Current & Future Applications of Point of Care Testing

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Point of Care Testing

• Definition
  • tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories (College of American Pathologists)
  • Classic example: bedside glucose testing in the hospital
Point of Care Testing

• What about laboratory instruments used at the point of care, e.g. benchtop blood gas analyzer in the respiratory intensive care unit?

• What about point of care devices used in the laboratory, e.g. B-type naturiestic peptide device in the core lab?

• Testing distinctions and boundaries are becoming more and more blurred
What is Going On?

Settings & Operators

- Non-traditional operators
  - "Non-professional setting"
- Traditional operators
  - "Professional setting"

Tests

- Waived
- Moderately complex
- Highly complex
The Drivers

• New testing opportunities
  • Home INR testing
  • Accident scene blood gas/electrolyte testing
  • Emergency department HIV testing
  • Underdeveloped countries

• New counseling opportunities
  • Clinic-based INR testing
  • STD clinic HIV testing
The Drivers

- Care process optimization
  - Rapid creatinine testing for cardiac catheterization lab
  - Arterial blood gas testing in the ICU
  - Physician office laboratories

- Patient care outcomes
  - Intensive insulin therapy in critical care patients
  - Intraoperative transfusion algorithms
The Drivers

- Patient care outcomes
  - Intensive insulin therapy in critical care patients
  - Intraoperative transfusion algorithms

- Disaster recovery
  - Internal & external – Hurricane Katrina
  - Emergency preparedness
  - Epidemics / outbreaks

- Testing platforms
  - Availability – BNP example
  - Match to test volumes – POL example
The Drivers

• Regulatory requirements
  • Ease of waived testing requirements, both CLIA and Joint Commission
  • Many POCT programs and physician office laboratories intentionally limit their menus to waived tests only

• Attractiveness and potential of waived testing market to industry
The Drivers

• Workforce issues
  • National laboratory technologist shortage
    • Projected need for 710,000 technologists by 2012
      • ~12,200 new technologists needed each year
      • 4,000 – 6,000 new graduates each year
  • Movement toward licensure in multiple states
### Educational Background of Testing Personnel

<table>
<thead>
<tr>
<th>Role</th>
<th>1998</th>
<th>2005</th>
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<tbody>
<tr>
<td>Clinical Laboratory Scientists (4 yr degree)</td>
<td>33%</td>
<td>24%</td>
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<tr>
<td>Bachelor of Arts / Bachelor of Science (4 yr degree)</td>
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<tr>
<td>Clinical Laboratory Technician (2 yr degree)</td>
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POCT: Common Use

- Glucose
- Blood gas analysis/electrolytes
- Activated clotting time for high dose heparin monitoring
- Urine dipsticks, including pregnancy
- Occult blood
- Hemoglobin
- Rapid strep
POCT: Available but Variable Use

- Cardiac markers
- Drug/toxicology
- INR
- Heparin
- Coagulation for hemostasis assessment (TEG)
- D dimer for thromboembolism
- Magnesium
- Lactate
- Transcutaneous bilirubin
- Lipids
- Hemoglobin A1c
- Microalbumin, creatinine
- HIV
- Influenza
- Helicobacter pylori
- Other bacteria
POCT: Come & Gone

- Basic metabolic panel
- ABO typing, crossmatch
POCT: Emerging

- Complete blood count
- White blood cell count
- Coagulation for transfusion algorithms
- Platelet function testing
  - Transfusion needs
  - Anti-platelet therapy
POCT: Future

• Microbiology
  • Outbreaks / epidemics
  • Methicillin resistant staph aureus

• Endocrine testing to guide surgical therapy
  • Parathyroid hormone
  • ACTH
  • Gastrin
  • Growth hormone

• Sepsis markers

• Stroke markers

• DNA testing
POCT Issues

• Evidence base for effectiveness is very mixed
  • NACB Laboratory Medicine Practice Guideline on Evidence-Based Practice for POCT
    • Systematic review and grading of available scientific evidence related to:
      - pH
      - Cardiac markers
      - Parathyroid testing
      - Bilirubin
      - Coagulation
      - Critical care
      - Reproduction
      - Drug testing
      - Infectious disease
      - Occult blood
      - Renal
      - Diabetes

• [http://www.aacc.org/AACC/members/nacb/LMPG/OnlineGuides/PublishedGuidelines/poct/default.htm](http://www.aacc.org/AACC/members/nacb/LMPG/OnlineGuides/PublishedGuidelines/poct/default.htm)
POCT Issues

