TITLE: Point of Care Testing Compared to Laboratory Testing for the Assessment of White Blood Cell Counts and Differentials: A Review of the Clinical Effectiveness, Diagnostic Precision and Accuracy, Cost-Effectiveness, and Guidelines

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CONTEXT AND POLICY ISSUES

White blood cell (WBC) counts and their subgroups of cell types such as neutrophils, lymphocytes, monocytes, eosinophils and basophils (often called "differentials"), are common clinical measurement to diagnose and monitor a variety of pathologic conditions such as bacterial or viral infections, inflammation, leukemia, immunodeficiency states, and post-chemotherapy, or as part of a complete blood cell count in a routine health checkup.[1] WBC counts and differentials are currently performed in central laboratories using blood analyzers with blood collected by venipuncture. Point of care (POC) analyses of complete blood cell counts are being developed with the aim to reduce turnaround time and increase the chance that more timely medical decisions can be made in remote sites, or in outpatient settings. Currently, four POC WBC systems are being used: Chempaq XBC (Chempaq A/S, Denmark), HemoCue WBC (HemoCue AB, Angelholm, Sweden), pocH -100i (Sysmex Corporation, Kobe, Japan), and ABX-MicrosCRP200 (Horiba Medical, Montpellier, France). The HemoCue, pocH-100i and ABX-MicrosCRP200 systems are available for use in Canada.[2-4]

This Rapid Response review aims to compare the clinical effectiveness, accuracy, precision, and cost-effectiveness of POC testing technologies to assess WBC counts and differentials compared to central laboratory methods. Guidelines associated with the use of POC testing to assess WBC count and differentials will also be examined.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of the point of care testing (POCT) technologies to assess white blood cell (WBC) counts and differentials when compared to clinical laboratory test methods?

2. What is the diagnostic accuracy and precision of the POCT technologies to assess WBC counts and differentials when compared to clinical laboratory testing methods?

3. What is the cost-effectiveness of using PCOT to assess WBC counts and differentials when compared to clinical laboratory testing methods?

4. What are the guidelines associated with the use of POCT to assess WBC counts and differentials?

KEY FINDINGS

In general, POC testing is reliable and produces comparable results to a standard reference analyzer. The HemoCue WBC analyzer was also found to be stable under different conditions, and the counts can be interfered by a number of pathologic conditions. A guideline from the International Council for Standardization in Hematology (ICSH) was developed in 2008 to provide information on how to develop and manage a POC service so that reliable hematology results are produced. There were no studies on comparative clinical effectiveness, and cost effectiveness between POC WBC testing and standard laboratory testing.

METHODS

Literature Search Strategy

A focused search (with main concepts appearing in title, abstract or major subject heading) was conducted on key resources including PubMed, 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, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2008 and September 17, 2013.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed for relevance. Full texts of any relevant titles or abstracts were retrieved, and assessed for inclusion. The final article selection was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Pediatric and adult patients
Intervention	POCT technologies for white blood cell counts and differentials (e.g. Sysmex pocH-100i, Hemocue WBC)
Comparator	Standard laboratory tests
Outcomes	Clinical effectiveness (including clinician satisfaction and how they perceive its applicability)

	Patient outcomes (i.e. turn-around times, impact on clinical decisions, and safety and harms) Diagnostic accuracy and precision Cost-effectiveness Guidelines on the use of the POCT for WBC and differential
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled studies (RCTs), observational studies, economic evaluations, and guidelines.

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria in Table 1, if they were bench test studies, if they were published prior to January 2008, if they were duplicate publications of the same study, or if they were referenced in a selected systematic review.

Critical Appraisal of Individual Studies

The quality of the included studies and guidelines were assessed using QUADAS tool [5] and AGREE[6] checklists.

Numeric scores were not calculated. Instead, the strengths and limitations of the study are summarized and presented.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search yielded 409 citations, with four potentially relevant reports identified from other sources. After screening of abstracts from the literature search and from other sources, 21 potentially relevant studies were selected for full-text review. Five studies met the selection criteria and were included in the review.[7-11] The PRISMA flowchart in Appendix 1 details the process of the study selection.

Summary of Study Characteristics

A detailed summary of the included study is provided in Appendix 2.

