QALYs: 0.158 for POCT, 0.161 for standard care (P = 0.250).</p>	<p>POCT is unlikely to be considered cost-effective by UK standards, suggested further research.</p>
<i>Calzavacca et al., 2012⁵ – NRS</i>				
<p>Evaluate the precision of POCT creatinine devices.</p>	<p>ICU; POC creatinine vs. laboratory serum creatinine</p>	<p>250 samples from 82 critically ill patients</p>	<p>Mean difference between POCT and lab test: +9.6 µmol/L (95% limits of agreement: -11.2 to +30.4 µmol/L)</p> <p>Mean percentage difference: 8.7%</p> <p>Differences increased with higher lactate, hemocrit levels.</p>	<p>POCT creatinine testing had a slight bias versus laboratory values but were deemed appropriately accurate for clinical use.</p>
<i>Birkhahn et al., 2011⁹ – NRS</i>				
<p>Evaluate POCT cardiac assay.</p>	<p>ED; POCT (including creatinine kinase) vs. central laboratory values</p>	<p>151 patients presenting to the ED for evaluation of acute coronary syndrome.</p>	<p>Time saving from POCT: 390 minutes</p> <p>Accelerated POCT pathway could</p>	<p>Authors suggest that POCT cardiac assay could have a large impact on patient care.</p>

Table 1: Summary of Studies Examining Cardiac Markers and Creatinine Kinase				
Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness; Cost-effectiveness	Author Conclusions
			benefit approximately 60% (95% CI, 52%-68%) Estimated cost saving \$7.40 (95% CI, \$6.40-\$8.70) per patient hour saved.	
<i>Straface et al., 2008²¹ – NRS</i>				
Evaluate POC cardiac testing vs central laboratory testing	ED; POCT cardiac assay(including creatinine kinase) vs. central lab troponin test	5,244 patients presenting to the ED with chest pain	POCT NPV for AMI: 99.9% POCT overall diagnostic accuracy for AMI: 99.7% PPV for lab: 36.4%	The rapid POCT assay was found to be superior to the lab troponin-only testing for the triage of patients with chest pain or AMI.

AMI = acute myocardial infarction; CHD = coronary heart disease; CI = confidence interval; ED = emergency department; NPV = negative predictive value; NRS = non-randomized study; POCT = point of care test; PPV = positive predictive value; QALY = quality adjusted life years; RCT = randomized controlled trial; UK = United Kingdom

Lactate

Three non-randomized studies^{3,12,13} examining the use of POC lactate testing were identified. Overall, the POCT for lactate was found to be effective for the diagnosis of bacterial meningitis,³ feasible for the reduction of time needed for the identification of lactate levels and for risk stratification,¹² and was found to be reliable for use in the emergency department.¹³ Further detail is included in Table 2.

Table 2: Summary of Studies Examining POC Lactate Testing				
Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
<i>Majwala et al, 2013³ - NRS</i>				
To validate a POC lactate testing to aid in diagnosis of bacterial meningitis.	Uganda (healthcare setting unclear); POC lactate test vs. laboratory testing	145 patients with clinical meningitis	Strong linear relation between POCT and lab testing: R(2) = 0.86; P < 0.001 Area under the ROC curve for POCT: 0.92 (95% CI = 0.85-0.99, P < 0.001)	POC lactate testing was found to be effective for the diagnosis of bacterial meningitis. Authors stated it may be useful when laboratory services are difficult to access or analyses

Table 2: Summary of Studies Examining POC Lactate Testing				
Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
			POCT lactate concentration of 7.7 mmol/L resulted in 88% sensitivity and 90% specificity for the diagnosis of bacterial meningitis	are delayed.
<i>Goyal et al., 2010¹² - NRS</i>				
Evaluate POCT to decrease time to diagnosis.	ED; POC finger prick lactate test vs. whole blood lactate	149 patients with sepsis, 44 received both whole blood and POCT	Median time from triage to test result: POCT = 21 min; lab = 172 min	Lactate POCT at triage was found to be feasible for the reduction of time to the identification of lactate levels and risk stratification of patients with sepsis
<i>Shapiro et al., 2010¹³ - NRS</i>				
Examine the feasibility and accuracy of POC lactate testing, prediction of mortality	ED; i-STAT POCT for lactate; laboratory serum lactate	699 patients with suspected infection (34 of whom died)	Area under the ROC for mortality: POCT = 0.72; lab = 0.70 POCT lactate was average 0.32 (95% CI -0.35-0.98) lower than the lab measurement. Agreement kappa POCT and lab: 0.97	POCT for lactate was found to be reliable and feasible for use in the ED.

