Rapid Molecular Technology
Improving Patient Outcomes

A Better Way

Ed Hochwalt, MT, MBA
Director of Corporate Accounts

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Objectives

• Provide a brief overview of molecular PCR technology
• Learn about rapid applications available today
• Provide insight as to how rapid applications have impacted patient care based on current literature
• Provide an understanding of the impact on hospital costs related to rapid results.
• Discuss ways in which antibiotic stewardship can be influenced by rapid test results.

MDx is Fastest Growing Segment of IVD Market

Significant growth is expected in oncology and portions of infectious disease in the critical care segment due to high value tests*

<table>
<thead>
<tr>
<th>Year</th>
<th>USD B</th>
<th>Source: Astute analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>$3.9B</td>
<td>17% CAGR 2008-2013</td>
</tr>
<tr>
<td>2013</td>
<td>$8.7B</td>
<td></td>
</tr>
</tbody>
</table>

*Includes oncology, CNS and infectious disease panels, and other emerging tests.
*Tests that provide critical information to help physicians make clinically relevant decisions, as a result are marketed at a premium price.
When It Comes To Multiplexing: Not All NAATs Are Created Equal

<table>
<thead>
<tr>
<th>Amplification Technology</th>
<th>Used By</th>
<th>Isothermal?</th>
<th>Level of Multiplexing (commercial product)</th>
<th>Quantitative CE IVD?</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCR</td>
<td>Cepheid, Roche, BD &amp; most of Dx and research world</td>
<td>No</td>
<td>20-80 targets</td>
<td>Dozens</td>
</tr>
<tr>
<td>HDA</td>
<td>BioHelix</td>
<td>Yes</td>
<td>One target</td>
<td>0</td>
</tr>
<tr>
<td>SDA</td>
<td>BD</td>
<td>Yes</td>
<td>2-3 targets</td>
<td>0</td>
</tr>
<tr>
<td>NASBA</td>
<td>BioMerieux</td>
<td>Yes</td>
<td>One target (HIV viral load)</td>
<td>1</td>
</tr>
<tr>
<td>TMA</td>
<td>Gen-Probe</td>
<td>Yes</td>
<td>Three targets (HPV is an exception)</td>
<td>0</td>
</tr>
<tr>
<td>Loop Mediated Isothermal Amplification</td>
<td>Eiken,宏基因, Quidel, Alere</td>
<td>Yes</td>
<td>One target</td>
<td>0</td>
</tr>
</tbody>
</table>

Polymerase Chain Reaction (PCR)

Guidelines for Diagnosis, Treatment, and Prevention of Clostridium difficile Infections

The sensitivity of GDH antigen detection has led to its use as a screening test as part of CDI testing algorithms, although it should be noted that as many as 10% of patients with toxigenic organisms can be missed by this method.

Evidence suggests that NAATs for toxigenic C. difficile are good stand-alone tests for toxigenic C. difficile. There are several Food and Drug Administration (FDA)-approved NAATs, including PCR assays and isothermal amplification tests. PCR is an excellent confirmatory test, but data for isothermal amplification testing are not yet sufficient to recommend it.
**PCR Cycles**

- Target
  - Cycle 1: 4 copies
  - Cycle 2: 8 copies
  - Cycle 3: 16 copies
- Heating and cooling cycle is repeated several times and it is called thermal cycling.

**How to Detect Amplified Target?**

- Real-time PCR
- Continuous amplification and detection in one tube
- Use a target specific probe labelled with a fluorescent dye
- Instrument collects fluorescent data and provides result

**MRSA/SA target design**

**SCCmec cassette**

- This is a MRSA
- The strain is now MSSA
- It is an "empty cassette"
- Xpert Results: Spa+, orfX+, mecA-

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Molecular Testing Process

3 major steps to the process
- DNA Extraction - Isolating the DNA from cells
- DNA Amplification - Manufacturing multiple copies of the DNA of interest - Real-time PCR
- DNA Detection - A mechanism of detecting the DNA of interest

