Microbiology Beyond the Microscope: The Business of Science in the Clinical Microbiology Laboratory

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The Permanente Medical Group
NCASM Spring Meeting
March 5, 2016
Disclosures

- Research Studies with:
  - POCARED
Overview

Discuss Triggers & Sources for Candidate Technology

Review Key Features of a Good Business Case

Identify Strategic Considerations to Presenting a Business Case

Present Examples of Business Cases for the Clinical Microbiology Laboratory
THE BACKDROP
The Role of the Clinical Microbiology Laboratory

- Assist in Diagnosis of infectious Diseases
  - Patient Care
  - Patient Outcomes
  - Infection Control
  - Cost of Care

- Constant Challenges in Microbiology
  - Newly Emerging & Re-emerging Pathogens
  - Antimicrobial resistance/Fewer antibiotics
  - Global Society, increased mobility of resistance and new pathogens across continents
  - Bioterrorism – challenge for public health
The Backdrop: Operational Challenges to Clinical Microbiology

- Budget Cuts
- Shrinking Workforce
- Changing Technology
- Legislation

Microbiology Laboratory

Improving Patient Care
Spending in Healthcare

- Costs have risen >10X from 1980-2010
- The U.S. spent more than > 17% of GDP on health care
  - Higher than any other developed nation.

CMS, Office of Actuary, National Health Statistics Group, Congressional Budget Office (CBO)
Graphs from Time Magazine, March 4, 2013
The Backdrop: Spending for Laboratory Testing

- Spending on lab testing is 3-4% of total expenditures
  - $90 billion annually
  - Growing 30% per year
  - Newer, esoteric, proprietary
- Estimated 60-70% of all decisions regarding diagnosis, treatment, admission & discharge based on laboratory test results\(^1\)

\(^1\)Silverstein MD, 2003
More ≠ Better
Healthcare dollars spent vs. Life Expectance

- U.S. spends more on medical care per person than most countries
- US spending is not reflected in outcomes
- Life expectancy is shorter than in most other developed nations & many developing ones

Time Magazine, March 4, 2013
Opportunities to Remove Waste

Figure. Proposed “Wedges” Model for US Health Care, With Theoretical Spending Reduction Targets for 6 Categories of Waste

Berwick, Donald M., MD, MPP and Hackbart, Andrew D., MPhil “Eliminating Waste in US Health Care”, JAMA, April 11, 2012-Vol.37, No. 14
Laboratory Strategies that Add Value

- Develop outreach by extending lab services outside the four walls of the laboratory
- Build electronic connectivity solutions
- Lean internal laboratory processes
- Develop test utilization tools
- Understand & leverage the laboratory’s role over the continuum of care
Decision Points for New Technology
Triggers for the Implementation Assays/Technology

- Clinical requests
- Change in clinical care
- Treatment or research protocol
- Change in laboratory standard of practice
  - Clinical practice guidelines
- Public health issue
- Volume
- Cost vs reimbursement
- Quality considerations
Sources for Candidate Assays/Technology

- Physicians, other care-givers
- Hospital/Lab Admin
- Laboratory staff
- Literature
- In-house studies
- In-house ordering data
- Benchmarking
- National guidelines/regulations
Points for Focused Evaluation: Clinical Assay Requirements

- Assay requirements—Quantification, genotyping, detection or differentiation of subtypes
- Performance requirements—Sensitivity, specificity; screening vs diagnostic use
- Quantitative accuracy and precision
- Sample type(s)
- Volume and turnaround time
Points for Focused Evaluation: Initial considerations

- In-house capabilities
  - Space
  - Staffing & expertise

- Capital

- Platforms in place

- IT support

- Pre-analytical considerations

- Control and clinical material for validation

- Evaluation of currently used method (if any)
  - In-house or reference lab
  - Molecular or non-molecular
  - Unmet needs
Points for Initial Evaluation—The Initial “WEEDOUT”

- Assay availability
  - IVD, LDA, RUO
  - Chemistry, Instrumentation, Targets
  - Internal and external controls

- Method capabilities
  - Quantitative/qualitative/multiplex
  - Sample type
  - Intended use
  - Manufactures Claims

