POC TESTING: COST V CONVENIENCE

Presented by:
Jim Poggi
Principal
Tested Insights, LLC
January 29, 2019
LEARNING OBJECTIVES

- Describe the one, clear clinical reason to perform lab tests at POCT
- Identify how lab testing impacts health screening, management of peri-acute conditions and chronic disease management
- Discuss more about the relationship between MACRA and in-office lab testing
- Explain information on lab testing and morbidity/mortality for the 10 leading causes of death in the US
- Assess how utilization management influences test selection
DISCUSSION TOPICS

Managing patient wellness and acute intervention visits
- Clinical rationale for point of care testing
- Vital signs and Lab tests: thoughts on their synergy
- Patient centric rationale

Leveraging the “obvious”: 2-3% of the cost; 70% of the decisions
- Is it really that simple?
- Myth v reality: What does the data say?

Can we truly reduce cost and improve patient outcomes with POC lab testing?
- Cancer/FIT/FOBT
- Diabetes/A1C
- Influenza

Utilization management: policing or coaching, or both

Why test and why NOT test at the point of care?
- Answering the fundamental question
- Tests that make sense at the point of care; tests that need specific settings and expertise to make sense
- What criteria must be satisfied for successful point of care testing implementation?
    - Readiness, willingness and ability to test are critical parameters

Wrapping it all up: POC and YOUR budget
CLINICAL PERSPECTIVE ON POC TESTING

The primary reason to select POC testing:
To have tests available during the patient encounter that can be used to initiate or modify a patient treatment program
Speed diagnosis, OR assess progress after initiation of therapy
    Provide a progress assessment to the patient
Confirm patient compliance with a treatment program
    Diet, exercise, use of medication, lab tests, specialist treatment
Enable positive communication and solidify the relationship with the patient
Help the patient to understand and internalize THEIR responsibility for managing and maintaining their health
VITAL SIGNS...IMPORTANT BUT NOT ENOUGH

Vital signs are a critical element of every patient encounter

- Temperature, respiration, pulse rate, weight, heart and lung exam by stethoscope
  - Why these parameters?
  - Are you healthy or asymptomatic?
  - If you have symptoms, what do you have and can I “fix” it?

What is the credible role of lab testing in this setting?

Hypothesis: Vital signs in combination with specific lab tests are complementary at the point of care
General Screening, Risk Based Screening, Treatment Plan Follow up, Acute Symptoms. Vitals and labs
work together for the most common patient presentation scenarios:

Typical reasons a patient presents for care
- Well patient physical
- Medicare annual wellness visit
- Peri-acute conditions: presentation of symptoms
  - General malaise/physical discomfort/fever/infection
  - Respiratory symptoms
  - Shortness of breath/discomfort upon exertion
  - Unusual thirst, frequent urination, mental confusion
- Treatment Plan Follow up
PATIENT CONVENIENCE…

Hey, people, there’s a patient in here…

One healthcare trip not two or more

Rather than one healthcare visit followed (or not) by a trip to the lab
Avoid putting the lab test request slip in the garbage can… maybe along with the FOBT test card

Understand where you are with your health and what you should do about it

Increase confidence in your clinical care giver team

ASK, learn and take charge of your health

How many needed tests DON’T get done due to inconvenience?
Check your LIS/EMR for “pending” test requests
SO, WHY TEST? MACRA AND MEDICARE


- **Links quality of care and patient outcomes to reimbursement**
- **Rewards patient care quality, not quantity**
WHAT ARE THE NEW MACRA PROGRAMS AND METRICS?

There are two pathways to implement MACRA for physician practices

Merit-based Incentive Payment System (MIPS)

• Quality
• Cost (begins in 2019)
• Improvement activities
• Promoting Interoperability

Advanced Alternative Payment Methods (APM)

How does lab testing fit into MACRA?

• Lab directly impacts 3 out of 4 MACRA metrics
  • Lab results factor into the 277 Quality metrics
    • Examples include liver panel testing for alcohol abuse metrics and statin use as well as pediatric ADHD medication management and anti-depressant medication
  • Lab results coupled with EHR/LIS impact Improvement Activities and Promoting Interoperability
MACRA: LOVE THE CARROT; BEWARE THE STICK!

