Complete Summary

GUIDELINE TITLE

Coagulation. Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing.

BIBLIOGRAPHIC SOURCE(S)

Zucker ML, Johari V, Bush V, Rao S. Coagulation. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 21-9. [76 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

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SCOPE

DISEASE/CONDITION(S)

Conditions requiring point-of-care coagulation testing

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Evaluation

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To examine the application of evidence-based medicine (EBM) to the form of diagnostic testing known as point-of-care testing (POCT).

  Note: For the purpose of this document, POCT is defined as "clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing). POCT refers to any testing performed outside of the traditional, core or central laboratory."

- To systematically review and synthesize the available evidence on the effectiveness of POCT, with specific focus on outcomes in the areas of:
  1. Patient/health
  2. Operational/management
  3. Economic benefit
- To evaluate the available literature and identify those studies, if any, that objectively demonstrate the utility of point-of-care coagulation testing compared with more traditional laboratory analyses

TARGET POPULATION

Patients undergoing point-of-care coagulation testing

INTERVENTIONS AND PRACTICES CONSIDERED

Point-of-care coagulation testing including:

- Activated partial thromboplastin time (aPTT)
- Prothrombin time/international normalized ratio (PT/INR)
- Activated clotting time/(ACT)

MAJOR OUTCOMES CONSIDERED

- Patient outcomes (e.g., bleeding, transfusion requirements, recurrent ischemia)
- Diagnostic accuracy of point-of-care coagulation tests
- Turnaround times (TAT)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For a specific clinical use, pertinent clinical questions were formulated and key search terms were ascertained for the literature search. Literature searches were conducted through online databases (PubMed, MEDLINE, BioMedNet) and private libraries maintained by members of the Laboratory Medicine Practice Guideline (LMPG) team. Articles identified from author collections were only included if they are indexed on one of the 3 public search engines. All searches were performed using extremely broad search criteria. These searches were defined by the test name and any of the terms "bedside," "point of care," "near patient," or "whole blood." The majority of the publications identified consisted of correlation analyses, either point of care to laboratory or between different point-of-care systems. Such studies were excluded from further consideration because they do not directly address the clinical utility of these systems.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Abstracts identified by the literature searches were reviewed by 2 individuals to determine initial eligibility or ineligibility for full-text review, using Form 1 (Appendix A - see the "Availability of Companion Documents" field). If there was not consensus, then a third individual reviewed the abstract(s). To be included in the full systematic review of the clinical question, articles selected for full text review were examined for at least 1 relevant outcomes measurement. The systematic review consisted of creating evidence tables using Form 2 (Appendix A - see the "Availability of Companion Documents" field) that incorporated the following characteristics:

1. Study design—Prospective or retrospective, randomized, and controlled, patient inclusion/exclusion criteria, blinding, number of subjects, etc.
2. Appropriateness of controls
3. Potential for bias (consecutive or nonconsecutive enrollment)
4. Depth of method description—full-length report or technical brief
5. Clinical application—screening, diagnosis, management
6. Specific key outcomes and how they were measured
7. Conclusions are logically supported

For the assessment of study quality, the general approach to grading evidence developed by the US Preventive Services Task Force was applied (see the "Rating Scheme for the Strength of the Evidence" field). Once that was done, an assessment of study quality was performed, looking at the individual and aggregate data at 3 different levels using Forms 3 and 4 (Appendix A - see the "Availability of Companion Documents" field). At the first level, the individual study design was evaluated, as well as internal and external validity. Internal validity is the degree to which the study provides valid evidence for the populations and setting in which it was conducted. External validity is the extent to which the evidence is relevant and can be generalized to populations and conditions of other patient populations and point-of-care testing (POCT) settings.

The synthesis of the volume of literature constitutes the second level, Form 5 (Appendix A - see the "Availability of Companion Documents" field). Aggregate internal and external validity was evaluated, as well as the coherence/consistency of the body of data. How well does the evidence fit together in an understandable model of how POCT leads to improved clinical outcome? Ultimately, the weight of the evidence about the linkage of POCT to outcomes is determined by assessing the degree to which the various bodies of evidence (linkages) "fit" together. To what degree is the testing in the same population and condition in the various linkages? Is the evidence that connects POCT to outcome direct or indirect? Evidence is direct when a single linkage exists but is indirect when multiple linkages are required to reach the same conclusion.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The field of point-of-care testing (POCT), diagnostic testing conducted close to the site of patient care, was divided into disease- and test-specific focus areas. Groups of expert physicians, laboratorians, and diagnostic manufacturers in each focus area were assembled to conduct systematic reviews of the scientific literature and prepare guidelines based on the strength of scientific evidence linking the use of POCT to patient outcome.

