

Laboratory Value Pyramid & Clinical Lab 2.0

Adding Value in the Era of Population Health, Precision Medicine, and Value-Based Payment

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Atomic Bombs for 2018 and 2019

Medicare to Pay Differently

- Labs to be hit first,
on Jan. 1, 2018!
(PAMA)
- Physicians to be hit second,
during 2019.
(MACRA / MIPS)

A Word on MACRA...

Understanding MIPS & APMs

- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).
- Replaces SGR formula.
- New payment model for physician professional fees; data baseline is 2017.
- Merit-Based Incentive Program (MIPS).
- Advanced Alternative Payment Models (APMs).
- Speeds transition away from Fee-for-Service.

Payment Under MACRA

MIPS OR APM

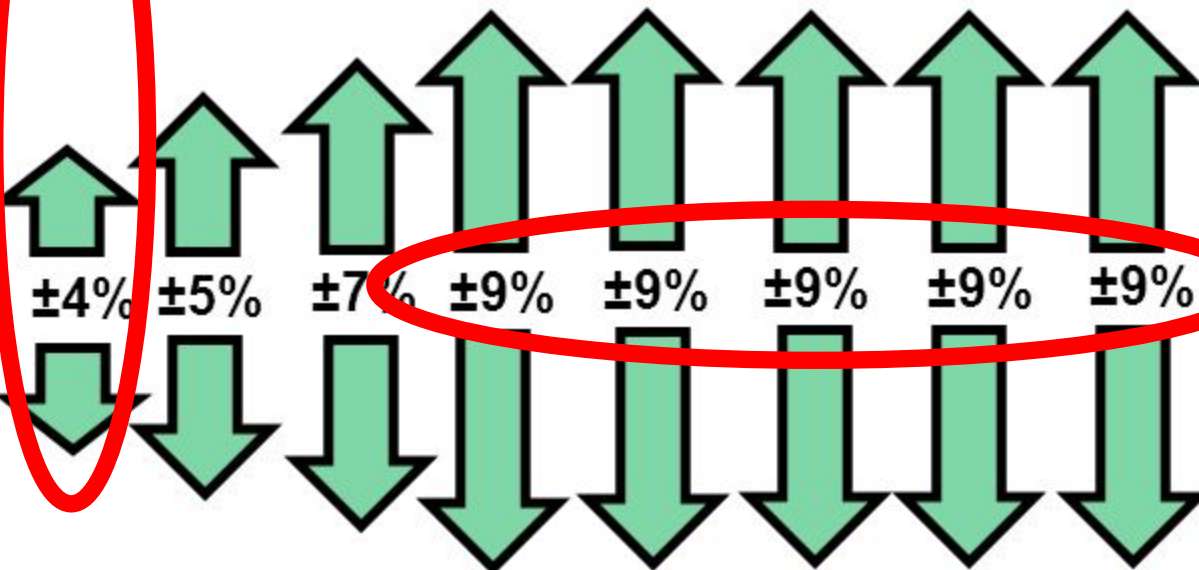
APM: Bonus of 5% of PFS payments annually

APM
0.75% annually;
no bonus payments

0.0% annual update

2019 2020 2021 2022 2023 2024 2025 2026

MIPS
0.25% annually, PLUS
penalties/bonus up to
 $\pm 9\%$



American Hospital
Association

A Word on PAMA

Lab Market Price Reporting

- Protecting Access to Medicare Act of 2014 (PAMA).
- Medicare Part B lab spend: \$7 billion in 2015.
- On Friday, September 22, CMS published 2018 Medicare Part B Clinical Laboratory Test Fees.
- **CMS now says fee cuts will total \$680 million** just in 2018! *(That's up from the \$400 million estimate.)*
- Less revenue from lab services that have CPT code reimbursement from 2018 forward.

What's Changing for Labs?

- Pressure to cut cost, boost productivity.
- New standards of quality. *(Think Six Sigma quality.)*
- Adoption of 'System of Prevention.'
- Payment based on value.
- More intense use of information technology and data analytics.

Coming to a lab near you...

Cultural transformation in the operation
of Medical Laboratories

Why These Changes?

New Clinical Care Paradigms

- Keep patients out of hospitals!
- Detect disease early, when easier to treat.
- Actively help patients manage their chronic diseases.
- Use incentives to encourage positive lifestyle choices and activities.
- Support these goals with molecular and genetic knowledge as it is developed.

Powerful Healthcare Trends

Attributes of 'New' Healthcare

- Integrated healthcare networks that deliver seamless, integrated clinical care.
- Payment based on value, not fee-for-service.
- Personalized or precision medicine, (requiring more diagnostic testing).
- Proactive care, not reactive care.
- Healthcare big data, informed by clinical lab test results.

Understanding Volume to Value

- **Old:** hospitals, physicians, labs paid by fee-for-service.
- *More tests = more revenue.*
- **New:** payment for value
- *Now, more tests = higher costs, less profit.*
- Labs must demonstrate that their lab test services contribute to improved patient outcomes and lower cost of care.

Attributes of 'New' Lab

- Speedier work flow, shorter cycle times.
- Attacks non-value added processes.
- Continuously improves.
- Sophisticated use of informatics.
- Collaborates with providers to deliver more value from lab test data.
- Contributes to measurable improvement in patient outcomes, lower cost of care.

Key Attributes for Labs

- **ONE:**
Achieve operational excellence via adoption of quality management systems.
- **TWO:**
Develop mastery of information technology to sustain lab's operational performance and contribute to improving patient outcomes.
- **THREE:**
Engage in effective collaborations with physicians in care settings outside the lab.

Creates New Opportunities for Lean

- All change involves people.
- Effective change involves improving existing workflow, both clinically and operationally.
- Need for change plays to the strength of your skills in Lean, Six Sigma, process improvement.
- You are poised to make essential contributions in helping your lab and your hospital evolve with precision medicine and value-added care.

But Changes Needed for Labs to Deliver Value

- Future success for labs requires changes in lab operations; plus...
- ...a working culture where lab staff and pathologists can recognize value.
- Shift from “system of inspection” to “system of prevention” teaches lab team to recognize value-added vs non-value added.
- Use of modern quality tools and practices.