• Separate rooms necessary
  - Isolation, amplification and detection
• Time
• Contamination
• Non-Automated
• End point analysis (Gels)

Separate rooms necessary – Isolation, amplification and detection

The Molecular Lab in a Cartridge

• All Testing Done Within Cartridge
  - Sample Prep / Extraction
  - Amplification
  - Detection

• Any PCR Protocol
  - DNA extraction → Bacterial menu
  - RNA reverse transcription → Virus menu
  - Nested PCR → Ultra-sensitivity
  - Multiplexing → ‘All-in-one’ tests incl. Controls

Uniquely Scalable: Low to High Throughputs

‘Molecular Server Cabinet’ architecture enables system to grow with testing needs

Multiplexing

Honeycomb: Strategic Extension into High-Level Multiplexing

- Over 1,000 wells for Real-Time PCR of 100s of Targets
- Both qualitative and multiplexed quantitative mRNA expression
- Identical Cartridge – proven sample prep
BD Max – next generation for BD

Illumigene - LAMP

Illumigene - LAMP technology

BioFire Diagnostics : System Offering

Others

GenMark

Liat and Cobas - Roche

Hologic Panther

Focus
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**Potential Patient Impact**

- Delayed or Wrong Diagnosis
- Misuse or Overuse of Antibiotics
- Cross-infection
- Increased Length of Stay

**Potential Economic Impact**

- Unnecessary Antibiotics Expense
- Isolation Expenses
- Blocked Bed Expenses

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**Economic and Medical Cost of Delayed Diagnosis**

<table>
<thead>
<tr>
<th>Time to Test Results</th>
<th>Costs Money and Lives</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Hours</td>
<td></td>
</tr>
<tr>
<td>24 Hours</td>
<td></td>
</tr>
<tr>
<td>48 Hours</td>
<td></td>
</tr>
</tbody>
</table>

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**Rapid Detection of Methicillin-Resistant Staphylococcus aureus using the Cepheid GeneXpert® Dx System and the Xpert™ MRSA Test**

**Article highlights**

1. **TAT**
   - Culture – 35.8 Hrs
   - PCR – 6.9 Hrs
2. Culture is not as sensitive as PCR
3. Culture resulted in 7,584 fewer Potential Contact Precaution Hours (PCPH) which equates to an additional 44 potential HAIs
4. Avoided 11 infections*

\[11 \times \$23,000 = \$253,000 \text{ in cost avoidance over a 4 month period}\]

*Davis, et al
In the U.S., sepsis kills nearly 600 patients each day!

The Need for Laboratory Speed

- Rapid Antibiotic Therapy Saves Lives
  - Targeted antibiotic therapy increases survival by ~25-45%
  - For every hour appropriate antibiotic is delivered sooner, survival increases by ~7-10%.

1. Kumar et al., 2006. Crit. Care Med. (34)

Is This Too Late?

- Loss of homeostasis
- Organ dysfunction
- Death

Traditional vs. Rapid Identification

Active role of Microbiology: improved integration with patient care
Rapid Detection of MRSA & SA – Blood Culture
On-Demand Results Reduces LOS and Cost

**The Ohio State University College of Medicine**

- Implementation of the Xpert® MRSA/SA BC test coupled with an infectious disease pharmacist’s consultation resulted in:
  - Mean time of switch from vanco to cefazolin/nafcillin (optimal antibiotic therapy) occurred 1.7 days sooner (for MSSA bacteremic patients)
  - Mean length of stay was 6.2 days shorter (for both MRSA and MSSA bacteremic patients)
  - Mean hospital costs were $21,387 less (for both MRSA and MSSA bacteremic patients)

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### Implementation of Polymerase Chain Reaction to Rule Out *Clostridium difficile* Infection Is Associated With Reduced Empiric Antibiotic Duration of Therapy