CI = confidence interval; ED = emergency department; L = litre; min = minutes; mmol = millimol; NRS = non-randomized study; POC = point of care; POCT = point of care test; ROC = receiver operating characteristic; vs. = versus

Glucose

Twelve non-randomized studies^{4,6-8,10,14-20} were identified that compared POC glucose testing with central laboratory glucose measurements in critical care patients. Overall, POC glucose testing was found to be inferior to laboratory testing and not precise enough to manage critically ill patients who require tight glycemic control.^{8,10,15,17,18,9} POCT was also found not to be appropriate for patients with suspected ketoacidosis.¹⁴ In the operating room, authors of one study concluded that glucose levels could be safely monitored using POCT,⁴ and the authors of a second study cautioned against its use.⁶ Authors of one study found that the Radiometer 700 may be comparable to laboratory testing⁸ and although it fell short of ISO guidelines, the authors of one study found that when calibrated to give serum-like results, the AccuCheck Inform may

be acceptable for the monitoring of critically ill patients.¹⁶ The authors of one included study suggested a mathematical correction for commonly used glucometers.²⁰

Further detail is included in Table 3.

Table 3: Summary of Studies Examining POC glucose testing				
Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
<i>Akinbami et al., 2012⁴ – NRS</i>				
Examine the accuracy of POC glucose testing using capillary blood.	Operating room; Precision Xceed Pro glucometer vs. laboratory testing using arterial blood.	72 paired samples from patients undergoing surgery.	<p>Mean glucose levels: POCT = 146 ± 35 mg/dL; lab = 147 ± 36 mg/dL</p> <p>Collection time was similar between the two methods</p> <p>Regression analysis: strong positive correlation (0.91) between POCT and lab values (P<0.001)</p> <p>Differences in values between the two tests would not alter the diagnosis of hyper- or hypoglycemia using traditional thresholds.</p>	Authors concluded glucose levels during surgical procedures could be safely monitored using POC testing, however higher values may need repetitive testing.
<i>Mraovic et al., 2012⁶ – NRS</i>				
To evaluate the accuracy of intraoperative POC glucose testing.	Operating room; ACCU-CHEK(R) Inform vs. central laboratory testing	176 paired samples from surgical patients	<p>Mean absolute difference between POCT blood glucose and lab value: 24.3 mg/dL</p> <p>Mean absolute relative difference: 16.5% SD \pm 26.4%</p> <p>23% of POCT values fell outside Clinical and Laboratory Standards Institute guideline vs. 3.4%</p>	Authors found that POC glucose testing compared poorly to laboratory testing and cautioned against using POCT as the only intraoperative glucose testing method.

Table 3: Summary of Studies Examining POC glucose testing

Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
			for laboratory testing.	
<i>Robinson & Sharp, 2012⁷ – NRS</i>				
Assess the accuracy of 6 POC blood glucose testing devices.	Clinical setting; Optium Xceed, Nova StatStrip Xpress, OneTouch Ultra2, Accu-Chek Performa, Contour TS, vs laboratory testing	Patient characteristics not included in the abstract	<p>5 of 6 POCT met the ISO accuracy standards.</p> <p>Optium Xceed: >95% of readings were within $\pm 12.5\%$ of the reference glucose levels ≥ 72 mg/dL and ± 9mg/dL at glucose levels <72 mg/dL; fewest error messages</p> <p>Nova StatStrip Xpress: greatest number of error messages recorded.</p> <p>OneTouch Ultra2, Nova StatStrip Xpress, Accu-Chek Performa, and Contour TS readings were influenced by blood hemocrit levels.</p>	The Optium Xceed was found to be the most likely device to comply with anticipated higher accuracy standards and had the highest level of accuracy when measuring blood glucose with a POCT.
<i>Watkinson et al., 2012⁸ – NRS</i>				
To examine the precision of POC glucose test devices in an intensive care unit	ICU; MediSense Precision PCchi, HemoCue DM, Radiometer 700 vs. laboratory measurement	206 adult patients	Variation coefficients: MediSense = 5.1% HemoCue DM = 2.5% Radiometer 700 = 2.1% Laboratory = 2.3%	Authors found the MediSense POCT not to be precise enough for critically ill patients and the Radiometer 700 to be comparable to laboratory testing.
<i>Denfeld et al., 2011¹⁰ – NRS</i>				
To determine the difference between glucose concentrations measured by	Hospital; POC glucometer vs. laboratory	46 cardiothoracic surgery patients	POCT: glucose concentration significantly higher than lab. Mean = 12.3 mg/dL SD	In cardiothoracic surgery patients, the glucose concentrations measured by