Attributes of Lab 1.0 vs. Lab 2.0

Clinical Lab 1.0: *Transactional*

Clinical Lab 2.0: *Integrative*

SICK CARE

- Receive Test Sample
- Result Test Sample

HEALTH CARE

- Population Health using Lab data
- Total Cost-of-Care leveraging Lab data
- Time-to-Diagnosis
- Optimization of: diagnosis, therapy, monitoring
- Care Optimization
- Screening Optimization

DISEASE SCREENING

- Protocol-driven
- Scheduled by Treating Physician
- Lab is derivative

RISK MANAGEMENT

- Identification of Risk
- Real-time tracking of Risk
- Escalation/De-escalation of Acuity

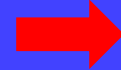
Attributes of Lab 1.0 vs. Lab 2.0

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WELLNESS PROGRAMMING

- Managed by Treating Physician
- Lab is Derivative



WELLNESS PROGRAMMING

- Gaps-in-Care closed using Lab data
- Outcomes of program using Lab data

Predictive Analytics

- What will happen? When? Why?

PAYMENT MODELS

- Lab is a Commodity
- Value is Cost-per-Test



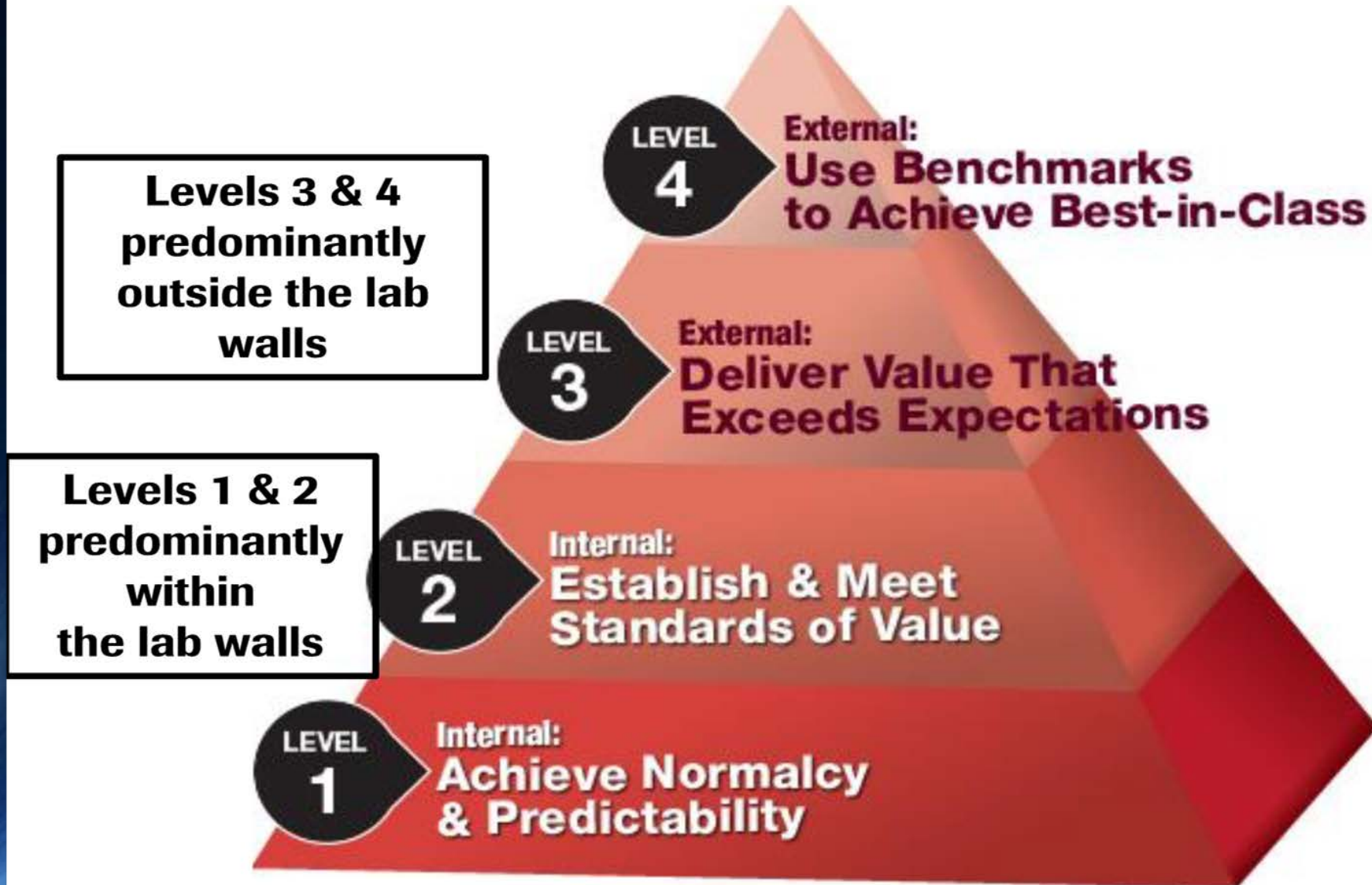
PAYMENT MODELS

- Value of Lab for Total Cost-of-Care

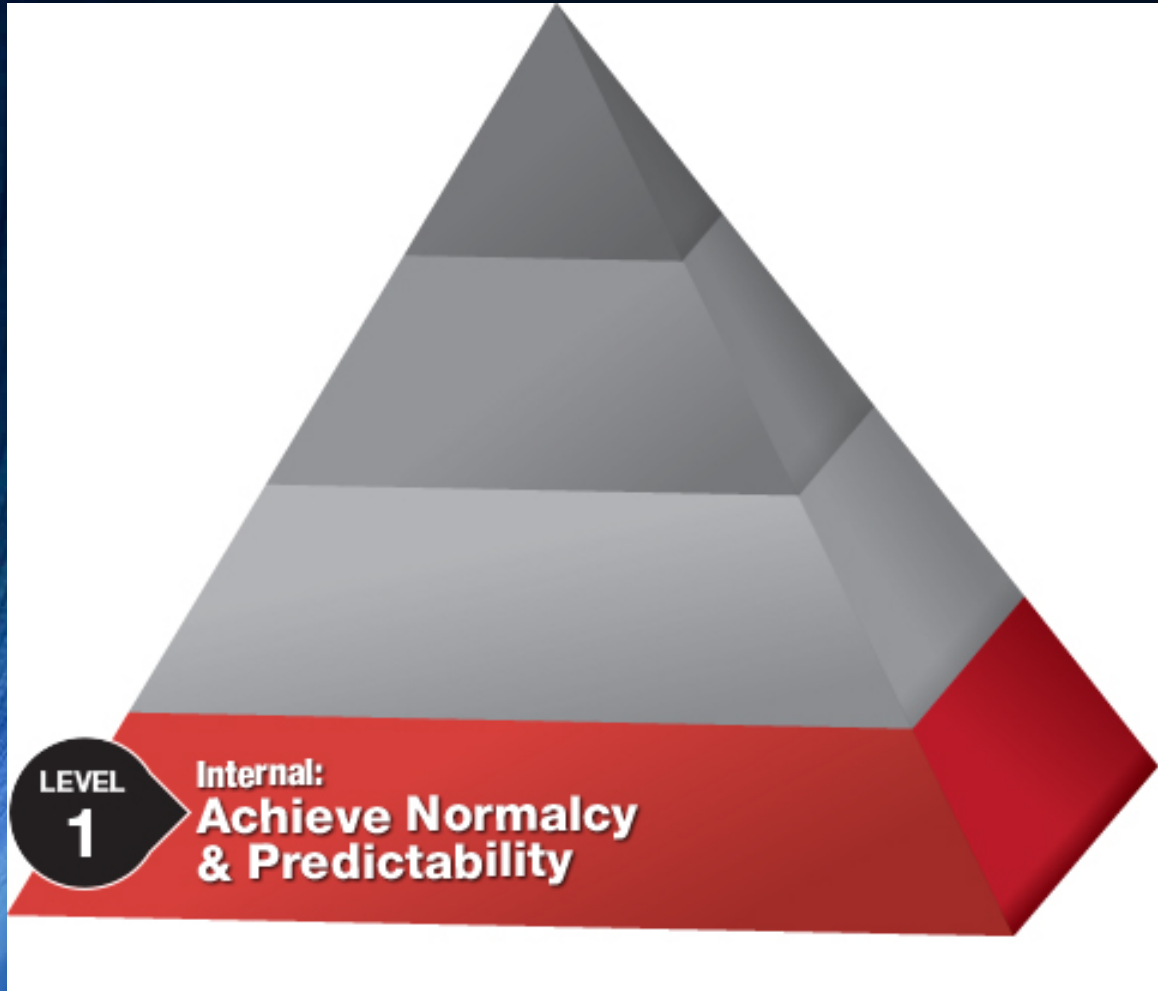
Opportunity to Use... Laboratory Value Pyramid

**Four-step path for labs to move
from current state to best-in-class.**

The Four Levels of the Lab Value Pyramid

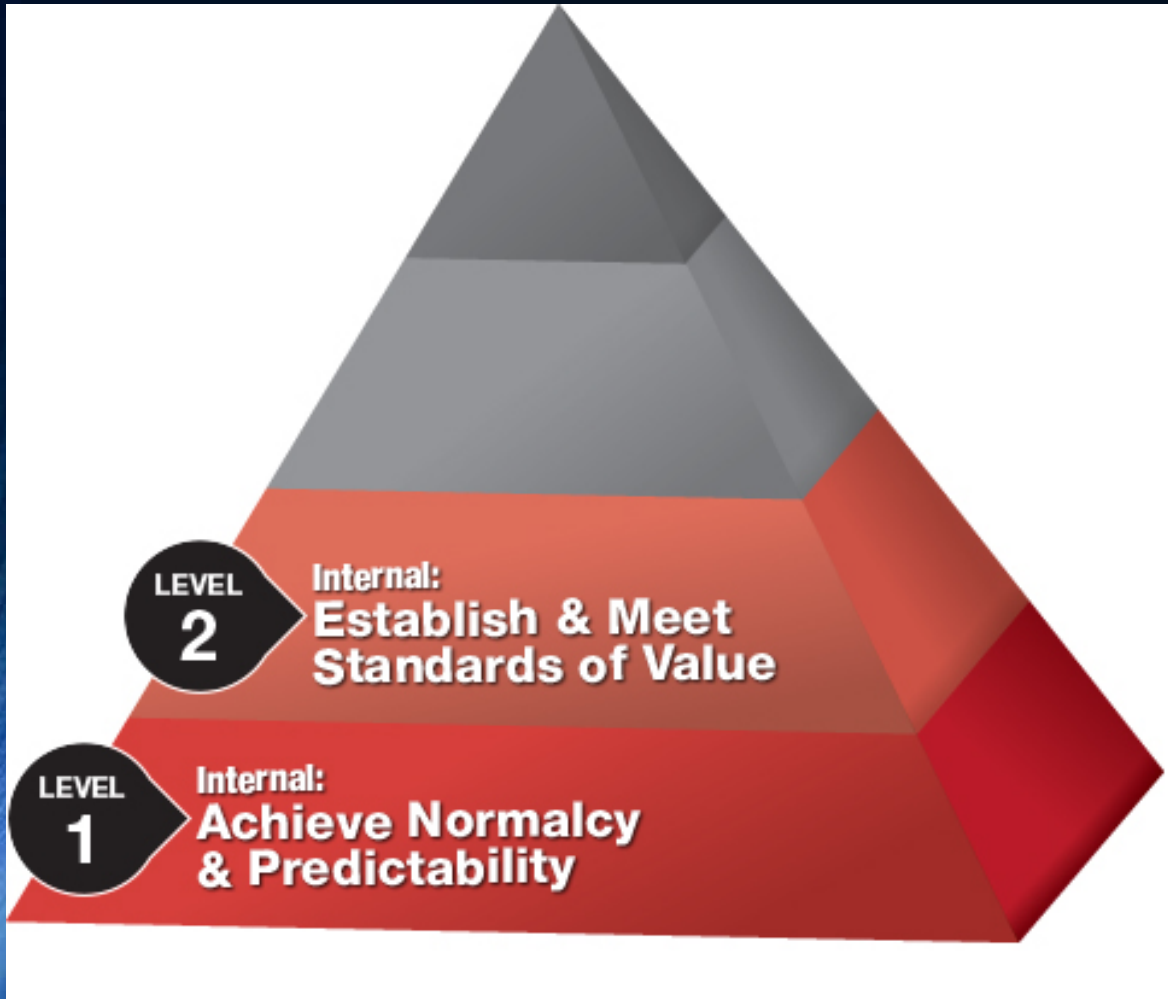


Level One: Achieve Normalcy and Predictability



- First steps to adopt the system of prevention.
- Incorporate real-time, visible performance metrics of lab processes alongside traditional QC data.
- Mindset of continuous improvement.
- Adopt culture that regularly engages outside experts to help lab staff understand key issues and develop appropriate solutions for further improvement throughout the lab.

