Complete Summary

GUIDELINE TITLE

Diagnosis and management of diabetes mellitus. Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing.

BIBLIOGRAPHIC SOURCE(S)

Aarsand AK, Alter D, Frost SJ, Kaplanis B, Klovning A, Price CP, Sacks DB, Sandberg S, St. John A, Swaminathan R, Winter WE. Diagnosis and management of diabetes mellitus. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 44-62. [196 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Type 1 and 2 diabetes mellitus
- Gestational diabetes

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Management

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Health Care Providers
Hospitals
Nurses
Patients
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 literature to determine whether guidelines can be developed to support point-of-care testing (POCT) in the diagnosis and management of diabetes

TARGET POPULATION

- Patients with type 1 and 2 diabetes mellitus
- Pregnant women with gestational diabetes

INTERVENTIONS AND PRACTICES CONSIDERED

Point of care glycosylated hemoglobin (HbA1c) testing in both the primary and secondary care setting

Note: The following tests were considered but not recommended: self-monitoring blood glucose (SMBG) in primary care, point-of-care (POC) blood glucose in

gestational diabetes, fructosamine, blood ketones, urine albumin screening in primary and secondary care.

MAJOR OUTCOMES CONSIDERED

- Patient outcomes (e.g., glycosylated hemoglobin levels, glycemic control, changes in management)
- Clinical utility of tests
- Patient and clinician satisfaction
- 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.

See the original guideline document and Appendix B (see the "Availability of Companion Documents" field) for specific details of the literature searches.

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

Self-Monitoring of Blood Glucose

One study dealing with cost-effectiveness of self-monitoring blood glucose (SMBG) in type I diabetes mellitus (DM) found that urine monitoring was cost-effective, whereas blood monitoring was not. However, these findings are difficult to transfer to other settings.

A second study found that bedside glucose testing is not inherently more expensive than centralized laboratory measurements, but implementation on inefficient care units with low use can add substantially to the cost. Much of the excess cost of the bedside method can be attributed to the high costs of quality control and quality assurance, training, and documentation.

A third study compared the operating cost of point-of care (POC) testing for glucose and an electrolyte/glucose/blood urea nitrogen (BUN) chemistry panel with the cost of central laboratory stat testing in a 204-bed community hospital. In the scenarios studied, POC testing costs exceed central laboratory stat costs from 1.1 to 4.6 times. The more the POC testing is used, the greater the excess costs compared to the central laboratory. Cost analysis demonstrates that the investment in acquiring automated transport and data management systems for the hospital was far less expensive than POC testing for an individual stat test and on an annual cost basis.

Glycosylated Hemoglobin (HbA1c) Testing

Economic assessments of the use of diagnostic tests are rare, and invariably the economic data are poor. In the field of laboratory medicine, the main emphasis has been on the cost per test, and there has been little attention given to the wider benefits of testing. The situation is no different in the case of point of care testing (POCT) for HbA1c. One group of researchers looked at the use of a wide range of healthcare resources, including outpatient visits and contact time with staff, and found that POCT did not lead to any significant change in the use of resources. Another group of researchers found that the costs of POCT for HbA1c were higher than the laboratory provided service; when a laboratory analyzer was taken down to the clinic and run by a technologist, the costs were marginally higher that that of the conventional laboratory service. However, from an analysis of the retrospective cohort study, they found that there was a reduction in clinic visits using the POCT modality (from 2.28 visits per year per patient to a figure of 1.81), which helped to ameliorate the increased cost of testing. The prospective trial of POCT was only undertaken for a 3-month period, and a longer study is needed to provide more robust economic data.

Economic modeling from the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) studies shows an economic benefit from intensive glycemic control, with a long-term benefit, albeit at increased short-term cost. An economic analysis of diabetes care in the Kaiser Permanente healthcare system has shown that improved glycemic control does lead to an improved economic outcome when judged in terms of the long-term benefit, primarily due to the reduction in hospital costs associated with emergency admissions, increased periods of hospital stay, and more clinic visits. It is only by modeling the use of POCT into this environment that the true economic assessment of POCT can be made.

Refer to the original guideline document for more information on cost analysis.

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.

These recommendations are compared with those given by the World Health Organization, the American Diabetes Association (ADA), the National Academy of Clinical Biochemistry (NACB), and the National Institute for Clinical Excellence (NICE).