Based on clinician scores on MACRA metrics, the clinician will either receive favorable reimbursement increases or unfavorable reimbursement decreases.

<table>
<thead>
<tr>
<th>Year</th>
<th>Reimbursement Modifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>+/- 4%</td>
</tr>
<tr>
<td>2020</td>
<td>+/- 5%</td>
</tr>
<tr>
<td>2021</td>
<td>+/- 7%</td>
</tr>
<tr>
<td>2022</td>
<td>+/- 9%</td>
</tr>
<tr>
<td>2023 forward</td>
<td>+/- 9%</td>
</tr>
</tbody>
</table>
LAB COSTS AND MEDICAL DECISION MAKING

Leveraging the “obvious”: 2-3% of the cost; 70% of medical decisions

Is it really that simple?

• While widely quoted, the 2-3% of cost, 70% of medical decisions is over-simplified
• The truth about cost: from the 2016 Office of the Inspector General Report

  Medicare payments for lab tests under the Clinical Laboratory Fee Schedule totaled $6.8 billion in 2016, accounting for about 2 percent of all Part B payments in 2016

• The truth about lab data and medical decisions:
  • In 2017, there were 1173 lab CPT codes in the Clinical Lab Fee Schedule
  • It’s all about Pareto’s rule: the top 25 lab tests account for over 60% of all spending on lab tests
  • Spending is concentrated on tests with high clinical value in screening and making immediate medical decisions, e.g. TSH, CMP, CBC, lipids, Vitamin D, A1C

Sources: Lewin Report 2009, COLA, AACC, OIG September, 2016 Report
DOES PATIENT SCREENING REDUCE MORBIDITY AND MORTALITY?

The preponderance of the evidence worldwide confirms that it does

- MOST of the 10 leading causes of death in the US are declining
  - Screening and changes in health habits are largely responsible
- Diabetes testing and both colorectal and prostate testing have been researched extensively worldwide
  - Recommendations have been made to screen in at risk certain populations
    - Data shows the results
- Screening for infectious diseases, while somewhat controversial for some respiratory diseases, shows a reduction in morbidity and mortality
  - CDC recommends HIV, HPV and HCV screening
IS LAB TESTING MAKING A DIFFERENCE IN PATIENT OUTCOMES?

Screening updates: CRC screening age at initiation lowered to 45 from 50
PSA screening recommendation re-instated for men 55 to 69
Source: USPSTF
POCT HbA1c Boosts Screening, Identification of Prediabetes, Diabetes

The Sample: May 2017

Date: MAY.1.2017 // Source: Clinical Laboratory News

Topics: Chronic Diseases, Delivery Methods, Lab Management, Testing Methods

A comparison of point-of-care (POCT) HbA1c testing versus standard diabetes screening tests in family medicine clinic patients found that POCT HbA1c identified significantly more patients with previously undiagnosed hyperglycemia and prediabetes (Ann Fam Med 2017;15:162–4). The authors also determined that systematically screening patients via POCT HbA1c “greatly increases the chances for a screen to occur.”

The study compared POCT HbA1c and standard test results in demographically similar clinic patients who were at least 45 years old and not already diagnosed with diabetes who had not received HbA1c testing within the past year or taken steroids within the past 3 months. Overall, 324 were included in the standard practice arm of whom 73 (22%) received testing, nearly all undergoing fasting or random blood glucose tests. Another 164 patients underwent POCT HbA1c testing with 90% of those offered consenting to this type of testing.

POCT HbA1c in comparison to standard testing identified significantly more patients who unknowingly had diabetes or prediabetes, 10% and 53%, respectively, versus 8% and 33%. HbA1c cutoffs were ≤5.6% for euglycemia, >5.7–6.4% for prediabetes, and ≥6.5% for diabetes.
INFLUENZA: MAKING THE CASE FOR POC

Influenza is a key seasonal cause of morbidity and mortality.

The graph shows the trend of influenza and pneumonia cases from 1975 to 2015. The number of cases has fluctuated but generally remains high.