**William J. Peppard, PharmD, BCPS,* and Nathan A. Ledeboer, PhD, D (ABMM)**

#### Table 2. Primary and secondary clinical and economic outcomes

<table>
<thead>
<tr>
<th></th>
<th>EA (n = 79)</th>
<th>PCR (n = 77)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of antibiotic therapy in days</td>
<td>2.81 (1.84-3.81)</td>
<td>1.24 (0.84-1.30)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diagnostic test performed per patient, mean (CI)</td>
<td>2.7 (2.64-2.81)</td>
<td>1.04 (0.84-1.24)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Duration of antibiotic duration in days, mean (CI)</td>
<td>1.46 (1.01-2.32)</td>
<td>0.62 (0.38-1.32)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total treatment cost per patient† (CI)</td>
<td>61.57 (26.95-110.73)</td>
<td>61.57 (26.95-110.73)</td>
<td>0.826</td>
</tr>
<tr>
<td>Diagnostic test cost‡ (CI)</td>
<td>11.16 (7.08-16.04)</td>
<td>11.16 (7.08-16.04)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Antibiotic therapy cost (CI)</td>
<td>36.91 (22.05-51.29)</td>
<td>26.64 (13.08-36.26)</td>
<td>0.26</td>
</tr>
<tr>
<td>Contract isolation cost (CI)</td>
<td>19.39 (8.05-31.73)</td>
<td>8.19 (3.45-17.42)</td>
<td>0.311</td>
</tr>
</tbody>
</table>

Notes: † = N = 79; ‡ = N = 77; CI = confidence interval; EA = empirical antibiotic; PCR = polymerase chain reaction.

The rapid reporting of PCR test results was associated with a reduced empiric CDI antibiotic duration of therapy. When combined with fewer diagnostic laboratory tests performed per patient, shorter length of empiric antibiotic therapy, and briefer duration of contact isolation, the higher acquisition cost of the PCR test was offset and resulted in cost neutrality. These findings provide additional data to support the routine use of the PCR test.

### What is quality in health care.....NOT?

Doing the same thing over and over again and expecting different results

– Albert Einstein, definition of insanity
The U.S. Healthcare Environment

Trends in Healthcare Landscape

Focus is on value, performance & prevention

Moving away from fee-for-service to fee-for-value
Payments tied to quality and cost savings
Increased accountability and transparency

Medicare Incentive Programs

Maximum Potential Impact of CMS Incentive Programs on DRG Payments

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>FY 2015</th>
<th>FY 2016</th>
<th>FY 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Inpatient Quality Reporting Program</td>
<td>-2.0%</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>(Reduction to annual update)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital Value-Based Purchasing Program</td>
<td>+/-1.0%</td>
<td>+/-1.25%</td>
<td>+/-1.50%</td>
<td>+/-1.75%</td>
<td>+/-2.0%</td>
</tr>
<tr>
<td>(Incentive/Penalty)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reducing Hospital Readmission Program</td>
<td>-1.0%</td>
<td>-2.0%</td>
<td>-3.0%</td>
<td>-3.0%</td>
<td>-3.0%</td>
</tr>
<tr>
<td>(Penalty)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preventable Hospital-Acquired Conditions</td>
<td>-1.0%</td>
<td>-1.0%</td>
<td>-1.0%</td>
<td>-1.0%</td>
<td></td>
</tr>
<tr>
<td>Provision (Penalty)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

A Single Episode May Contribute to Multiple Penalties

*Each year Medicare sets the hospital payment update for IQR through a formal rulemaking process for participating acute care hospitals.

HAI Measures as Part of Quality Reporting

CMS Hospital Inpatient Quality Reporting (IQR) Program

Infection Type          | Reporting Begins | Payment Determinations |
-------------------------|------------------|------------------------|
Central Line Blood Stream Infection | 01/01/2011 | FY 2014 |
Catheter-Associated Urinary Tract Infection | 01/01/2012 | FY 2014 |
Surgical Site Infection | 01/01/2012 | FY 2014 |
MRSA Bacteremia Infection | 01/01/2013 | FY 2015 |
C dif from C difficile infection | 01/01/2013 | FY 2015 |
Data Captured and Made Publicly Available

Patients can make more informed decisions as to where to seek care based on hospital performance compared to others in the same area.