Table 3: Summary of Studies Examining POC glucose testing

Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
POCT and laboratory testing			9.8; (t = 8.5, P < .001) As hemocrit increased, the differences between the POCT value and lab value increased.	POCT differed significantly from laboratory values. POCT glucose devices may not be appropriate for maintaining tight glycemic control in this population.
<i>Blank et al., 2009¹⁴ – NRS</i>				
To compare blood glucose levels measured from POCT versus laboratory values.	ED; MediSense PCx POCT vs. laboratory test	54 patients with suspected diabetic ketoacidosis; 10 to 86 years of age; 63% female	POCT: underestimated glucose values in 93% of samples Higher glucose values resulted in increased differences between the POCT result and the laboratory result.	POC glucose testing was found to be unreliable for patients with suspected diabetic ketoacidosis.
<i>Cook et al., 2009¹⁵ – NRS</i>				
To compare blood glucose values measured by POCT using fingerstick and CVC samples versus laboratory testing using a CVC sample	Hospital (convenience sample); POCT vs. laboratory test	67 critically ill patients	POCT vs. laboratory values differed significantly for catheter (t(1,66) = -9.18; P < .001) and fingerstick (t(1,66) = 6.53; P < .001) samples. Catheter and fingerstick samples did not differ for POCT (P = 0.98) Hemocrit levels explained the differences between POCT and laboratory glucose values (from both sites)	If glucose must be tightly controlled, POCT may lead to faulty treatment decisions.

Table 3: Summary of Studies Examining POC glucose testing

Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
<i>Meynaar et al., 2009¹⁶ – NRS</i>				
To evaluate the accuracy of a glucose POCT versus the central laboratory measurement.	ICU with a computerized insulin protocol; AccuCheck Inform calibrated to give serum-like results vs. laboratory glucose	32 critically ill patients; mean age 71.6	Mean difference between POCT and laboratory glucose measurements: 8% (11 mg/dL) (95% CI 9-13 mg/dL, P< .001) When results ranged from 0.20 to 0.44, hemocrit did not influence POCT results.	AccuCheck Inform calibrated to give serum-like results was found to yield acceptable results in critically ill patients; however it fell short of ISO guidelines by approximately 1%.
<i>Shearer et al., 2009¹⁷ – NRS</i>				
To compare blood glucose values measured by POCT using fingerstick and CVC samples versus laboratory testing using a CVC sample.	ICU; POCT fingerstick vs. POCT CVC vs. laboratory CVC	63 critically ill patients	POCT values from both sites differed significantly from laboratory values: POCT fingerstick: (t(1,61) = 5.01; P < .001) POCT CVC: (t(1,61) = 3.91; P < .001) 20% of POCT values differed from lab values by more than 20 mg/dL POCT values did not vary based on sample site.	POC glucose testing may lead to dosing errors with respect to insulin titration and tight glucose control in critically ill patients.
<i>Desachy et al., 2008¹⁸ – NRS</i>				
Determine the accuracy of a POC glucose test strip using capillary blood.	Hospital; POC glucose test strip vs. laboratory testing	85 critically ill patients requiring glucose monitoring	POCT values were different from laboratory values in 15% of the samples – low perfusion index was predictive of these conflicts (P = 0.04)	POC glucose measurements using test strips should be interpreted with caution in critically ill patients. Whole blood POC tests may be more reliable except in patients with arterial hypofusion