The infographic provides statistics for the burden of flu disease from 2017 to 2018:
- 49 million flu illnesses
- 960,000 flu hospitalizations
- 79,000 flu deaths

These numbers are more than the combined populations of Texas and Florida, the number of staffed hospital beds in the U.S., and the average number of people who attend the Super Bowl each year.


Get vaccinated.
www.cdc.gov/flu
<table>
<thead>
<tr>
<th>Complexity</th>
<th>Manufacturer</th>
<th>Product</th>
<th>Platform/Instrument</th>
<th>Influenza Virus Types Detected</th>
<th>Influenza Virus Subtypes Detected</th>
<th>Other Respiratory Viruses Differentiated</th>
<th>Approved Specimens</th>
<th>Test Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLIA waived</td>
<td>Abbott</td>
<td>ID NOW™ Influenza A &amp; B 2</td>
<td>ID NOW™ Platform</td>
<td>Influenza A and B</td>
<td>None</td>
<td>None</td>
<td>NPS, NS direct, or NPS and NS in VTM</td>
<td>&lt;15 min</td>
</tr>
<tr>
<td>CLIA waived</td>
<td>BioFire, Inc.</td>
<td>FilmArray® Respiratory Panel EZ</td>
<td>FilmArray 2.0 EZ</td>
<td>Influenza A and B</td>
<td>H1, H1pdm09, H3</td>
<td>Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Parainfluenza Virus, Respiratory Syncytial Virus</td>
<td>NPS in VTM</td>
<td>1-2 hr</td>
</tr>
<tr>
<td>CLIA waived</td>
<td>Cepheid</td>
<td>Xpert Xpress Flu</td>
<td>GeneXpert Xpress</td>
<td>Influenza A and B</td>
<td>None</td>
<td>None</td>
<td>NPS, NS in VTM</td>
<td>30-60 min</td>
</tr>
<tr>
<td>CLIA waived</td>
<td>Cepheid</td>
<td>Xpert Xpress Flu/RSV</td>
<td>GeneXpert Xpress</td>
<td>Influenza A and B</td>
<td>None</td>
<td>Respiratory Syncytial Virus</td>
<td>NPS, NS in VTM</td>
<td>30-60 min</td>
</tr>
<tr>
<td>CLIA waived</td>
<td>Mesa Biotech, Inc</td>
<td>Accula Flu A/Flu B</td>
<td>Accula Dock</td>
<td>Influenza A and B</td>
<td>None</td>
<td>None</td>
<td>NS direct</td>
<td>&lt;30 min</td>
</tr>
<tr>
<td>CLIA waived</td>
<td>Roche Molecular Diagnostics</td>
<td>Cobas® Influenza A/B Assay</td>
<td>Cobas® Liat® Analyzer</td>
<td>Influenza A and B</td>
<td>None</td>
<td>None</td>
<td>NPS in VTM</td>
<td>&lt;30 min</td>
</tr>
<tr>
<td>CLIA waived</td>
<td>Roche Molecular Diagnostics</td>
<td>Cobas® Influenza A/B &amp; RSV Assay</td>
<td>Cobas® Liat® Analyzer</td>
<td>Influenza A and B</td>
<td>None</td>
<td>Respiratory Syncytial Virus</td>
<td>NPS in VTM</td>
<td>&lt;30 min</td>
</tr>
<tr>
<td>CLIA waived</td>
<td>Sekisui Diagnostics</td>
<td>Silaris Influenza A &amp; B</td>
<td>Silaris Dock</td>
<td>Influenza A and B</td>
<td>None</td>
<td>None</td>
<td>NS direct</td>
<td>&lt;30 min</td>
</tr>
<tr>
<td>Complexity Level</td>
<td>Manufacturer</td>
<td>Test Description</td>
<td>Assay Details</td>
<td>Test Duration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>--------------</td>
<td>------------------</td>
<td>---------------</td>
<td>--------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>BioFire, Inc.</td>
<td>FilmArray®</td>
<td>Influenza A and B, H1, H1pdm09, H3</td>
<td>Adenovirus, Coronavirus (HKU1, NL63, 229E, OC43), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Parainfluenza Virus (1, 2, 3, 4) Respiratory Syncytial Virus</td>
