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Achieving Better Quality of Care with Point of Care Testing

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Objectives

- Define Point-of-Care Testing
- Identify resources for evidence-based practice
- Integrate POCT into clinical pathways of care
- Describe challenges with resulting POCT in an electronic medical record

2

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POCT Definition

- 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.
- Nichols JH (editor) National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Evidence Based Practice for Point of Care Testing. AACC Press; 2007.

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3

Point of Care Testing

- Advantages
  - Immediate results - no lab transportation
  - Small blood volume
  - Wide menu of tests available
  - Whole blood and other samples available
  - Works within clinical patient flow
- Disadvantages
  - More expensive than traditional laboratory tests
  - Quality is questionable as anyone can run the analysis
  - Difficulties with regulatory compliance and documentation
  - Lack of appreciation for preanalytic, analytic, postanalytic issues
  - Compliance issues with billing and charge capture
- Where is the link between POC and Outcomes?

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Outcomes

- *Definition:* result, end, consequence, conclusion, end result, payoff. Collins Thesaurus of the English Language– Complete and Unabridged 2nd Edition. 2002 © HarperCollins Publishers 1995, 2002
- Quality outcomes – better technical performance
- Medical - discharge, faster recovery, less complications
- Patient and physician satisfaction
- Resource management – fewer people, less time, more efficiency
- Financial – less cost, reagents, controls, instrument maintenance, fewer office visits, lost time from work

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Evidence-Based Medicine

- Evidence-based medicine (EBM) or evidence-based practice (EBP) aims to apply the best available evidence gained from the scientific method to clinical decision-making.
- Seeks to assess the strength of evidence of the risks and benefits of treatment (including lack of treatment) and diagnostic tests.
- Evidence quality can range from meta-analyses and randomized-controlled clinical trials to conventional wisdom and opinion.

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6

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Point of Care Testing

- 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.

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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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NACB Guidelines

- Group of experts systematically reviewed the scientific literature linking POCT to patient outcomes
- Graded the evidence
- Developed a comprehensive set of recommendations on best practice linking POCT and outcomes

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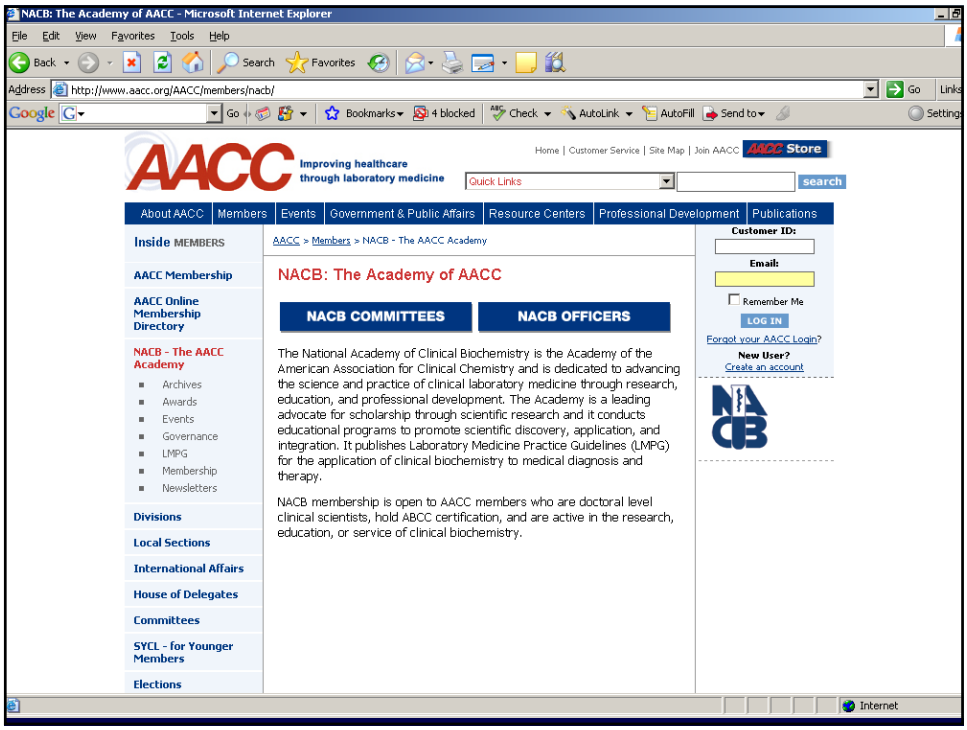
9



