Proactive Visual Risk Pattern Reporting –
Visual Recognition of Patient Risk with Prescriptive Analytic Diagnostic Informatics

- Rapid Risk Pattern Triage of Complex Patients to Avert Diagnostic Adverse Events
WHY ……………….. Is Proactive Visual Risk Pattern Reporting Needed?

Adverse medical events (AME) are increasing, especially diagnostic and medication errors in High Risk patients.

Healthcare organizations and providers must rapidly detect High Risk, High Cost patients to improve patient outcomes and avoid penalties.

High Risk patients are most vulnerable to AME caused by their Critical Organ Damage.
Is Proactive Visual Risk Pattern Reporting Needed?

“We cannot improve what we do not measure”
“If we keep the patient’s complexity at the center of our thoughts, we will not make mistakes”
“All politics is local - All health care is local”
Clinical Decision Support by Laboratory Medicine needs to be packaged, presented, and explained in more meaningful ways.

Clinical laboratory “flag” for a single lab result it is never as useful as visually displaying that result in the time-based context of a patient’s tests and clinical events profile. Ref. Jackson, Brian

Visual strategies include ranked, severity – graded Significantly Abnormal (SA) biomarker results matched to the Critical Organs/System (COS) that secreted them, caused by cellular damage in those COS

Where to Begin to Avert Diagnostic Medical Error

Optimize the Risk - Mitigating Clinical Value of Common Non – Molecular Biomarkers

in Blood and Body Fluids

For local cohorts of High Risk inpatients and outpatients

Starting with their

Most Common Diseases
Most Common Comorbidities
Most Common Cocomplications
Most Common Diagnostic Adverse Events
Most Common Medication Adverse Events

especially in

Elderly females >65 with multiple chronic conditions

Diagnostic errors are common, greater than medication and surgical errors, and increasing in acute and ambulatory care

“If the diagnosis is not right, then medications will not be correctly prescribed”

Ref. Schiff GD, NEJM 2010;362(12):1066–9

MOST DIAGNOSTIC ERRORS OCCUR IN AMBULATORY CARE 57%
Most frequent missed Dx: Cancer Heart Disease Orthopedic Injury

EMERGENCY DEPT
16%
Most frequent missed Dx:
Orthopedic Injury
Heart disease
Cerebrovascular stroke

INPATIENT CARE
26%
Complications
Heart disease
Cancer

Source: Malpractice Risks in the Diagnostic Process CRICO Strategies, Boston, MA 2014
High Risk Patients are Complex with Critical Organ / System Dysfunction and Polypharmacy leading to the most frequent Diagnostic Errors (DxE)

The most frequent Diagnostic Errors (DxE) are linked to significant dysfunction of major critical organs/systems. Ref. Leape, LL et al, The Nature of Adverse Events in Hospitalized Patients, N Engl J Med 1991; 324:377-384

DxE occur most frequently in high risk patients in critical organs/systems: lung, heart, vascular, blood (inflammation), (endocrine)

Diagnostic Errors do not occur in isolation, they are linked to patient risk co-factors and their interaction with other critical organs

HIGH RISK patient’s DxE can be averted using PATTERNS of common, low tech BIOMARKERS tracking pathophysiologic changes

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary embolism</td>
<td>26 (4.5)</td>
</tr>
<tr>
<td>Drug reaction or overdose</td>
<td>26 (4.5)</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>23 (3.9)</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>19 (3.3)</td>
</tr>
<tr>
<td>Acute coronary syndrome</td>
<td>18 (3.1)</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>18 (3.1)</td>
</tr>
<tr>
<td>Stroke, including hemorrhage</td>
<td>15 (2.6)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>13 (2.2)</td>
</tr>
<tr>
<td>Fracture, various types</td>
<td>13 (2.2)</td>
</tr>
<tr>
<td>Abscess, various locations</td>
<td>11 (1.9)</td>
</tr>
<tr>
<td>Pneumonia, including type</td>
<td>10 (1.7)</td>
</tr>
<tr>
<td>Aortic aneurysm/dissection</td>
<td>9 (1.5)</td>
</tr>
<tr>
<td>Appendicitis</td>
<td>9 (1.5)</td>
</tr>
<tr>
<td>Depression</td>
<td>9 (1.5)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>8 (1.4)</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>8 (1.4)</td>
</tr>
<tr>
<td>Anemia</td>
<td>6 (1.0)</td>
</tr>
<tr>
<td>Bacteremia</td>
<td>6 (1.0)</td>
</tr>
<tr>
<td>Metastatic cancer</td>
<td>6 (1.0)</td>
</tr>
<tr>
<td>Spinal cord compression</td>
<td>6 (1.0)</td>
</tr>
</tbody>
</table>
Q. Who is the FIRST to have scientific, quality – controlled knowledge of a patient’s significantly abnormal high risk test results?