Hospitals will be able to assess how they perform relative to others competing for the same patient population.

Hospitals will be able to assess the impact of incentives or penalties on their overall financial health.

Budgetary Headaches Move Toward Value-Based Medicine

From Silo

To Holistic Approach

• Moving away from the lowest cost per test to Total Cost of Care
• Focus on medical outcome, quality and prevention

Two Areas to Measure When Considering PCR

Understand current patient pathway and medical interventions around lab results.

Quantify impact on health system resources.

Quantify the total cost of diagnosis.

Ripple Effect Beyond the Lab

Physician decisions

Lab test result

Pharmacy costs

Infection Control actions & costs

Housekeeping actions & costs

Bed management and administrative costs
1 negative Xpert MRSA PCR test = 3 negative cultures

Gets MRSA-negative patients out of costly isolation rooms

Table 3. First PCR Test Performance Compared to Three Sequential CA in Intervention Arm Population.

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Sensitivity % (95% CI)</th>
<th>Specificity % (95% CI)</th>
<th>Positive Predictive Value % (95% CI)</th>
<th>Negative Predictive Value % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two sequential CA</td>
<td>93.9 (86.4 to 97.7)</td>
<td>92.0 (85.9 to 95.6)</td>
<td>96.1 (79.0 to 93.1)</td>
<td>96.6 (91.8 to 99.1)</td>
</tr>
<tr>
<td>Three sequential CA</td>
<td>92.0 (85.9 to 95.6)</td>
<td>92.0 (85.9 to 95.6)</td>
<td>96.1 (79.0 to 93.1)</td>
<td>96.6 (91.8 to 99.1)</td>
</tr>
<tr>
<td>One Xpert MRSA</td>
<td>96.6 (91.8 to 99.1)</td>
<td>96.6 (91.8 to 99.1)</td>
<td>96.6 (91.8 to 99.1)</td>
<td>96.6 (91.8 to 99.1)</td>
</tr>
</tbody>
</table>

Estimated Effect on Unnecessary Contact Precaution
Days Avoided and Costs Saved

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Passive cultures</th>
<th>Active surveillance cultures</th>
<th>PCR screening (1 Xpert MRSA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinuation rates of contact precautions</td>
<td>6.6%</td>
<td>26.2%</td>
<td>63.8%</td>
</tr>
<tr>
<td>Fewer contact precaution days</td>
<td>104</td>
<td>418</td>
<td>1841</td>
</tr>
<tr>
<td>Cost savings</td>
<td>$86,950</td>
<td>$349,472</td>
<td>$1,539,180</td>
</tr>
</tbody>
</table>

**Group B Strep (GBS) Monetizing**

Undetermined pre-natal care Antepartum screening in Labor/Delivery

All suspect patients admitted enter in facility without prior GBS result. Currently THH is not able to timely screen these patients. Protocols are to hang “penicillin” IV on both mother and baby until cleared by Physician. Early detection would avoid excessive cost and additional time on the floor increasing LOS by 1-2 days.

Normal Labor/ Delivery 24-36 hour stay

<table>
<thead>
<tr>
<th>Cost per patient/month</th>
<th>$816.00/month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic cost</td>
<td>$97,320 savings/year</td>
</tr>
</tbody>
</table>

Savings per Year estimated at $97,920

**Rapid Molecular Testing for TB to Guide Respiratory Isolation in the U.S.: A Cost-Benefit Analysis**

Results: Among a hypothetical cohort of 234 individuals undergoing evaluation for presumed active TB annually, 0.4% had culture-positive TB. Compared to smear microscopy, Xpert reduced isolation bed utilization from an average of 2.7 to 1.4 days per patient, leading to a 44% reduction in total annual isolation bed usage from 632 to 328 bed-days. Xpert saved an average of $2,276 (95% uncertainty range: $1,592–$4,750) per admission, or $331,750 per year, compared to smear microscopy.

