Arizona Society of Pathologists

Using

in laboratory medicine

to improve operations and outcomes

April 2, 2016

Ron B. Schifman, MD
Southern Arizona VA Healthcare System
Big Data

A buzz word that describes massive amounts of structured and unstructured data, or data that expands or changes rapidly.

Technology (tools and processes) that organization uses to handle and analyze large amounts of data.
Big Data

advertisers - monitoring social media to learn about customer behavior, preferences, or responses to campaigns

financial services - predict risk

hospitals – predict readmission
Big Data

Healthcare Analytics Startups

A New Approach:
Predictive analytics powered by an evidence-based medical graph.

Striving to combine the brilliance of a physician with the analytic power of big data, we've tied hundreds of healthcare data sets together and spent over 20,000 physician hours to build a medical graph: raw big data processed into usable curated big knowledge.
**Real-time Insights**

Provide every doctor at your healthcare center with fast, accurate reports to help them diagnose individual patients with high accuracy and personalized treatment recommendations. We provide these insights across a broad spectrum of disease states and conditions.

Our key objective is to deliver care at:
- **2x Speed**
- **2x Accuracy**
- **1/2 Cost**

**Retrospective Insights**

'Peer Review' shows radiologists the areas where they can improve the most, based on validated predictive models, not just human judgement.

This provides you with a business intelligence dashboard, that can feature:
- Historical and current misdiagnoses
- Missed afflictions
- Accuracy Rates by:
  - Radiologist
  - Affliction
  - Time of Day, Day of Week, Holidays
  - Service Provider
Big Data

Healthcare Analytics

IBM Watson Health Announces Plans to Acquire Truven Health Analytics for $2.6B, Extending Its Leadership in Value-Based Care Solutions.

Liberate Your Data

Bring Together all the Data Necessary to Thrive Through Transformation

Get the Best Information in the Hands of Those That Need It - Today

Leverage the Collective Intelligence of a Network of Leading Care Innovators
Big Data

Healthcare Analytics

IBM Acquires Phytel

BY MARKET
- Accountable Care Organizations
- Physician Practices
- Hospitals
- Health Systems
- Integrated Delivery Networks
- Community Health Centers
- Consultants

BY NEED
- Reduce Total Cost of Care
- Prepare for Value Based Care
- Increase Patient Engagement
- Measure Quality and Outcomes
- Scale Care Management
- Improve Patient Satisfaction
- Reduce Avoidable Readmissions
- Quality for PCMH
- Manage Medicare Risk
- Maximize Your IT Investment

BY PHM

100 Top Hospitals
- Phytel
- Our Platform
- Client Success
- Resources

50 Top Cardiovascular Hospitals
- Our Platform
- Client Success
- Resources

16 Top Health Systems
- Our Platform
- Client Success
- Resources

Effectively scale to provider-led population health providers.

Clinical Analytics
Patient Outreach
Care Coordination

Pressed Release

Backed by Proven, Peer-Reviewed Analytics

IBM Acquires Phytel

Phytel

70 Top Hospitals
- Phytel
- Our Platform
- Client Success
- Resources

50 Top Cardiovascular Hospitals
- Phytel
- Our Platform
- Client Success
- Resources

16 Top Health Systems
- Phytel
- Our Platform
- Client Success
- Resources

Department of Veterans Affairs
**Big Data**

**Healthcare Analytics**

**Epic, Watson at work on interoperability**

IBM Watson Health also collaborates with 14 cancer centers

By Bernie Monegain  |  May 06, 2015  |  10:54 AM

IBM Watson Health is collaborating with Epic and Mayo Clinic to apply cognitive computing capabilities of Watson to EHRs, and also with 1 cancer institutions to reduce from weeks to minutes the ability to translate DNA insights.

Epic has more than 350 customers – some of the largest and most recognized healthcare systems in the world, IBM pointed out in announcing the collaboration – “and they exchanged more than 80 million medical records in the last 12 months, both within and outside the Epic community,” officials.
Big Data
Performance and Value Metrics

Performance Measurement

Patients, employers, and payers alike expect the highest quality of care and value from their providers. The achievement of key performance metrics has become a prerequisite for contract models.