Table 3: Summary of Studies Examining POC glucose testing

Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
				and generalized mottling
<i>Hoedemaekers et al., 2008¹⁹ – NRS</i>				
Determine the accuracy of 3 POC glucose test devices compared to laboratory values	ICU and non-intensive care unit; Accu-Chek Sensor, Precision, HemoCue vs. laboratory	Critically ill patients requiring intensive insulin treatment	Mean absolute difference between the lab value and Accu-Chek: -0.32 mmol/L (95% CI - 0.84 to 1.48 mmol/L) Paired samples from Accu-Chek, Precision, and Hemocue did not meet ISO standards. In all Accu-Chek samples that did not meet ISO standards, the POCT value was higher than the lab value	The three POCT were found to be inaccurate for both ICU and non-intensive care unit patients. In the ICU, inaccurate POCT values were most likely to be elevated.
<i>Mann et al., 2008²⁰ – NRS</i>				
To determine the error rates of three POC glucose test devices and to calculate a correction formula when hemocrit values are abnormal	Hospital; three POCT devices vs. laboratory	196 surgical, trauma, cardiothoracic, medical, and burn ICU patients	POCT results were consistently elevated vs. the laboratory values Hemocrit ≤25%, POCT error rates: 15.4% to 22.3%. 25% < hemocrit < 34%. POCT error rates: 16.4% to 18.4%	The significant error rates from POCT glucometers can likely be corrected by a mathematical formula.

CI = confidence interval; CVC = central venous catheter; dL = deciliter; ICU = intensive care unit; ISO = International Organization of Standardization; L = litre; mg = milligram; mmol = millimol; POC = point of care; POCT = point of care test; SD = standard deviation; vs. = versus

Multi-test

Two studies, one randomized² and one non-randomized,¹¹ were identified that examined the use of non-cardiac multi-parameter POCT. Authors of the RCT found that the POC chemistry test shortened test turnaround time and time to a clinical decision in the emergency department² and the authors of the non-randomized study found that the POC assay was appropriate with

respect to the glucose and lactate measurements in a critical care setting.¹¹ Further detail is included in Table 4.

Table 4: Summary of Studies Examining Non-Cardiac Multi-Parameter POCT				
Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
<i>Lee et al., 2011² – RCT</i>				
To compare clinical decision making time using a POC chemistry test vs. a central laboratory	ED; Piccolo chemistry test vs. central laboratory	2323 patients; 1167 in POCT, 1156 in central laboratory group, baseline characteristics similar	Median turnaround time shorter in POCT group (14 mins) than lab group (55 mins) P<0.001 Median door to clinical decision time shorter in POCT group (46 mins) than laboratory group (86 mins). P<0.001	The POCT chemistry device was found to shorten test turnaround and time to clinical decision.
<i>Leino & Kurvinen, 2011¹¹ – NRS</i>				
Determine if POCT using whole blood is comparable to central laboratory plasma measurements	Clinical setting unclear; blood gas analysis, electrolytes, glucose, lactate, and hemoglobin using i-STAT, Radiometer ABL 825, RapidLab 865 vs. central laboratory measurements	Critically ill patients	Glucose and lactate measured with POCT were highly with laboratory results.	POCT for glucose and lactate were appropriate for a critical care setting.

ED = emergency department; min = minute; NRS = non-randomized study; POC = point of care; POCT = point of care test; RCT = randomized controlled trial; vs. = versus

Pediatric Patients

Six non-randomized studies, three examining POC bilirubin testing,^{22,25,27} one examining a multi-parameter POCT,²³ and two examining POC glucose testing,^{24,26} were identified. Overall, POCT was found to be acceptable for bilirubin testing,^{22,25,27} it reduced the blood volume needed for multi-parameter tests,²³ and the results were mixed for glucose testing.^{24,26} Further detail is provided in Table 5.