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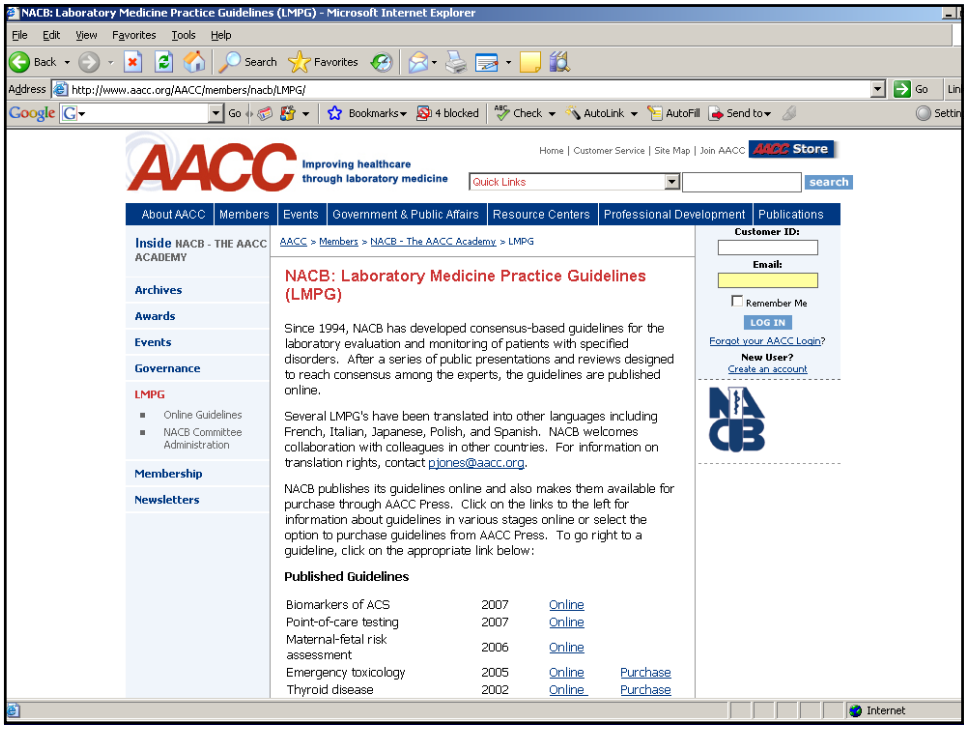

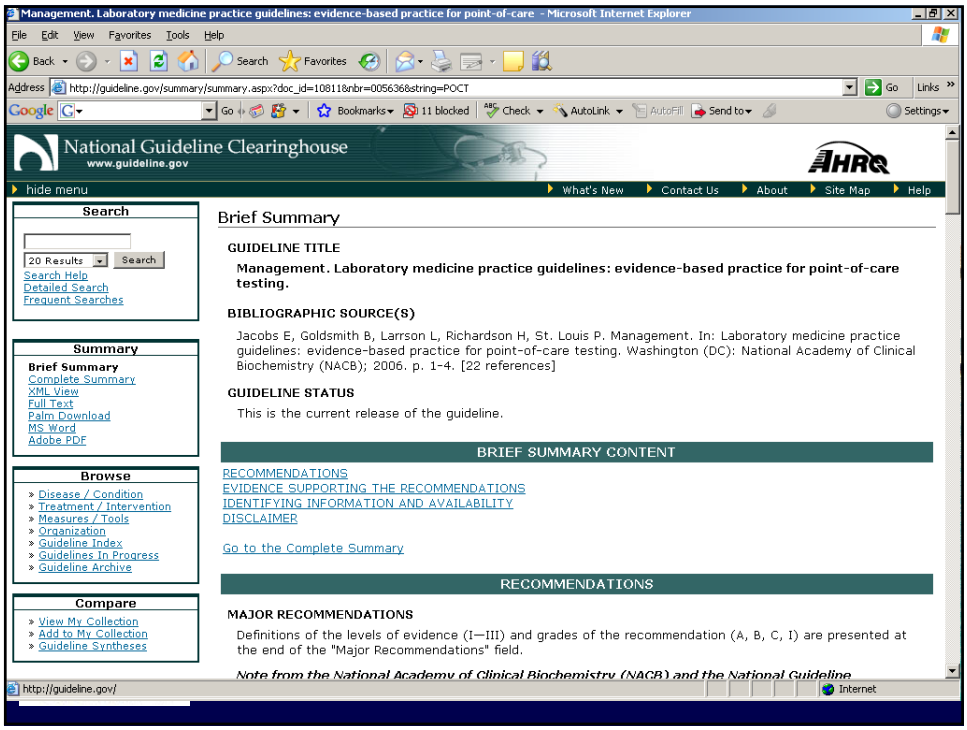

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The National Academy of Clinical Biochemistry

Presents

LABORATORY MEDICINE PRACTICE GUIDELINES

EVIDENCE-BASED PRACTICE FOR POINT-OF-CARE TESTING

AACCPress

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13

EBM for POCT LMPG

- 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

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14

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EBM for POCT LMPG

- This LMPG is the most comprehensive collection of our POCT 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.
  - To identify areas of research that are needed to establish the link between POCT and outcomes

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15

Evidence Based Practice for POCT

- 13 chapters
- 75 analytes
- 190 recommendations
- 75 authors + 4 consultants
- 546 pages
- 113 literature searches
- 1280 reference citations
- 3 peer-reviewed supporters:
  - American Society for Microbiology (ASM)
  - College of American Pathologists
  - IFCC – Committee on Evidence-Based Laboratory Medicine