Q. Who is the FIRST earliest interpreter of the patient’s significantly abnormal high risk test results?

Q. Whose responsibility is it to rapidly identify multiple significantly abnormal test results and translate them into useful language for clinical physicians?

Q. Who has the analytic & informatics tools to decide the level of clinical significance of multiple abnormal or positive results at the time of reporting? A person or a machine? Clinical significance levels drive therapy.

Q. Where is the balance between strict reporting of uninterpreted abnormal, or positive results and interpretation of the significantly abnormal results that alert a clinical physician to promptly initiate needed treatment?

Q. Where is the dividing line between reporting masses of positive data vs reporting data that assures patient safety?
The Emergence of *Diagnostic Science* in High Risk Care Management

*Introducing Disruptive Innovative Technologies*

The idea solves problem(s)

People want to use it

It is easy to use

Bigger isn’t always better

*Disruptive Innovative Technologies are typically simpler, cheaper, more reliable and convenient*

Than Sustaining Established Technologies

**Predictive Diagnostic Informatics Add Value Beyond Test Results**

**GOAL:** Rapidly Separate High Risk, High Cost (35%) from Low Risk, Low Cost patients (65%)

Laboratory Medicine – directed, Proactive interventions are highly effective

**METHOD:** Rapid Visual Image Reports convert raw test results to **High Risk Patient Metrics**

*Measure what matters*
*Measure to gain knowledge*
*Report What Matters For Physicians*

What Matters for C – Suite and Risk Management

Pathophysiology and Severity level of COS damage in High Risk patients
Point of Encounter Data Interpretation
Daily severity level track & trend graphics thru treatment & acute care course

Hospitals Must Rapidly Triage ID High Risk Patients to Avoid Stiff Penalties for Poor Patient Outcomes

They Need a “Risk Oversight” Preventive Informatics platform in a recurring High Risk Data Base for:
Early recognition of patient recidivism for rapid ID of new High Risk patients
High Risk Patient Metrics
Intensifies Clinical Decision Support to Avert Adverse Diagnostic Events

1. Patient’s *Significantly Abnormal* Clinical and Blood Biomarkers
2. The Patient’s *Number & Location of Interactive Critical Organ Comorbidities*
3. The Patient’s *Number of Medications and Medication Classes*
4. The Patient’s *Significantly Abnormal* Biometric Indicators

Staging Phases for Biomarkers as Risk Signal Markers

Risk marker: A risk marker is associated with the disease; it may be a measure of the disease process itself.

Patients with *common diseases* using *common medications* can be protected from adverse events using patterns of abnormal *common* biomarkers, using successive staging tools:

1. Signal Detection
2. Signal Strength Measurement
3. Signal Integration
4. Pattern Recognition of Targeted Signals
THE CLINICAL VALUE OF LAB MEDICINE DIAGNOSTIC DECISION SUPPORT

CHANGE THE PARADIGM ........

FROM ANALYTIC QUALITY by MACHINES to CLINICAL KNOWLEDGE VALUE by HUMANS

FROM PASSIVE DATA DELIVERY to PRESCRIPTIVE, VISUAL KNOWLEDGE

Single Biomarker Results do not make a Diagnosis

PATTERNS of Simple, Non-Molecular Biomarkers are “Trigger Signals” for Common Diagnoses

Proactive Visual Risk Pattern Reporting of “a vital few” CORE critical biomarkers using pattern recognition is "Reporting Wisely©"

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As with a fingerprint, one line does not identify the individual, neither does a single biomarker test identify a disease or illness.

Ref. Ryback RS, Rawlings RR, Quadratic Discriminant Analysis as an aid to interpretive reporting of clinical laboratory tests, JAMA 1982; 2489 (18): 2342-45
Pattern Formation with Single Biomarkers

Biomarker results on blood and body fluids “cluster” into characteristic patterns for each diagnostic entity

Ref: Boyd JC, Pattern Recognition to assist in Test Interpretation, Clinical Laboratory Medicine, 1982;2(4):717-34
Risk Trigger Signals
Simultaneous detection & Severity grading of Multiple, Significant Abnormal biomarkers
Discriminant Pattern Analysis of Significantly Abnormal Blood Biomarkers
Targeted Combinations of Patient-Specific Test Results (Patterns)
Patterns of abnormal biomarker results infer pathophysiologic dysfunction
“Trigger Signal” Pattern Recognition Correlation
Significantly Abnormal (SA) Biomarker results “cluster” into characteristic patterns for each disease entity
Patterns of abnormal biomarker results infer pathophysiologic dysfunction
Rapid Visual Image Reports of Significantly Abnormal (SA)“Risk Trigger Signals” focusing on Critical Organ/System pathophysiology
Cybernetics incorporates a change in a closed, local signaling loop, where action is reflected in (feedback) that triggers a larger system change.

