NACB Evidence-Based Practice for POCT

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What is Evidence-Based Medicine?

- Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients
  - Sackett et al BMJ 1996;312:71-72.

- Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values
  - Centre for EBM 2004 (www.cebm.utoronto.ca)

What is Evidence-Based Medicine?

- Best research evidence
  - Clinically relevant research, basic sciences
  - Patient centered research into accuracy and precision of diagnostic tests, power of prognostic markers and efficacy/safety of therapeutic, rehabilitative and preventive regimens.
- Clinical expertise
  - Ability to use clinical skills and past experience
  - Identify patient's unique health state, diagnosis, risks and benefits of interventions and patient's personal values and expectations
- Patient values
  - Patient's unique preferences, concerns and expectations
  - Need to integrate into clinical decisions

New Model of Medicine

Szabo L. Doctors health the system. USA Today March 31, 2004:8D.

The New Terminology of EBM

- Consensus Recommendations – Advice on an aspect of patient care based on peer opinion
- Clinical Protocols – Guidance covering an aspect of clinical care, standardizes practice, minimizes variation
- Outcome Study – Scientific research defining the end result or effect of a change in patient management.
- Systematic Review – Synthesis and grading of the quality of research literature, conducted in a predefined manner
- Practice Guidelines – Systematically developed statement based on scientific evidence that guides patient management decisions for specific clinical conditions and decreases variation in clinical practice.
- Critical Pathway – Evidence-based multidisciplinary plans of care, defining the optimal timing and sequences of clinical processes. Improves care by standardizing clinical practice and communication.

Point of Care Testing

- The field is young
- Proliferation of misinformation – Faster is often understood to mean better outcomes without research to back this conclusion
- Hospital pressure to move patients faster, want faster turnaround of lab results – POCT seen as a solution to remove patient bottlenecks
- Physicians want the latest technology – new technology equates with better patient care
- Each lab must research new test requests to determine clinical utility, cost effectiveness, management and reimbursement issues.

The Need for Evidence-Based POCT

- Clinicians, staff and laboratorians need guidance to apply POCT in the most effective manner for patient benefit.
- This guidance should be based on a concurrence of the scientific evidence to date.
- This need for evidence-based practice was the concept behind the NACB Laboratory Medicine Practice Guidelines for POCT

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http://www.aacc.org/members/nacb/Pages/default.aspx

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NACB: The Academy of AACC

NATIONAL ACADEMY of CLINICAL BIOCHEMISTRY
THE ACADEMY OF AACC

Composed of leading scientists, NACB is dedicated to advancing the science and practice of laboratory medicine. We do this in three ways: by advocating for scholarship through scientific research; by promoting scientific discovery, application, and integration through our educational programs; and by publishing Laboratory Medicine Practice Guidelines (LMPG), our signature program, which applies clinical biochemistry to medical diagnosis and therapy. Click here for a message from NACB President, Dr. Stephan Kahn.

FEATURED GUIDELINE

Follow-Up Testing for Metabolic Diseases Identified by Expanded Newborn Screening Using Tandem Mass Spectrometry

*See all **Laboratory Medicine Practice Guidelines***

NEWS FROM NACB

news & views
ADVANCING SCHOLARSHIP IN LABORATORY MEDICINE

ADDITIONAL RESOURCES >>>

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Photo Gallery of Academy events at the 2009 Annual Meeting

start | POCT EBM Para... | POCT EBM Webi... | Disconnected - ... | Calendar - Micro... | Calculator | NACB: The Acad... | EBM Lectures | 10:55 AM

Point of Care Testing PDF - Windows Internet Explorer

http://www.aacc.org/members/nacb/LMPG/OnlineGuide/PublishedGuidelines/poct/Pages/poctpdf.aspx

Point of Care Testing PDF

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    - Online Guidelines
      - Draft Guidelines
      - Published Guidelines
        - Emerging CV Risk Factors - 2009
        - Expanded Newborn Screening - 2008
        - Tumor Markers Quality Requirements - 2008
        - ACS and Heart Failure - 2007
        - *Point of Care Testing - 2007*
        - Emergency Toxicology - 2003
        - Major Tumor Markers - 2009
        - Maternal-Fetal Risk Assessment - 2006
  - NACB Committee Administration