Level Two: Establish Standards & Meet Standards of Value

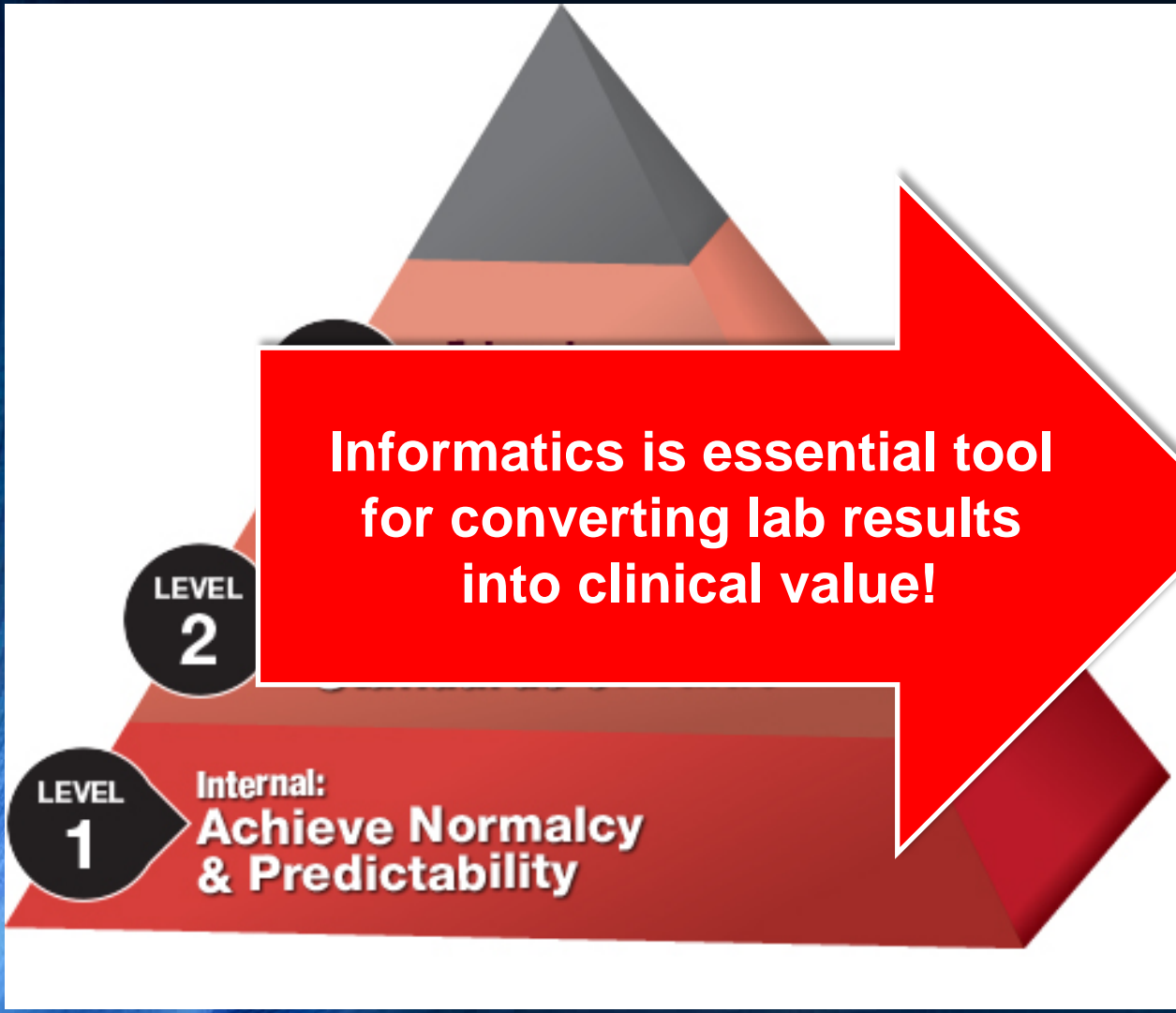


- Establish criteria for value via benchmarking within the lab.
- Transition from a lab-result-only mentality to one of a lab performance mentality.
- Incorporate quality in patient results, customer & employee satisfaction, production best practices, supply chain best practices, financial best practices, and similar.
- Manage lab as a well-run business with all the accountability that comes in running a well-run business.
- Lab staff can identify value-added tasks from non-value-added and uses Lean and Six Sigma to continually improve value.

Recognizing Level Two

- Lab is competent at this level when those outside the lab — including your boss and your boss' boss — want to know about the core competencies you have established, how you did it, what benefits it provided, then ask you to help them do something similar in another area of the organization.