WHICH Informatics Metrics Tools Support Early Detection of High Risk Patients?

- Signal Detection
- Signal Severity Grading
- Signal Integration into Patterns
- Pattern Match with Critical Organs

Risk Trigger Signals
Simultaneous detection & Severity grading of Multiple, Significant Abnormal biomarkers
Discriminant Pattern Analysis
Targeted Combinations of Patient-Specific Test Results (Patterns)
Patterns of abnormal biomarker results infer pathophysiologic dysfunction
Rapid Visual Image Reports of Significantly Abnormal (SA) “Risk Trigger Signals” focusing on Critical Organ/System pathophysiology
Cybernetics incorporates a change in a closed, local signaling loop, where action is reflected in (feedback) that triggers a larger system change.

Detection of High Risk Patients?
Q. WHAT is the Value of Visual Risk Pattern Triage for Laboratory Medicine?

Creates a “First Responder” role for Laboratory Medicine professionals to create value in the care pathway, with Pathophysiologic Risk Finding

More complex tasks that require critical thinking
Decision support analysis of high value results
Risk triage and real – time tracking/trending of risk acuity levels
Risk severity level staging for interactive multiple critical organ damage
Preemptive mitigation of adverse medication effects

Relative prevalence of various covariates that influence pharmacokinetics

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Young adults</th>
<th>Elderly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver disease</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Renal disease</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>++</td>
<td></td>
</tr>
<tr>
<td>Polypharmacy</td>
<td>+</td>
<td>+ +++</td>
</tr>
</tbody>
</table>
The interactive effect of comorbid conditions is "The Domino Effect Principle" caused by interactive multiple chronic diseases.

1. Malfunction of one organ system affects another

2. Multiple disease states induce multiple abnormal biomarker production

3. Two or more coexisting diseases suggests an underlying common etiological pathway that influences clinical care.

The Value of Interpreting Pathophysiologic Risk Data

The evidence base for use of physiologic data in risk adjustment is overwhelming

Increasingly available, particularly in hospital chains
Unexpected advantage of using lab values in model
Ability to create metrics related to labs
Much less expensive than manual chart abstraction
Has tremendous face validity with clinicians
Relatively easy to combine with other data

Ref. Gabriel Escobar, November 3, 2008, Annual AHRQ Conference,
The most commonly involved organs/systems with combined dysfunction caused by interactive comorbidities are:

- Hepatic
- Renal
- Cardiac
- Blood - Inflammation
- Blood - Acid Base
- Blood - Volume
- Blood - Cells
- Metabolic/Endocrine
- Pulmonary organs/systems.


Pathophysiologic Induction of Comorbid Critical Organ Dysfunction by Pathophysiologic Connectivity Of Critical Organs & Systems (COS)

COS Pathophysiologic CELLULAR DAMAGE produces multiple abnormal biomarkers
Common, non-molecular, **significantly abnormal** Biomarkers are the first sentinel “Trigger Signal” indicators of critical organ/system dysfunction (COD).

COD creates High Risk pathophysiologic states and Interactive Comorbidities in other critical organs, caused by the first organ, create more abnormal biomarkers.

Abnormal Biomarkers often occur in PATTERNS. Errors overlap and cluster into certain patterns of errors.


Laboratory Medicine’s **Risk Pattern Recognition** of significantly abnormal common biomarkers is the physician’s earliest sign of multiple organ dysfunction in a complex patient.
The Health Care Site’s “High Risk First Responder” is Laboratory Medicine
There is a Great Need for Bidirectional Data Flow

**“REPORTING WISELY”**
to PHYSICIANS
Graded, Interpreted, Correlated Results

**CHOOSING WISELY**
Targeted Diagnostic Orders
Established by Local Expert Interdisciplinary Team Physicians

Diagnostic Test Data Provider
“FIRST RESPONDER”

Clinical Physicians

Chasm of Heuristic Uncertainty

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### Examples of Disruptive Paradigm Change

<table>
<thead>
<tr>
<th>Infrequently or no longer used</th>
<th>Replaced by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pony Express</td>
<td>Telegraph</td>
</tr>
<tr>
<td>Longhand personal letters</td>
<td>Electronic mail, texting devices</td>
</tr>
<tr>
<td>Black &amp; White TV/movies</td>
<td>Color/Technicolor</td>
</tr>
<tr>
<td>Audio weather reports on</td>
<td>Visual Color gradient weather</td>
</tr>
<tr>
<td>radio, once daily</td>
<td>maps, 24/7</td>
</tr>
<tr>
<td>Hard copy, uninterpreted</td>
<td>Severity – graded, color – coded</td>
</tr>
<tr>
<td>Black &amp; white test reports</td>
<td>graphic images “fast tracked”</td>
</tr>
<tr>
<td></td>
<td>to clinicians</td>
</tr>
</tbody>
</table>
Types of Data Analytics