Point of Care Testing PDF

The National Academy of Clinical Biochemistry

Laboratory Medicine Practice Guidelines

Evidence-Based Practice for Point-of-Care Testing

Published Guidelines -- PDF Format

Access to Entire Document
(Right click to save entire document to your computer)

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Evidence-Based Practice for POCT

- POCT is an increasingly popular means of delivering laboratory testing.
- When used appropriately, POCT can improve patient outcome by providing a faster result and therapeutic intervention.
- However, when over-utilized or incorrectly performed, POCT presents a patient risk and potential for increased cost of healthcare.
- This LMPG systematically reviews the existing evidence relating POCT to patient outcome, grades the literature, and makes recommendations regarding the optimal utilization of POCT devices in patient care.
- Develop liaisons with appropriate professional, clinical organizations: ACB, ADA, ACOG, CAP, etc.

Evidence-Based Practice for POCT Organizing Committee

- James H. Nichols, Ph.D. (Chair)
- Robert H. Christenson, Ph.D.
- William Clarke, Ph.D.
- Ann Gronowski, Ph.D.
- Catherine Hammett-Stabler, Ph.D.
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- Ian Watson, Ph.D.
- William E. Winter, M.D.
- Marcia Zucker, Ph.D.

EBM for POCT LMPG Planning

- Split diversity of POCT into disease groups
- Introductory section for quality assurance that crosses all disciplines
- Focus groups (clinician, laboratory, industry)
  - Formulate pertinent clinical questions
  - Conduct systematic reviews of literature
  - Develop practice recommendations
- Publicized draft recommendations
- Reviewed and resolved public comments
- Published final LMPG

Evidence-Based Practice for POCT
Focus Group Chairs

- Introduction/Management - Ellis Jacobs, Ph.D.
- Cardiac – Robert H. Christenson, Ph.D.
- Diabetes – Christopher Price, Ph.D.
- Reproduction – Ann M. Gronowski, Ph.D.
- Infectious Disease – Robert Sautter, Ph.D.
- Coagulation – Marcia Zucker, Ph.D.
- Parathyroid – Lori J. Sokoll, Ph.D.
- Drugs – Ian Watson, Ph.D.
- Bilirubin Screening – Steven Kazmierczak , Ph.D.
- Critical Care – Greg Shipp, Ph.D.
- Renal – William A. Clarke, Ph.D.
- Occult Blood – Kent Lewandrowski, M.D.
- pH – James Nichols, Ph.D.

Evidence Based Practice for POCT Introduction/Management Focus Group

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  Ontario Medical Association: Quality Management Program – Laboratory Services, Ontario, Canada
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  Ste-Justine Hospital, Montreal, Quebec, Canada

EBM Practice for POCT
Systematic Review - Definition

POCT is clinical laboratory testing conducted close to the site of patient care, typically by patients or clinical personnel whose primary training is not in the clinical laboratory sciences. POCT refers to any testing performed outside of the traditional, core or central laboratory.

EBM Practice for POCT
Systematic Review - Objective

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

Systematic Review Format for Clinical Questions

- What is the effect on *Outcome* when comparing *POCT to Core Lab Testing* (Identify comparison) for *screening patient for Disease X* (cite clinical application) in the *Emergency Room* (list patient population)?
- Does POCT for *Disease X* (clinical application/assay/disease) improve *Outcome* (list outcome of interest) in *Patients* (describe population or setting) compared to core lab testing (identify comparison being measured)?

Key components:

How - Clinical application (screening, diagnosis, management)

What - Comparison being measured (core vs POCT)

Where - Patient population or clinical setting (ED, home, clinic)

Why - Outcome (clinical, operational, economical)

Systematic Review Search Strategies

- Medline or PubMed, supplemented with
  - National Guideline Clearinghouse
  - Cochrane Group or EBM Reviews
  - Authors personal manuscript collections
- Limited to
  - Peer-reviewed articles with abstracts
  - English language
  - Human subjects