Study design

Four observational studies[7-10] and one guideline[11] were identified. The studies used patient blood samples, and the guideline was about development and management of a POC hematology service.

Population

The populations included in the selected studies were patients undergoing a routine blood count,[7] oncology patients,[8] patients in various clinical settings (emergency department, primary care, obstetrics and gynecology offices, pediatric clinics, and hematology-oncology clinics),[9] and term and preterm newborns.[10]

Interventions and comparators

POC analyzers examined in the selected studies were the HemoCue WBC analyzer,[7] the Sysmex pocH-100i analyzer,[8] the Chempaq XBC analyzer,[9] and the ABX-MicrosCRP200 analyzer.[10]

Lab tests examined as comparators were the Sysmex XE-2100 analyzer,[7,10] the Sysmex XE-2100 analyzer or the Abbott CD-4000 analyzer,[8] and the Beckman Coulter LH750 analyzer.[9]

Outcomes

The main study outcomes were precision of the POC analyzer and the accuracy compared to standard laboratory methods.[7-10] Recommendations were reported in the included guideline.[11]

Summary of Critical Appraisal

Two included studies[7,9] did not mention an important criteria for test validity, which is the period of time between the index test (POC WBC) and the reference test (standard laboratory method). The interval between tests is important to be reasonably sure that the clinical condition or quantity being measured does not change between the two tests. Three studies provided detailed description of the execution of the index test,[8-10] and three did not report results of uninterpretable or intermediate results.[7,9,10] Findings from each included study cannot be generalizable since results were from subsets of patients such as oncology patients,[8] newborns,[10] or from an unclear spectrum of patients.[7,9]

The guideline scope, purpose, and recommendations were clear, the methods used to search for and select evidence were clear, and appropriate professional groups were involved in formulating recommendations.[11] Explicit links between the evidence and the recommendations were not provided. Potential cost implications of applying the recommendation were not included in the recommendation. It was unclear whether patients' views and preferences were sought, and whether the guidelines had been piloted among target users

Details of the strengths and limitations of the included studies are summarized in Appendix 3.

Summary of Findings

Main findings of included studies are summarized in detail in Appendix 4.

1. <u>What is the clinical effectiveness of the point of care testing (POCT) technologies to assess white blood cell counts (WBC) and differentials when compared to clinical laboratory test methods?</u>

There was no evidence found for this research question.

2. <u>What is the diagnostic accuracy and precision of the POCT technologies to assess WBC counts and differentials when compared to clinical laboratory testing methods?</u>

Four observational studies examined the diagnostic accuracy and precision of POC technologies to assess WBC counts and differentials compared to clinical laboratory testing

methods.[7-10] In general, POC testing is reliable and produces results comparable to a standard reference analyzer. The HemoCue WBC analyzer was also found to be stable under various conditions, but the counts can be interfered by a number of pathologic conditions.

An observational study compared the HemoCue WBC analyzer to the Sysmex XE-2100 analyzer.[7] WBC counts were performed on 500 blood samples for routine blood counts from a hospital. HemoCue WBC was found to be precise and provides comparable results to standard laboratory tests. For precision testing, the coefficient of variation (CV) varied between 2.0% and 11.0%, and standard deviation (SD) ranged from 0.08 x 10^9/L to 0.54 x 10^9/L over a wide range of WBC counts. For accuracy assessment, the correlation coefficient (r) was 0.997 compared to laboratory values; 98% of WBC counts were within a 10% difference and 2% within a 15% difference. Hemocue WBC was stable with no statistical difference between POC values and reference values at three different temperatures or with three different anticoagulants used. For interference testing, HemoCue WBC values were found to be higher than reference count in patients with sickle cell disease, thalassemia major and reticulocytosis ($P < 0.05$) but were not affected by thrombocytosis, iron deficiency, lymphoma or myeloma.

An observational study compared the Sysmex pocH – 100i analyzer to the Sysmex XE-2100 analyzer or Abbott CD-4000 analyzer.[8] WBC counts were performed on 838 blood samples from oncology patients. The Sysmex pocH – 100i analyzer produced reliable results comparable to the lab analyzer. Imprecision was less than 5% of counts. Compared to laboratory values, the correlation coefficient (r) was ≥ 0.95**.** Vote-outs (inability of the analyzer to provide a result) were 10.6% for the pocH – 100i and 5% for the XE-2100.