Example

Diagnostic – Why did this result happen? What went wrong? Diagnostic test report
Descriptive – Answers the question....What happened? Proactive interpretation of results
Predictive – Provides insight into a future event
  - Uses signal strength detection tools to find sentinel risk biomarkers
  - Measures degree of critical organ damage (COD)
  - Pinpoints and correlates multiple sites of COD
  - Matches COD with patient’s medications and clinical risk cofactors
  - Creates organ – specific patterns of significantly abnormal biomarkers

Prescriptive – Optimizes and structures Visual Risk Pattern reporting through Informed estimation of what will happen.

Visual Risk Pattern Recognition Informatics Visualizes patient critical organ/system risk severity levels in color – coded reports to physicians that ranks the greatest to the least dysfunction


Pattern Recognition Analysis Combines Significantly Abnormal (SA) “Trigger Signal” data inputs using local expert – designed Risk Pattern Training Sets with a locally – designed Application Processing Interface (API)
TARGETING “TRIGGER SIGNALS” OF DIAGNOSTIC ADVERSE EVENTS (DxE) WITH THE PARETO RULE (80/20 RULE)

Clinical Experts reduce XS data to 40 – 50 CORE CRITICAL “Trigger Signal” Patterns

Data Reduction from 80% to .................................................. 20%

Expert Clinicians

Choose the Vital Few Trigger Signal Indicators for the Site’s Most Common High Risk Patient’s Diseases

Lab Medicine Experts

Report Visual Trigger Signals in Risk-Graded Patterns Related to Organ/System Pathophysiology

Report Optimized “Trigger Signal Patterns” Targeting the Site’s Patients at High Risk for Diagnostic Adverse Events

The Trivial Many

Physician Choices
13,000 diagnoses
4,000 med–surg procedures
4,000+ tests on blood, fluids, cells
2,500+ radiol/imaging tests
25,000+ medications & therapeutics

The Vital Few Core Critical Biomarkers

Clinical Experts reduce XS data to 40 – 50 CORE CRITICAL “Trigger Signal” Patterns
Very Few Common Biomarkers are Needed to Provide “Trigger Signals” of Diagnostic Error

<table>
<thead>
<tr>
<th>Critical Org/System</th>
<th>CORE Critical Biomarkers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygenation</td>
<td>pO2, pCO2, Hgb, Hct, SaO2</td>
</tr>
<tr>
<td>Acid Base</td>
<td>pH, pCO2, Na, K, Cl, HCO3, lactate, AG</td>
</tr>
<tr>
<td>H2O Balance</td>
<td>Osmolality</td>
</tr>
<tr>
<td>Hemostasis /Coag</td>
<td>PLT, PT, D-dimer, FDP</td>
</tr>
<tr>
<td>Inflammation</td>
<td>WBC, PMN, Bands, LYM</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>cTn, BNP, NTproBNP,</td>
</tr>
<tr>
<td>Tissue Perfusion/</td>
<td></td>
</tr>
<tr>
<td>Distribution</td>
<td></td>
</tr>
<tr>
<td>Metabolism (endo)</td>
<td>lactate</td>
</tr>
<tr>
<td>Metabolism (hep)</td>
<td>Glu, HbA1c, Ketones, Ca,</td>
</tr>
<tr>
<td>Excretion</td>
<td>ALT, AST, Br, AlkP, TP, Alb</td>
</tr>
<tr>
<td></td>
<td>Cr, CrCl, Ur microalb, UrOsm</td>
</tr>
</tbody>
</table>
Multiple Sentinel Biomarkers in Patterns Integrate Pathophysiologic “Trigger Signals” into a Unified Picture of Patient Risk


Multiple biomarker tests, their correlations and relationships, identify an illness

Ref. Ryback RS et al, Quadratic Discriminant Analysis as an Aid the Interpretive Reporting of Clinical Laboratory Tests, JAMA 1982; 248(18):2342-45
Physician’s Pattern Recognition of Targeted, Significantly Abnormal Biomarker “Trigger Signals”

Pattern Recognition allows physicians to make a diagnosis with a single glance
The overall pattern is recognition by “Gestalt” Ref. Cutler, p 152

The Gestalt Laws of Organization describe how people perceive visual components as organized patterns or wholes, instead of many different parts. "Gestalt" is a German word that partially translates to "configuration or pattern" along with "whole or emergent structure.”

