The Future Outlook for Laboratory Point-of-Care Testing

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POCT White Paper Available

www.orchardsoft.com/whitepapers
Audience Survey
Q & A Process
Objectives

1. Explain the current factors and healthcare changes that are shaping the laboratory POCT market.

2. Identify how POCT will change with the restructuring of the healthcare delivery system.

3. Outline the benefits and challenges laboratories face in the oversight and management of POCT.

4. Evaluate POCT connectivity needs and concerns, including the importance of including POCT in healthcare analytics.
Our Changing Healthcare Landscape
Healthcare Costs at Nearly 18% of GDP
Aging Population & Increase in Chronic Disease

Top 5% of Spenders Account for 50% of All Spending

![Bar Chart]

NIHCM Foundation analysis of data from the 2012 Medical Expenditure Panel Survey. This survey captures health spending for the U.S. civilian, non-institutionalized population and thus excludes spending for institutional care, such as nursing homes.
Healthcare Reform

- PPACA
  - PCMHs, ACOs
  - Bundled payment plans
- MU
- PAMA

- Healthcare touches all of us.
- Work together to make improvements.
- Where can the lab make positive contributions?
“Better, Smarter, Healthier”

Source: HHS.org: U.S. Department of Health & Human Services
Lab’s Evolution in Healthcare

- Expand your reach.
- Increase clinical effectiveness.
- Contribute to positive patient outcomes.
- Integrate and collaborate with other departments.
Benefits of POCT & Changing Healthcare Landscape: Driving the POCT Market
POCT Definition

- The College of American Pathologists (CAP) defines POCT as “testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient.”

- Often means testing is performed by non-laboratory personnel.
Factors Stimulating POCT Demand

1. Increasing older population; more chronic disease
2. Healthcare reform; patient-centered care
3. Improved care & potential long-term savings
4. Continued lab staff shortages
5. Improved benefits & technology advancements
6. Meets diversity of needs for variety of remote locations
Healthcare Reform

• Encouraging provision of better and more convenient access to healthcare for all patients, particularly those with chronic diseases

• Goal of improving patient satisfaction
POCT Supports PCMH in Efforts to:

- Improve access to care
- Improve quality of care
- Improve patient experiences
- Enhance disease understanding and awareness by the patient
Aligns with MU Goals

Convenience factor of POCT increases patient satisfaction.
Improved Care & Downstream Cost Savings

- Improve care (potential long-term savings)
  - Reduce post-op care time
  - Reduce ED time
  - Reduce hospital admissions
  - Reduce LOS
  - Optimize drug treatments
  - Decrease inappropriate use of drugs
Improved Benefits

• Lean process
  - Optimize efficiency and use of staff time
  - Less pre-analytical error
  - Fewer steps than processing in core lab
• Faster results = faster treatment
  - Move patients through the system faster
  - Handle more patients at a time
Advances in Technology

• Tests that needed a laboratory for testing can now be accurately tested at the POC

• Simple enough to be correctly performed by moderately trained staff

• Complex molecular diagnostic products are being developed directly for the POC market
Size Matters

• Less sample required
  – Pediatric or neonatal
  – ICU

• Device Portability
  – Remote locations
    ▪ underserved populations
    ▪ rural areas
    ▪ locations with limited infrastructure or personnel
The Face-to-Face Advantage

• Provider can examine the patient in conjunction with the results
  – eliminates the need to remember a case

• Allows for face-to-face instructions
  – can improve patient understanding of treatment plan
“There’s absolutely no substitute for having immediate results of a drug test result and looking a patient in the eye.”

-Gary M. Reisfield, MD, Dept. of Psychiatry, Univ. of Florida College of Medicine; AACC POCT Virtual Conference, April 2015
CLIA Waived Status

- Majority of POCT is CLIA-waived
- More POCT are able to qualify for CLIA-waived status
  - easy to use
  - less regulatory
Increase in # of CLIA-waived Tests

CLIA-waived tests

Thousands of tests systems

1992 2014
Steady Increase in CLIA CoW Labs

CLIA-enrolled Labs

>250,000

29%

71%

CoW Labs

Other CLIA Labs

CoW Labs

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About the POCT Market
Manufacturing companies are pushing the envelope to make POCT devices faster, easier, and more reliable.

The global POC diagnostics market is forecasted to grow at a CAGR of 9.3% from 2013 to 2018 – to reach $27.5 billion by 2018.
Largest Market Segment

GLUCOSE
- Rising incidence of diabetes
- Increase in home-based POC usage

- International Diabetes Federation

![Millions of patients graph showing an increase from 382 million in 2013 to 592 million in 2035.]

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Fastest-growing Market Segment

CARDIAC

• Abbott i-STAT System
  – i-STAT’s volumes have tripled

• Alere Triage System
  – 70% increase in volume for cardiac tests
List of Challenges & Concerns

- Analytical quality (reliability of test results)
- Management & Oversight
- Testing performed by non-lab trained personnel
- Regulatory requirements
- POCT connectivity
Analytical Quality Concerns

• Risk of errors often raises concern over the reliability of test results
• Laboratory offers a controlled testing environment
  – testing conditions for POCT can vary tremendously
Analytical Quality: Variability

- Greater variability in results compared to central laboratory testing
- May not be possible to compare variant methodologies
- Differences in specimen types (e.g., serum, plasma, or whole blood) can also affect comparative results (new CLSI)
- May not be FDA approved for all uses that a similar test in the central laboratory can be used for
Where Do Errors Occur?