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 4: Coagulation
- Chapter 5: Critical care
- 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

Blood Glucose

Type 1 Diabetes Mellitus

Does blood glucose self-testing (i.e., primary care setting) lead to an improved patient (clinical) outcome in diabetes mellitus? (Literature Searches 36 and 37 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 60. There is insufficient evidence to recommend for or against routinely using self-monitoring blood glucose (SMBG). There is fair evidence that SMBG can improve health outcome. The balance between benefits and costs must be evaluated in each single environment. The consensus agreement to use SMBG in diabetes mellitus (DM) type 1 among experts is very strong (e.g., the American Diabetes Association [ADA]), and it is difficult to advise against SMBG. However greater objective evidence is still required to decide whether SMBG is really needed and which patients will benefit from it. If SMBG is going to be used, high-quality instruments should be chosen and patients must be educated in their practical use, as well as being instructed in how to use the results to monitor their insulin therapy. The evidence to support the guideline developers' view is from systematic reviews, randomized controlled trials (RCTs), as well as controlled trials without randomization, and cohort/case control studies. The evidence is, however, conflicting, and our recommendation is therefore of type I, i.e., there is insufficient evidence to recommend for or against routinely using SMBG.
Strength/consensus of recommendation: I
Level of evidence: I and II

Type 2 Diabetes Mellitus

Guideline 61. Type 2, insulin treated. The evidence to support the guideline developers' view is from systematic reviews, RCTs and controlled trials without randomization, and cohort/case control studies. The evidence is, however, conflicting and the guideline developers' recommendation is therefore of type I, i.e., there is insufficient evidence to recommend for or against routinely using SMBG. (Literature Searches 36 and 37 - Refer to Appendix B - see the "Availability of Companion Documents" field)
Strength/consensus of recommendation: I
Level of evidence: I and II

Guideline 62. Type 2, not insulin treated. The guideline developers conclude that the evidence is insufficient to recommend for or against routinely using SMBG. The evidence to support the guideline developers' view is from systematic reviews, RCTs and controlled trials without randomization, and cohort/case control studies. The evidence is conflicting, with a lot of poor studies, although there is some evidence that SMBG is not effective in improving glycemic control or avoiding hypoglycemic attacks. Recommendation is therefore of type I, i.e., the guideline developers conclude that the evidence is insufficient to recommend for or against routinely using SMBG. If SMBG is going to be used, high-quality instruments should be chosen and patients must be educated in their practical use, as well as being instructed in how to use the results to monitor their insulin therapy. (Literature Searches 36 and 37 - Refer to Appendix B - see the "Availability of Companion Documents" field)
Strength/consensus of recommendation: I
Level of evidence: I and II

Does blood glucose self-testing (i.e., primary care setting) lead to an economic benefit in diabetes mellitus? (Literature Searches 36 and 37 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 63. There is insufficient evidence of economical aspects to recommend for or against routinely using SMBG.
Strength/consensus of recommendation: I (there is little evidence)
Level of evidence: III

Does blood glucose point-of-care testing (POCT) in the hospital (i.e., secondary care setting) lead to an improved patient (clinical) outcome in diabetes mellitus compared with central laboratory testing? (Literature Searches 38 and 39 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 64. There is insufficient evidence to recommend for or against routinely using POC glucose testing in the hospital.
Strength/consensus of recommendation: I (there is little evidence)
Level of evidence: III

Does blood glucose POCT in the hospital (i.e., secondary care setting) lead to an economic benefit compared with central laboratory testing? (Literature Searches 38 and 39 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 65. The guideline developers recommend against routinely using POC glucose testing in the hospital setting on economic grounds.
Strength/consensus of recommendation: C
Level of evidence: II

Does blood glucose POCT (primary and secondary care) lead to an improved patient (clinical) outcome (mother and/or baby) in the case of the pregnant woman with gestational diabetes when compared with central laboratory testing? (Literature Searches 40 and 41 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 66. There is insufficient evidence to recommend for or against routinely using SMBG. The evidence to support the guideline developers' view is both from a systematic review, RCTs, as well as controlled trials without randomization, and cohort/case control studies. The evidence is, however, conflicting, and the guideline developers' recommendation is therefore of type I, i.e., there is insufficient evidence to recommend for or against routinely using SMBG. If SMBG is going to be used, high-quality instruments should be chosen and patients must be educated in their practical use, as well as being instructed in how to use the results to monitor their insulin therapy. It seems, however, rational to apply the same policy as for DM type I.
Strength/consensus of recommendation: I
Level of evidence: II