Ref, Wikipedia, Science

The whole brain’s Default Mode Network initiates physician’s predictions and simulations that unite information from the past, constructed as concepts, to form predictions about the present as categorization patterns.
Anomaly Detection Using Pattern Recognition

All the real knowledge which physicians possess, depends on methods by which they distinguish the similar from the dissimilar ("anomalies")

Anomaly detection identifies patterns in a given dataset that do not conform to normal behavior, by using Discriminant Pattern Analysis (DPA) of Significantly Abnormal (SA) Blood Biomarkers provides Medical Decision-Making (MDM) data patterns by simultaneous evaluation of organ/system-specific SA

Physicians think in clusters (patterns) of "Trigger Signals" to make diagnoses

Laboratory Medicine DPA deploys "Trigger Signal" Pattern Recognition informatics to "cluster" SA Biomarker results into characteristic patterns for each disease


Pattern Recognition Analysis is used to expedite anomaly detection in the patient's data
**PATTERNS of Simple, Non-Molecular Biomarkers are “Trigger Signals” for Common Diagnoses**

**Evidence Supporting Patterns of Common, Non-Molecular Biomarkers Predicting High Risk States**

- **Acute Heart Failure**
  - BP/HR
  - SaO2
  - cTn
d  - K >4.6
  - Age
c  - K <3.9
  - Cr ↑1mg/dl

- **CHF**
  - BNP
  - NT-pBNP
  - Microalb
  - CRP

- **CHF vs Acute Dyspnea**
  - BNP >500μg/l

- **CHF very likely**
  - NTpBNP >1800
  - BNP <100μg/l

- **CHF improbable**
  - NTpBNP <300

- **COPD**
  - ↑BUN
  - ↑Alb
  - ↑PaCO2

**Evidence-Base**

- DeFilippi C, Circulation 2004;
- Palazzoli A
Severity Scoring Systems Predict Degree of Abnormality

Quantitative Measurement of Organ/System Dysfunction

Signal strength, the degree of abnormality of a biomarker is useful:

- **Significantly Elevated**
- **Significantly Decreased**
- **Significant Abnormal (SA)**

Local test site Reference Limits

- Extremis
- Severe 3+
- Mod Dysf 2+
- Mild Dysf 1+
- 0
- Mild Dysf -1
- Mod -2
- Severe -3
- Extremis -4

A test result value of ten times above or below the reference range limit is much more likely to be clinically significant than one that is only slightly increased.

A test result value of ten times above or below the reference range limit is much more likely to be clinically significant than one that is only slightly increased.

The capacity of a physician to correlate a test result with a clinical problem rises in direct proportion to the degree of deviation from the midrange of the reference range of values.

Great deviations are explainable

Minor deviations have no significance

Ref. Harwood & Cole JAMA 1978
The Purpose of Diagnostic Visual Analytics to Predict High Risk States

WHY Clinical Decision Support information for physicians needs to be displayed visually:

Visual color – coded patterns are perceived faster by the brain, than numbers

Doctors don’t like numbers
Physicians have difficulty understanding a host of numerical concepts

Clinical Decision Support information needs to be displayed visually because

Risk prediction happens, when the physician associates objects and the color Red with danger.
Ref Barrett, p.129 -130

The brain’s visual cortex neurons increase their firing rate when visualizing the color Red.

For the physician’s brain to convert a visual image into the experience of red, it must possess the concept “Red”

Prior visual stimuli that are red in color creates the concept “Red” from prior experience with other red objects with a wavelength of 600 – 625 nm.
Signal vs Noise Graph

STRONG SIGNAL > 10x Ref Level

Test Result Reference Limit
Dysfunction Levels

↑4
BNP 11213

↑3
SaO2 78%

↑2
K 5.8
PMN 79

↑1
CO2 22.7
pH 7.47

0
Temp 36.1

↓1

↓2

↓3

↓4

NOISE
(weak signal)
The Cognitive Value of Lab Medicine Color – Coded Risk Levels for Rapid Action by Clinicians

INTERPRETATION BY LOCAL LAB

- 10x
- 10X

HIGH RISK “TRIGGER SIGNALS” OF CRITICAL ORGAN/SYSTEM DAMAGE – RESULTS ARE 5 X to 10X > or < REFERENCE LIMITS

- 5x
- 5X

MODERATE DEGREE OF ORGAN/SYSTEM DYSFUNCTION

- Yellow

MILD DEGREE OF ORGAN/SYSTEM DYSFUNCTION

- Green

RESULTS ARE WITHIN LOCAL TEST SITE’S REFERENCE LIMITS
The color code, relates to one's state of mind as an indication of mental state preparedness. Col. J.D.Cooper USMC used it to relate to the degree of peril one needs to do something about, and which allows one to move from one level of mindset to another to enable proper management of a given situation. The color code helps one "think". Information is encoded by the brain based on the position of the colors. As the level of danger increases, one's willingness to take certain actions increases. One is not in any color state because of a specific threat or danger, but rather in a mental state which enables taking a difficult psychological step.
### Why Proactive, Visual Reports Should Replace Passive, Uninterpreted Raw Data Reports