- Analytical Performance Data
  - Sens, Spec, Precision

- Published Evaluations
  - Performance vs reference standard

- Clinical Performance Data
  - Is there evidence of disease causality?
  - Is the data age and population appropriate?
  - Will test results change patient care?
  - Are medications available and on formulary?
Points for Focused Evaluation:
Assay Practical Operating Characteristics

- Throughput
- Ease-of use
- Reliability
- Rgt shelf-life
- Packaging
- Disposables

- Instrumentation
- Automation
- Software/interface
- Rgts required but not supplied
- Actual labor
- Support
Points for Focused Evaluation: COST

- **Cost assessment**
  - Current costs
    - In-house – Rgts & Ancillary Rgts
    - Reference lab
    - Include costs for collection, packaging, transport
    - QC/QA – including maintaining materials & meeting CAP requirements
  - Development/validation costs
  - Start-up (instrumentation) costs
  - Operating costs
    - Disposables
    - Reagents (packaging/shelf-life)
Reimbursements

- Payer mix
  - Fee for service vs capitation

- CPT coding
  - Specific
  - Generic
  - Multiple

- Standard of care

- IVD, ASR, RUO

- Reimbursement vs assay cost
Final decisions– Who passes Go?

- Understand what data you need to pull
- Engage the right stakeholders
- Work towards what is needed
- Balance of Priorities
- Final Decision may not always be the most obvious one
Talking to Administration

Building a Better Business Case
Presenting to Administration:

1. Know Your Audience
2. Speak Their Language
3. Keep Their Attention

Keep it Simple & Stay on Message
What is a Business Case?

‘A document that forms the basis of advice for executive decision-making for an asset investment. It is a documented proposal to meet a clearly established service requirement. It considers alternative solutions and identifies assumptions, benefits, costs and risks.’
Why are Business Cases Important?

- Provides an accounting of costs
- Documents/Quantifies benefits and achievement of goals
- Articulates identified issues, risks & solutions
- Communicates the resources required for implementation
- Demonstrates a need for an increased capital budget
The Business Case Should Cover:

- The business need or requirement
- The options to best address the business need or requirement
- Analysis of the benefits and costs of the options
- Recommendations regarding the preferred option
- Risk identification and mitigation strategy
- Implementation strategy
Key Considerations to Laboratory Capital Requests:

- What is the need & what is driving it?
- What is the acquisition benefit (ie faster TAT = decreased LOS)?
- Does the technology provide an additional benefit to laboratory operations (ie new test volume, workflow, staffing)?
- How is test volume trending?
- Are there any major construction costs to consider?
- What is the return on investment?
- Does it improve patient, employee and physician satisfaction?
- Does it support performance improvement (quality & cost savings) somewhere else in the continuum of care?
- What is the benefit to the patient?
A Simple Business Case
What to Quantitate?

Return on Investment $= \text{ROI}$

Annual cost savings of new technology
$(\text{current costs} - \text{estimated new costs})$

cost of acquisition

Determines how long it will take to recuperate the cost of converting to the new technology
Economic Justification Index (EJI)

- EJI = payback period for the reduction in costs
  - 0.5 = 2 yrs
  - 1 = 1 yr
  - 2 = 6 mo

- Factors difficult to quantify, need to be monitored to measure gains
  - Reduced ergonomic injuries
  - Quality
  - Turn around time
Strategic Justification Index (SJI): Evaluating Qualitative Changes

- Change Factors: (1) quality (2) safety (3) procedure enhancement (4) audit trail (5) more timely decisions (6) flexibility

- Assign value of 0-2 to six change factors
  - 0 = not important,
  - 1 = moderately important
  - 2 = very important
  - SJI = Sum of six change factors/12 (highest possible score)
  - SJI = 1; very high value,

- All six change factors are very important to the organization.
Overall Project Justification

Utilize Tools for the Road to Success
Business Case: Automation
The Shrinking Clinical Microbiology Workforce

### Staffing Shortage

#### Student Enrollment in U.S. Medical Technologist Programs

- 1983: 8,296
- 1999: 5,117

#### % U.S. Laboratory Professionals Eligible for Retirement by 2010

- 40%

#### Number of U.S. Medical Technologist Programs

- 1983: 630
- 1999: 273

#### Annual Staffing Projections for U.S. Laboratories: 2002-2012

- Lab professionals entering job market per year: 4,000
- Total # of lab professionals needed per year: 14,000
- 9,800 staffing shortfall annually