Level Three: Deliver Value That Exceeds Expectations



**Informatics is essential tool
for converting lab results
into clinical value!**

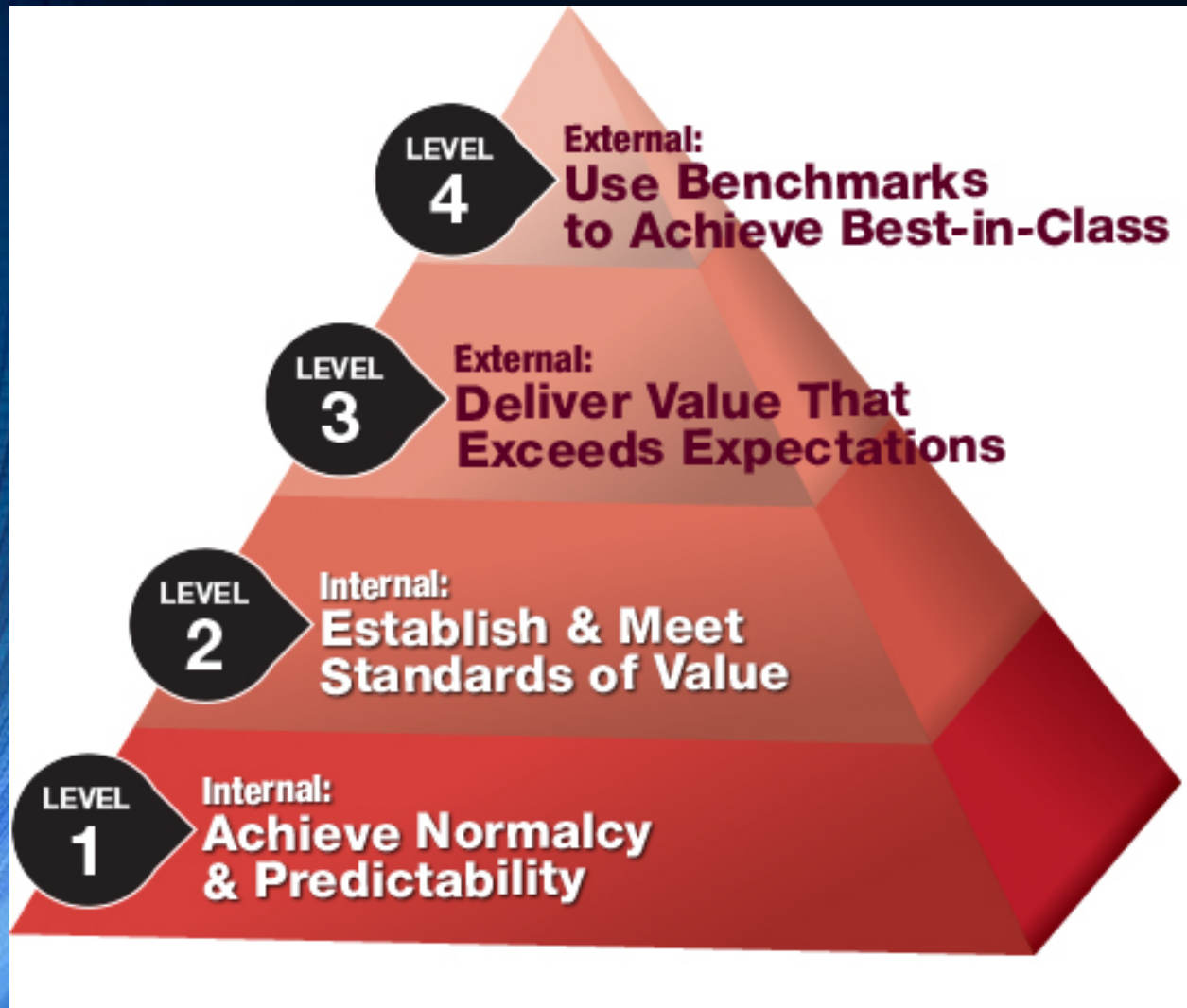
LEVEL 1 Internal:
**Achieve Normalcy
& Predictability**

- Shift from service provider of lab results to a vital contributor in generating clinical value.
- Apply knowledge of your core competencies that were created in level one and level two to other areas outside the walls of the lab.
- Shift from a state of being held hostage by IT, LIS, HIS, and middleware to one of being proactive and in-charge based on value creation.
- Cost-justify IT projects that integrate essential lab patient info into algorithms that diagnose more accurately and sooner, thus contributing to shorter hospital stays, reduced diagnostic workups, and less chance of readmission within 30 days.

Recognizing Level Three

- Your lab is competent at level three when your reputation and outcomes are recognized outside of your hospital and institution by your peer groups.
- Regular requests for speaking engagements, requests for publications, citations in publications and similar outside recognition start to happen.

Level four: Use Benchmarks to Achieve Best-in-Class

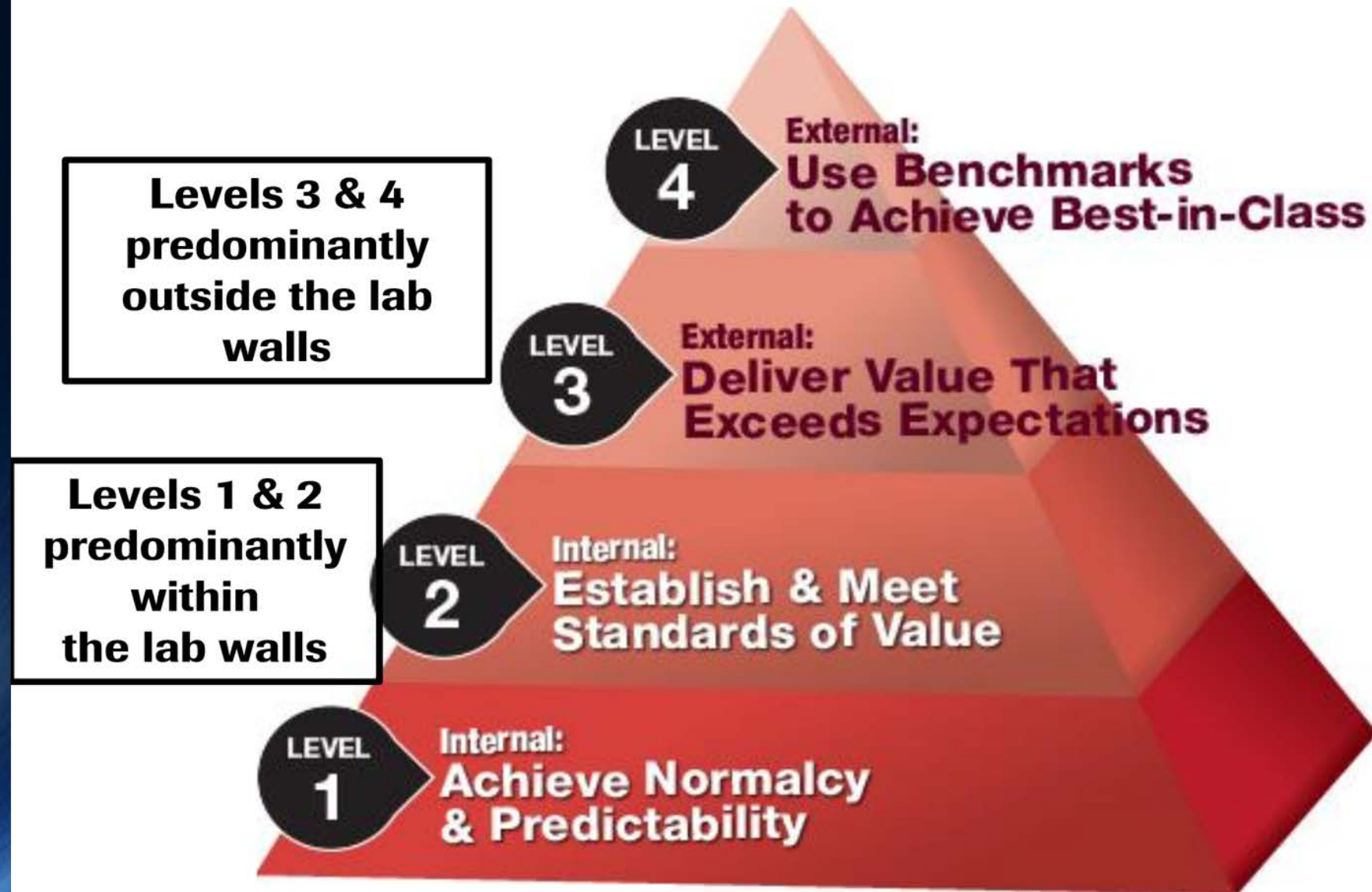


- Your lab's practices and competencies are recognized as best-in-class by your peer groups and third party reviewers.
- You are consulting with other hospitals and systems to help them replicate what you have done within your institution.
- Your lab is recognized as among "the best in the business" because of how your lab team uses all the attributes from the first three levels.
- Extra credit! Your lab has created the **database structure** that allows it to mine the value of lab test data.