Both Report Raw Data without New Knowledge

#### Traditional Passive, Uninterpreted Test Result Report

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Patient Value</th>
<th>Flaged Result</th>
<th>Reference Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-dimer</td>
<td>500</td>
<td></td>
<td>750 μg/L</td>
</tr>
<tr>
<td>WBC mm3</td>
<td>&lt;2000</td>
<td>*</td>
<td>4500-11,000 Age &gt;60</td>
</tr>
<tr>
<td>Lactate mg/dL</td>
<td>5-15</td>
<td></td>
<td>4500-11,000 Age &gt;60</td>
</tr>
<tr>
<td>pO2(PaO2) mmHg</td>
<td>&lt;40</td>
<td>*</td>
<td>80-95</td>
</tr>
<tr>
<td>pCO2(PaCO2) mmHg</td>
<td>&lt;20</td>
<td>*</td>
<td>35-45</td>
</tr>
<tr>
<td>pH art</td>
<td>&lt;7.2</td>
<td>*</td>
<td>7.35-7.45</td>
</tr>
<tr>
<td>TCO2 mmo/L</td>
<td>5</td>
<td>*</td>
<td>23-30</td>
</tr>
<tr>
<td>HCO3 mmo/L (venous)</td>
<td>&lt;15</td>
<td>*</td>
<td>22-26</td>
</tr>
<tr>
<td>Cl mmo/L</td>
<td>&lt;80</td>
<td>*</td>
<td>97-107</td>
</tr>
<tr>
<td>Na mmo/L</td>
<td>&lt;125</td>
<td>*</td>
<td>135-145</td>
</tr>
<tr>
<td>K mmo/L</td>
<td>&lt;2.5</td>
<td>*</td>
<td>3.5-5.0</td>
</tr>
<tr>
<td>pH ven</td>
<td></td>
<td></td>
<td>7.32-7.43</td>
</tr>
<tr>
<td>pCO2 mmHg (ven)</td>
<td></td>
<td></td>
<td>38-50</td>
</tr>
</tbody>
</table>
NEW KNOWLEDGE and VALUE is added with Human Interpretation of Raw Data

THE NEW PATIENT – SPECIFIC REPORT

REPORTING WISELY

A PROACTIVE, VISUAL, RISK-STRATIFIED REPORT

<table>
<thead>
<tr>
<th>Patient's Significant Abnormal Biomarkers</th>
<th>Low Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal</td>
<td>Abnormal</td>
<td>Abnormal</td>
</tr>
<tr>
<td>Low Risk</td>
<td>High Risk</td>
<td>Very High</td>
</tr>
</tbody>
</table>

RESULTs WITHIN LOCAL TEST SITE'S REFERENCE LIMITS

COLOR CODE FOR SIGNIFICANTLY ABNORMAL BIOMARKERS
- Minimal
- Mod Severe
- Severe
- Elevated >5X Reference Limit
- Life-Threatening ELEVATED > 10X Reference Limit
Visualization promotes easier data consumption

Caban JJ, Gotz D. Visual analytics in healthcare—opportunities and research challenges. J Am Med Inform Assoc 2015; 22 (02) 26

Four primary criteria are needed to define Patient Risk Vulnerability Criteria

1. CAUSE Find the etiology(ies) of the disease

2. LOCATION Each patient risk factor’s origin must be related to a Critical Organ/System

3. PATHOPHYSIOLOGY Each organ/system must have characteristic pathophysiologic changes

4. SEVERITY The severity level of the patient’s Significantly Abnormal biomarkers are graded on a risk scale. using test reference limits
<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
<th>Low morbidity/mortality (M/M) risk</th>
<th>Biomarker changes minimal</th>
<th>Biomarker changes moderate to severe</th>
<th>Biomarker changes severe to life-threatening</th>
<th>Biomarker changes signal impending mortality if no action</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>No complications or comorbidities</td>
<td>Low</td>
<td>minimal</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Disease limited to one organ or system</td>
<td>Increased</td>
<td>moderate to severe</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Organ/system involvement</td>
<td>Great</td>
<td>severe</td>
<td>3</td>
<td>changes to life-threatening</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>Highest risk of CC/CM with life-threatening potential</td>
<td>Ultimate</td>
<td>signal impending</td>
<td>4</td>
<td>mortality if no action</td>
<td></td>
</tr>
</tbody>
</table>
Visual color–coded patterns are perceived faster by the brain’s primary visual cortex (V1), than numbers.