Total Laboratory Automation for Clinical Microbiology:
## Pre-Analytical Automation

### Table 2. Comparison of Automated Specimen Processors

<table>
<thead>
<tr>
<th>Feature</th>
<th>PREVI Isola</th>
<th>Innova</th>
<th>WASP</th>
<th>InoQua</th>
</tr>
</thead>
<tbody>
<tr>
<td>De-cap/cap containers</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td># different media at once</td>
<td>5</td>
<td>6</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td># samples at once (max)</td>
<td>114</td>
<td>200</td>
<td>72</td>
<td>288</td>
</tr>
<tr>
<td># plates streaked at once</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Up to 5 at once</td>
</tr>
<tr>
<td>Streak only mode</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes – MI module</td>
</tr>
<tr>
<td>Inoculate gram slide</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Inoculate broth tube</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes - Copan only</td>
</tr>
<tr>
<td>Detect ESWab presence</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Method of Inoculation</td>
<td>Pipette</td>
<td>Re-useable loop</td>
<td>Re-useable loop</td>
<td>Pipette</td>
</tr>
<tr>
<td>Throughput</td>
<td>~180 inoculations/hr</td>
<td>~130 inoculations/hr</td>
<td>~130 inoculations/hr</td>
<td>250+ inoculations/hr</td>
</tr>
<tr>
<td>Integrate into track system</td>
<td>Future?</td>
<td>No</td>
<td>Future?</td>
<td>Yes - today</td>
</tr>
<tr>
<td>Sample vortex/agitation</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Streaking Method</td>
<td>Spiral- plastic comb</td>
<td>Custom- loop</td>
<td>Custom- loop</td>
<td>Custom- rolling bead</td>
</tr>
<tr>
<td>Sort plates by incubator</td>
<td>Yes - standard</td>
<td>Yes - standard</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Consumables/Waste</td>
<td>Streaking comb, pipette tip, extra cap</td>
<td>Re-useable loop</td>
<td>Re-useable loop</td>
<td>Re-useable bead, pipette tip</td>
</tr>
</tbody>
</table>
## Specimen Processor ROI

### Costs Saved with Automated Microbiology Specimen Processor

<table>
<thead>
<tr>
<th>Method</th>
<th>#FTEs/day</th>
<th>#days/wk</th>
<th>Annual labor* costs</th>
<th>Labor savings/yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual</td>
<td>2.5</td>
<td>7</td>
<td>$129,872.50</td>
<td>-</td>
</tr>
<tr>
<td>Automated</td>
<td>1.0</td>
<td>7</td>
<td>$51,949.00</td>
<td>$77,923.50</td>
</tr>
</tbody>
</table>

*Labor Costs base on Lab Assistant I with bonuses, benefits & Time off according to Salary.com January 2013

### Cost of Automated Microbiology Specimen Processor

<table>
<thead>
<tr>
<th></th>
<th>Yr 1</th>
<th>Yr 2</th>
<th>Yr 3</th>
<th>Yr 4</th>
<th>Yr 5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automation Capital</td>
<td>$250,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$250,000</td>
</tr>
<tr>
<td>LIS</td>
<td>$10,500</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$10,500</td>
</tr>
<tr>
<td>Service Contract</td>
<td>-</td>
<td>$12,500</td>
<td>$12,500</td>
<td>$12,500</td>
<td>$12,500</td>
<td>$50,000</td>
</tr>
<tr>
<td>Total</td>
<td>$260,500</td>
<td>$12,500</td>
<td>$12,500</td>
<td>$12,500</td>
<td>$12,500</td>
<td>$310,500</td>
</tr>
</tbody>
</table>
**Specimen Processor ROI**

<table>
<thead>
<tr>
<th></th>
<th>Costs/Payback Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Labor Saving</td>
<td>$77,923.50</td>
</tr>
<tr>
<td>Five Year Costs</td>
<td>$310,500.00</td>
</tr>
<tr>
<td>Payback Period (ROI)</td>
<td>3.98 yrs</td>
</tr>
</tbody>
</table>