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16

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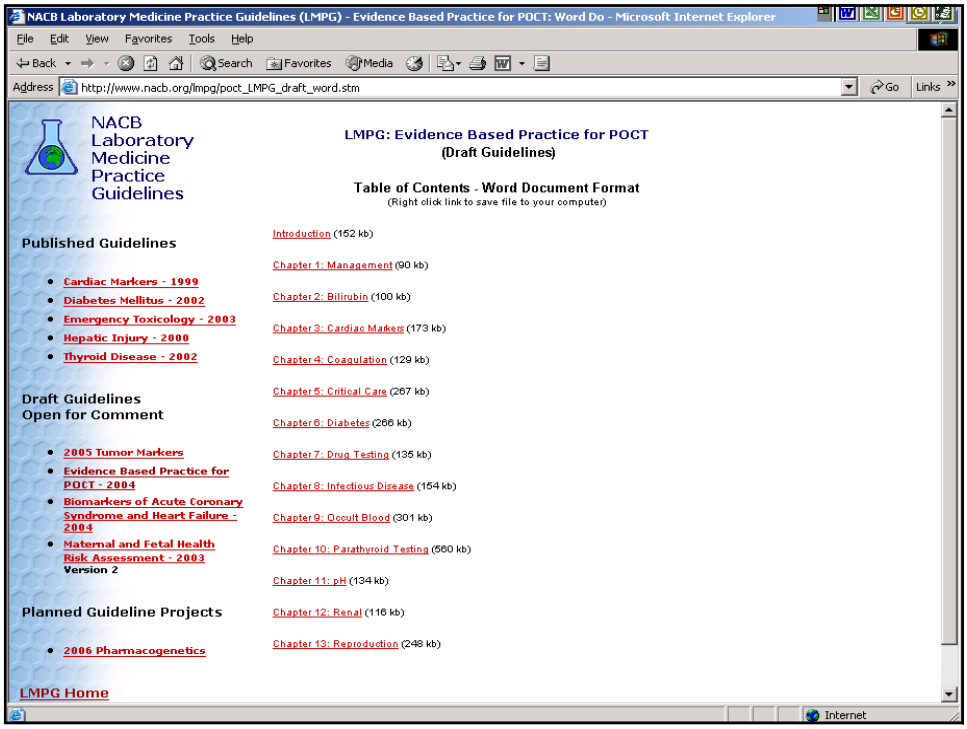

Systematic Review Recommendation

- Strength/Consensus of Recommendation:
  - A – Strongly recommend POCT (Good evidence POCT improves important clinical outcomes, benefit outweighs risk)
  - B – Recommend POCT (Fair evidence support)
  - C – 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

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Level of Evidence

- I at least one, well-conducted, randomized-controlled trial
- II randomized studies with small numbers, case and cohort controlled trials
- III clinical experience or expert opinion

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19

NACB POCT Guidelines

- Few randomized controlled trials in the POCT literature (Most II and III level evidence)
- POCT alone doesn't improve outcomes without a change in patient management to utilize the result in a faster manner
- Laboratory input is required to ensure quality of test results

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Occult Blood Recommendations

- **Can gastroccult testing of gastric fluid from a nasogastric tube be used to detect gastrointestinal bleeding in high-risk intensive care unit patients receiving antacid prophylaxis?**
- **Recommendation:** *We cannot currently recommend for or against the use of gastroccult to detect gastric bleeding in intensive care unit patients receiving antacid prophylaxis. Only one study to our knowledge has indirectly addressed this issue. No randomized controlled trials have been performed. (Strength/consensus of recommendation: I, Level III – small study, clinical evidence)*

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21

Bleeding in ICU Patients

- A small study with 41 patients showed that 13/14 patients with positive gastroccult tests had a source of upper GI bleeding as seen by upper endoscopy.
- However, patients with negative gastroccult tests did not undergo upper endoscopy.

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Baystate Gastroccult Testing

- Discontinued without incident
- Approached Chief of GI and Division of Healthcare Quality with clinical utility.
- Researched literature
- Developed recommendation and justification
- Draft letter to medical staff reviewed by select clinicians
- General announcement and test removal

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23

Gastroccult Discontinuation

- No peer-reviewed literature indicating improved outcomes based on Gastroccult
- Use of test after NG tube placement leads to positive results solely due to trauma of tube insertion
- Overt bleeding is a medical concern and doesn't require test to detect
- pH is medically useful, pH paper is a better alternative because it's easier to QC, already available on units and lower cost
- Elimination would reduce hospital burden of training and POCT documentation on nursing staff and reduce risk of developer mixup with hemoccult.