One observational study compared the Chempaq XBC analyzer to the Beckman Coulter LH750 analyzer.[9] WBC counts were performed on 60 blood samples from different clinical services. The Chempaq XBC analyzer produced reliable results comparable to the lab analzyer. Variation between assays was less than 6% of counts. Compared to laboratory values, the correlation coefficient (r) was 0.96**,** with a difference of < 15% for all POC values.

An observational study compared the ABX-MicrosCRP200 analyzer to the Sysmex XE-2100 analyzer.[10] WBC counts were performed on 150 blood samples of term and preterm newborns. The ABX-MicrosCRP200 analyzer produced reliable results comparable to the lab analyzer. The Coefficient of variation between the 2 methods was 1.8%. Compared to laboratory values, the ABX-MicrosCRP200 analyzer overestimated the WBC counts by 1.27 x 10^9/L; the correlation coefficient (r) was 0.98 (SD: 1.28 x 10^9/L).

3. <u>What is the cost-effectiveness of using PCOT to assess WBC counts and differentials when compared to clinical laboratory testing methods?</u>

There was no evidence found for this research question.

4. <u>What are the guidelines associated with the use of POCT to assess WBC counts and differentials?</u>

A guideline from the International Council for Standardization in Hematology (ICSH) was developed in 2008 to provide information on how to develop and manage a POC service so that reliable hematology results are produced.[11] The scope of the guideline was measurement of

complete blood count, including WBC differentials. Potential cost implications of applying the recommendation were not included in the recommendation.

In general, the guideline made the following statements:

- "*a POC testing committee should be established in every hospital to take responsibility for all POC testing and ensure it is appropriate and accreditable"* (p. 108).
- "*The POCT devices should generate results that are comparable to those of the local reference laboratory"* (p. 109).
- "*It is essential that the results of tests be documented including the operator identification"* (p. 110).
- *"All aspects of quality must be considered, including personnel, training, equipment, reagents and appropriateness and timeliness of the service"* (p. 111).
- "*Training protocols must be established and all potential operators must achieve an adequate level of competence"* (p. 111).

A summary of recommendations for implementation and management of POC hematology testing was in Appendix 4.

Limitations

The limited number of studies included in the review caution the interpretation of the findings. The findings from the included study lack generalizability since results were from subsets of patients. There were no studies on comparative clinical effectiveness, and cost effectiveness between POC WBC testing and standard laboratory testing.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

In general, POC testing is reliable and produces comparable results with a standard reference analyzer. Since the cost-effectiveness of POC WBC analyzers and their effect on quality of care are still unclear, thorough considerations have to be made before implementation of POC testing.

POC technologies are evolving. Other than the four main POC WBC analyzers HemoCue WBC, Chempaq XBC, pocH – 100i, and ABX-MicrosCRP200 that are currently on the market, there are many POC technologies that are in development. Reliable WBC counts and differentials were successfully performed using developing technologies such as microfluidic impedance cytometry,[12-16] the microcavity array method,[17] or a QBC centrifugal system.[18] Validation of the use of these technologies in clinical practice may result in a convenient, reliable and cost-effective way to eventually replace central laboratory methods in counting WBC and differentials.

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References

1. Blood: principles and practice of hematology. In: Handin RI, Lux SE, Stossel TP, editors. Philadelphia: Lippincott Williams & Wilkins; 2003. p. 471.

2. MaDOX Department of Primary Health Care Monitoring & Diagnosis in Oxford. Diagnostic technology: point-of-care test for total white blood cell count [Internet]. Oxford (UK): University of Oxford; 2010 Jan 2. [cited 2013 Sep 18]. Available from: http://madox.org/horizon-scanning-reports/201011/point-of-care-test-for-total-white-blood-cell-count

3. Point-of-care analyzers, coagulation; hematology; urine [Internet]. Plymouth Meeting (PA): ECRI Institute; 2012. (Healthcare Product Comparison System). [cited 2013 Oct 11]. Available from: https://www.ecri.org/ Subscription required.