ROI = Return on Investment
Automation Allows for Cost Effective Growth

KPSC LA FTE vs Cum Test Growth
2004-2012

From 2004-2012 KP membership grew ~ 15%
Monitor Gains: Benefits that are Difficult to Capture on Initial Assessment

- Ergonomic injuries
- Quality
  - Consistency in plating
- Efficiency
  - Resource use
- Safety
- Turnaround time
- Growth
Business Case: Mass Spectrometer for Bacterial Identification
MS Options

Vitek MS (BMX)

MALDI BioTyper MS (Bruker)
Pros

Vitek MS
- FDA for GN, GP & Yst
- Less extraction
- Myla interface available
- Disposable bar-coded slides
- Longer Flight tube
  (Better in the >10KDalton protein range, future applications ie, resistance markers could be important)
- BMX is a company specialized in microbiology

MALDI Biotyper
- FDA for GN GP & Yst
- 110 VAC line
- Formic Acid/with matrix reduces extraction steps
- Interface solns available
- Table top footprint
- Reusable metal slides with disposable options
- Option with BD (Kiestra) & Copan for total lab automation
  (Biotypers on Kiestra in Europe)
- Bruker is a company specialized in MS
Cons

Vitek MS
- 220 VAC line
- Larger foot print (floor model)
- Myla is sole interface solution
- Unclear how this will work with BD for full lab automation

MALDI Biotyper
- Slower to Market with FDA approvals
- Cleaning of reusable slides
- Disposable slide will add to the cost of ID
Other

Vitek MS

- **Plate set up tracking (Myla):** Software Prep Station for scanning and linking data to target slide & AST
  - For manual set-up Copan Biotracer available.
- **Database:** Uses a population based algorithm (global spectra from up to 18 different strains)

MALDI Biotyper

- **Plate set up tracking:**
  - Two options (1) Copan Biotracer (2) Bruker Biotyper Pilot/satellite
    (Barcodes can be scanned and worklist goes to Biotyper with results)
- **Automated Rgt Addition:**
  - Galaxy adds formic acid/matrix
- **Database:** Main Spectra (Strain based)
### MS Costs*

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitek MS</td>
<td>$200,000 (add cost for Myla)</td>
</tr>
<tr>
<td>MALDI Biotyper</td>
<td>$200,000 (add cost for interface)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Vitek MS</th>
<th>MALDI Biotyper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Smear Reagents</td>
<td>$0.39 (GN,GP)</td>
<td>$0.29</td>
</tr>
<tr>
<td></td>
<td>$0.41 (YST)</td>
<td></td>
</tr>
<tr>
<td>Labor (2 min/ID)</td>
<td>$2.36</td>
<td>$2.36</td>
</tr>
</tbody>
</table>

- **Vitek MS rgts costs:** $0.36/spot for slide, $0.03/spot for matrix soln, Yst add $0.02/spot for formic acid
- **MALDI Biotyper costs:** Bacterial Standard $0.05 + Matrix $0.11 + Cleaning slide $0.12 + toothpick (<$0.01)

*Costs Based on 2012 estimates of methods*
## KPSC Cost Savings Per Year & ROI Summary
### (GN, GP & Yst)

<table>
<thead>
<tr>
<th>Assay</th>
<th>Reagents</th>
<th>Labor</th>
<th>Equipment</th>
<th>Rgt Savings</th>
<th>Labor Savings</th>
<th>Total Savings*</th>
<th>ROI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Biochem</td>
<td>$366,712</td>
<td>$294,679</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Vitek MS</td>
<td>$32,756</td>
<td>$85,428</td>
<td>$200,000</td>
<td>$333,956</td>
<td>$209,251</td>
<td>$543,207</td>
<td>&lt; 6 mo</td>
</tr>
<tr>
<td>Bruker</td>
<td>$25,963</td>
<td>$104,942</td>
<td>$200,000</td>
<td>$340,749</td>
<td>$189,737</td>
<td>$530,486</td>
<td>&lt; 6 mo</td>
</tr>
</tbody>
</table>

**Current Biochem Cost =**
1 FY Sum of Vitek ID Cards + API + top ten spot test biochemical's for GP, GN & Yst

**Note:** Labor not included in spot tests, QC not included, Does not include Gram stain costs
## Business Case Template: MS