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Gastroccult Cost Savings

- Reagent: (12,000 tests/year)
  - Cards $21,000
  - Developer $ 5,000
- Labor
  - Nursing (5 min/test, 45K= 125d) $22,000
  - Competency (1100 x 15 min) $ 6,000
  - Lab oversight (4hr x 8 units x 12 mo) $ 8,500
- Total Annual Savings Estimate $62,500
- Total billed previous year 12
- Cost estimate for pH replacement $ 250

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NACB LMPG POCT Creatinine

- Does the measurement of BUN/Creat POC result in improved outcomes?
  - Quicker time to treatment
  - Decreased wait time
  - Decreased length of stay
- Locations
  - Inpatient
  - ED
  - Dialysis
  - Cardiovascular diagnostics
  - Chemotherapy?

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NACB LMPG POCT Creatinine

- Found only 3 studies, 2 in ED for BUN
  - Tsai et al 210 patients POC faster TAT (8 vs 59 mins) but higher cost ($14 – 16 vs $11)
  - POC could be cost effective with higher volume, but didn't consider LOS or throughput
  - Parvin et al. 4985 patients POC did not decrease LOS (209 mins vs 201 mins core lab)
- 1 CVDL study for BUN/Creatinine

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27

Clinical Chemistry 46:4
543–550 (2000)

Laboratory Management

Clinical Outcomes of Point-of-Care Testing in the Interventional Radiology and Invasive Cardiology Setting

James H. Nichols,[1*] Thomas S. Kickler,[1] Karen L. Dyer,[1] Sandra K. Humbertson,[1] Peg C. Cooper,[2] William L. Maughan,[3] and Denise G. Oechsle[2]

Background: Point-of-care testing (POCT) can provide rapid test results, but its impact on patient care is not well documented. We investigated the ability of POCT to decrease inpatient and outpatient waiting times for cardiovascular procedures.

Methods: We prospectively studied, over a 7-month period, 216 patients requiring diagnostic laboratory testing for coagulation (prothrombin time/activated partial thromboplastin time) and/or renal function (urea nitrogen, creatinine, sodium, and potassium) before elective invasive cardiac and radiologic procedures. Overall pa-

0.02). For patients needing coagulation testing, wait times improved only when systematic changes were made in workflow (phase 4, 109 ± 41 min; n = 12; P = 0.01).

Conclusions: Although POCT has the potential to provide beneficial patient outcomes, merely moving testing from a central laboratory to the medical unit does not guarantee improved outcomes. Systematic changes in patient management may be required.

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28

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CVDL Outcomes Trial

- Prior to therapeutic intervention, patients require coagulation (PT/aPTT) and/or renal function testing (Na/K, BUN/Creat)
- Phase 1 – workflow and patient throughput determined using central lab testing.
- N = 135 patients over 95 days
- Despite arriving 120 minutes early if lab work needed, 44% of results not available prior to scheduled procedure time.
- Average patient wait time was 167 minutes

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29

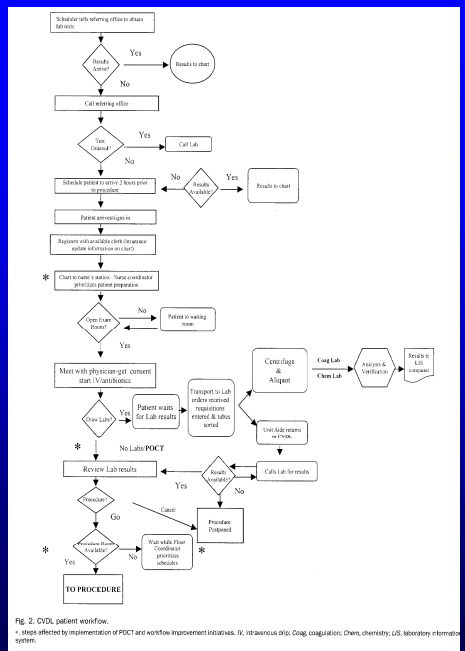

Fig. 2. CVDL patient workflow.

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JHH CVDL Outcomes Trial

- POCT improved wait times over core laboratory, but not significantly.
- Significant changes only occurred after unit workflow reorganized to optimize use of POCT results (implemented communication center between admit and procedure rooms); decreased wait times 63 mins for coag (N=9, p = 0.014) and 47 mins for renal (N=18, p = 0.02)
- Hospital chose not to implement POCT once patient workflow was streamlined for efficiency

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31

POCT Creatinine in Oncology

- Oncology Center – 2 blocks from hospital
- Patients need estimate of renal function before administration of chemotherapy
- Hematology laboratory onsite performs cell counts and simple chemistries by a POC device
- Creatinine sent to core lab – periodic courier pickup (every 2 hours), means patients could wait up to 4 hours before testing completed
- Need faster turnaround time for results