Does blood glucose POCT (primary and secondary care) lead to an economic benefit in the case of the pregnant woman with gestational diabetes when compared with central laboratory testing? (Literature Searches 40 and 41 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 67. There is insufficient evidence of economical aspects to recommend for or against routinely using SMBG in gestational diabetes mellitus. No studies have evaluated the possible economic benefit of SMBG in gestational diabetes.
Strength/consensus of recommendation: I
Level of evidence: III

Glycosylated Hemoglobin (HbA1c) Testing

Does the provision of the HbA1c result at the POC lead to an improved patient (clinical) outcome when compared with central laboratory testing? (Literature Search 42 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 68. The guideline developers conclude that there is good evidence to support the use of POCT for HbA1c in both the primary and secondary care setting. The benefit comes from the diabetes specialist having the result at the time of the patient consultation. This recommendation assumes that the POCT is implemented under proper conditions, e.g., trained and certificated operators, quality control and quality assurance, and with an analytical system comparable with that used in the central laboratory. The evidence base would benefit from studies conducted over a longer period of time.
Strength/consensus of recommendation: A
Level of evidence: I and II (2 RCTs and 2 controlled trials)

Does the provision of the HbA1c result at the POC lead to an economic benefit when compared with central laboratory testing? (Literature Search 42 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 69. The guideline developers conclude that there is some evidence to show that POCT testing for HbA1c will lead to an economic benefit. However, the data are limited, and more detailed studies are required that should focus on the wider benefit of POCT, i.e., beyond the immediate costs of providing the test and the change in clinic attendance. The evidence would benefit from studies conducted (and impacts judged) over a longer period of time.
Strength/consensus of recommendation: I
Level of evidence: II (randomized controlled trial and controlled trial, but small numbers)

Does patient self-testing for HbA1c lead to an improved patient (clinical) outcome when compared with central laboratory testing? (Literature Search 42 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 70. The guideline developers cannot make a recommendation here, because no studies have been reported.
Strength/consensus of recommendation: I
Level of evidence: III (no studies addressing the question)

What is the optimal frequency of HbA1c testing? Does more frequent testing lead to better outcomes? (Literature Search 42 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 71. There are no studies that have investigated the optimal frequency of POCT for HbA1c, and therefore the guideline developers can only recommend that the guidelines generated from studies using a laboratory service for the measurement of HbA1c be adopted in the POCT setting. There are no studies that have formally investigated the frequency of measurement of HbA1c in any setting. The guideline developers therefore recommend that HbA1c testing be performed between 2 and 4 times per year, in line with the patient's individual requirements. It is recommended that more frequent testing be required in those patients with extremely increased HbA1c levels and less frequently in those with levels approaching the reference range.
Strength/consensus of recommendation: I
Level of evidence: III (opinion of respected authorities based on clinical experience)

Fructosamine

Does the provision of the fructosamine result at the POC lead to an improved patient (clinical) outcome when compared with central laboratory testing? (Literature Search 43 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 72. Inadequate data are available to determine whether provision of fructosamine at the POC will improve glycemic control.
Strength/consensus of recommendation: I

Does the provision of the fructosamine result at the POC lead to an economic benefit when compared with central laboratory testing? (Literature Search 43 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 73. No studies have evaluated the possible economic benefit of fructosamine POCT.
Strength/consensus of recommendation: I

Does patient self-testing for fructosamine lead to an improved patient (clinical) outcome when compared with central laboratory testing? (Literature Search 43 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 74. Published evidence does not support the hypothesis that patient self-testing for fructosamine (compared to central laboratory testing) leads to improved patient outcome. There are few published studies and the data are contradictory.
Strength/consensus of recommendation: I
Level of evidence: III

What is the optimal frequency of fructosamine testing? Does more frequent testing lead to better outcomes? (Literature Search 43 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 75. No studies have addressed the optimal frequency of fructosamine POCT.
Strength/consensus of recommendation: I

