
NACB Evidence-Based Practice for POCT

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Evidence Based Practice for POCT Introduction/Management Focus Group

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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



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.



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 will systematically review the existing evidence relating POCT to patient outcome, grade the literature, and make recommendations regarding the optimal utilization of POCT devices in patient care.
- ◆ Develop liaisons with appropriate professional, clinical organizations: ACB, ADA, ACOG, CAP, etc.



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



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
- ◆ Publicize draft recommendations
- ◆ Review and resolve public comments
- ◆ Publish final LMPG



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



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



Group /No.	Citation	Abstract Review			Full Text Review			Comments
		Include?			Include?			
		1	2	3	1	2	3	
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 ?

Identified by Database Search - 92

Selected Based on Abstract Review - 52

Manuscript Review

6 selected

27 rejected

3 disagreement

16 not done



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



Evidence Based Practice for POCT Implementing Guidelines

- ◆ Need to widely publicize available guidelines
- ◆ Discuss guidelines with key clinicians
- ◆ Integrate guidelines into practice pathways, ordering protocols and diagnostic decision trees
- ◆ Conduct well-designed studies and publish outcomes data to add to the available evidence knowledge base



Evidence Based Practice for POCT

- ◆ EBM offers fact-based support for medical decision-making, reducing subjectivity and practice variability.
- ◆ The POCT LMPG promises to be the most comprehensive collection of our POCT outcomes knowledge base.
- ◆ Recommendations from this LMPG will be 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.





QUESTIONS

