Appropriate Use of Laboratory Tests

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April 6th, 2019

Agenda

• Introduction
• Personalized Healthcare – a history
• Appropriate usage of laboratory tests – understanding the numbers
• Break
• Modern Laboratory testing – conception to implementation
Introduction

JEFF VOGEL

- Graduate of The Ohio State University
- 6 years laboratory experience
- 4.5 years account management
- 4.5 years product development marketing
- Fun fact – Love to cook, but hate to bake

The Age of Personalized Healthcare

It all begins with you!

Benefits of Personalized Healthcare
- Better informed clinical decisions
- Increased chance of positive health outcomes
- Focus on prevention and predictions
- Treatment compliance
- Reduced cost
### A Brief History

**Healthcare Insurance Portability and Accountability Act**
- Signed into law on August 21, 1996
- “improve the portability and accountability of health insurance coverage”

Who May Get Records?
- HIPPA – gives patients the right to obtain a copy of their medical records from any medical provider
- Must be provided within 30 days of a request

Protected Health Information
- Personalized health information
- Limited and controlled by HIPPA requirements
- Can be a treasure trove of personal information
Arizona House Bill 2645
- “Do-it-yourself lab testing without doctor’s orders”
- Pushed by Theranos, a former Palo Alto, CA based medical diagnostics company
- Signed into law by Governor Doug Ducey

A Step Too Far?!?!
THE RIGHT TOOL FOR THE JOB!
Terms to Define
- Diagnostic Sensitivity
- Diagnostic Specificity
- Positive Predictive Value
- Negative Predictive Value

Diagnostic Sensitivity
- Measures the proportion of actual positive results that are correctly identified as such
- “true positive rate”
- The percentage of sick people who are correctly identified as having the condition
Diagnostic Specificity
- Measures the proportion of actual negatives that are correctly identified as such
- “the true negative rate”
- The percentage of healthy people who are correctly identified as not having the condition

Positive Predictive and Negative Predictive Values
- Proportions of positive and negative results that are true positive and true negative results
- The values are not intrinsic to the test; they also depend on the sample population
- Prevalence of the disease in the sample population can drastically PPV and NPV
Syphilis
- Bacterial infection caused by sexual contact
- Affects 700,000 – 1.6 million pregnancies per year
- If untreated has a mortality rate of 8% to 58%
- US – Sharp increase in syphilis 1990s - present

Syphilis Screening Recommendations (CDC)
- Pregnant Women
- At least annually for sexually active men who have sex with men
- Persons with HIV
A Case for Clinician Directed Testing

**Syphilis Total Diagnostic Assay**

Commercially available screening test for Syphilis
- 98% Sensitivity
- 99% Specificity

How the General Public Perceives Testing

100 Patient Samples Screened for Syphilis

- Positive Sample
- Negative Sample
How Laboratorians Perceive Testing

100 Patient Samples Screened for Syphilis

- True Positive
- True Negative
- False Positive
- False Negative

Screening the Correct Population

100 Patient Samples Screened for Syphilis

- 36 True Positives
- 2 False Positives
- Positive Predictive Value of 94.7%
Screening the Wrong Population

100 Patient Samples Screened for Syphilis

- 1 True Positive
- 2 False Positives
- Positive Predictive Value of 33%

Conclusion

We need appropriate use of laboratory testing!

Needs
- Directed
- Indicated
- Understood
LEAVE IT TO THE PROFESSIONALS!

Modern Laboratory Testing
Conception to Implementation
The Food and Drug Administration

- Founded June 30, 1906

FDA Mission
- Responsible for protecting the public health
- Ensures the safety, efficacy, and security of medication, biological products and medical devices
- Ensures the safety of our nation's food supply, cosmetics, and products that emit radiation

510(k) Clearance
- Many new assays, especially on established instruments go through the FDA's 510(k) clearance process
- The new device must show substantial equivalence to an established device
- 510(k) cleared medical devices always have a predicate device
The path to a new test

Lyme Testing?

FDA Pre-submission

Assay Development Phases

1. Planning
   - Predicate Selection
   - Early Market Research
2. Feasibility
   - Conceive Assay
     - Antigen Selection
     - Sample collection
3. Development
   - Validate design
   - Prove Concept
4. Transfer and Validation
   - Transfer assay design to manufacturing
   - Validation Studies
5. Launch
FDA Submission

Validation Data

If substantially equivalent

SUCCESS

BIO-RAD