<td>NPS in VTM</td>
<td>1-2 hr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>BioMerieux</td>
<td>FilmArray® Torch</td>
<td>Influenza A and B, H1, H1pdm09, H3</td>
<td>Adenovirus, Coronavirus (HKU1, NL63, 229E, OC43), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Parainfluenza Virus (1, 2, 3, 4) Respiratory Syncytial Virus</td>
<td>NPS in VTM</td>
<td>30-60 min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>BioFire, Inc.</td>
<td>FilmArray® Torch</td>
<td>Influenza A and B, H1, H1pdm09, H3</td>
<td>Adenovirus, Coronavirus (HKU1, NL63, 229E, OC43), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Parainfluenza Virus (1, 2, 3, 4) Respiratory Syncytial Virus</td>
<td>NPS in VTM</td>
<td>30-60 min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Cepheid</td>
<td>Xpert Flu</td>
<td>GeneXpert</td>
<td>Influenza A and B, H1pdm09</td>
<td>None</td>
<td>NPS in VTM, NA, NW</td>
<td>1 hr</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Cepheid</td>
<td>Xpert Xpress Flu/RSV</td>
<td>GeneXpert</td>
<td>Influenza A and B, H1pdm09</td>
<td>None</td>
<td>Respiratory Syncytial Virus</td>
<td>NPS, NW, NA in VTM</td>
<td>1 hr</td>
</tr>
<tr>
<td>Moderate</td>
<td>Cepheid</td>
<td>Xpert Xpress Flu</td>
<td>GeneXpert</td>
<td>Influenza A and B, H1pdm09</td>
<td>None</td>
<td>None</td>
<td>NPS in VTM</td>
<td>30-60 min</td>
</tr>
<tr>
<td>Moderate</td>
<td>Cepheid</td>
<td>Xpert Xpress Flu/RSV</td>
<td>GeneXpert</td>
<td>Influenza A and B, H1pdm09</td>
<td>None</td>
<td>Respiratory Syncytial Virus</td>
<td>NPS in VTM</td>
<td>30-60 min</td>
</tr>
<tr>
<td>Moderate</td>
<td>Focus Diagnostics (DiaSorin)</td>
<td>Simplexa™ Flu A/B &amp; RSV Direct</td>
<td>Integrated Cycler</td>
<td>Influenza A and B, H1pdm09</td>
<td>None</td>
<td>Respiratory Syncytial Virus</td>
<td>NPS in VTM</td>
<td>&lt;2 hr</td>
</tr>
<tr>
<td>Moderate</td>
<td>Focus Diagnostics (DiaSorin)</td>
<td>Simplexa™ H1N1 2009</td>
<td>Integrated Cycler</td>
<td>Influenza A</td>
<td>None</td>
<td>Respiratory Syncytial Virus</td>
<td>NPS, NA, NPA</td>
<td>2-4 hr</td>
</tr>
<tr>
<td>Moderate</td>
<td>GenMark Diagnostics</td>
<td>ePlex Respiratory Pathogen Panel</td>
<td>ePlex</td>
<td>Influenza A and B, H1, H1pdm09, H3</td>
<td>Adenovirus, Coronavirus (229E, HKU1, NL63, OC43), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Parainfluenza Virus (1, 2, 3, 4), Respiratory Syncytial Virus (A, B)</td>
<td>NPS in VTM</td>
<td>2 hr</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Biocartis</td>
<td>Idylla™ Respiratory IFV-RSV Panel</td>
<td>Idylla</td>
<td>Influenza A and B, H1pdm09, H3, H275Y mutation</td>
<td>Respiratory Syncytial Virus</td>
<td>NPS in VTM</td>
<td>30-60 min</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Luminex</td>
<td>Aries® Flu A/B &amp; RSV</td>
<td>Aries</td>
<td>Influenza A and B</td>
<td>None</td>
<td>Respiratory Syncytial Virus</td>
<td>NPS in VTM</td>
<td>1-2 hr</td>
</tr>
</tbody>
</table>
Upper respiratory conditions have multiple etiologic organisms; where do we stop?