Recognizing Level Four

- Your lab is competent at level four when you use third-party benchmarks and your lab ranks in the highest percentiles.
- Your lab can combine its lab test data with large sets of clinical data and identify ways to add value for which hospitals, insurers, and others will pay.

The Four Levels of the Lab Value Pyramid



*Timely, accurate information needed
in real time for Operational and Clinical Success*

Healthcare Big Data, Lab Informatics

- Labs must regain control of information technology.
- Real-time analytics for managing work processes.
- Database capabilities to assemble lab test data with other relevant clinical data.
- Ability to analyze large amounts of data to identify opportunities to improve value of lab test results by helping physicians improve patient outcomes.

Informatics, Big Data, & Labs

- Healthcare big data will address two ends of the care spectrum:
 - ◆ Analysis in support of population health management.
 - ◆ Analysis in support of personalized medicine; diagnosis and treatment of individuals.
- Lab test data is essential in support of both activities.
- Lab test data comprises 70% or more of the average patient's health record.

Delivering More Value with Lab Testing

- Accurate lab results reported on time won't be good enough!
- Labs must help hospitals, physicians use lab tests more efficiently...
- ...to produce better patient outcomes while lowering overall cost of care

Added Value Case Study

How innovative labs and clinicians are leveraging lab tests to improve patient outcomes!

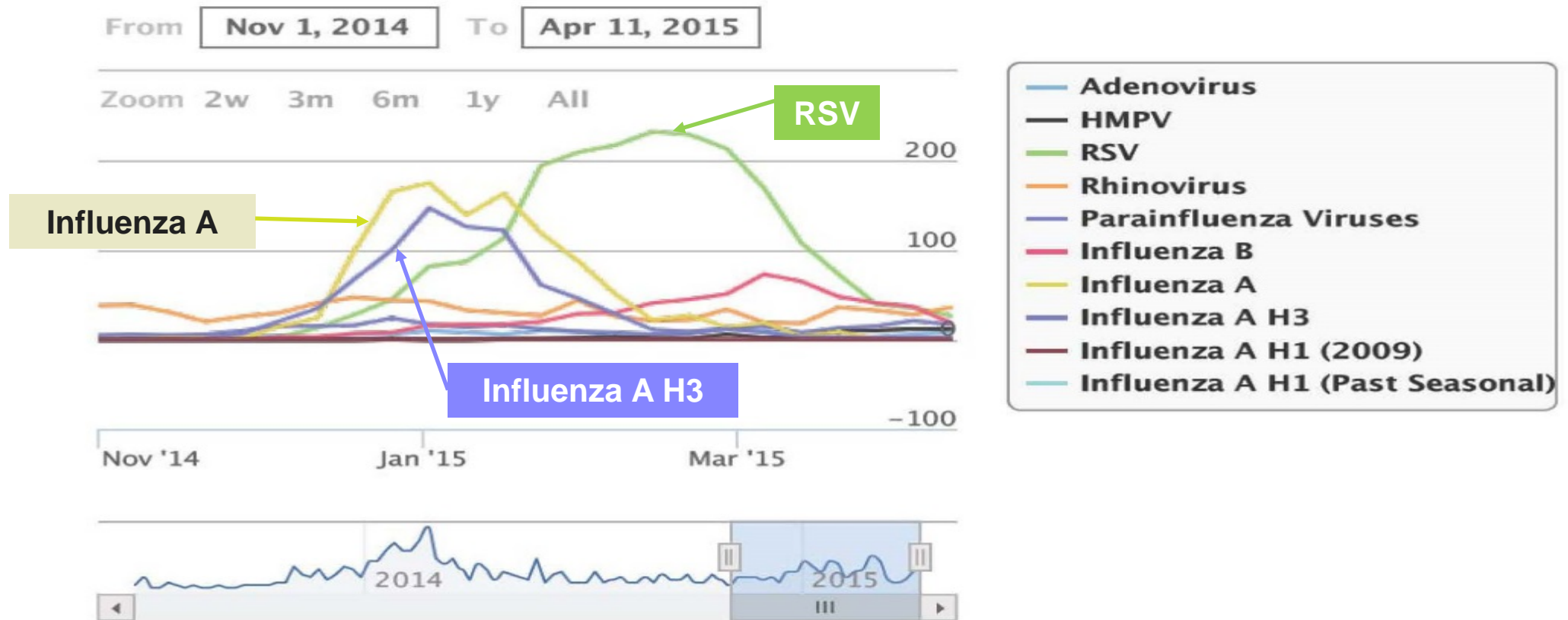
Foundation for this success is robust lab informatics and data analysis capabilities that convert lab data into intelligence that physicians can use.

Big Data Led by the Lab

- Example of TriCore Reference Laboratory in Albuquerque, New Mexico.
- Formed in 1998 by University of New Mexico Health Sciences Center and Presbyterian Healthcare Services .
- Produces 70% of patient lab results in New Mexico.
- Has access to patient clinical data electronic health record (EHR) systems.

What ifyou could detect disease prevalence in real time?