Systematic Review
Study Selection Criteria/Grading

- Abstracts – eligible, ineligible, uncertain for full review
- Full-text review – include or exclude for grading
  - Examines at least one relevant outcomes measurement
  - Is published in a peer-review journal
- Systematic Review – create evidence tables
  - Study design – Type I (RCT), II, or III (consensus)
  - Appropriateness of controls
  - Potential for bias (consecutive or nonconsecutive enrollment)
  - Depth of method description- full length report or technical brief
  - How the outcome was measured
  - Conclusions are logically supported

Systematic Review
Assessment of Study Quality

- Level 1 Strata
  - Individual Study Design
  - Individual Study Internal Validity
  - Individual Study External Validity
- Level 2 Strata – Synthesis of the Volume of Literature
  - Aggregate Internal Validity
  - Aggregate External Validity
  - Coherence/Consistency
- Level 3 Strata – Weight of Evidence as POCT links to Outcome
  - Quality of evidence from Strata 2 for each link between POCT & Outcomes
  - Degree to which there is a complete chain of linkages supported by adequate evidence to connect POCT to Outcome
  - Degree to which the complete chain of linkages “fit” together
  - Degree to which the evidence connects POCT to Outcome is “direct”

Systematic Review Recommendation

- Recommendations could be used if evidence based
- Consensus documents not research evidence and inclusion should weigh link to outcomes
- Health outcomes (benefit/harm) matter most
- Recommendation Language:
  - A – Strongly recommend POCT (Good evidence POCT improves important clinical outcomes, benefit outweighs risk)
  - B – Recommend POCT (Fair evidence support)
  - C – No recommendation (Fair outcomes, but balance of benefit and harm too close to justify)
  - D – Recommend against POCT (Fair evidence against)
  - I – Insufficient evidence to recommend for or against POCT

AHRQ Publication 02-E016, Systems to Rate the Strength of Scientific Evidence, Bethesda, MD, April 2002. http/www.ahrq.gov

EBM for POCT LMPG QA/Management Questions

- Does the application of Quality Assurance to Point-of-Care Testing reduce medical errors?

- Does management improve the quality of Point-of-Care Testing ?

QA/Management Question 1 Search Results

Search Terms/Hits: Medline OVID (1966-October Week 5, 2003)

Point of Care Testing	NPT	Quality Assessment
Point-of-Care Testing	POCT	EQA
Bedside Testing	Decentralized	Accreditation
Ancillary Testing	Regulations	Error
Near Patient Testing	Standards	Errors
Near-Patient Testing	Quality Assurance	Mistakes

Search Criteria:

(Point of Care Testing OR Point-of-Care Testing OR Bedside Testing OR Ancillary Testing OR Near Patient Testing OR Near-Patient Testing OR NPT OR POCT OR Decentralized) AND (Regulations OR Standards OR Quality Assurance OR Quality Assessment OR EQA OR Accreditation) AND (Error OR Errors OR Mistakes)

QA/Management Question 1 Search Results

#	Search History	Results
1	Point of Care Testing	300
2	Point-of-Care Testing	300
3	Bedside Testing	74
4	Ancillary Testing	75
5	Near Patient Testing	126
6	Near-Patient Testing	126
7	NPT	597
8	POCT	152
9	Decentralized	1321
10	Regulations	12480
11	Standards	43426
12	Quality Assurance	10661
13	EQA	136
14	Accreditation	9262
15	Quality Assessment	3823
16	Error	45464
17	Errors	40086
18	Mistakes	2577
19	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	2524
20	10 or 11 or 12 or 13 or 14 or15	74824
21	16 or 17 or 18	80109

Search 22 (19 AND 20 AND 22) = 7 articles

		Abstract Review				Full Text Review				
Group /No.	**Citation**	**Include? 1**	**2**	**3**	**Reviewers**	**Include? 1**	**2**	**3**	**Reviewers**	**Comments**
I1-1	1. Bolann BJ, Omenas B. [Quality assurance of laboratories outside hospitals. Use of internal control]. [Norwegian]. Tidsskrift for Den Norske Laegeforening 1997; 117:(21)3088-92.									
I1-2	2. Kost GJ. Guidelines for point-of-care testing. Improving patient outcomes. [Review] [167 refs]. American Journal of Clinical Pathology 1995; 104:(4 Suppl 1)S111-27.									
I1-3	3. Kost GJ. Preventing medical errors in point-of-care testing: security, validation, safeguards, and connectivity. Archives of Pathology & Laboratory Medicine 2001; 125:(10)1307-15.									
I1-4	4. Mock T, Morrison D, Yatscoff R. Evaluation of the i-STAT system: a portable chemistry analyzer for the measurement of sodium, potassium, chloride, urea, glucose, and hematocrit. Clinical Biochemistry 1995; 28:(2)187-92.									