What else is out there?
- Rhinovirus
- Coronavirus
- Adenovirus
- Parainfluenza viruses
- RSV Viruses

Oh, Yeah, It doesn’t hurt to have a good swab
The good news is, with national efforts like the Choosing Wisely campaign now underway, UM has left the confines of the clinical laboratory. While the duties of clinical laboratory professionals have never truly ended at the walls of the laboratory, the truth of this is now more apparent than ever. Addressing UM concerns is simply a matter of:

• reviewing your test menus for obsolete tests;

• creating reflexive test algorithms to ensure appropriate pre-test probabilities;

• crafting targeted pop-up messages;

• starting a laboratory test formulary committee;

• developing and delivering provider report cards; and

• pairing all of this with appropriate education.

Quoted from Geoffrey Baird, Bench Matters, December 2015
PUTTING “UTILITY” IN UTILIZATION MANAGEMENT

Key challenges to remember with decentralized POC

- Reference ranges should be looked at because it could be different from main lab reference ranges.
- Storage requirements for the test, look into conductivity and databases, Policies and procedures
- If the doctor’s office is part of a system there should be standardization across the system
- Check to make sure that the tests are truly waived test and not moderate
- According to the guidelines is the medical director on the CLIA license appropriate?
- If the tests are moderately complex make sure that everyone involved in the testing from the medical director to the people training to the testers have the appropriate education.
EMR: TRUTH OR DARE...

<table>
<thead>
<tr>
<th>Performance Category</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>60%</td>
<td>50%</td>
<td>30%</td>
</tr>
<tr>
<td>Cost</td>
<td>0%</td>
<td>10%</td>
<td>30%</td>
</tr>
<tr>
<td>Improvement Activities</td>
<td>25%</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td>Promoting Interoperability</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
</tr>
</tbody>
</table>
TEST SELECTION: MULTIPLE VIEWS AND CHOICES
PEER SUPPORT: CHOOSING WISELY PROGRAM

Our Mission
The mission of Choosing Wisely is to promote conversations between clinicians and patients by helping patients choose care that is:
- Supported by evidence
- Not duplicative of other tests or procedures already received
- Free from harm
- Truly necessary

Facts and Figures
Launched in 2012, Choosing Wisely is a leading effort to encourage conversations aimed at reducing unnecessary tests and treatments in health care. Here are some ways the campaign is helping influence these conversations:

- **80+ PARTNERS**
- **70 CONSUMER ORGANIZATIONS DISTRIBUTED**
- **550+ PATIENT-FRIENDLY MATERIALS TO MILLIONS OF CONSUMERS**

Clinician Lists
Complete lists of recommendations by society can be found by clicking the society name or via individual recommendation pages.

American Academy of Pediatrics – Committee on Infectious Diseases and the Pediatric Infectious Diseases Society
Don’t initiate empiric antibiotic therapy in the patient with suspected invasive bacterial infection without first confirming that blood, urine or other appropriate cultures have been obtained, excluding exceptional cases.

American Academy of Pediatrics – Committee on Infectious Diseases and the Pediatric Infectious Diseases Society
Don’t use a broad spectrum antimicrobial agent for perioperative prophylaxis or continue prophylaxis after the incision is closed for uncomplicated clean and clean-contaminated procedures.

http://www.choosingwisely.org/
## WELLNESS MANAGEMENT: THE BROADEST VIEW OF POC TESTING

<table>
<thead>
<tr>
<th>Situation</th>
<th>Diseases screened for</th>
<th>Some test examples</th>
<th>Waived</th>
</tr>
</thead>
<tbody>
<tr>
<td>General screening</td>
<td>Heart disease, diabetes, general health, anemia</td>
<td>CBC, CMP, BMP, Glucose, urinalysis</td>
<td>Yes</td>
</tr>
<tr>
<td>Risk based screening</td>
<td>HIV, HCV, colorectal cancer, lead poisoning, stroke</td>
<td>HIV, HCV, CBC, FOB/FIT, lead, PT/INR, myoglobin, d-dimer, lipids, HPV</td>
<td>Most</td>
</tr>
<tr>
<td>Follow up</td>
<td>Diabetes, lipids/cardiac, clotting/stroke, kidney, UTI</td>
<td>PT/INR, lipids, A1C, urinalysis, ALT/AST</td>
<td>Yes; All</td>
</tr>
<tr>
<td>Acute onset of symptoms</td>
<td>respiratory, GI pain, anemia/bleeding, UTI, disorientation, dehydration</td>
<td>Flu, strep, RSV, CBC, urinalysis, gastric blood, amylase, glucose</td>
<td>Yes, All</td>
</tr>
</tbody>
</table>
# Chronic Disease and POC Testing…

