The AACC CPOCT Division Presents

Promoting a Culture of Quality and Consistency in Critical and Point-of-Care Testing
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Promoting a Culture of Quality and Consistency in Critical and Point-of-Care Testing

24th International Symposium October 4-6, 2012
Hilton Prague Hotel Prague, The Czech Republic

Collaborating Societies

AACC Critical and Point-of-Care Testing Division
Czech Society of Clinical Biochemistry (CSKB)
European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)
Under the auspices of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)
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Nova Biomedical
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Session 1:

Moderator: Martha Lyon, PhD

Why are there differences in reported benefits and outcomes with tight glycemic protocols in critical care patients? A debate.
Session 2:

Moderator: Robbert Slingerland, PhD

Sources and Prevention of Errors in Point-of-Care Testing
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Vendor Presentations

Moderator: Anne Skurup
HemoCue
Abbott Diabetes Care
Nova Biomedical
Session 3:

Moderator: Ian Watson, PhD

Point-of-Care Testing Beyond the Hospital
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Session 4:

Moderator: Linda Sandhaus, MD
Developing Effective Strategies to Achieve Quality POCT Results
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Vendor Presentations

Moderator: Brad Karon, MD, PhD
Siemens Healthcare Diagnostics
Alere
Radiometer

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Session 5:
Moderator: Larry Crolla, PhD
New Technologies in Point-of-Care Testing
Dr. Jeffrey A. DuBois, Ph.D. FACB  
Past Chair AACC POCT Division  
Chair of the 24th International Symposium
Our World

“\textit{The ability to convert visions to things is the \textbf{secret of success!}}”

\textit{Henry Ward Beecher}
Overview

- Point of Care Industry
- Where we are today
- Where we are going
- Summary and concluding remarks
CPOCT - Myth or Reality?

Myth

REALITY

Open Connectivity - Conceptual Diagram

Vendor Support Team

Poct IS Server

"Patient Test Results can be sent with or without an accession number. Non-accessioned results require LIS/HIS interface capable of creating an order and resulting the test to the order."
IVD, CPOCT, MDx Markets

IVD Global Market 2011 = 44 BN
• US = 47%
• Europe = 31%
  Germany #1
  France  #2
• POCT Global Market = ~14 BN
• Molecular Dx Market = ~ 5 BN*

* fastest growing segment %CGR
IVD Market Size Today 44 billion
Market Size Drivers

**RESTRAINTS**
- Lack of budget and skilled labor
- Stringent Regulatory framework to stifle the growth of the market.

**DRIVERS**
- Rising incidence of chronic and infectious diseases
- Rapidly ageing population
- Rise in Point of Care Testing
## Environmental Differences

<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>Outpatient</th>
<th>Alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Menu</strong></td>
<td>Broad range</td>
<td>Restricted</td>
<td>Several</td>
</tr>
<tr>
<td><strong>Performed By</strong></td>
<td>Lab staff, RN, MD</td>
<td>RN, MD, staff</td>
<td>Tech., Patient</td>
</tr>
<tr>
<td><strong>Information Management</strong></td>
<td>Many CIS/HIS systems</td>
<td>Uneven access to CIS/HIS/LIS</td>
<td>Generally, no CIS/HIS access</td>
</tr>
<tr>
<td><strong>Regulation</strong></td>
<td>CLIA</td>
<td>Hospital Lab</td>
<td>Primarily unregulated</td>
</tr>
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Novel POCT Issues

- Many axes of scalability
  - Geographic
  - Device complexity
  - Available communication infrastructure
  - Cost
- ‘Razor Blade’ economic model (single use or throw-away device)
- Regulatory & Compliance issues
- Accessibility and Warehousing of Data
Where Are We Today

• POCT provides patients & providers with immediate benefits
• Costs are less controversial:
  Paradox: cost per test (volume vs convenience) or total cost benefit
  Very few studies to show real cost benefit of POCT
• Dramatic clinical benefits
  Portland protocol & Greet van den Berghe
  coagulation
  ABG’s for critical care (has become the standard of care)
• New Opportunities:
  Data integration with monitors & pharmacy to improve patient safety
  Expand scope of connectivity beyond lab to patient care services
  Data mining
  Better Outcomes for patient, providers, and society
Perspectives

Other Possibilities

• Patient Centered
• Care Provider Centered
• IT Centered

Instrument, Method, or PATIENT?
Reducing Medical Errors

Under the best of circumstances...

“Things” happen!
"We" need "Quality" Results and Quality Practices!

- Hospital errors cause **100,000 deaths** yearly.
- These are **preventable** deaths.
- What's wrong, and can it be made right?

- U.S. surgeons operate on the wrong person or body part **as often as 40 times a week**.

- The number of patients who die each year from hospital errors is equal to **4 jumbo jets crashing each week**.

- One study of Medicare patients found that **1 in 7 died or were harmed by their hospital care**.
Meeting the requirements or needs of the testing site’s customers -- doctors and patients -- and satisfying their expectations
Criteria for Quality POCT in 2012:

- Correct test ordered
- Correct patient
- Correct time for collection
- Correct specimen and processing
- Correct (accurate) test result
- Correct patient record
- Correct clinical interpretation (leading to the)
- Correct and timely clinical response

“Wrongs” instead of “Corrects” jeopardize quality and patients’ safety
Characteristics of Quality POCT Results

- Useful
- Accurate
- Precise
- Reliable
- Timely
Quality in POCT Requires:

Planning
Planning
Planning
&

Effective Communication