Explores provides a comprehensive Platform and Suite of Applications for measuring ambulatory, inpatient, and specialty care quality, utilization, and outcomes across hundreds of metrics including pre-built libraries for patient centered medical homes, accountable care organizations, disease management, HEDIS, health and wellness, and specialties services.

Risk Adjustment
Explores metric risk adjustment helps level the playing field for the reporting of patient outcomes and adjusting for the differences in severity of illness among patients. We support popular risk adjustment for inpatient and ambulatory models, such as 3M’s APR-DRG and EAPG.

Benchmarking
Explores intra-organization benchmarking provides direct comparisons of key performance indicators, helping to monitor, assess, and improve performance within an organization. Explores also provides inter-organization benchmarks across those who participate in the Explores Network. The combined de-identified data across these members enables organizations to learn together with their peers that are facing similar challenges. Our customers choose us, in part, because of our unique ability to harmonize and curate data at scale, so that the metrics and directives they enable are consistent and accurate.

Up-to-date network-wide reporting and measures relative to performance targets, program return-on-investment, and pinpointed opportunities for continued improvement such as...

<table>
<thead>
<tr>
<th>Leadership</th>
<th>Value-Based Care</th>
<th>Support for GPRO reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Care coordinators</td>
<td>- Medicare Advantage</td>
<td>- Provider scorecards and performance plans</td>
</tr>
<tr>
<td>- Providers</td>
<td>- Employee Health plan</td>
<td>- HCC and proper coding opportunities</td>
</tr>
<tr>
<td>- Program Specific Measure Libraries &amp; Scorecards</td>
<td>- Physician-based HEDIS</td>
<td>- Contract performance</td>
</tr>
<tr>
<td></td>
<td>- Inpatient quality and efficiency</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Utilization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Pre-built Reports &amp; Data Marts</td>
<td></td>
</tr>
</tbody>
</table>
Big Data
Population Health

Population Analytics

Explorys solutions enable insight into populations and contracts relative to past and predicted outcomes and costs. Our value-based-care Program Framework provides insight into population disease burden, utilization patterns, and per-member-per-month (PMPM) costs using a rich combination of claims and clinical data from across the continuum of care. This enables providers and health plans alike to assess risk and pinpoint opportunities to mitigate it.

Pre-built Programs
Explorys provides modifiable templates for major value-based-care programs making it easy to launch quickly.
- Medicare Shared Savings Program ACO
- Commercial ACOs
- Medicare Advantage
- Patient Centered Medical Homes (PCMH)
- Employee Health Plans

A Wide Range of Risk Models
Because Explorys provides a true platform, our model makes the most sense for their initial myriad of options, including 3rd party, com
- Population profiles including sex, age stratification, and share of chart.
- Historical utilization including cost and utilization, and EBM distribution across risk and projected utilization such as condition.

The Explorys Risk Model
Explorys clients have an option to implement analytic and population health management in-class performance (both the R2 and MAF analytics applied to a richer data set).

When done well, population management improves quality, efficiency, and outcomes. It drives suboptimal utilization and unnecessary costs out of the process. For healthcare systems competing in the value-based care arena, population management is a cornerstone of an effective program.

The Explorys EPM Suite provides targeted information and directives for care coordinators, providers, and patients to drive performance, including:

Registries and Work Lists
- To mitigate time-sensitive risks of unnecessary utilization and poor outcomes
- To proactively manage diseases
- To meet performance goals and objectives of programs

Workflow
- Integrated into the daily process of care coordinators and providers
- Automated assignment, alerts, notes, and reminders
- Communicate via integrated 3rd party portal, telephone, and correspondence.
Big Data