<table>
<thead>
<tr>
<th>Disease</th>
<th>Screening test available?</th>
<th>Is screening waived?</th>
<th>Monitoring Test available?</th>
<th>Is monitoring waived?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Disease</td>
<td>Yes</td>
<td>Yes; e.g. BNP</td>
<td>Yes</td>
<td>Yes; e.g. BNP</td>
</tr>
<tr>
<td>Cancer</td>
<td>Yes; FOBT/FIT/PSA</td>
<td>Yes; iFOBT in particular</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Chronic lower respiratory disease</td>
<td>Yes; electrolytes, blood gases</td>
<td>Some electrolytes</td>
<td>Yes</td>
<td>Some electrolytes</td>
</tr>
<tr>
<td>Cerebrovascular (stroke)</td>
<td>Yes</td>
<td>Some; d-dimer, PT/INR</td>
<td>Yes</td>
<td>Some; d-dimer, PT/INR</td>
</tr>
<tr>
<td>Unintentional Injuries</td>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alzheimer’s Disease</td>
<td>N/A</td>
<td>Rule out tests exist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>Yes</td>
<td>Yes; glucose</td>
<td>Yes; A1C</td>
<td>Yes</td>
</tr>
<tr>
<td>Pneumonia and influenza</td>
<td>Yes</td>
<td>Rapid pneumonia and flu tests</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>Yes</td>
<td>Yes; creatinine, BUN</td>
<td>Yes; creatinine, BUN</td>
<td>Yes</td>
</tr>
<tr>
<td>Intentional self-harm</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Chronic diseases in the 10 leading causes of death daily comprise most non acute patient encounters
<table>
<thead>
<tr>
<th>What's the test?</th>
<th>Why?</th>
<th>CLIA Category</th>
<th>Thoughts/comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>Quick check for anemia</td>
<td>Waived</td>
<td>Fast, easy, accurate</td>
</tr>
<tr>
<td>hCG</td>
<td>Pregnancy can strike at any time</td>
<td>Waived</td>
<td>Important for nutritional needs, pre-natal care and before imaging studies</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>Fast, easy, non invasive health screen</td>
<td>Waived</td>
<td>Should be part of every annual physical</td>
</tr>
<tr>
<td>Glucose</td>
<td>Diabetes, especially type 2, is on the rise worldwide</td>
<td>Waived</td>
<td>Treatment can’t begin without a good diagnosis; use an accurate quantitative test</td>
</tr>
<tr>
<td>CBC</td>
<td>Infection, anemia, general health</td>
<td>Waived/Moderate</td>
<td>Next to glucose, UA and hCG, the best tool in the general use lab tool belt</td>
</tr>
<tr>
<td>CMP</td>
<td>General metabolic assessment</td>
<td>Waived/Moderate</td>
<td>Tells the story of overall patient status in health AND disease</td>
</tr>
<tr>
<td>BMP</td>
<td>Limited general health assessment</td>
<td>Waived/Moderate</td>