### Maldi-TOF

**Position Statement:**

**Recommendation:** Replace the current Vitek Identification and API strips with the Maldi-TOF identification system.

### Supporting Information/Pros & Cons

<table>
<thead>
<tr>
<th>Assay</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
</table>
| Bruker  | • Currently a clinical trial site (can use data for validation)  
• 110 VAC line (no need to Vent)  
• Interface solutions available  
• Internet connection available for remote diagnostics  
• Table-top footprint  
• Reusable metal slides with disposable option to follow  
• Smart Acquisition Software which improves efficiency by stopping to collect data on a specific spot once there is adequate data  
• Partnering with Siemens, Copan, and BD for Full-Lab Automation | • Clinical trials for Gram Negative Bacteria (GN) in process. Gram positive (GP) and yeast (Yst) to follow  
• Submission to FDA pending  
• Cleaning the reusable slide  
• ~10% of GP, GN, and Yst extraction step needed for Identification |
| Vitek MS| • Submitted to FDA for GN, GP, and Yst  
• Myla Interface available January 2013  
• Disposable barcoded slides  
• A company that specializes in Microbiology | • 220 VAC line  
• Large footprint (floor model)  
• Must use Myla only for Interface solution |
### Business Case Template: MS

#### Cost Impact:

<table>
<thead>
<tr>
<th>Assay</th>
<th>Cost/reportable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruker</td>
<td>Reagents: Direct (90%) $0.29, Extraction Method (10%) $0.49, Labor: Direct (90%) $1.02, Extraction Method (10%) $ 3.35, Reagents, labor/specimen: ~$2.38, Cost for equipment: $200,000</td>
</tr>
<tr>
<td>Vitek MS</td>
<td>Reagents: Direct (100%) $0.39 (Bacteria), $0.41 (Yst), Labor: $1.02, Reagents, labor/specimen: ~$2.23, Cost for equipment: $200,000</td>
</tr>
</tbody>
</table>

#### Cost Savings Summary per Reportable Per Year [GN, GP & Yst]:

<table>
<thead>
<tr>
<th>Assay</th>
<th>Reagents</th>
<th>Labor</th>
<th>Equipment</th>
<th>Rgt Savings</th>
<th>Labor Savings</th>
<th>Total Savings [including the cost of instrument/reportable adds 0.89/reportable]</th>
<th>ROI (yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruker</td>
<td>$25,963</td>
<td>$104,942</td>
<td>$200,000</td>
<td>$340,749</td>
<td>$189,737</td>
<td>$461,808</td>
<td>0.43</td>
</tr>
<tr>
<td>Vitek MS</td>
<td>$32,756</td>
<td>$85,428</td>
<td>$200,000</td>
<td>$333,956</td>
<td>$209,251</td>
<td>$474,529</td>
<td>0.50</td>
</tr>
<tr>
<td>Current Biochemicals</td>
<td>$366,712</td>
<td>$294,679</td>
<td>$200,000</td>
<td>$333,956</td>
<td>$209,251</td>
<td>$474,529</td>
<td></td>
</tr>
</tbody>
</table>

*See attached ROI for each System.*
Limitations Beyond the Laboratory Operations, Testing Costs & Analytical Analysis

- With any new technology…..
  - Often a lack of published clinical impact studies

- Assumptions……..
  - Results are reliable
  - Providers will trust the results or know what to do with the results
    - Monitor
    - Comes with experience
  - Actionable results = improved outcomes
Defining Outcome

- **Laboratory**
  - Appropriate test utilization
  - Reduced laboratory cost
  - Increased productivity
  - Better TAT
  - Improved Quality

- **Clinical**
  - Reduced antibiotic use
  - Decreased LOS
  - Decrease morbidity/mortality
  - Decrease re-admissions

- **Overall Cost**
  - Healthcare system as a whole
## Executive Summary of Outcomes: Integration of MS ID with ASP on Sepsis