Doctors don’t like numbers

Physicians have difficulty understanding a host of numerical concepts


V1 acts as the primary relay station for visual input, transmitting information to two primary pathways labeled the dorsal and ventral streams. The dorsal stream includes areas V2 and V5, and is used in interpreting visual ‘where’ and ‘how.’ The ventral stream includes areas V2 and V4, and is used in interpreting ‘what.’ Neurons in extended V4 provide input to the inferior temporal lobe. “IT” cortex is thought to integrate color information with shape and form.
Severity-Graded “Trigger Signals” Point to Adverse Events
Day 1, Admission Biomarker Results – Case 12-2010

<table>
<thead>
<tr>
<th>Clinical</th>
<th>Scientific Biomarkers</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>AB</td>
</tr>
<tr>
<td>H2O</td>
<td>Bcoag</td>
</tr>
<tr>
<td>Bni</td>
<td>C</td>
</tr>
<tr>
<td>Mhep</td>
<td>Mend</td>
</tr>
<tr>
<td>E</td>
<td></td>
</tr>
<tr>
<td>Airway</td>
<td>AcidB</td>
</tr>
<tr>
<td>Pulm</td>
<td>Blood</td>
</tr>
<tr>
<td>H2O</td>
<td>Blood</td>
</tr>
<tr>
<td>Hemo</td>
<td>InflammCirc</td>
</tr>
<tr>
<td>Metab</td>
<td>Metab</td>
</tr>
<tr>
<td>Excr</td>
<td>Endoc Renal</td>
</tr>
<tr>
<td>†&lt;sub&gt;SaO2&lt;/sub&gt; 78%</td>
<td></td>
</tr>
<tr>
<td>↑JVP14cm</td>
<td></td>
</tr>
<tr>
<td>BP105/43</td>
<td></td>
</tr>
<tr>
<td>P 60 paced</td>
<td></td>
</tr>
<tr>
<td>R 28</td>
<td></td>
</tr>
<tr>
<td>↓ urine</td>
<td></td>
</tr>
<tr>
<td>↓ somn</td>
<td></td>
</tr>
<tr>
<td>SOB ↑</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BNP 11213</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cr 2.7</td>
</tr>
<tr>
<td>BUN 74</td>
</tr>
<tr>
<td>K 5.8</td>
</tr>
<tr>
<td>Hgb 39.6</td>
</tr>
<tr>
<td>CO2</td>
</tr>
<tr>
<td>Hct 12.9</td>
</tr>
<tr>
<td>Glu 276</td>
</tr>
<tr>
<td>P 5.1</td>
</tr>
</tbody>
</table>

Severity Level:
- Extremis
- Severe
- Dysf
- Mod
- Severe
- Dysf
- Mild
- Dysf
- Within
- Ref Int
**HOW to Do It?**
Focus on the Risk Detection Power of Patterns of High Value

Use FREE SOFTWARE: R., Python, Excel

Create a Local customized application processing interface (API)
Data Interface Integration Capability
Focus on “Significantly Abnormal” (SA) Scientific Biomarkers

1. Locally – Designed, Expert Approved Clinical and Scientific Risk Patterns

2. Clinical specialists reduce XS biomarker data to 40 – 50 CORE CRITICAL “Trigger Signal” Patterns

3. Use desktop and software programs that allow for order entry, local expert rules management software and middleware

4. The software should include the local care site’s Clinical Expert interdisciplinary team’s choices for Risk Patterns needed for early triage of high risk patients
Clinical laboratory reports traditionally “flag” a single lab result, but it is not as useful as visual display.
## Critical Organ/System Origin & Cause of Significantly Abnormal Clinical & Scientific Severity – Graded Biomarkers

<table>
<thead>
<tr>
<th>Critical Organs &amp; Systems (COS)</th>
<th>Pathophysiologic</th>
<th>Subjective</th>
<th>Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>A - Pulmonary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-Airway</td>
<td>Hypoxia</td>
<td></td>
<td>CO2 22.7</td>
</tr>
<tr>
<td>B - Acid base/electrolyte</td>
<td>Ischemia/Infection</td>
<td></td>
<td>K 5.8</td>
</tr>
<tr>
<td>B - Blood Oxygenation</td>
<td>Hypoxia</td>
<td></td>
<td>Hgb 39.6</td>
</tr>
<tr>
<td>C - Cardiac Circulatory</td>
<td>Cardiogenic Shock</td>
<td></td>
<td>BNP 11213</td>
</tr>
<tr>
<td>D - GI</td>
<td>Diarrhea/Vom</td>
<td></td>
<td>P 60 paced</td>
</tr>
<tr>
<td>E - Excretion</td>
<td></td>
<td></td>
<td>Cr 2.7</td>
</tr>
</tbody>
</table>

### Notes
- **Subjective** includes clinical and scientific data.
- **Objective** includes biomarkers.

The critical organs and systems are ranked by degree of mortality and morbidity for the patient.
Griner emphasized the need to know the diagnostic value of the degree of abnormality of a test and the reliability of the test’s interpretation. Ref. Griner PF, Panzer RJ, Greenland P, Clinical Diagnosis and the Laboratory, Year Book Medical Publishers, Inc, Chicago IL 1986, p. xii-xiv

A Clinical Decision Level is needed for patient management - a threshold value used to warn of significant pathophysiologic effects caused by Critical Organ dysfunction.

