Point-of-Care Testing: Is Faster Really Better?

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Overview

• Define POCT
• Discuss quality concerns with POCT
• Identify evidence-based methods for optimizing quality of POCT

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.
POCT Potential

- Immediate results - no lab transportation
- Portable devices
- Small blood volume
- Wide menu of tests available
- Whole blood and other samples available
- Works within clinical patient flow while patient is still being examined by physician
- Improved patient outcome when POCT linked to treatment, moves patient through system faster, more cost effective despite POCT reagents costing more than core lab on a per test basis

The POCT Market

<table>
<thead>
<tr>
<th>Year</th>
<th>Market Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>US$ 4.9 Billion world-wide</td>
</tr>
<tr>
<td>2003</td>
<td>US$ 6.8 Billion world-wide</td>
</tr>
</tbody>
</table>

- 25% of IVD testing market
- Projected annual growth of 12%

- Hospital POCT
- Blood Glucose
- POL
- Home Testing

PoC Glucose


Projected POCT Market

<table>
<thead>
<tr>
<th>Year</th>
<th>Market Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>US$ 13.1 Billion world-wide</td>
</tr>
<tr>
<td>2015</td>
<td>US$ 20.2 Billion world-wide</td>
</tr>
</tbody>
</table>

- Decreased glucose growth (managed care, price discounts)
- Increase IA and molecular POC
- 5% annual growth, glucose <5%

- Central Lab (69%)
- POCT (31%)
- Central Lab growth in select areas of molecular, flow cytometry, AP keeps pace with POC growth

CLIA Laboratory Certificates
June 2010 (212,534 Labs)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance</td>
<td>19,296</td>
<td>9.1%</td>
</tr>
<tr>
<td>(International)</td>
<td>23</td>
<td>0.01%</td>
</tr>
<tr>
<td>Waiver</td>
<td>139,078</td>
<td>65.4%</td>
</tr>
<tr>
<td>PPMP</td>
<td>38,216</td>
<td>18.0%</td>
</tr>
<tr>
<td>Accreditation</td>
<td>15,944</td>
<td>7.5%</td>
</tr>
<tr>
<td>(International)</td>
<td>26</td>
<td>0.01%</td>
</tr>
</tbody>
</table>

Audience Poll

- Staff in a hematology/oncology clinic have stool guaiac cards for occult blood testing. Staff have been waiting some time for cytology results of blood in nipple discharge to triage and predict risk of breast cancer. Since occult blood cards are already available at the clinic, staff begin to use the cards to test nipple discharge. What are your thoughts on this application?
  A. Why not? the cards are available and result turnaround time would be faster.
  B. The test can be used, but would be an off-label, LDT.
  C. The clinician should follow-up positive guaiac with cytology
  D. The test should not be used, cytology is better.

POCT Issues

- Test “creep” is a real concern with POCT, when POCT intended for one application expands to other patients and clinical uses on the floor without validation
- Physician's consider a test is a test. If stool guaiac can test occult blood in stool, it must work on other sample types.
- Not true, stool guaiac cards specifically designed and validated only for stool. Gastric guaiac tests have separate developer pH optimized for use with gastric samples!
- Off-label use would require lab validation as an LDT and high-complexity CLIA license
Point-of-Care Testing

Quality Issues
- Complaints about SMBG devices represent the largest number filed with the FDA for any medical device (by 1993, over 3200 incidents, including 16 deaths).
- Nine patients at two nursing facilities in Southern California were diagnosed with hepatitis B infection transmitted in association with blood glucose monitoring. State of California Health and Human Services, Department of Health Services, Licensing and Certification Program. Recommendations on the prevention and control of HBV transmission in diabetic patients who require blood glucose testing. July 2000.

Audience Poll
- Pregnancy and urine dipstick testing are occurring in a shared space used by two clinical teams (pre-op and cardiac cath). Due to high staff turn-over, QC is missed about 1-2x/week, but patient testing occurs anyways. Staff who do perform QC, also fail to recognize unsuccessful results, but go on and test patients. What is the optimal solution?
  A. Allow the practice to continue as some QC is better than no QC
  B. Remove testing from the site altogether
  C. Retrain all of the staff on importance of QC
  D. Reassign QC to one team, with frequent follow-up

POCT is a Complex System
- Laboratory
  - One site
  - Limited instrumentation to perform bulk of testing
  - Limited staff, focused on same equipment daily
  - Staff trained in laboratory skills
- POCT
  - Dozens of sites, hundreds of devices and thousands of operators
  - Staff are clinically focused on patient not on equipment, don’t understand quality control
  - Staff do not have laboratory training background
  - Testing delegated to lower level staff (TAs, MAs)
POCT Standardization

- POCT has thousands of staff, must perform same technique, repeatedly without deviation
- Standardize equipment, procedure, process
  - One manufacturer, one policy
  - Assists float staff, consider infrequent operators
  - Standardized training to common checklist
- Shortcuts may be taken without realizing consequences

Case Discussion
Falsely Decreased Glucose Results

- Complaint from an ICU of sporadic falsely decreased glucose results
- Immediate repeat test on same meter, gave significantly higher “clinically sensible” values
- Inspection of unit found nurses taking procedural shortcuts to save time
- Bottles of test strips dumped on counter in spare utility room
- Some strips not making it into trash, falling back on counter and being “REUSED”

POCT

- POCT misnomer: Faster is Better!
- POCT has a number of considerations – reason considered less reliable than core lab tests
  - Staff competency
  - Regulatory compliance
  - Method limitations
  - Result documentation and connectivity
- Also consider change in metabolites from delays in transport to core lab – glucose, pO2
Integrating POCT

- When should POCT be considered?
- How to implement?
- Many hospitals have core laboratory model with centralized testing
- Management of acute patients requires more rapid diagnostics – ED, OR, ICU
- Delays in transportation or processing drive need for POCT
- Health systems with outpatient clinics have more complex TAT issues that may drive POCT and menus different from inpatient care.