Conclusions: Molecular testing for TB could provide substantial savings to hospitals in high-income countries by reducing respiratory isolation usage and overall length of stay.
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Key Prevention Strategies

- Prevent infection
- Diagnose and treat infection effectively
- Use antimicrobials wisely
- Prevent transmission

Clinicians hold the solution!

CDC Antimicrobial Resistance Recommendations

- Xpert C diff/EPI
- Xpert Carba-R (in development)
- Xpert CT/NG
- Xpert VAN-A
- Xpert MRSA, SSTI and Blood Culture, Pre-surgical
- Xpert MTB/RIF
- Xpert GBS

Campaign to Prevent Antimicrobial Resistance in Healthcare Settings

CDC

PUBLIC HEALTH THREAT

- Cost of infection per year: hospitalizations or affecting 100,000,000,000 USD.

RESISTANCE OF CONCERN
- Methicillin-resistant Staphylococcus aureus (MRSA)
- Vancomycin-resistant enterococci (VRE)
- Carbapenem-resistant enterobacteriaceae (CRE)
- Multidrug-resistant tuberculosis (MDR-TB)
- Carbapenem-resistant Acinetobacter baumannii (CR-AB)
- Carbapenem-resistant Pseudomonas aeruginosa (CRPA)
- Carbapenem-resistant Enterobacteriaceae (CRE)

CLOSTRIDIUM DIFFICILE

- 250,000
- 14,000
- $1,000,000,000 (in USD cost per year)

Antimicrobial resistance (AMR) is an increasing threat to global health, economy, and society. It is estimated that antibiotic-resistant infections cause an additional 700,000 deaths per year worldwide, with a significant economic burden. The rise in resistance is due to the overuse and misuse of antibiotics, as well as the spread of resistant strains from one country to another. Therefore, it is critical to implement strategies to combat antimicrobial resistance, such as promoting rational use of antibiotics, improving infection control practices, and developing new antimicrobial agents.
New Epidemic Strain of \textit{C. difficile}

- **Name:** BI/NAP1/027, toxinotype III
  - Historically uncommon (particularly in U.S. strain collections), now epidemic
  - Current strain more resistant to fluoroquinolones
  - Carries extra toxin known as **binary toxin**
  - Mutations in **toxins A and B regulatory gene** (\texttt{tcdC}) and increased toxin production \textit{in vitro}
  - Shows increased spore production

---

**CDC Recommendations**

**WHAT YOU CAN DO**

- CEOs, Medical Officers, and other Healthcare Facility Leaders Can:
  - Support better testing (nucleic acid amplification tests) tracking, and reporting of infections and prevention efforts.
  - Focus strategies for rapid detection and isolation of patients with \textit{C. difficile} are in place and followed.

---

**The Society for Surgery of the Alimentary Tract**

**Predicting Recurrence of \textit{C. difficile} Colitis Using Bacterial Virulence Factors: Binary Toxin Is the Key**

David B. Stewart, Arthur Berg, John P. Hegarty
Surgery/Division of Colon and Rectal Surgery, Penn State Hershey Medical Center, Hershey, PA

**Conclusions:**

1. **Binary toxin** is an independent predictor of CDC recurrence, which has not previously been reported.
2. The combination of **binary toxin** and **\texttt{tcdC}** mutation is associated with the highest number of CDC recurrences, such that their combined presence is associated with a 70% recurrence rate.
3. \textit{C. difficile} which produces binary toxin may require longer antibiotic regimens to prevent disease recurrence.

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**Does multiple targets mean more information for the physician?**

**Binary Toxin and Death after \textit{Clostridium difficile} Infection**

*Emerg Infect Dis. 2011 Jun*

- Patients with binary toxin had higher case-fatality rates than patients without binary toxin.