4. Health Canada. Medical Devices Active Licence Listing (MDALL) [Database on the Internet]. Ottawa (ON): Health Canada; 2012. [cited 2013 Oct 11]. Available from: http://webprod5.hc-sc.gc.ca/mdll-limh/index-eng.jsp

5. Whiting P, Rutjes AW, Reitsma JB, Bossuyt PM, Kleijnen J. The development of QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. BMC Med Res Methodol [Internet]. 2003 Nov 10 [cited 2013 Aug 13];3(25). Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC305345

6. The AGREE Collaboration. Appraisal of guidelines for research and evaluation (AGREE) instrument [Internet]. London: The AGREE Research Trust; 2001 Sep. [cited 2013 Sep 10]. Available from: http://www.agreetrust.org/?o=1085

7. Osei-Bimpong A, Jury C, McLean R, Lewis SM. Point-of-care method for total white cell count: an evaluation of the HemoCue WBC device. Int J Lab Hematol [Internet]. 2009 Dec [cited 2013 Sep 18];31(6):657-64. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2784871

8. Van Hecke I, Vanden Bempt I, Malfait R, Van Den BJ. Evaluation of the Sysmex pocH-1001 haematology analyser in an outdoor oncology service. Acta Clin Belg. 2010 Jul;65(4):248-51.

9. Rao LV, Ekberg BA, Connor D, Jakubiak F, Vallaro GM, Snyder M. Evaluation of a new point of care automated complete blood count (CBC) analyzer in various clinical settings. Clin Chim Acta. 2008 Mar;389(1-2):120-5.

10. Papa F, Rongioletti M, Majolini MB, Collegiani V, Vaccarella C, Notarmuzi ML, et al. Fast bedside measurement of blood count and C-reactive protein in newborns compared with conventional methods. Clin Lab. 2012;58(9-10):951-7.

11. Briggs C, Carter J, Lee SH, Sandhaus L, Simon-Lopez R, Vives Corrons JL, et al. ICSH Guideline for worldwide point-of-care testing in haematology with special reference to the complete blood count. Int J Lab Hematol. 2008 Apr;30(2):105-16.

12. Hollis VS, Holloway JA, Harris S, Spencer D, van BC, Morgan H. Comparison of venous and capillary differential leukocyte counts using a standard hematology analyzer and a novel microfluidic impedance cytometer. PLoS ONE [Internet]. 2012 [cited 2013 Sep 18];7(9):e43702. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3447872

13. Holmes D, Pettigrew D, Reccius CH, Gwyer JD, van BC, Holloway J, et al. Leukocyte analysis and differentiation using high speed microfluidic single cell impedance cytometry. Lab Chip. 2009 Oct 21;9(20):2881-9.

14. Shi W, Guo L, Kasdan H, Tai YC. Four-part leukocyte differential count based on sheathless microflow cytometer and fluorescent dye assay. Lab Chip. 2013 Apr 7;13(7):1257-65.