Laboratory Medicine

March 2014 Clinical Laboratory News: Volume 40, Number 3

The Rise of Big Data
Trends and Opportunities for the Lab

By Nancy B. Williams

Even as many doctors struggle to give up their pen and paper charts, some innovators are already shifting healthcare information technology into warp speed. Researchers, health systems, and other stakeholders are analyzing huge amounts of aggregated information—big data—to elucidate patterns that remained hidden under old data models. Blending biostatistics, bioinformatics, computer programming, and operational research, big data is expected to transform the process of clinical decision-making. And of course, much of this data will come from laboratory medicine. The promise of big data is taking these
Cerner, Tableau Collaborate to Provide Advanced Data Exploration Capabilities to Health Care Organizations

Interactive Data Analysis Provides Health Care Organizations With Insight Into Patient Care, Operational Effectiveness

KANSAS CITY, Mo., April 8, 2015 (GLOBE NEWSWIRE) -- Cerner Corp. has collaborated with Tableau Software to enhance the data discovery experience of health care organizations through interactive data exploration.

The integration of Tableau’s visual analytics with Cerner’s HealtheAnalytics™ and HealtheEDM™ enterprise data warehouse and analytic offerings enables health care organizations to manipulate data and make new discoveries. Through this data mining and analysis, health care organizations can derive meaningful insight to identify trends, improve clinical decision support and help enable continuous improvement.

"With preventable health conditions rising, finding new ways to improve health and care through data analysis is key," said Adam Christmann, general manager, reporting and analytics, Cerner. "By providing our clients with the ability to easily know, predict and evaluate population data, they have the ability to make strategic decisions that can impact outcomes based on large volumes of data."

Tableau provides a highly intuitive interface, which allows health care organizations to discover trends and insights in data that might have gone undetected in static reports based on traditional business intelligence approaches. Tableau is rated as an industry leader by KLAS for ‘Ease of Use.' Tableau has been ranked highest along the ‘Ability to Execute’ axis by Gartner in the Magic Quadrant for Business Intelligence and Analytics Platforms, Gartner, Inc., February, 2015.

"Tableau’s mission is to help people see and understand their data. Our collaboration with Cerner is an exciting step forward in doing this," said Scott Jones, senior vice president of Americas sales, Tableau Software. "Combining Cerner’s leading health care information technology expertise with Tableau’s advanced data discovery capabilities will support organizations in making data-driven decisions through face-up, meaningful information."

Pat Hanrahan
CANON Professor of Computer Science and Electrical Engineering at Stanford University.
Tableau

Healthcare Analytics
VHA Corporate Data Warehouse

Source Systems
- VistA
- HDR
- NPCD
- DSS
- ADR
- VA
- DoD
- CMS

VHA – VHA clinical systems
VHA – VHA administrative and financial systems

Metadata Repository
Conformed Dimensions

Diabetes
OEF/OIF

Outpatient Encounters

Closed Loop Information System

Data Warehouse

Research Data Marts
Region Warehouses
Prog Office Data Marts

Common Query, Reporting, Analysis, and Data Mining Tools

Program Offices
- Pharmacy Benefits
- Prosthetics
- Dental

Extract, Transform, Load

Value Added Data

Acquire Data
Populate Warehouse
Create Marts
Access Information

1. Acquire Data
2. Populate Warehouse
3. Create Marts

Value Added Data

HD – Health Data Repository
NPCD – National Patient Care Database
DSS – Decision Support System
ADR – Administrative Data Repository
DoD – Dept. of Defense
CMS - Centers for Medicare & Medicaid Services
Big Data

Test performance
Hemolysis (preanalytical)
Germline and phenotype testing (analytical)

Evidence-based laboratory practices
Myoglobinuria
Protein C

Population health
High and low risk (birth cohort) HCV screening

Utilization
Germline mutation and phenotype testing
Benchmarking
Test performance (preanalytical)

Hemolysis

Clinical Laboratory Quality Practices When Hemolysis Occurs

Peter J. Hawes, MD; Christopher M. Lehman, MD; Bruce A. Jones, MD; Frederick A. Meyer, MD; Gary J. Horowitz, MD

- Context—Hemolysis specimens delay clinical laboratory results, produce unnecessary testing, complicate physician decisions, and increase patient care costs.
- Objective—to determine quality improvement practices when hemolysis occurs.
- Results—We used the College of American Pathologists' Laboratory Quality Improvement Program (LabQIP) and the College of American Pathologists' Program for Quality Improvement in Laboratory Medicine (CAP-PQIM) to identify quality improvement practices in clinical laboratories that address hemolysis.
- Conclusion—Hemolysis is a common problem in clinical laboratories, and hemolysis is an important factor in laboratory quality improvement. Hemolysis practices vary widely among laboratories. There is no consensus on the best practices for reducing hemolysis in clinical laboratories.