**Fidaxomicin Non-inferior to Vancomycin for Treatment of \textit{C Difficile} Infection**

February 3rd issue of the *New England Journal of Medicine*

- When the drugs were used to treat a first recurrence of \textit{C. difficile} infection, the rate of second recurrence within two weeks was 7.6% with Fidaxomicin versus 27.4% with Vancomycin
- Four week recurrence rates were 19.7% and 35.5% for Fidaxomicin and Vancomycin, respectively with non-027 CDI cases.
- In 027 CDI cases performance with Vancomycin and Fidaxomicin were similar
Rapid Detection of Xpert BC - MRSA & SA

Rapid Detection of MSSA and MRSA from Blood Cultures Using the GeneXpert MRSA/SA Blood Culture Assay

Violeta Rekasius, Patricia Grajales, P. C. Schreckenberger
Department of Pathology, Loyola University Medical Center, Maywood, IL

A total of 210 unique patient blood culture samples were tested. There was 100% agreement with all Staphylococcal species when the conventional cultures and susceptibility methods were compared to the real time PCR method. In all, there were 22 MSSA and 28 MRSA. There were 152 CONS, where the PCR indicated MSSA negative and MRSA negative. In addition there were 8 cultures that grew non-Staphylococcal species which tested PCR negative for MSSA and MRSA.

The superior sensitivity and specificity of this method has been confirmed in two recent reports (1,2). In our study there was a total of 24% clinically relevant samples with Staphylococcus aureus and 72% non-Staphylococcus aureus samples.

**CONCLUSIONS**
The GeneXpert® MRSA/MSSA Blood Culture PCR assay provides a rapid and a highly diagnostic tool to detect MSSA and MRSA, which in turn results in faster diagnosis and targeted antibiotic treatment.

**PCR Can Improve Patient Management and Avoid Unnecessary Antibiotics**

- Child comes to Emergency Department with symptoms of meningitis;
- CSF is sent to laboratory for Enterovirus testing, including PCR
- **Viral Dx and discharge in 4-6 h**

**Xpert MRSA/MSSA SSTI in the ED**

Talar et al, JOSA 2011
- Retrospective blinded review
- Admitted adults with complicated SSTI
- Phase I: Baseline
- Phase II: ED use of rapid test, MD education
- Phase III: PharmD direction

**Key US publications**

Impact of GeneXpert MTB/RIF on Antibiotic Stewardship

Impact of Xpert MTB/RIF on Patients and Tuberculosis Programs in a Low-Burden Setting

A Hypothetical Trial


Conclusions:
* Xpert could greatly reduce the frequency and impact of unnecessary empiric treatment, contact investigation, and housing
Neisseria Gonorrhoeae resistance - Urgent

Rapid CT/NG NAAT testing is now recommended for same-day therapy

A key change in the 2015 Guidelines is the recommendation of alternative treatment regimens (for N. gonorrhoeae):
- Antimicrobial resistance on the rise, combo-therapy now recommended in US.
- Medication should be provided on site, on the same day, simultaneously, and under direct observation. If medications are not available when treatment is indicated, linkage to an STD treatment facility should be provided for same-day treatment (p.62-63)

In addition, should any person who tests positive for chlamydia or gonorrhea, along with women who test positive for trichomoniasis, should be re-screened 3 months after treatment (p. 7).

There is now a rapid CT/NG test that provides on-demand random access, with results in less than 90 minutes.

Where does the cost impact come from?

- **Lab** – Budget usually gets the hit
  - Reduced labor
  - Reduce send-outs
  - Increase potential billing revenue
- **Infection prevention**
  - Reduce PPE usage
  - Increase efficiencies for nursing staff
  - Decrease costs related to HAI
  - Present on admission status
  - VRE – Oncology, immuno-suppressed
- **Pharmacy**
  - Reduction in unnecessary antibiotic
    - MRSA vs Staph aureus vs non MSSA/MRSA, Enterovirus, C diff/027, unknown GBS status
    - Utilization of most appropriate antibiotics – Pre-surgical, ER
  - Reduce LOS from most effective therapy
- **Housekeeping – cleaning – curtains**
- **Bed Management – increase revenue**
- **ER – Patient management – call backs?** Ie Chlamydia/Gonorrhea
- **Patient satisfaction surveys**

Questions