Final guidelines were made according to Agency for Healthcare Research and Quality (AHRQ) classification (see the "Rating Scheme for the Strength of the Recommendations" field). The guidelines are evidence based and require scientific evidence that the recipients of POCT experience better health outcomes than those who did not and that the benefits are large enough to outweigh the risks. Consensus documents are not research evidence and represent guidelines for clinical practice, and inclusion of consensus documents was based on the linkages to outcomes, the reputation of the peer organization, and the consensus process used to develop the document. Health outcomes, e.g., benefit/harm, are the most significant outcomes in weighing the evidence and drafting guidelines.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B - The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were presented in open forum at the American Association for Clinical Chemistry (AACC) Annual Meeting (Los Angeles, CA, USA) in July 2004. Portions of these guidelines were also presented at several meetings between 2003 and 2005. Participants at each meeting had the ability to discuss the merits of the guidelines and submit comments to the National Academy of Clinical Biochemistry (NACB) Web site for formal response by the NACB during the open comment period from January 2004 through October 2005.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (I—III) and grades of the recommendation (A, B, C, I) are presented at the end of the "Major Recommendations" field.

Note from the National Academy of Clinical Biochemistry (NACB) and the National Guideline Clearinghouse (NGC)*: The Laboratory Medicine Practice Guidelines (LMPG) evidence-based practice for point-of-care testing sponsored by the NACB* have been divided into individual summaries covering disease- and test-specific areas. In addition to the current summary, the following are available:

- Chapter 1: Management
- Chapter 2: Transcutaneous Bilirubin Testing
- Chapter 3: Use of Cardiac Biomarkers for Acute Coronary Syndromes
- Chapter 5: Critical Care
- Chapter 6: Diagnosis and Management of Diabetes Mellitus
- Chapter 7: Drugs and Ethanol
- Chapter 8: Infectious Disease
- Chapter 9: Occult Blood
- Chapter 10: Intraoperative Parathyroid Hormone
- Chapter 11: pH Testing
- Chapter 12: Renal Function Testing
- Chapter 13: Reproductive Testing

Activated Partial Thromboplastin Time (aPTT)

Is there evidence of improved clinical outcome using point-of-care aPTT testing? (Literature Search 10 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 23. The guideline developers recommend that the use of point-of-care aPTT be considered a safe and effective alternative to laboratory aPTT testing for anticoagulation and hemostasis monitoring.
Strength/consensus of recommendation: B
Level of evidence: I and II (at least 1 randomized controlled trial, small randomized controlled trials, nonrandomized controlled trials, and multiple time series without intervention)

Guideline 24. The guideline developers strongly recommend that therapeutic ranges, workflow patterns, and cost analysis be evaluated, and where necessary altered, during the implementation of point-of-care aPTT testing to ensure optimization of patient treatment protocols.
Strength/consensus of recommendation: A
Level of evidence: II (small randomized controlled trials and nonrandomized controlled trials)

Prothrombin Time/International Normalized Ratio (PT/INR)

Is there evidence of improved clinical outcome using point-of-care PT testing? In the hospital? (Literature Search 11 – Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 25. The guideline developers recommend that the use of point-of-care PT be considered a safe and effective alternative to laboratory PT testing for hemostasis monitoring.
Strength/consensus of recommendation: B
Level of evidence: I and II (at least 1 randomized controlled trial, small randomized controlled trials, nonrandomized controlled trials, and multiple time series without intervention)

Guideline 26. The guideline developers strongly recommend that critical ranges, workflow patterns, and cost analysis be evaluated, and where necessary altered, during the implementation of point-of-care PT testing to ensure optimization of patient treatment protocols.
Strength/consensus of recommendation: A
Level of evidence: II (small randomized controlled trials, nonrandomized controlled trials)

Is there evidence of improved clinical outcome using point-of-care PT testing? In the anticoagulation clinic?

Guideline 27. The guideline developers recommend that the use of point-of-care PT be considered a safe and effective alternative to laboratory PT testing for oral anticoagulation monitoring and management.
Strength/consensus of recommendation: B
Level of evidence: II and III (controlled trials without randomization, cohort or case-control analytic studies, and opinions of respected authorities)

Is there evidence of improved clinical outcome using point-of-care PT testing? For patient self-testing (PST)/patient self-management (PSM)?