CLINICAL RESEARCH STUDY
Reducing Blood Sample Hemolysis at a Tertiary Hospital Emergency Department

Marcus Eng Hock Eng, MBBS, MPH, FAMS; Yi Wang, PhD; Chai Lim, MBBS

- Background—Hemolysis is a common problem in clinical laboratories, and hemolysis is an important factor in laboratory quality improvement. Hemolysis practices vary widely among laboratories. There is no consensus on the best practices for reducing hemolysis in clinical laboratories.
- Methods—We conducted a randomized controlled trial in the emergency department of a tertiary hospital in Singapore. Patients were randomized to either a standard hemolysis management protocol or a modified protocol that included a new hemolysis management protocol. The primary outcome was the proportion of samples with hemolysis.
- Results—The modified protocol was associated with a significantly lower proportion of samples with hemolysis (P < 0.05). The modified protocol also led to a reduction in the number of samples requiring retesting.
- Conclusion—Reducing hemolysis in clinical laboratories is important for improving laboratory quality and reducing patient care costs. The modified protocol was associated with a significant reduction in the proportion of samples with hemolysis.

Practices for Identifying and Rejecting Hemolized Specimens Are Highly Variable in Clinical Laboratories

Peter J. Hawes, MD; Christopher M. Lehman, MD; Bruce A. Jones, MD; Frederick A. Meyer, MD; Gary J. Horowitz, MD

- Background—Hemolysis is a common problem in clinical laboratories, and hemolysis is an important factor in laboratory quality improvement. Hemolysis practices vary widely among laboratories. There is no consensus on the best practices for reducing hemolysis in clinical laboratories.
- Methods—We conducted a survey of clinical laboratory directors and managers to identify the practices used for identifying and rejecting hemolized specimens.
- Results—There was great variability in the practices used for identifying and rejecting hemolized specimens. The most common practices were visual inspection, manual testing, and automated testing. However, there was no consensus on the best practices for reducing hemolysis in clinical laboratories.
- Conclusion—Reducing hemolysis in clinical laboratories is important for improving laboratory quality and reducing patient care costs. There is no consensus on the best practices for reducing hemolysis in clinical laboratories. Further research is needed to identify the best practices for reducing hemolysis in clinical laboratories.
Benchmarking
Test performance (preanalytical)

Hemolysis

16 facilities (November 2014)
• 220,596 serum potassium results of which 22,442 (10.2%) from ED.
• Median hemolysis rate: 3.5% ED – 0.7% Other
Effect of vitamin K deficiency (INR) on protein C activity and antigen values

Protein C and INR
102 VA laboratories and 25,461 cases

Protein C testing with elevated INR results
The incidence of abnormal protein C results with normal (<1.1) INR levels was 2.9% and accounted for 48.9% of all protein C tests.

Protein C was frequently tested when INR results were elevated; 17.2% and 10.9% of cases with INRs of ≥1.5 and ≥2.0 were tested for protein C respectively.