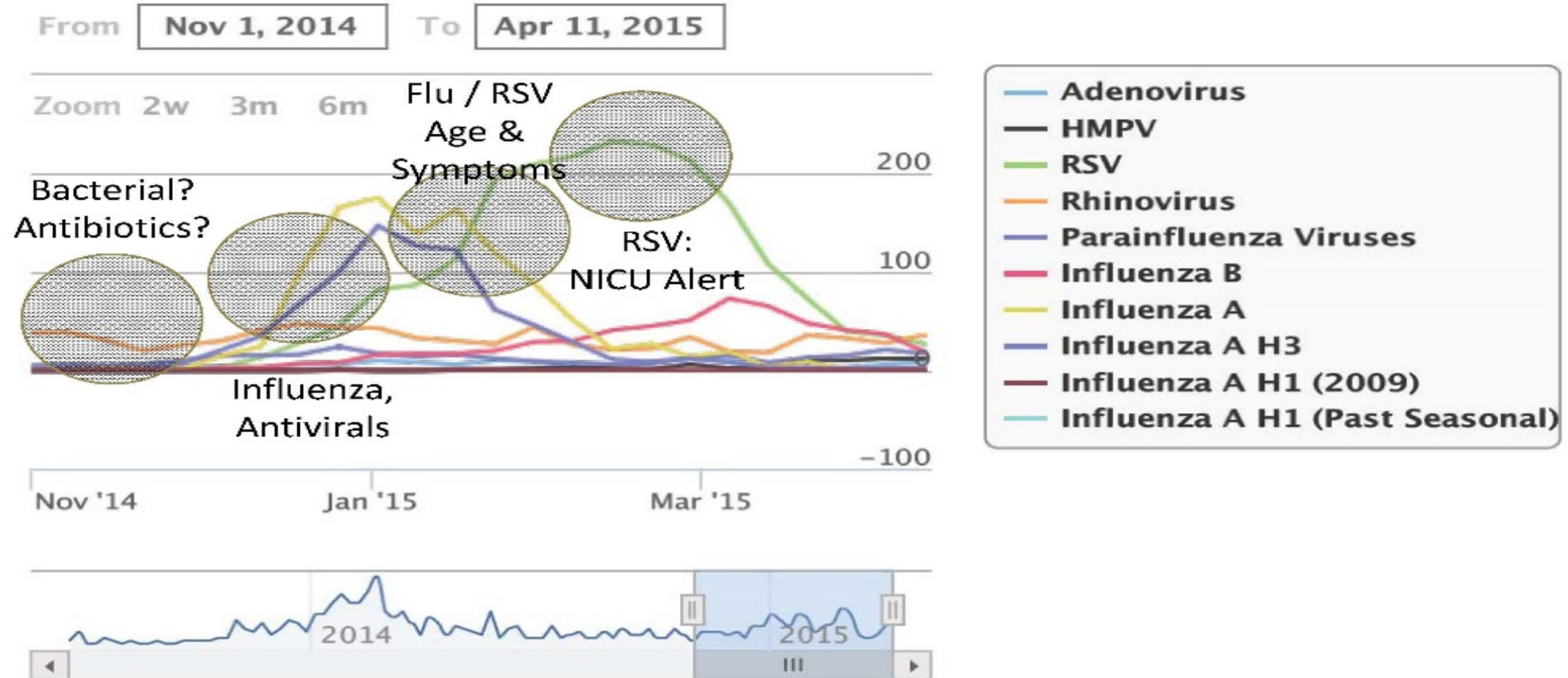
Patients Tested With Upper Respiratory Symptoms



Diagnostic Surveillance

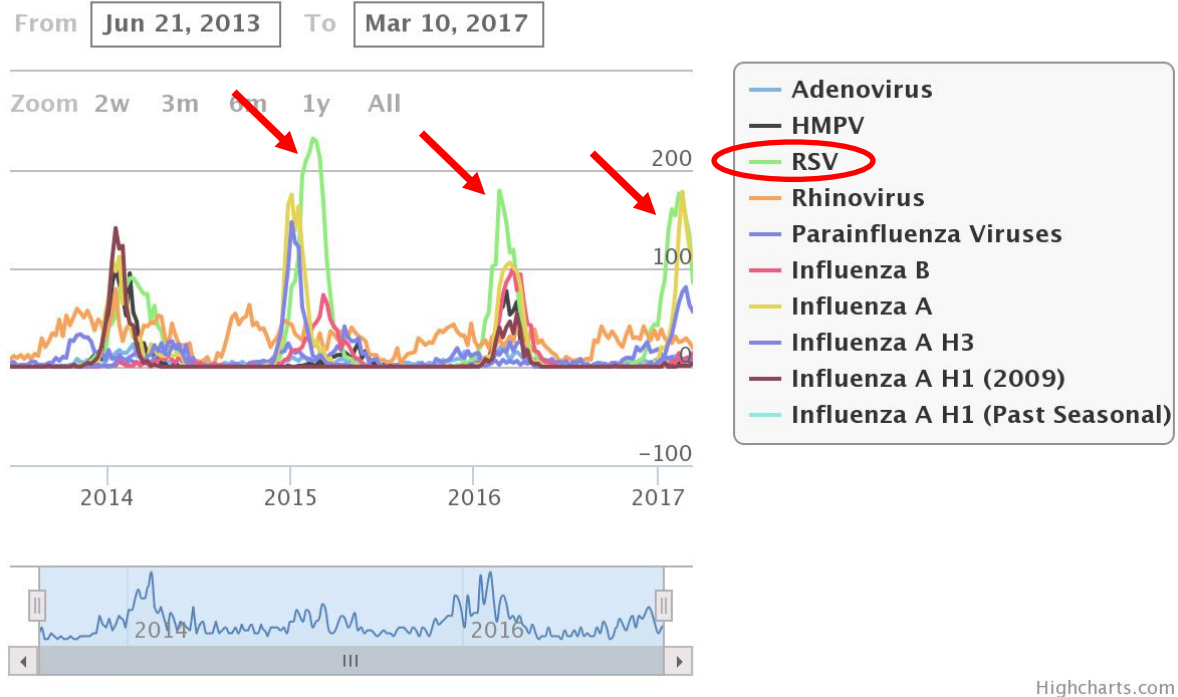
What ifyou could detect disease prevalence in real time?