Guideline 28. The guideline developers recommend the use of point-of-care PT as a safe and effective method for oral anticoagulation monitoring for appropriately trained and capable individuals.
Strength/consensus of recommendation: B
Level of evidence: I, II, and III (at least 1 randomized controlled trial, small randomized controlled trials, nonrandomized controlled trials, and opinions of respected authorities)

Activated Clotting Time (ACT)

Is there evidence of improved clinical outcome with ACT testing? Is there evidence for optimal target times to be used with ACT monitoring? In cardiovascular surgery? (Literature Search 12 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 29. The guideline developers strongly recommend ACT monitoring of heparin anticoagulation and neutralization in the cardiac surgery arena.
Strength/consensus of recommendation: A
Level of evidence: I and II (at least 1 randomized controlled trial, small randomized controlled trials, nonrandomized controlled trials)

Guideline 30. There is insufficient evidence to recommend specific target times for use in ACT-managed heparin dosing during cardiovascular surgery.
Strength/consensus of recommendation: I (conflicting evidence across clinical trials)

Is there evidence of improved clinical outcome with ACT testing? Is there evidence for optimal target times to be used with ACT monitoring? In interventional cardiology?

Guideline 31. The guideline developers strongly recommend ACT monitoring of heparin anticoagulation and neutralization during interventional cardiology procedures.
Strength/consensus of recommendation: A
Level of evidence: II (small randomized controlled trials, nonrandomized controlled trials, and case-controlled analytic studies from more than 1 center or research group)

Guideline 32. The guideline developers recommend the use of target times specific to ACT system used that differ if specific platelet inhibitors are used concurrently with heparin. Without intravenous platelet inhibitors, the evidence suggests that targets of >250 seconds with the Medtronic ACTII or >300 seconds with the Hemochron FTCA510 tube assay are appropriate.
Strength/consensus of recommendation: B
Level of evidence: II (small randomized controlled trials, nonrandomized controlled trials, case-controlled analytic studies from more than 1 center or research group)

Guideline 33. With the intravenous platelet inhibitors abciximab or eptifibatide, a target of 200 to 300 seconds is recommended; with tirofiban, a somewhat tighter range of 250 to 300 seconds is recommended.
Strength/consensus of recommendation: B
Level of evidence: I (at least 1 randomized controlled trial)

Is there evidence of improved clinical outcome using ACT testing? Is there evidence for optimal target times to be used with ACT monitoring? In extracorporeal membrane oxygenation (ECMO)?

Guideline 34. The guideline developers strongly recommend ACT monitoring to control heparin anticoagulation during ECMO.
Strength/consensus of recommendation: A
Level of evidence: III (opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees)

Guideline 35. The guideline developers recommend that ACT target times for ECMO be determined according to the ACT system in use.
Strength/consensus of recommendation: B
Level of evidence: III (opinions of respected authorities according to clinical experience, descriptive studies, or reports of expert committees)

Is there evidence of improved clinical outcome using ACT testing? Is there evidence for optimal target times to be used with ACT monitoring? In other applications (e.g., vascular surgery, intravenous heparin therapy, dialysis, neuroradiology, etc)?

Guideline 36. There is insufficient evidence to recommend for or against ACT monitoring in applications other than cardiovascular surgery, interventional cardiology, or extracorporeal oxygenation.
Strength/consensus of recommendation: I

Definitions:

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B - The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

It is hoped that these guidelines will be useful for those implementing new testing, as well as those reviewing the basis of current practice. These guidelines should help sort fact from conjecture when testing is applied to different patient populations and establish proven applications from off-label and alternative uses of point-of-care testing (POCT). These guidelines will also be useful in defining mechanisms for optimizing patient outcome and identify areas lacking in the current literature that are needed for future research.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The material in this monograph represents the opinions of the editors and does not represent the official position of the National Academy of Clinical Biochemistry or any of the cosponsoring organizations.
- Point-of-care testing (POCT) is an expanding delivery option because of increased pressure for faster results. However, POCT should not be used as a core laboratory replacement in all patient populations without consideration of the test limitations and evaluation of the effect of a faster result on patient care.

- A critical assumption made in this document is that all point-of-care coagulation monitoring instruments are equally accurate and precise. There are insufficient data to allow recommendations based on specific instrumentation for these tests, and it must be the responsibility of the individual facility to evaluate available systems before implementation in a clinical setting. Although many of the studies described in this document were performed using point-of-care instruments that are no longer available in the marketplace, the value of the studies remains and should not be discounted.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Zucker ML, Johari V, Bush V, Rao S. Coagulation. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 21-9. [76 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

National Academy of Clinical Biochemistry - Professional Association

SOURCE(S) OF FUNDING

National Academy of Clinical Biochemistry

GUIDELINE COMMITTEE

Guidelines Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Preface and introduction. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. i-xvi.
- Appendix A: NACB LMPG data abstraction forms. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing.

Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 149-153.
- Appendix B: literature searches. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 154-186.

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on August 10, 2007. The information was verified by the guideline developer on September 24, 2007. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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