Core Lab Errors

Pre-analytical
Post-analytical

POCT Errors

Analytical
Management/Oversight

- Testing may include dozens of sites, hundreds of POCT devices/kits, and thousands of operators that have to be managed in order to assure quality.
POC Management Teams

1. Determine the test menu.
2. Select methodologies.
3. Establish policies and procedures.
4. Confirm certification management (proper training).
5. Oversee regulatory compliance.
7. Provide advisory assistance to the end users.
Who’s Responsible?

Regulatory standards hold the laboratory director responsible for managing and supervising POCT quality.
Figure 1 An example of the point-of-care testing organizational chart at a large health care network.

Testing Performed by Non-laboratory Personnel

• Clinical personnel with minimal laboratory knowledge (Nurses or MAs)
• Often unfamiliar with routine laboratory procedures
  – importance of proper patient preparation, sample collection, calibration, instrument maintenance, and quality control.
• Focused on direct patient care
More Concerns

• Simplicity of waived testing can be deceptive
  – many ways that staff can unintentionally produce an incorrect result
  – interpretation is often subjective and may be visually and/or lighting dependent

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Regulatory Responsibilities

Laboratory has knowledge, skill set to oversee…
• > 55 standards for POCT
• Another 75 in common checklist
• > 300 in lab general checklist
• Jan 2015…added 10 criteria specifically for waived testing
  – competency testing for staff performing testing **at all levels of complexity**
  – proficiency testing for waived tests

*COLA Laboratory Accreditation Manual, January 2015. www.cola.org*
Top 3 CLIA-waived Deficiencies

- Not performing QC as required by the manufacturer
- Not having a current package insert
- Not complying with storage expiration dates
Competency Assessments vs. Training

• Initial training – before POC device operation
  – CA at specific intervals
  – Specific requirements vary between agencies and between waived and non-waived testing.

• For waived testing, CAP and CRI require annual competency testing for all operators
  – CLIA only requires annual competency assessments for personnel performing non-waived testing

• Specific Requirements for how to perform CA
“Off-label” Testing

Use of a test outside of the FDA’s approved, intended parameters, and outside of what is indicated by the manufacturer, is considered “off-label” testing, and immediately becomes subject to non-waived CLIA guidelines.
Importance of POCT Connectivity
POCT Connectivity: Crucial Piece of the Puzzle

• True value of POCT results… integration!

• Having results electronically available in the EHR increases the value of POCT.
POCT Results in the EHR…

• Quicker diagnosis and treatment
  – Results accessible to all members of healthcare team
  – Supports timely care decisions

• Automated billing

VALUE
Increasing Importance of Medical Analytics

• Inclusion of POC results in data analytics
Progression of POCT Connectivity

- Manual paper records
- POC device with direct computer connection
- POC device connected via network connection
- Manual entry in EHR
- POC device with middleware solution
- Wireless connectivity between POC device & EHR/LIS
About Connectivity Solutions

- Preferred connectivity solution = middleware that allows multiple devices to interface
- Can be dependent on the capabilities of the POC devices
Software to Handle Regulatory Challenges

• Advanced POCT software solutions can track certification management
Future Outlook for POCT
POCT Progression

POCT Future

- ACTH
- DNA testing
- Endocrine testing
- Epidemics
- Gastrin
- Growth hormone
- Microbiology
- MRSA
- PTH
- Sepsis
- Stroke markers
POCT in Cancer

• Early detection of cancer may be possible through capture and analysis of CTCs.
  – Microfluidic device capable of detecting CTCs
  – Broad implications for advancing cancer research
Antibiotic stewardship

- POCT to identify a bacterium and its susceptibility patterns could help reduce the use of inappropriate antibiotics and drug-resistant super-bugs
- MALDI-TOF mass spectrometry
  - in a few hours can provide results that in the past would have taken up to 36 hours
Molecular POCT

Traditional microbiology = extended TAT

• Hospitals
  – rapid PCR testing to test for MRSA/C. diff to reduce HAI

• Clinics
  – monitor viral load for HIV/HCV to modify treatments
New Patient-centered Apps

Wearable biosensors

Lab tests on a chip
New Healthcare Paradigm

With the development of smaller devices and wireless communication, the way in which providers care for patients is changing dramatically and patients are beginning to take a bigger role in their own healthcare.
The Laboratory’s Responsibility in POCT
When & Where POCT Fits?

- When having the result immediately is imperative to treatment
  - thereby reduces downstream costs
- When patient benefits from real-time counseling based on immediate results
Right POCT in the Right Situations Can Improve:

- Consistency
- Accuracy
- Provider satisfaction
- Patient satisfaction
- Patient engagement
- And ultimately patient outcomes.
Lab Professionals…

• Understand the intricacies of testing and the importance of proper laboratory processes
• Have an obligation to be involved in the oversight and growth of POCT
• Can influence decisions that will encourage appropriate POCT usage where it is most beneficial to improve patient care
Must Understand & Accept that…

"Sometimes, it's good to get a different perspective."
Integration of POCT offers another opportunity for laboratorians to be an integral part of the future of diagnostics.
“The purpose of life is to contribute in some way to making things better.”

- Robert F Kennedy
Thank You!