At the time of patient encounter, physicians need to have scientific data documenting:

- the type and number of a patient’s pathophysiologic abnormalities
- the degree of pathophysiologic abnormality of each disease/condition,
- and the patient’s CLINICALLY SIGNIFICANT ABNORMALS
### Medical Diagnostic Error (DxE) Risk Aversion Targets

<table>
<thead>
<tr>
<th>Risk Cofactors</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Cumulative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Risk Aversion Targets</strong></td>
<td>Age +</td>
<td>Gender +</td>
<td>Basal Metabolic Index +</td>
<td>No of Meds +</td>
<td>Medication +</td>
<td>Classes +</td>
<td>Organ/System</td>
<td>Abnormal Biomarkers</td>
<td>No. of Significantly</td>
<td>Patient Risk</td>
<td>Severity Level</td>
</tr>
<tr>
<td><strong>Risk Level</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ultimate</td>
<td>4</td>
<td>90</td>
<td>M</td>
<td>46 - 47</td>
<td>18 - 12</td>
<td>10+</td>
<td>Hospital</td>
<td>Amb Care</td>
<td>7 - 9</td>
<td>8 - 10</td>
<td>Ultimate</td>
</tr>
<tr>
<td>4</td>
<td>80</td>
<td>F</td>
<td>46</td>
<td>9</td>
<td>Hematologics</td>
<td>Steroids</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Severe</td>
<td>3</td>
<td>70</td>
<td>F</td>
<td>45</td>
<td>3 - 5</td>
<td>Cardiovasc Rx</td>
<td>Anticoagulants</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>60</td>
<td>M/F</td>
<td>44</td>
<td>2 - 4</td>
<td>CNS Agents</td>
<td>Antidepressants</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Moderate</td>
<td>2</td>
<td>30</td>
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</tr>
<tr>
<td>1</td>
<td>20</td>
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<td>1 - 2</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Low</td>
<td>1</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Basic Elements for Local Construction of a Dashboard Diagnostic Report

RANKED CRITICAL ORGANS AND SYSTEMS WITH SIGNIFICANTLY ABNORMAL BIOMARKERS

 Ranked by Degree of Mortality and Morbidity for the Patient

NON SIGNIFICANT BIOMARKERS

SEVERITY–GRADED LEVEL OF SIGNIFICANTLY ABNORMAL CLINICAL AND SCIENTIFIC BIOMARKERS

A pulmonary
B acid base/elec
B oxygenation
B inflam/immun
B coagulation
C cardiovasc
CNS
D gi distribution
A gi absorption
M endocrine
M hepatic
E excretion

X axis

Y AXIS
**Best Practices for Designing Useful Proactive Visual Risk Pattern Dashboards**

**KNOW YOUR AUDIENCE and WHAT USERS NEED**

**IT MUST BE SELF – EXPLANATORY and INTUITIVE**

**LESS IS MORE - Fit only the MOST IMPORTANT data on a ONE page**

Use **WHITE space** to allow the eye to focus on the MOST IMPORTANT

Use **FLAT DESIGN** in 2 dimensions with a clean, clutter-free layout

FLOW THE DATA from Top to Bottom and Left to Right

( in Western cultures, and in others, use the culture’s specific norms)

**DRILL DOWN CAPABILITY TO SEE A MORE DETAILED VERSION**

Provide an **interactive link** where users can get more information

---

**Change the reporting format paradigm** from

“factory” to patient-centered risk level reporting machine to human logic, raw, ungraded monochrome data to visual color – coded images

**Simplify, Interpret, Classify, Correlate and Visualize**

High Risk Patient’s Pathophysiologic Data

Evidence base for use of physiologic data in risk adjustment is overwhelming

Increasingly available, particularly in hospital chains

Much less expensive than manual chart abstraction

Has tremendous face validity with clinicians

Relatively easy to combine with other data

Unexpected advantage of using lab values in model

Ability to create metrics related to labs

Ability to link relationships – test results to meds

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Ref. Gabriel Escobar, M.D., Mortality Measurement; What Real Time Lab and Clinical Data Can Contribute to Precision and Predictions, November 3, 2008, Annual ANA Conference,