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32

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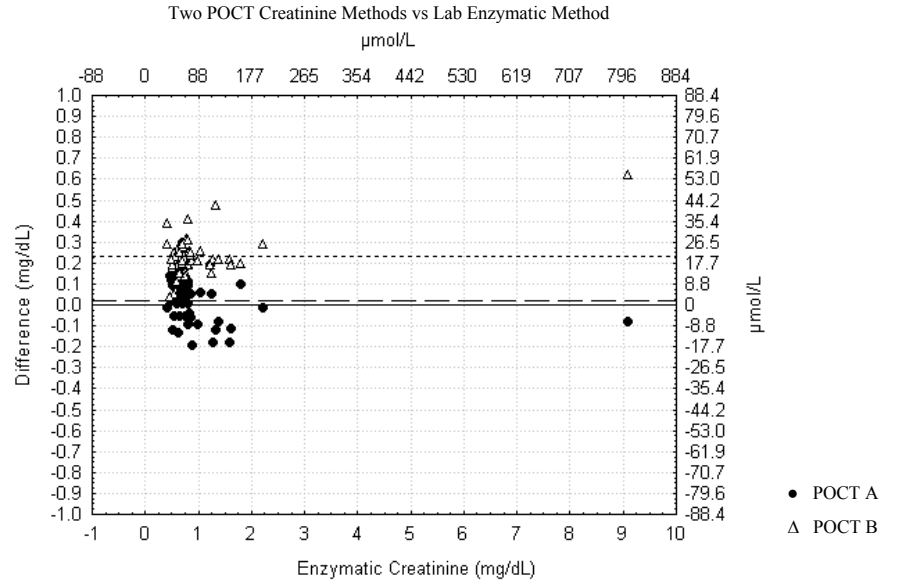

Nichols JH, Bartholomew C, Bonzagi A, Garb JL, Jin L. *Clin Chim Acta* 2007;377(1-2):201-5.

33

POCT Improves Patient Outcome

- Evaluated POCT creatinine (POCTA vs POCT B)

MDRD 60 mL/min	POCT A vs Jaffe	POCT B vs Jaffe
+ Predictive Value	100%	67%
Efficiency	94%	90%
	POCT A vs Enz	POCT B vs Enz
+ Predictive Value	88%	60%
Efficiency	96%	88%

- POCT gave higher creatinine levels, called more patients abnormal.
- Physicians had to adjust their cutoff levels for management decisions to higher creatinine (lower GFR) when utilizing POCT compared to lab
- POCT led to faster results and moved patients through clinic, resulting in increased patient and physician satisfaction

Nichols JH, Bartholomew C, Bonzagi A, Garb J, Jin L. Clin Chem Acta 2007;377:201-5.

34

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POCT Information Management

- POCT creatinine leads to improved outcomes when integrated into the patient pathways of care in oncology setting
- But, POCT is a different technology
- Results are not equivalent to other laboratory methods without considering unique performance characteristics
- Another example: glucose meter limitations
  - Extremes of Hgb/Hct (<20 – 25% and >50 - 60%)
  - Maltose/xylose/galactose interference on some glucose dehydrogenase based methods
  - Affects patients receiving dialysis fluids containing Icodextrin
  - Erroneously low results if patient severely dehydrated, hypotensive, in shock or hyperglycemic-hyperosmolar state (with or without ketosis) [limitation of all meters]
  - Investigated by comparing capillary to venipuncture in ED and core lab Blank FSJ et al. J Emerg Nurs 2009;35(2):93-6.

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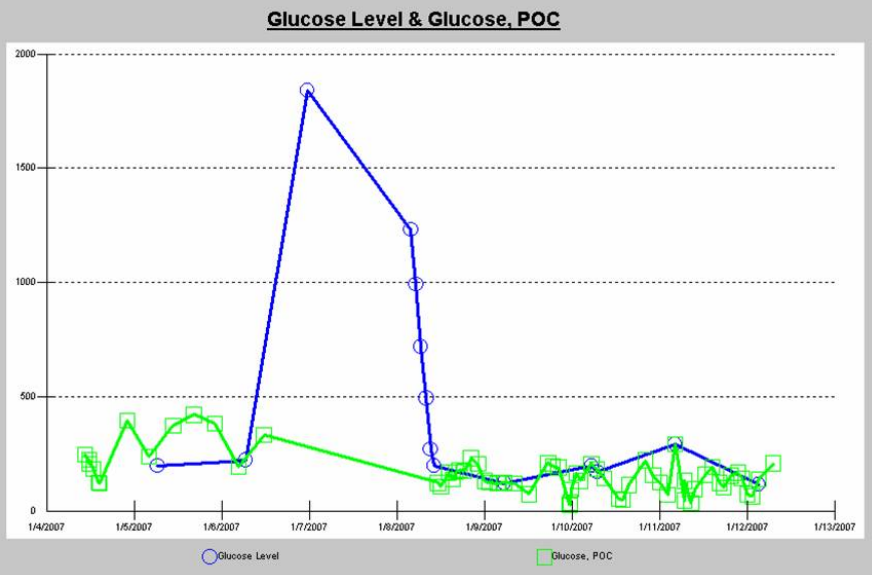
35



Blank FSJ, Miller M, Nichols J et al.; J Emerg Nursing 2009;35(2):93-6.