QA/Management Question 2
Search Results

Does management improve the quality of Point-of-Care Testing ?

Search Criteria:

Point of Care Testing AND (Management OR Organization)

Identified by Database Search	-	92
Selected Based on Abstract Review	-	52
Manuscript Review	-	10

Consensus Documents for QA/Management of POCT

- Management of in vitro Diagnostic Medical Devices. Medical Devices Agency, UK MDA DB2002(02), March 2002
- Management and Use of IVD Point of Care Test Devices. Medical Devices Agency, UK MDA DB2002(03), March 2002
- ISO/WD 22870 Amendment to ISO 15189: Annex D (Normative) Point-of-Care-Testing (POCT)

Consensus Documents for QA/Management of POCT

- Application of a Quality System Model for Laboratory Services – NCCLS, GP26-A, 2003
- Point-of-Care in Vitro Diagnostic (IVD) Testing – NCCLS, AST2-A, 1999
- Wellness Testing Using IVD Devices – NCCLS, AST3-A, 1999
- Additional Criteria on Point of Care (POC) Testing (Addendum to Essential Criteria for Quality Systems of Medical Laboratories) - European Communities Confederation of Clinical Chemistry (EC4), 2000

QA/ Management
Final Recommendations

We recommend that a formal process of quality assurance of POCT be developed in support of risk management and a reduction in medical errors. (Level B, Class III – Opinions of respected authorities)

We recommend the use of an interdisciplinary committee to manage POCT (Level A, Class II-3 – Time controlled studies, Class III – Descriptive studies and Expert Opinion (consensus documents)

QA/Management
Final Recommendations (cont.)

We recommend training programs to improve the quality of POCT (Level A, Class II-2 – Cohort/Case Controlled study, II-3 – Time controlled study

We recommend Data Management as a mechanism to improve the quality of POCT (Level B, Class II-3 – Time controlled study, Class III – Expert Opinion.

We recommend the use of Continuous Quality Improvement with Quality Indicators (Level A, Class II-3 – Time Controlled studies.

Evidence Based Practice for POCT pH Guidelines I

- **Does the use of pH paper for assisting the placement of nasogastric tubes, compared to clinical judgment (air, pressure) improve the placement of tubes on inpatient, endoscopy, home care and nursing home patients?**
- *We recommend the use of pH testing to assist in the placement of nasogastric tubes. The choice of measuring pH with an intragastric electrode or testing tube aspirates with a pH meter or pH paper will depend on consideration of the clinical limitations of each method, and there is conflicting evidence over which method is better. (Class II – prospective comparative trials and expert opinion)*

Evidence Based Practice for POCT pH Guidelines II

- **Does continuous gastric pH monitoring, compared to random gastric pH determinations, improve patient symptoms and severity in the management of achlorhydria and gastric reflux in inpatient and endoscopy patients?**
- *We recommend against the intermittent use of pH paper on gastric aspirates in the diagnosis of gastric reflux disease in favor of continuous monitoring. The role of pH testing to manage acid suppression therapy is controversial. Although the use of pH testing is common on critical care units, there is a lack of evidence that pH monitoring to adjust drug dosage improves either morbidity or mortality in these patients. (Class II – well designed case controlled and correlation trials and consensus opinion)*

Evidence Based Practice for POCT pH Guidelines III

- **Is one brand of pH paper better than another brand in improving patient symptoms and time to treatment of chemical burns in emergency and urgent care patients, and in improving the accuracy of nasogastric tube placement in inpatient, endoscopy, home care and nursing home patients?**
- *We cannot recommend one brand of pH paper over another brand of pH paper for use in the treatment of chemical burns or placement of nasogastric tubes. (Grade III – case reports and opinion)*

Evidence Based Practice for POCT pH Guidelines Take Home Messages

- pH paper useful on Critical Care, GI, and OB/GYN units
- pH paper not useful for diagnosis of GER or monitoring antacid/H2 therapy – use continuous pH monitoring
- Multiple color scales more accurate than single color pH paper compared to meters, effect on patient outcome not explored.
- No support for use in ED for acid/base exposure.