Table 5: Summary of Pediatric Studies

Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
<i>Coda Zabetta et al, 2013</i> ²²				
Evaluate the minimally invasive Bilistick test for the evaluation of neonates with jaundice.	Low-resource environment; Bilistick POCT vs. laboratory bilirubin	118 term and near term neonates with bilirubin levels of 24.8 to 501.0 µmol/L	POCT mean concentration: 215.6 (SD± 85.5) µmol/L Lab mean concentration: 226.1 (SD ±86.4) µmol/L Mean difference: 10.3 µmol/L	Bilistick was a minimally invasive option that provided accurate screening for pre-discharge or follow-up of infants with jaundice.
<i>Mahieu et al., 2012</i> ²³				
Evaluate whether a multi-parameter POCT analyzer affected the need for red blood cell transfusion, and blood loss for central laboratory testing in the NICU	NICU; Bedside POCT testing for bilirubin and electrolytes vs. laboratory bilirubin and electrolyte	Very low birth weight infants in the NICU. (serial cohorts of 2 years each before and after implementation of the POCT)	Net blood volume for testing decreased 23.7% for electrolytes, 22.2% for bilirubin. After POCT implementation, fewer infants required transfusion: 38.9% vs. 50%, (P<.05) Number of transfusions per infant decreased by 48% (1.57 vs. 2.53, P<0.01) 8.3% cost reduction per infant	Introduction of POCT testing reduced the need for transfusions in the NICU by reducing the blood volume needed for testing.
<i>Ramachandran et al., 2011</i> ²⁴				
Compare laboratory values of arterial or central venous blood glucose with POCT capillary blood glucose for children in shock.	PICU; bedside glucometer vs. laboratory	52 children aged 3 months to 18 years with a Pediatric Risk Mortality III score of 9.6	POCT mean: 135 ± 67 mg/dL (7.5 ± 3.7 mmol/L) Laboratory mean: 130 ± 67 mg/dL (7.2 ± 3.7	The capillary POCT glucose values were similar to the laboratory values for children in

Table 5: Summary of Pediatric Studies

Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
<i>Mielsch et al., 2010²⁵</i>				
To evaluate how bilirubin testing using POCT compared to laboratory testing.	Lab setting; RapidLab 1265 blood gas analyzer vs. laboratory	240 newborn patient samples (premature and low birth weight newborns excluded)	Correlation between lab values (x) and POCT values (y): $y=1.0x-0.1$ ($r=0.91$) 95% limit of agreement: ± 2.5 mg/dL	The RapidLab 1265 provided clinically useful bilirubin levels; the POCT device was deemed acceptable for use by trained employees in the NICU.
<i>Roth-Kleiner et al., 2010²⁶</i>				
To compare glucose measurements taken with POCT devices versus each other and a laboratory reference standard	Hospital; Elite XL, Ascensia Contour, ABL 735 vs. laboratory	1,324 newborns over a 1 year period	Elite XL: low specificity; but appeared more appropriate than Ascensia Contour to detect hypoglycemia Ascensia Contour: when hemocrit increased, there were important inaccuracies. ABL 735: most accurate of the POCTs; required 15 times more blood volume for testing	Careful evaluation of POCT systems deemed needed before it is used daily for newborn screening.
<i>Lam et al., 2008²⁷</i>				
To evaluate bilirubin testing using a transcutaneous POCT device.	ED in a regional hospital in China; JM-103 Minolta bilirubinometer vs. laboratory serum bilirubin measurement	113 neonates, mean age 5 days	POCT bilirubin levels correlated well with lab levels. Highest correlation coefficient: 0.83 ($P < 0.001$)	The JM-103 Minolta POCT was found to be a useful screening device to aid in quick

Table 5: Summary of Pediatric Studies

Study Objectives	Setting; POCT, Comparison	Patient Characteristics	Diagnostic Accuracy; Clinical effectiveness	Author conclusions
			Mean difference between POCT and lab:14 $\mu\text{mol/L}$ (SD $\pm 28 \mu\text{mol/L}$, $P < 0.001$) POCT tended to overestimate true serum bilirubin	decision-making regarding jaundiced neonates presenting to the ED and has potential for out-patient settings

dL = deciliter; ED = emergency department; L = litre; mg = milligram; μmol = micromol; NICU = neonatal intensive care unit; PICU = pediatric intensive care unit; POCT = point of care test; SD = standard deviation; vs = versus

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Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

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Non-Randomized Studies

Adults

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No literature identified.

Guidelines and Recommendations

No literature identified.

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APPENDIX – FURTHER INFORMATION:

Review Articles

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