Patients Tested With Upper Respiratory Symptoms



TriCore 1.0 Infectious Disease Report

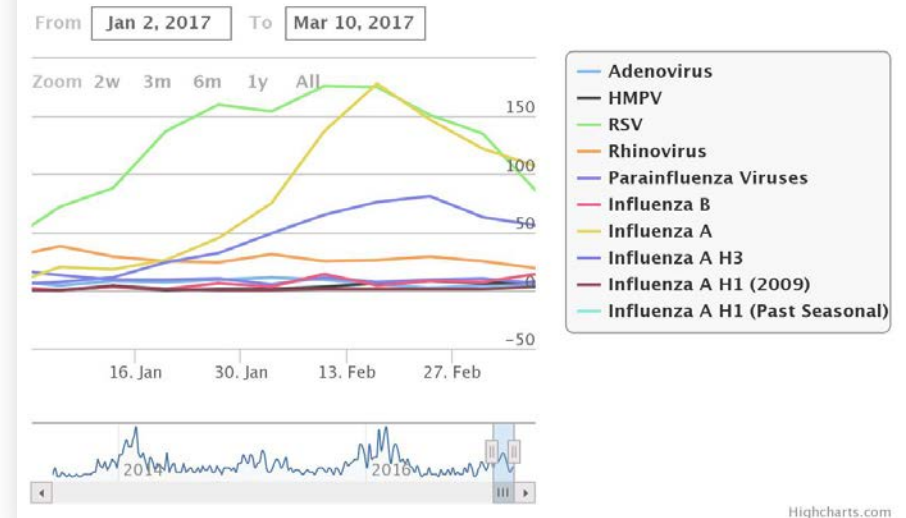
Respiratory Virus Detection by DFA, RVP or Flu/RSV



Features

- Published weekly
- >1,500 subscribers
- Easily modifiable to understand outbreaks

Respiratory Virus Detection by DFA, RVP or Flu/RSV



Disadvantages

- Lacks location identification
- Latent period: Up to a week

Summary—Key Points

- To be BEST-IN-CLASS, labs must:
 - ◆ Develop and use advanced informatics.
 - ◆ Achieve cultural transformation.
- Real-time analytics will drive automation, staff productivity, continuous improvement.
- End game for the successful lab is to use data and information while collaborating externally to improve patient outcomes.
- Remember: labs will be paid on the value they add to patient care.
(*Not for volume.*)

Learning from Lab Innovators



- **Gary W. Procop, MD, MS,**
Enterprise Laboratory
Stewardship Committee,
Cleveland Clinic.



- **Patrick Gontard, PhD,**
Geneva, Switzerland.

Learning from Lab Innovators



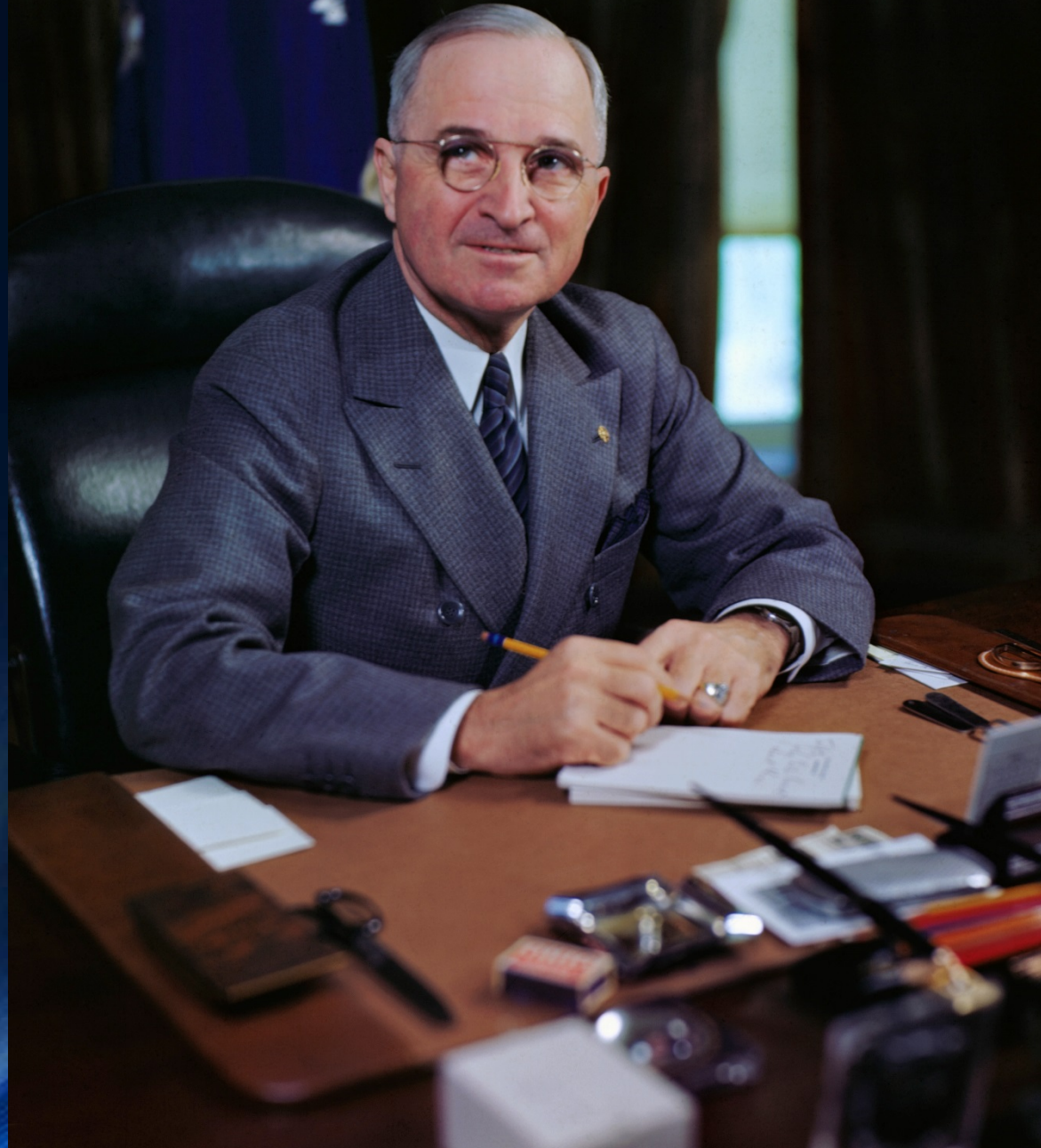
- **Denise L. Uettwiller-Geiger, PhD,**
John T. Mather Memorial
Hospital, Port Jefferson, NY.



- **Bonnie Messinger, CPHQ,** and
David J. Layton, BS, MS,
ARUP Laboratories, Salt Lake
City, UT.



Final Thoughts on Opportunity...



Men make history
and not the other way
around.

In periods where there
is no leadership,
society stands still.

Progress occurs when
courageous, skillful
leaders seize the
opportunity to change
things for the better.

—Harry S. Truman