POCT Improves Patient Outcome

- 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 (i-stat)
- 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


POCT Creatinine

<table>
<thead>
<tr>
<th>MDRD 60 mL/min</th>
<th>IRMA vs Jaffe</th>
<th>i-Stat vs Jaffe</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Predictive Value</td>
<td>100%</td>
<td>67%</td>
</tr>
<tr>
<td>Efficiency</td>
<td>94%</td>
<td>90%</td>
</tr>
<tr>
<td>IRMA vs Enz</td>
<td>i-Stat vs Enz</td>
<td></td>
</tr>
<tr>
<td>+ Predictive Value</td>
<td>78%</td>
<td>60%</td>
</tr>
<tr>
<td>Efficiency</td>
<td>90%</td>
<td>88%</td>
</tr>
</tbody>
</table>

- 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
POCT Improves Patient Outcome

- POCT creatinine improved patient care in our Heme/Onc clinic.
- Need for test, tied to technology, and management after test result (i.e., pharmacy utilized to estimate GFR and alter dose of medication)
- Test integrated into pathway of care
- Care is streamlined as testing can occur when needed and treatment can follow as soon as result is available

Lab vs POCT Dilemma

- POCT is a different technology than core laboratory testing
- Clinical criteria may need to be adjusted based on the technical performance of the method
- Clinicians should integrate POCT into care pathways, how test result is going to be utilized in patient management.

Audience Poll

- EMRs overlay results of same name, so physicians can plot results over time. How should POCT results best be displayed in an EMR?
  - Combined in the same field (i.e., all sodiums called sodium, no matter where performed).
  - Call each test method by different name (Blood gas glucose, glucose meter, core glucose, Dr. Smith's glucose)
  - Separate POC results away from lab by placing in the clinical notes section of record
  - Use different colors to display results of different methods (POC troponin blue, core lab troponin yellow)
Audience Poll

- How do physician’s know which test to order, POC versus central lab?
  A. Physicians should order whichever test is fastest
  B. Physicians should order one test, nursing will decide if more convenient to perform POCT or draw a sample for core lab.
  C. Labs should provide formal educational materials for physician ordering, like a pamphlet
  D. Physician order entry should utilize pop-up screens to guide physician ordering
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 to POC cartridge
  – Prevent routine ordering of test
  – Pop-up window reminder
• Initiatives reduced POC cartridge usage by 50 - 60%
The laboratory has been experiencing staffing problems in accessioning leading to TAT delay in results of coagulation testing for stroke patients in the ED. Stroke accreditation requires a 45 min TAT from order to result. POC PT/INR is offered to the ED as an option to meet requirements for stroke patients.

A. POCT PT/INR should be used on all stroke patients.
B. POCT PT/INR should be limited to stroke patients on coumadin
C. POCT PT/INR offers the ED ability to establish bleeding risk in all patients coming to ED.
D. POCT PT/INR should continue to go to the core lab and lab administration should work on filling staffing needs.
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

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)
- Take home point, the method should match the clinical need and workflow!
Audience Poll

- POC data management provides operator and QC lock-out features that ensure only trained operators perform testing and QC is analyzed and successful at defined time intervals. Data management also ties test results directly to the patient ID, however incorrect patient identification can send results to the wrong patient ID. Barcoding scanning of patient wristbands reduces the chance of manual patient ID errors, but doesn’t entirely eliminate ID errors – Why?
  
  A. Staff remove barcoded wristbands in the OR
  B. Staff fail to check wristband identifiers periodically
  C. Patients may be admitted with wristbands from previous admission or other hospitals/nursing homes
  D. Patients may be barcoded with another patient’s information

Falsely Increased Hgb Results

- Spurious increased Hgb results 18 – 23 g/dL (55 – 70% Hct) on ICU patients
- Meter, QC and reagents examined and fine, no single operator tied to trend
- Continue to experience spuriously high results, trend went on for several weeks
- One day, POC coordinator watching operator perform Hgb test in spare utility room. Operator took shortcut (procedure is to load cuvette from fresh drop of well mixed sample)
- Instead, operator was filling cuvette from drop of blood remaining from glucose test. Test strip was absorbing plasma portion of sample and artificially increasing Hgb/Hct in remaining drop!
- Remedial action to retrain entire unit staff!

Summary

- POCT is a rapidly evolving field due to escalating demands on health care for faster test results
- Faster is NOT always better!
- Many considerations in delivery of quality POCT. Need to link delivery of test to pathways of care to meet medical need.
- Don’t be shy to get involved. POCT is opportunity for the lab to work more closely with healthcare team (preanalytic, analytic and postanalytic efficiency).
Self-Assessment Questions

• What is an advantage of POCT?
  1. Expense
  2. Speed
  3. Lack of limitations
  4. Ease of training

• How do we integrate tests into patient care?
  1. Demand staff document results
  2. Purchase POCT equipment
  3. Recommend tests be performed in a core lab
  4. Match test method to clinical need

• What is a limitation of POCT?
  1. Small number of staff involved
  2. Multiple tests available
  3. Variety of locations where testing is performed
  4. Speed of testing