

Complete Summary

GUIDELINE TITLE

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

BIBLIOGRAPHIC SOURCE(S)

Jacobs E, Goldsmith B, Larrson L, Richardson H, St. Louis P. Management. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 1-4. [22 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
 METHODOLOGY - including Rating Scheme and Cost Analysis
 RECOMMENDATIONS
 EVIDENCE SUPPORTING THE RECOMMENDATIONS
 BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
 QUALIFYING STATEMENTS
 IMPLEMENTATION OF THE GUIDELINE
 INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
 CATEGORIES
 IDENTIFYING INFORMATION AND AVAILABILITY
 DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Any disease or condition requiring point-of-care testing (POCT)

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Family Practice
 Geriatrics

Internal Medicine
Pediatrics

INTENDED USERS

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

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 review and assess quality assurance practices associated with POCT

TARGET POPULATION

Patients undergoing point-of-care testing (POCT)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Developing a formal process of quality assurance of point-of-care testing (POCT)
2. Using an interdisciplinary committee to manage POCT
3. Training programs
4. Data management
5. Using Continuous Quality Improvement with Quality Indicator

MAJOR OUTCOMES CONSIDERED

- Patient/health
- Operational/management
- Economic benefit

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. Searches were conducted on MEDLINE or PubMed and were supplemented with the use of the National Guideline Clearinghouse, the Cochrane Group, or evidence-based medicine (EBM) reviews. Additionally, authors' personal article collections were used. Acceptable citations were limited to peer-reviewed articles with abstracts, those published in English, and those involving human subjects.

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.

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 2: Transcutaneous Bilirubin Testing](#)
- [Chapter 3: Use of Cardiac Biomarkers for Acute Coronary Syndromes](#)
- [Chapter 4: Coagulation](#)
- [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](#)

Quality Assurance and Medical Error

Does the application of quality assurance (QA) to point-of-care testing (POCT) reduce medical errors? (Literature Search 1– Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 1. The guideline developers recommend that a formal process of QA of POCT be developed in support of risk management and a reduction in medical errors)

Strength/consensus of recommendation: B

Level of evidence: III (expert opinion)

Does Management Improve the Quality of POCT?

Guideline 2. The guideline developers strongly recommend the use of an interdisciplinary committee to manage POCT (Literature Search 2 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Strength/consensus of recommendation: A

Level of evidence: II and III (time-controlled studies, descriptive studies, and expert opinion–consensus documents)

Guideline 3. The guideline developers strongly recommend training programs to improve the quality of POCT.

Strength/consensus of recommendation: A

Level of evidence: II (cohort/case-controlled study and time-controlled study)

Guideline 4. The guideline developers recommend data management as a mechanism to improve the quality of POCT.

Strength/consensus of recommendation: B

Level of evidence: II and III (time-controlled study and expert opinion)

Guideline 5. The guideline developers strongly recommend the use of Continuous Quality Improvement with Quality Indicator.

Strength/consensus of recommendation: A

Level of evidence: II (time-controlled studies)

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 original guideline document 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.

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
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Jacobs E, Goldsmith B, Larrson L, Richardson H, St. Louis P. Management. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 1-4. [22 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

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Robert H. Christenson, Ph.D., FACB, University of Maryland School of Medicine, Baltimore, Maryland, USA; William Clarke, Ph.D., Johns Hopkins Medical Institutions, Baltimore, Maryland, USA; Ann Gronowski, Ph.D., FACB, Washington University, St. Louis, Missouri, USA; Catherine A. Hammett-Stabler, Ph.D., FACB, University of North Carolina Chapel Hill, Chapel Hill, North Carolina, USA; Ellis Jacobs, Ph.D., FACB, New York State Department of Health, Albany, New York, USA; Steve Kazmierczak, Ph.D., FACB, Oregon Health and Science University, Portland, Oregon, USA; Kent Lewandrowski, M.D., Massachusetts General Hospital, Boston, Massachusetts, USA; Christopher Price, Ph.D., FACB, University of Oxford, Oxford, UK; David Sacks, M.D., FACB, Brigham and Women's Hospital, Boston, Massachusetts, USA; Robert Sautter, Ph.D.,

Carolinas Medical Center, Charlotte, North Carolina, USA; Greg Shipp, M.D., Nanosphere, Northbrook, Illinois, USA; Lori Sokoll, Ph.D., FACB, Johns Hopkins Medical Institutions, Baltimore, Maryland, USA; Ian Watson, Ph.D., FACB, University Hospital Aintree, Liverpool, UK; William Winter, M.D., FACB, University of Florida, Gainesville, Florida, USA; Marcia L. Zucker, Ph.D., FACB, International Technidyne Corporation (ITC), Edison, New Jersey, USA

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 9, 2007. The information was verified by the guideline developer on September 24, 2007.

COPYRIGHT STATEMENT

National Academy of Clinical Biochemistry's (NACB) terms for reproduction of guidelines are posted with each set of guidelines.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx>.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 10/6/2008