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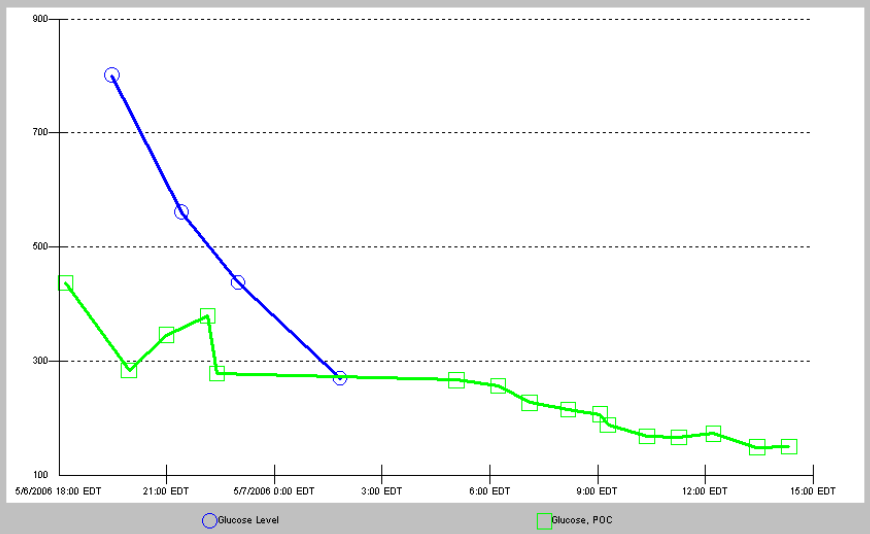
Glucose Level & Glucose, POC



Blank FSJ, Miller M, Nichols J et al.; J Emerg Nursing 2009;35(2):93-6.

37

POCT Information Management

- EMRs overlay results of the same name, so physicians can trend tests over time.
- POCT results cannot be freely interchangeable with other methodologies and electronic reporting must keep results separate.
- Need to call the test by a different name
- Separate physically in chart (lab results in lab tab and POCT results entered in nursing notes or use separate POCT tab for results)

38

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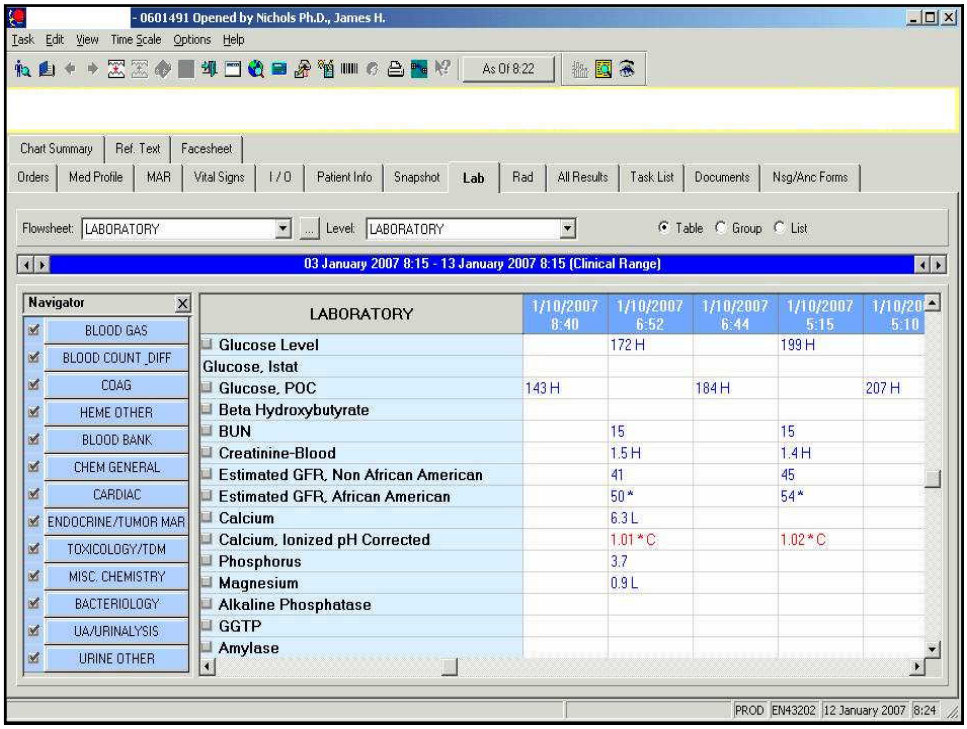