• **Standardization / comparability**
  - With multiple ways of performing the same test, this is becoming a critical issue for larger systems
  - POCT, Physician Office Lab, Stat Lab, Hospital Lab, Reference Lab

• **Examples**
  - Episodic POC INR testing prior to an invasive procedure
  - Cardiac markers in the ED
POC INR: Ongoing Monitoring vs Episodic Testing

POC INR Evaluation Difference Plot

-2.0
-1.0
0.0
1.0
2.0
3.0
4.0
5.0
6.0
7.0

Lab INR

POC INR - Lab INR

POC2 Lot 1

POC 1

POC 2 Lot 2

Mayo data
# POC Cardiac Markers

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<td>0</td>
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<tr>
<td>TnT positive</td>
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<td>5</td>
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<tr>
<td>TnT positive</td>
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</tbody>
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*Mayo data*
POCT Issues

• Complexity of data management and oversight
  • Training & competency assessment for potentially thousands of individuals
  • Quality control documentation
  • Quality performance
  • Reporting
  • Billing
  • Process control
POCT Issues

• Complexity of data management and oversight
  • Multiple testing platforms
  • Vendor specific vs vendor neutral data management systems
    • Interfaces to laboratory and/or hospital information systems
  • Manual POCT methods
POCT Issues

- Importance of process to achieve effective use of POCT
  - Is faster always better?
Point-of-Care Testing
ED Length Of Stay

Study eligible
N = 2067
LOS = 209

- All tests from central lab
  N = 345 (17%)
  LOS = 206

- iSTAT performed in ED
  N = 1722 (83%)
  LOS = 209

- No central lab tests
  N = 91 (5%)
  LOS = 164

- Central lab tests also performed
  N = 1631 (95%)
  LOS = 212

POCT in a Lab Setting
Point-of-Care Kiosk in the ED

ED Cardiac Length of Stay

Discharged patients
- Before POCT: 367 minutes
- After POCT: 297 minutes

Admitted patients
- Before POCT: 388 minutes
- After POCT: 351 minutes

Minutes

Lewandrowski K. Mass General Hosp., Dark Report, 8/13/01.
POCT in the ED - Will we adopt it?

Yes ←-------- Adequate Technology

Process ←----------------- Clinical Benefit ←----------------- Outcome

Inefficient ←----------------- Existing process ←----------------- Efficient

Replacement ←----------------- Cost ←----------------- Supplemental

For ←----------------- Local factors ←----------------- Against

Jason Kendall, North Bristol NHS, 2003
POCT in the ED

• Faster does not always lead to better outcome
  • Lab tests are rarely the rate limiting factor in ED disposition

• Process analysis is the key understanding and improving patient throughput in the ED

• Test menu selection is a critical component of the potential application of POCT
  • Match available tests to disposition decisions
  • May only decrease length of stay for a small subset of patients
POCT in Radiology

- Need for creatinine measurement prior to administration of contrast
  - Referral patients may come without a recent measurement – POCT would be useful to decrease waiting time for result
  - Decision points: 1.5 mg/dL for diabetic patients, 2.0 mg/dL for non-diabetic patients
- Device accuracy & precision not good enough at these decision points
- Designed new process to provide rapid results from lab

Mayo experience, 2004
JHH CVDL Outcomes Trial

• Cardiac catheterization setting

• POCT improved wait times over core laboratory, but not significantly

• Significant changes only occurred after unit workflow reorganized to optimize use of POCT results
  - Decreased wait times 63 minutes for coag (n=9, p=0.014) and 47 minutes for renal (n=18, p=0.02)

POCT Issues

• Verification and monitoring of analytical performance
  • Quality control
  • Calibration verification
  • Analytical measurement range verification
  • Method comparability

• Complicated by multiple instruments and multiple cartridges

• WE JUST DON’T KNOW WHAT THE PROPER APPROACH SHOULD BE
Ultimate Question

• Will point of care testing eventually replace the clinical laboratory?

• My opinion: no

• Why: spectrum of testing is always changing
Spectrum of Patient Care Testing

- Tests often evolve through this spectrum
  - What’s esoteric today may be POCT tomorrow with advances in technology, new therapeutic options, and new care models
  - New esoteric testing will grow substantially with the maturation of genomics and proteomics