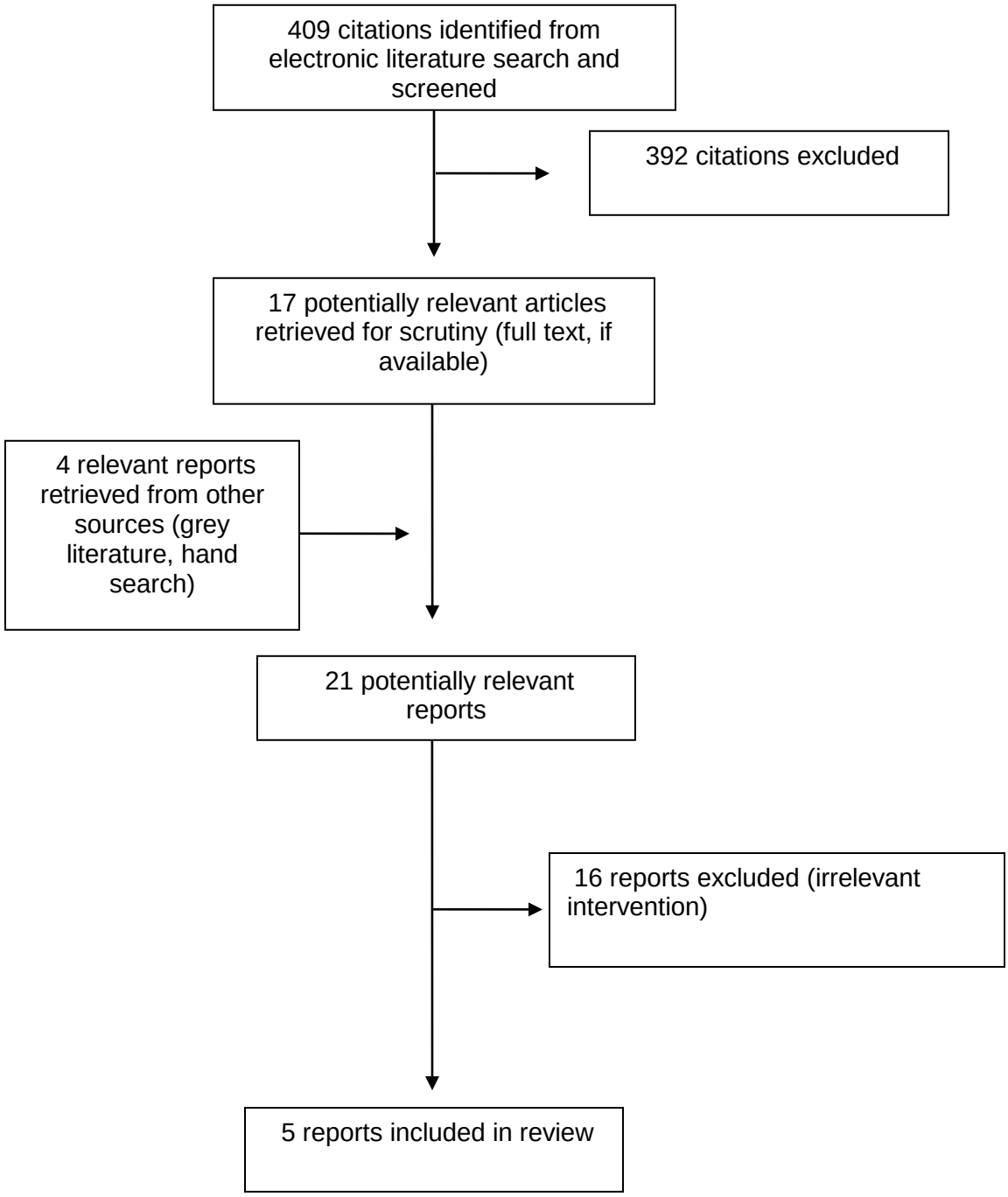
15. van Berkel C, Gwyer JD, Deane S, Green NG, Holloway J, Hollis V, et al. Integrated systems for rapid point of care (PoC) blood cell analysis. Lab Chip. 2011 Apr 7;11(7):1249-55.

16. Piacentini N, Demarchi D, Civera P, Knaflitz M. Blood cell counting by means of impedance measurements in a microsystem device. Conf Proc IEEE Eng Med Biol Soc. 2008;2008:4824-7.

17. Hosokawa M, Asami M, Nakamura S, Yoshino T, Tsujimura N, Takahashi M, et al. Leukocyte counting from a small amount of whole blood using a size-controlled microcavity array. Biotechnol Bioeng. 2012 Aug;109(8):2017-24.

18. Erhabor O, Richardson G, Mohammed I, Thornton C, Bark J, Hurst M, et al. Evaluation of the QBC Star centrifugal three-part differential haematology system. Br J Biomed Sci. 2013;70(2):67-74.

Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Study

Table A1: Characteristics of Included studies

First Author, Year, Country,	Study objectives	Intervention Comparator(s)	Included patients and study types	Main clinical outcomes reported
Trials				
Osei-Bimpong,[7] 2008, UK	To evaluate POC HemoCue WBC hematology analyzer	HemoCue WBC analyzer Comparator: Sysmex XE-2100 analyzer	500 blood samples for routine blood counts Observational study	Precision Accuracy Stability Interference
Van Hecke,[8] 2010, Belgium	To evaluate POC Sysmex pocH-100i hematology analyzer	Sysmex pocH-100i analyzer Comparator: Sysmex XE-2100 or Abbottt CD-4000 analyzer	838 blood samples from oncology patients Observational study	Imprecision Accuracy Vote-outs (inability of the analyzer to provide a result)
Rao,[9] 2008, US	To evaluate POC Chempaq XBC hematology analyzer	Chempaq XBC analyzer Comparator: Beckman Coulter LH750 analyzer	60 blood samples from different clinical services Observational study	Precision Accuracy
Papa,[10] 2012, Italy	To evaluate POC ABX-MicrosCRP200 hematology analyzer	ABX-MicrosCRP200 analyzer Comparator: Sysmex XE-2100 analyzer	150 blood samples of term and preterm newborns Observational study	Precision Accuracy
Guidelines				
Briggs,[11] 2008, UK, Kenya, Australia, US, Switzerland, Spain	"*These guidelines provide information on how to develop and manage a point-of-care (POCT) service so that reliable hematology results are produced regardless of where the test is performed.*" (p 105)	POC analyzers	NA	Recommendations

NA: not applicable; POC: point of care

Appendix 3: Summary of Critical Appraisal of Included Study

Table A2: Summary of Critical Appraisal of Included Study		
First Author, Publication Year	**Strengths**	**Limitations**
Critical appraisal of included studies on accuracy (QUADAS[5])		
Osei-Bimpong,[7] 2008		Unclear whether spectrum of patients was representative of the patients who will receive the test in practice (routine blood samples from a hospital) The time period between reference standard and index test not mentioned The execution of the index test not described in sufficient detail to permit replication of the test Uninterpretable/intermediate results not reported
Van Hecke,[8] 2010	The time period between reference standard and index test mentioned The execution of the index test described in sufficient details to permit replication of the test Uninterpretable/intermediate results reported	Spectrum of patients not representative of the patients who will receive the test in practice (blood samples from oncology patients)
Rao,[9] 2008	The execution of the index test described in sufficient details to permit replication of the test	Unclear whether spectrum of patients was representative of the patients who will receive the test in practice (blood samples from various clinical settings) The time period between reference standard and index test not mentioned Uninterpretable/intermediate results not reported
Papa,[10] 2012	The time period between reference standard and index test mentioned The execution of the index test described in sufficient details to permit replication of the test	Spectrum of patients not representative of the patients who will receive the test in practice (blood samples from newborns) Uninterpretable/intermediate results not reported
Critical appraisal of included studies on guidelines (AGREE[6])		
Briggs,[11] 2008	Scope and purpose of the guidelines are clear The recommendations are specific and unambiguous The method for searching for and selecting the evidence are clear Methods used for formulating the recommendations are clearly described Appropriate professional groups were involved in formulating recommendations Health benefits, side effects and risks were stated in the recommendations Target users of the guideline are clearly defined	Unclear whether the guideline was piloted among target users Unclear whether patients' views and preferences were sought Potential cost implications of applying the recommendation are not included in the recommendation