<td>Less data; typically no liver function tests</td>
</tr>
<tr>
<td>Lipid profile</td>
<td>Lipid disorders lead to serious complications and are often related to diabetes</td>
<td>Waived/Moderate</td>
<td>Use of statins has made lipid tests fundamental in adult medicine</td>
</tr>
<tr>
<td>A1C</td>
<td>Knowing average glucose level over time</td>
<td>Waived/Moderate</td>
<td>Are Ward and June sticking to their diet? How well controlled is their diabetes?</td>
</tr>
<tr>
<td>Flu</td>
<td>Know what you are treating</td>
<td>Waived/Moderate</td>
<td>Only about 30% of all flu tests are positive; ever wonder what the other causes are?</td>
</tr>
<tr>
<td>Strep</td>
<td>Prevent very dangerous complications</td>
<td>Waived/Moderate</td>
<td>Before antibiotics, strep was a serious cause of illness and death</td>
</tr>
<tr>
<td>RSV?</td>
<td>Some practices love it; others want it done in a more sophisticated lab</td>
<td>Waived/Moderate</td>
<td>This test has arguments for and against in house testing; new, molecular tests make it a better in office test choice than ever</td>
</tr>
<tr>
<td>FIT/FOBT</td>
<td>Colorectal cancer is highly curable if detected early</td>
<td>Waived</td>
<td>Colonoscopy has left these tests “behind” to a large extent; they are still important</td>
</tr>
<tr>
<td>What's the test</td>
<td>Practice type/patient type</td>
<td>CLIA category</td>
<td>Thoughts/comments</td>
</tr>
<tr>
<td>----------------</td>
<td>---------------------------</td>
<td>---------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Lead</td>
<td>Pediatric</td>
<td>Waived</td>
<td>Can prevent serious neurological damage via early detection</td>
</tr>
<tr>
<td>TSH</td>
<td>GP/IM/OBG</td>
<td>Waived/Moderate</td>
<td>Useful at annual physical</td>
</tr>
<tr>
<td>Free T4</td>
<td>GP/IM/OBG</td>
<td>Moderate</td>
<td>Reflex with abnormal TSH</td>
</tr>
<tr>
<td>PSA</td>
<td>GP/IM/URO</td>
<td>Moderate</td>
<td>New, multiple assay tests including PSA are better than ever</td>
</tr>
<tr>
<td>PT/INR</td>
<td>GP/IM/Cardio</td>
<td>Waived/Moderate</td>
<td>Important follow up for clotting disorders</td>
</tr>
<tr>
<td>BNP</td>
<td>GP/IM/Cardio</td>
<td>Waived/Moderate</td>
<td>Detect/follow up on heart failure</td>
</tr>
<tr>
<td>B12/Folate</td>
<td>GP/IM/OBG</td>
<td>Moderate</td>
<td>Differential diagnosis of anemia</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>GP/IM/OBG/Etc</td>
<td>Moderate</td>
<td>Depending on who you believe, either everyone or no one has a Vitamin D deficiency</td>
</tr>
</tbody>
</table>
WHEN THE RIGHT TREATMENT SETTING AND EXPERTISE IS CRITICAL