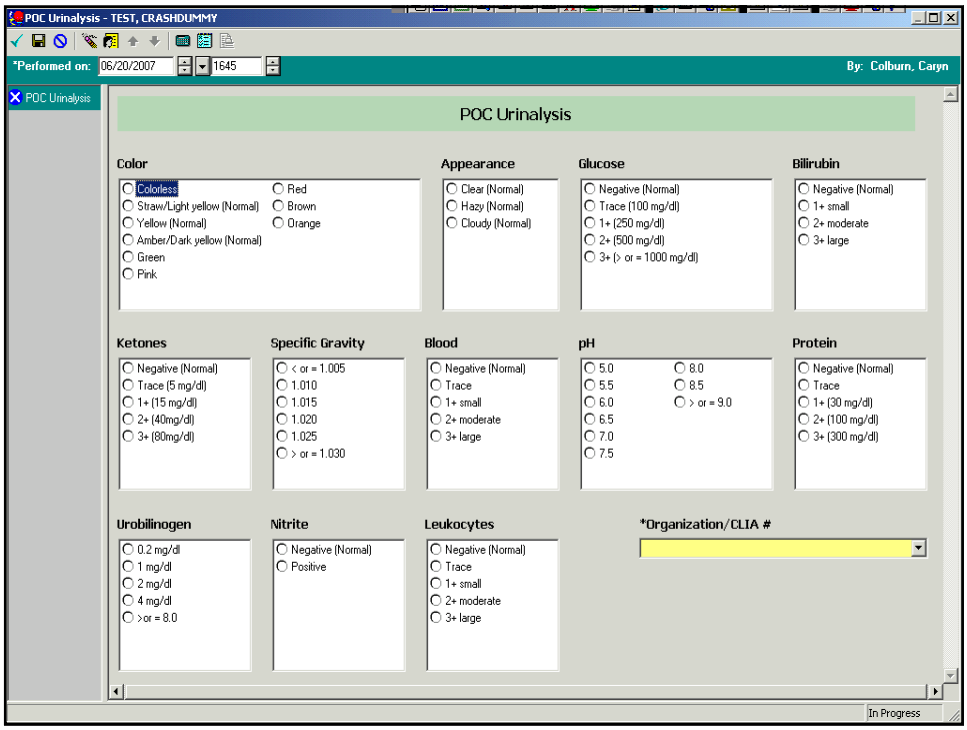

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Integrating POCT with Order Entry

- How do physicians know which test to order? POCT versus central lab?
- Educational pamphlet minimally effective
- More than a 10 fold difference in cost between a glucose by central lab, glucose meter, or BG POC
- Economic downturn forced us to reexamine clinical need for stat testing given cost differences
- Two initiatives to decrease inappropriate utilization
  - Change the name from i-Stat to POC cartridge
  - Prevent routine ordering of test
  - Pop-up window reminder
- Initiatives reduced POC cartridge usage by 50 - 60%

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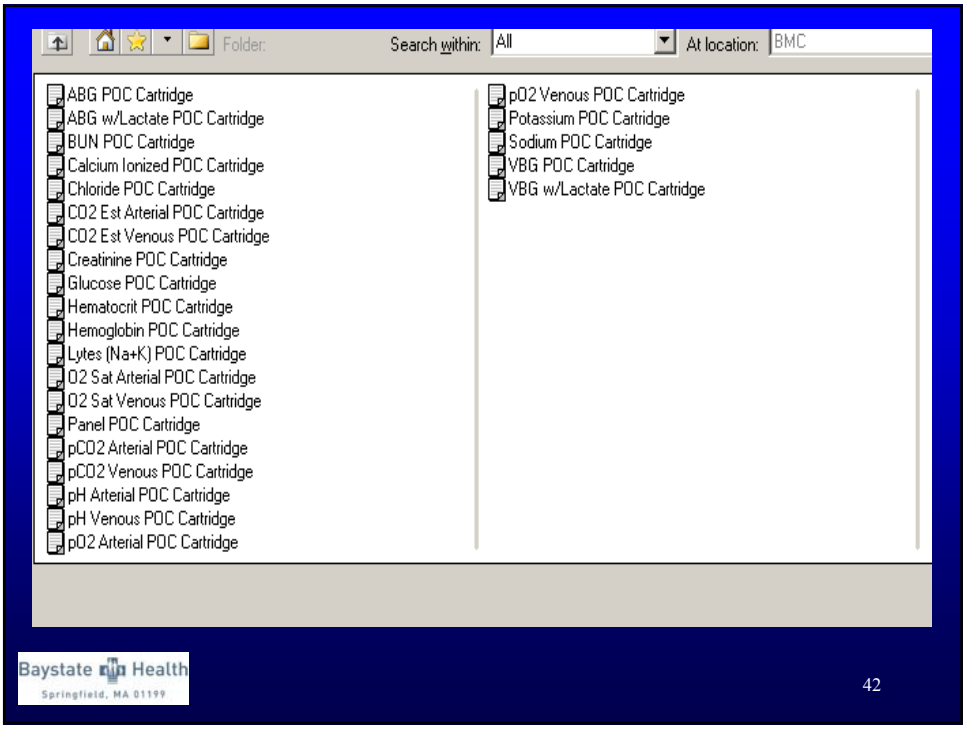
41