Appendix 4: Main Study Findings and Authors' Conclusions

Table A3: Main Study Findings and Authors' Conclusions

First Author, Publication Year	Main Study Findings	Authors' Conclusions
Research question 1 (clinical effectiveness of the point of care testing (POCT) technologies to assess WBC counts and differentials when compared to clinical laboratory test methods)		
There were no studies identified for this research question		
Research question 2 (diagnostic accuracy and precision of the POCT technologies to assess WBC counts and differentials when compared to clinical laboratory testing methods)		
Osei-Bimpong,[7] 2008	**Precision** CV ranged from 11.0% to 2.0% over a wide range of WBC counts (0.7 x 10^9/L to 27.4 x 10^9/L) SD ranged from 0.08 x 10^9/L to 0.54 x 10^9/L over a wide range of WBC counts (0.7 x 10^9/L to 27.4 x 10^9/L) **Accuracy** (compared to laboratory values) Correlation coefficient (r) = 0.997 98% of WBC counts were within a 10% difference 2% within a 15% difference **Stability** There was no statistical difference between POC values and reference values at 3 different temperatures (4°C, 22°C and 37°C) There was no statistical difference betreen POC counts with 3 different anticoagulants used (sodium citrate, K_2EDTA, K_3EDTA) **Interference** POC values were higher than reference count in patients with sickle cell disease, thalassemia major and reticulocytosis ($P < 0.05$) POC values were not affected by thrombocytosis, iron deficiency, lymphoma or myeloma.	"*This study has demonstrated that the newly developed HemoCue WBC provides a simple method to obtain reliable measurements with an accuracy that is comparable with that of a standardized reference analyser.*" (p 663)
Van Hecke,[8] 2010	**Imprecision** Less than or close to 5% **Accuracy** (compared to laboratory values) Correlation coefficient (r) ≥ 0.95 **Vote-outs (**inability of the analyzer to provide a result) pocH – 100i: 10.6% XE – 2100: 5%	"*In conclusion, the Sysmex pocH-100i demonstrates good imprecision…, produces reliable results in normal and in lower ranges comparable to the results of high throughput haematology analysers*" (p 248)
Rao,[9] 2008	**Precision** Between-assays variation < 6% **Accuracy** (compared to laboratory values) Correlation coefficient (r) = 0.96 All POC values were <15% difference	"*The Chempaq XBC analyzer provides accurate hematologic results that can facilitate rapid quantitative assessment of CBC parameters*…" (p 120)
Papa,[10] 2012	**Precision** CV = 1.8% **Accuracy** (compared to laboratory values) Correlation coefficient (r) = 0.98	"*The agreement between the two methods was high*" (p 951)

Table A3: Main Study Findings and Authors' Conclusions		
First Author, Publication Year	**Main Study Findings**	**Authors' Conclusions**
	SD: 1.28 x 10^9/L	
Research question 3 (cost-effectiveness of using PCOT to assess WBC counts and differentials when compared to clinical laboratory testing methods)		
There were no studies identified for this research question		
Research question 4 (guidelines associated with the use of POCT to asses WBC counts and differentials)		
Briggs,[11] 2008	**Summary of recommendation and management of POCT in hematology** *"The purpose and benefits of POCT at a particular site should be defined before initiating the service. The advice and involvement of an accredited clinical laboratory should be sought to achieve optimum quality and cost effectiveness […] A hospital POCT committee should be established and take responsibility for all POCT to ensure it is appropriate and accreditable […] The POCT committee should investigate the complete costs of the service, including purchase costs, revenue costs and the cost of staff training before initiating the service. A technical and practical performance evaluation of POCT devices should be carried out based on structured and appropriate assessments […] The POCT environment should be clean, well lit and may need temperature control. Service managers must perform a risk assessment of testing procedures. Space must be available for the storage of reagents, refrigerated if necessary, and for retained samples that have been tested but may require retesting or further tests. Written standard operating procedures for all process for the POCT must be available, from receipt of specimen, analysis on the instrument and reporting of results. It is recommended that there is a quick reference guide is available covering the key operating procedures for the instrument/device. This should be kept near to the POCT instrument. Staff must recognize that only trained operators may use the equipment. An up-to-date list of trained operators and competency training should be maintained […] Documentation must include the name of the operator, date, patient identity details, results, lot number of calibrant, reagents and quality control materials. This must be recorded at the same time as the analysis. Patient results should be transmitted to the laboratory or hospital information system, if possible, or sent to be stored in the patient's notes. A record of any maintenance and repair on the instrument and should also be kept and an 'error log' to assist in any investigation of potential incidents. Internal quality control (IQC) and external quality assessment (EQA) programmes must be established. POCT raises the possibilities of litigation ensuing from erroneous results. There is a need to establish locally who bears this legal responsibility and encourage them to seek the appropriate insurance cover."* (p. 113)	"*These guidelines provide information on how to develop and manage a point-of-care (POCT) service so that reliable haematology results are produced regardless of where the test is performed.*" (p. 105)

CBC: complete blood count; CV: coefficient of variation; K_2EDTA: dipotassium ethylenediaminetetraacetic acid; K_3EDTA: tripotassium ethylenediaminetetraacetic acid; POC: point of care; POCT: point of care testing; SD: standard deviation