Blood Ketones

Does the provision of the blood ketone result at the POC lead to an improved patient (clinical) outcome when compared with central laboratory testing? (Literature Search 44 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 76. In light of the absence of studies addressing this question, the guideline developers make no recommendation for or against routinely providing POCT for blood ketones.
Strength/consensus of recommendation: I
Level of evidence: II and III

Does the provision of the blood ketone result at the POC lead to an economic benefit when compared with central laboratory testing? (Literature Search 44 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 77. In light of the absence of studies addressing this question, the guideline developers make no recommendation for or against routinely providing POCT for blood ketones.
Strength/consensus of recommendation: I
Grade of evidence: II and III

Does patient self-testing for blood ketone lead to an improved patient (clinical) outcome when compared with central laboratory testing?

Guideline 78. In light of the absence of studies addressing this question, the guideline developers make no recommendation for or against routinely providing POCT for blood ketones.
Strength/consensus of recommendation: I
Grade of evidence: II and III

Urine Albumin

Does the provision of the urine albumin result at the POC (i.e., secondary-care setting) in the management of diabetes (e.g., early detection of diabetic nephropathy) lead to an improved patient (clinical) outcome compared with central laboratory testing? (Literature Search 45 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 79. There are no studies that have formally addressed the issue of screening for early signs of renal disease in patients with diabetes mellitus through the use of urine testing for protein or albumin at the POC. However, there is clear evidence to demonstrate an increase in urinary excretion of albumin associated with early diabetic nephropathy. Furthermore, there are several guidelines that advocate the regular checking of the urine albumin excretion in patients with diabetes mellitus.
Strength/consensus of recommendation: I
Level of evidence: III

Does the provision of the urine albumin result at the POC (i.e., secondary-care setting) in the management of diabetes (i.e., early detection of diabetic nephropathy) lead to an economic benefit when compared with central laboratory testing? (Literature Search 45 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 80. From the 1 available study, POCT for microalbuminuria with central laboratory confirmation of microalbuminuria is more expensive than testing alone, recognizing that this only takes into account the marginal cost of testing.
Strength/consensus of recommendation: I
Level of evidence: II (evidence from well-designed case-control study)

Does patient self-testing for urine albumin (i.e., primary-care setting) lead to an improved patient (clinical) outcome when compared with central laboratory testing? (Literature Search 45 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 81. In the absence of data on self-testing for microalbuminuria, there is no basis to recommend for or against this practice.
Strength/consensus of recommendation: I

What is the optimal frequency of urine albumin testing? Does more frequent testing lead to better outcomes? (Literature Search 45 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 82. In the absence of any data on the frequency of POCT for microalbuminuria, it is not possible to make any recommendation on this point, and guidance should be sought from the guideline documents that have been published on testing for microalbuminuria in diabetic patients.
Strength/consensus of recommendation: I
Level of evidence: III (opinions of respected authorities according to clinical experience)

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.

- In drawing together the conclusions from this review of the evidence on POCT in the diagnosis and management of diabetes mellitus, the reader is referred to an observation that "absence of evidence of effect does not constitute evidence of absence of effect". It has been acknowledged on many occasions in the literature that generating data on the outcomes from the use of "diagnostic tests" with robust study design can be extremely challenging, particularly true in the case of a complex condition such as diabetes mellitus, where, in the management of the condition, the test and the intervention are intimately linked and it is the combined use of test and intervention that yields an improved health outcome. In addition, it is also recognized that it can be difficult to design studies that minimize the risk of bias in the study results, as with the use of a randomized controlled study (RCT). Thus, as has been suggested in earlier systematic reviews of aspects of diabetes care, it may be necessary to look at other types of study design, e.g., observational studies. This effectively looks at a package of care and measures taken to involve patients in managing their own healthcare. In this respect, it is worthy of note that many of the current guidelines on the management of diabetes mellitus indicate the use of "diagnostic tests" as part of an "integrated package of care" and "taking account of patient's needs and expectations." Further research is needed on the use of POCT as part of an integrated package of care in the management of diabetes mellitus.

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

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Aarsand AK, Alter D, Frost SJ, Kaplanis B, Klovning A, Price CP, Sacks DB, Sandberg S, St. John A, Swaminathan R, Winter WE. Diagnosis and management of diabetes mellitus. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 44-62. [196 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.

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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.

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PATIENT RESOURCES

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