<table>
<thead>
<tr>
<th>Test name</th>
<th>Why Screen?</th>
<th>Why Not?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Troponin I</td>
<td>Speed AMI Dx</td>
<td>Treatment options?</td>
</tr>
<tr>
<td>Electrolytes</td>
<td>Metabolic imbalance/cardiac issues</td>
<td>Treatment options?</td>
</tr>
<tr>
<td>Blood gases</td>
<td>Metabolic imbalance</td>
<td>Invasive; skill/practice required</td>
</tr>
<tr>
<td>Toxicology</td>
<td>Patient counseling</td>
<td>Equipment and staff requirements</td>
</tr>
<tr>
<td>RSV</td>
<td>Knowing ASAP is important</td>
<td>Technology limitations*</td>
</tr>
</tbody>
</table>

*new molecular tests dramatically improve NVP in particular
A list of 37 clinical diagnostic scenarios produced by the American College of Physicians and published in Annals of Internal Medicine includes many uses of lab tests that, according to ACP’s physician workgroup, do not reflect high-value, cost-conscious care.

Examples of lab tests include:

- Measuring brain natriuretic peptide in the initial evaluation of patients with typical findings of heart failure.
- Annual lipid screening for patients not receiving lipid-lowering drug or diet therapy in the absence of reasons for changing lipid profiles.
- In asymptomatic women with previously treated breast cancer, performing follow-up complete blood counts, blood chemistry studies, tumor marker studies, chest radiography, or imaging studies other than appropriate breast imaging.
- Screening low-risk individuals for hepatitis B virus infection.
- Screening for cervical cancer in low-risk women age 65 years or older and in women who have had a total hysterectomy (uterus and cervix) for benign disease.
- Screening for colorectal cancer in adults older than 75 years or in adults with a life expectancy of less than 10 years.
- Screening for prostate cancer in men older than 75 years or with a life expectancy of less than 10 years.
- Using CA-125 antigen levels to screen women for ovarian cancer in the absence of increased risk.
- Ordering routine preoperative laboratory tests, including complete blood count, liver chemistry tests, and metabolic profiles, in otherwise healthy patients undergoing elective surgery.
- Performing preoperative coagulation studies in patients without risk factors or predisposing conditions for bleeding and with a negative history of abnormal bleeding.
- Performing serologic testing for suspected early Lyme disease.
- Performing serologic testing for Lyme disease in patients with chronic nonspecific symptoms and no clinical evidence of disseminated Lyme disease.
- Performing imaging studies, rather than a high-sensitivity D-dimer measurement, as the initial diagnostic test in patients with low pretest probability of venous thromboembolism.
- Measuring D-dimer rather than performing appropriate diagnostic imaging (extremity ultrasonography, CT angiography, or ventilation–perfusion scintigraphy), in patients with intermediate or high probability of venous thromboembolism.
- Performing an antinuclear antibody test in patients with nonspecific symptoms, such as fatigue and myalgia, or in patients with fibromyalgia.

WHAT DOES IT TAKE TO ASSURE EFFECTIVE TESTING

• Readiness
• Willingness
• Ability

Test selection is critical, but commitment and planning assure proper testing results.
READY TO TEST

- **Ready** to perform which tests?
- **Focus on tests that can be performed and discussed during the patient visit (15 minutes or less)**
  - This would include lipids, urinalysis, rapid pregnancy, respiratory and some cardiac markers as well as hemoglobin A1c
- **Facility Ready**
  - Space, water, power
  - Patient privacy
  - Medical records/EMR
- **Staff Ready**
  - Roles and responsibility established
  - Training plan in place and effective
  - Motivation/interest/understanding importance to the patient and practice
- **Patients Ready**
  - Informed and understand the rationale
- **Insurance Ready**
  - Understand which carriers permit testing
- **License Ready**
  - CMS 116 completed and CLIA number established and up to date?
WILLING TO TEST

- Willingness involves both confidence in the testing mission and commitment to implement the lab tests and overcome obstacles along the way.

- Clinicians and staff need to be committed to the decision to test at POC.
- Needs to portray confidence to the patients of the practice.
  - Most practices find patients prefer this level of service during the visit.

Needs to be prepared for “speedbumps”: product back orders, training plan modifications, facility modifications and the like.
  - They are all part of establishing a new level of service and will become routine over time.
- Willingness will help assure that the tests performed are continually challenged and how efficiently it manages this element of the practice.

Staff reluctance and training issues are key reasons for issues.
ABLE TO TEST

- **Ability:** tests every element of “readiness” and is the final assurance that the laboratory will run smoothly and provide the service level the practice and patients expect.

- Licensing, test selection and personnel considerations are paramount and need thorough understanding and evaluation.
  - Coordination with POCC and central lab are critical.

- On going training for all practice staff involved in lab testing is both required and important.
  - Continuing education is an essential element of an efficient, modern lab.

- Have a back up staff plan in place BEFORE initialization of testing.
  - Assure at least two personnel are ready, willing and able to perform tests to avoid service interruptions.

- Be prepared for patient questions about why the practice performs some tests and not others.
IMPLEMENTATION ESSENTIALS...

**Successful POC implementation includes**

- Coordination with POCC and central lab
- Staff meeting to introduce the solution
- Staff training
- Patient brochures and information
- Announcement to the patients
POC IMPACT ON BUDGETS AND COST OF CARE

- Can POC testing be justified on the basis of saving money on the lab budget?
  - Hypothesis: reductions in morbidity and mortality are SYSTEM WIDE health care cost impacts
  - There is SOME empirical data that patient cost and convenience can be captured by MACRA patient satisfaction metrics
  - Longitudinal patient morbidity and mortality data are the only true measure of the economic benefits of POC testing
    - Geisinger, Vanderbilt, MANY others are collecting data
  - Over time the overall health system can/will experience reductions in patient costs due to preventing avoidable acute interventions, reducing morbidity and forestalled mortality (you don’t win that one)