Evidence Based Practice for POCT pH Paper Summary

- pH paper is inexpensive and may be considered inconsequential to clinicians, but inaccuracies in pH can lead to inappropriate treatment (ie feeding tube placement) with the potential for serious and costly patient consequences.
- Need for strict QA.
- Further studies are needed that directly examine the effects of pH testing on patient outcome.

Evidence Based Practice for POCT Critical Care Summary

Is there evidence in the peer-reviewed literature that more rapid therapeutic turnaround time of a lab test result leads to outcome improvement in the setting for patients with disease?

Does POCT of lab test for patients with diseases in the setting improve outcome when compared to core laboratory testing?

Level of Evidence	Setting	Test
Good , Level 1, Strength A Level II, Strength B	Critical Care	Glucose Lactate
Fair , Level II, Strength B Level II, Strength B Level III, Strength B	ICU ED ICU	ABG K iCa
Little Known	ICU	Electrolytes
Insufficient	Critical Care	Mg

NEED RCT

Evidence Based Practice for POCT Critical Care Summary

Rapid TAT has been shown to be crucial in critical care settings. However, POCT is often placed without changing processes, which are often required before improvement outcomes can be observed. Need more well done RCT to show affect.

Evidence Based Practice for POCT Glucose Testing Summary

- Does self monitoring of blood glucose (SMBG) or ward blood glucose testing lead to improved health outcomes (clinical and/or economic) in patients with type 1, type 2 or gestational diabetes mellitus?
- ** There is insufficient evidence regarding improved clinical outcome to recommend for or against routinely using SMBG in type 1 diabetes mellitus. (Strength I, Level I and II) There is, however, some evidence that SMBG can improve health outcome, but the balance between benefits and costs must be evaluated in each single environment. The consensus agreement to use SMBG in type 1 diabetes among experts is very strong (e.g. the American Diabetes Association), and it is difficult to advise against SMBG.*

Evidence Based Practice for POCT Glucose Testing Summary

- Does self monitoring of blood glucose (SMBG) or ward blood glucose testing lead to improved health outcomes (clinical and/or economic) in patients with type 1, type 2 or gestational diabetes mellitus?
- ** In insulin and non-insulin treated type 2 diabetes, there is insufficient evidence to support that the routine use of SMBG leads to improved clinical outcomes. (Strength I, Level I and II)*
- ** In women with gestational diabetes, there is insufficient evidence regarding clinical outcome to recommend for or against the routine use of SMBG. (Strength I, Level II) It seems, however, rational to apply the same policy as for type 1 diabetes.*

Evidence Based Practice for POCT Glucose Testing Summary

- Does self monitoring of blood glucose (SMBG) or ward blood glucose testing lead to improved health outcomes (clinical and/or economic) in patients with type 1, type 2 or gestational diabetes mellitus?
- ** There is insufficient evidence of economic benefit to recommend for or against routinely using SMBG in type 1, type 2, or gestational diabetes. (Strength I, Level III)*
- ** Regarding the routine use of POCT glucose testing in the hospital setting, there is insufficient evidence as to improved clinical outcome to recommend for or against (Strength I, Level III), but based on only economic benefit, we recommend against routine use. (Strength C, Level II)*

Evidence Based Practice for POCT

- EBM offers fact-based support for medical decision-making, reducing subjectivity and practice variability.
- The POCT LMPG is the most comprehensive collection of our POCT outcomes knowledge base.
- Recommendations from this LMPG are useful:
  - To sort the facts from conjecture when implementing and utilizing POCT devices.
  - To establish proven applications from off-label and alternative uses of POCT
  - To define the mechanisms and strategies for optimizing patient outcome.

Acknowledgements

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QUESTIONS