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42

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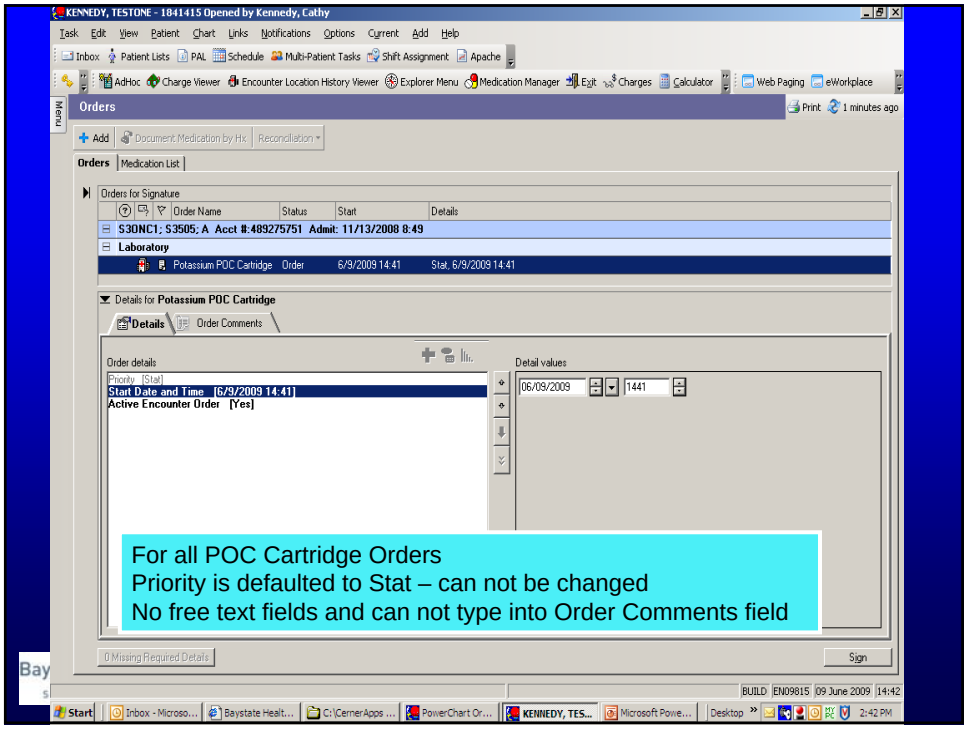

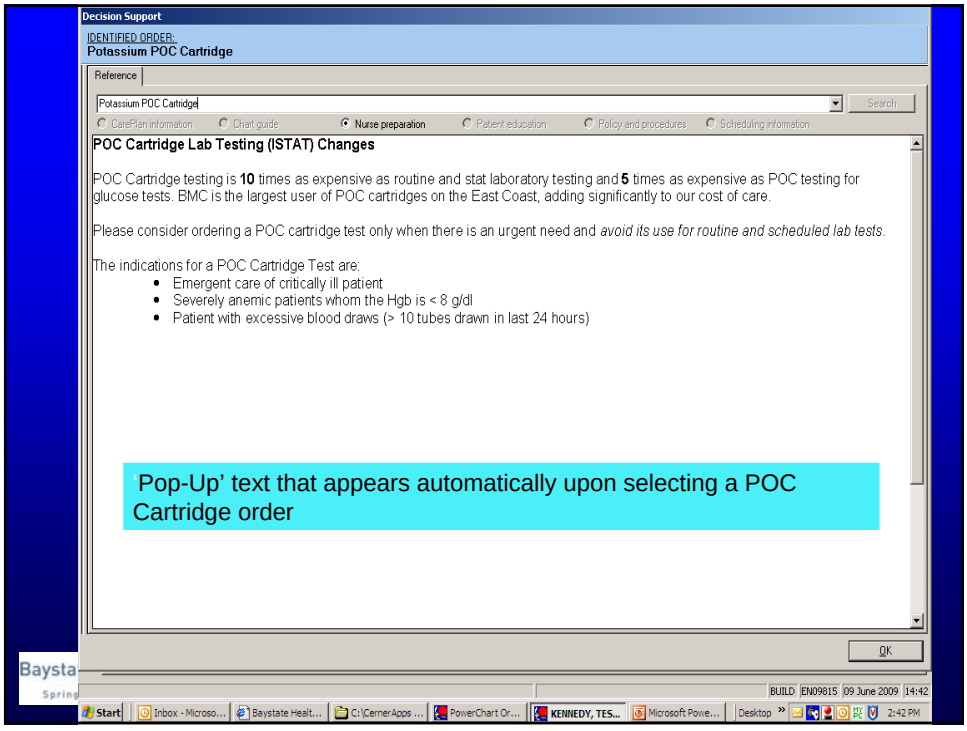

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Summary

- POCT is an increasingly popular means of delivering laboratory testing
- Faster isn't always equal to better outcomes unless POCT is integrated into pathways of care
- Sites adopting POCT should prove that the device achieves expected outcomes
- Reassess your current practice and investigate new POCT before and after implementation.
- POCT is a different methodology and ordering and resulting in an EMR is challenging

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45