<table>
<thead>
<tr>
<th>Study</th>
<th>Sepsis Target</th>
<th>Reduction in time to ID (hrs)</th>
<th>Impact on earlier Appropriate Tx (hrs)</th>
<th>Decrease Hospital LOS (Days)</th>
<th>Decrease ICU stay (Days)</th>
<th>30-day readmission rate w/same BSI (%)</th>
<th>Hospital Cost Avoidance Per Pt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodist Hospital</td>
<td>GN Bacteremia (n=201)</td>
<td>22.7</td>
<td>75 vs 29 (P =0.004)</td>
<td>11.9 vs 9.3 (P=0.01)</td>
<td>7.3 vs 6.3 (P=0.05)</td>
<td>Not Reported</td>
<td>$19,547</td>
</tr>
<tr>
<td>Houston, TX Perez et al 2013</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Univ Michigan</td>
<td>Aerobic GP, GN &amp; YST (n=501)</td>
<td>28.1 (P&lt;0.001)</td>
<td>90.3 vs 47.3 (P&lt;0.001)</td>
<td>14.2 vs 11.4 (P=0.06)</td>
<td>14.9 vs 8.3 (P=0.014)</td>
<td>3.5 vs 1.6 (P=0.262)</td>
<td>$19,253</td>
</tr>
<tr>
<td>Huang et al 2013</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1Perez et al 2013 Arch Path Lab Med  
2Huang et al 2013 CID
### KPNW Cost Savings Per Year: ROI with Outcome Analysis (GN, GP, ANA & Yst)

<table>
<thead>
<tr>
<th>Assay</th>
<th>Reagents</th>
<th>Labor</th>
<th>Equipment</th>
<th>Rgt Savings</th>
<th>Labor Savings</th>
<th>Total Lab Savings*</th>
</tr>
</thead>
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<tr>
<td>Current Biochem</td>
<td>$66,712</td>
<td>$52,381</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>MS</td>
<td>$3,942</td>
<td>$22,131</td>
<td>$200,000</td>
<td>$62,770</td>
<td>$30,250</td>
<td>$93,020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assay</th>
<th>Est Hospital Savings/pt (25% of published savings)(^1,2)</th>
<th># Pt Interventions to breakeven</th>
<th>Total Est Hospital Savings (n=245)(^1)</th>
<th>Total Est Lab &amp; Hospital Savings</th>
<th>ROI</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS</td>
<td>$5000</td>
<td>40</td>
<td>$1,225,000</td>
<td>$1,318,020</td>
<td>&lt; 6 mo</td>
</tr>
</tbody>
</table>

\(^1\) Perez et al 2013 Arch Path Lab Med,  
\(^2\) Huang et al 2013 CID
Rethinking the Approach: Evidence Based Medicine Approaches

- National Guidelines
- Use available literature on specific outcomes to model cost avoidance
- Generate the outcome data via a pilot
  - Lack of resources = rely on published data
  - Implement with in-house positive outcome with pilot
- “On-going” monitoring post implementation
  - Show the worth
Outcome data: It’s all in the Delivery

- ROI no longer simple
- Demonstrating & quantifying value is difficult within departmental silo structure
- Executive summary
- No longer a one stop business case
  - Bring the key players to the table
  - Admin will tell you what they need
  - Monitor metrics as goals
  - Provide continuous feedback to admin
Business Case: Summary

- Utilize tools to help identify simple go/no go decision practices to move forward with a project/technology
- Present options in a simple user friendly manner
- Present the Pros & Cons
- Not all business cases will be as straightforward as others, being prepared will get you a long way with administration
- You may surprise yourself when it comes to the results of a business case
The problem is never how to get new, innovative ideas into your mind, it is how to get old ideas out.

Dee Hock
Founder & CEO VISA
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QUESTIONS?

Thank you
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Change in HAC 2011-2013: Better Care and Cost Saving

Est Savings:
- Deaths Prevented: >50,000
- Pt harms Prevented: >1.3M
- Costs Saved: $11.9B

Summary

- Introducing technology alone ≠ improve outcomes

Challenges Remain:
- Quality peer reviewed outcome studies to establish best practices focusing on appropriate laboratory utilization & justify costs
- Standardized metrics that can be readily captured to assess impact & support resources (ie ASP)
- Partnering with manufactures to support outcome studies early on, so outcome data can accompany or follow assay release

Business cases need to include key cost drivers over the continuum of care

To facilitate coordinated efforts to improve patient care resources focused on health-care outcomes and total cost are needed