<table>
<thead>
<tr>
<th>INR Range</th>
<th>Functional Protein C Method</th>
<th>Antigen Protein C Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>PC ≤54%</td>
</tr>
<tr>
<td>&lt;0.9</td>
<td>289</td>
<td>7</td>
</tr>
<tr>
<td>0.9-0.99</td>
<td>3049</td>
<td>69</td>
</tr>
<tr>
<td>1.0-1.09</td>
<td>6231</td>
<td>201</td>
</tr>
<tr>
<td>1.1-1.19</td>
<td>3390</td>
<td>187</td>
</tr>
<tr>
<td>1.2-1.29</td>
<td>1465</td>
<td>195</td>
</tr>
<tr>
<td>1.3-1.39</td>
<td>710</td>
<td>170</td>
</tr>
<tr>
<td>1.4-1.49</td>
<td>442</td>
<td>170</td>
</tr>
<tr>
<td>1.5-1.59</td>
<td>340</td>
<td>168</td>
</tr>
<tr>
<td>1.6-1.69</td>
<td>280</td>
<td>160</td>
</tr>
<tr>
<td>1.7-1.79</td>
<td>205</td>
<td>135</td>
</tr>
<tr>
<td>1.8-1.89</td>
<td>221</td>
<td>155</td>
</tr>
<tr>
<td>1.9-1.99</td>
<td>156</td>
<td>147</td>
</tr>
<tr>
<td>2.0-2.09</td>
<td>177</td>
<td>145</td>
</tr>
<tr>
<td>2.1-2.19</td>
<td>189</td>
<td>158</td>
</tr>
<tr>
<td>2.2-2.29</td>
<td>132</td>
<td>116</td>
</tr>
<tr>
<td>2.3-2.39</td>
<td>169</td>
<td>144</td>
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<tr>
<td>2.4-2.49</td>
<td>148</td>
<td>126</td>
</tr>
<tr>
<td>2.5-2.59</td>
<td>128</td>
<td>117</td>
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<tr>
<td>2.6-2.69</td>
<td>123</td>
<td>107</td>
</tr>
<tr>
<td>2.7-2.79</td>
<td>137</td>
<td>118</td>
</tr>
<tr>
<td>2.8-2.89</td>
<td>94</td>
<td>86</td>
</tr>
<tr>
<td>2.9-2.99</td>
<td>79</td>
<td>65</td>
</tr>
<tr>
<td>3.0-3.09</td>
<td>77</td>
<td>72</td>
</tr>
<tr>
<td>3.1-3.19</td>
<td>204</td>
<td>188</td>
</tr>
<tr>
<td>3.2-3.29</td>
<td>142</td>
<td>129</td>
</tr>
<tr>
<td>3.3-3.39</td>
<td>82</td>
<td>72</td>
</tr>
<tr>
<td>3.4-3.49</td>
<td>44</td>
<td>40</td>
</tr>
</tbody>
</table>
Protein C – Functional vs Antigenic Testing

73.6% of protein C results are performed by functional methods. However, the relative percent varied by facility; 18 laboratories reported only antigenic protein C results while 30 reported only functional protein C results.

<table>
<thead>
<tr>
<th>Percentile</th>
<th>10th</th>
<th>25th</th>
<th>50th</th>
<th>75th</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>% functional protein C</td>
<td>0%</td>
<td>42.9%</td>
<td>80.0%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Distribution of % of all protein C tests performed using functional method among 102 laboratories over 14 years.

Distribution among 102 VA laboratories of all protein C tests as % measured by functional assay.
Performance of urine dipstick blood test for detecting myoglobinuria

81 facilities
7,579 cases

<table>
<thead>
<tr>
<th>Urine Myoglobin μg/L</th>
<th>Negative and trace dipstick blood</th>
<th>Positive dipstick blood</th>
<th>Total No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negative No. (%)</td>
<td>Trace No. (%)</td>
<td>ALL NEGATIVE</td>
</tr>
<tr>
<td>&lt;50</td>
<td>3,310 (96.8%)</td>
<td>431 (87.3%)</td>
<td>3,741 (95.6%)</td>
</tr>
<tr>
<td>50-99</td>
<td>42 (1.2%)</td>
<td>18 (3.6%)</td>
<td>60 (1.5%)</td>
</tr>
<tr>
<td>100-249</td>
<td>30 (0.9%)</td>
<td>27 (5.5%)</td>
<td>57 (1.5%)</td>
</tr>
<tr>
<td>250-999</td>
<td>27 (0.8%)</td>
<td>13 (2.6%)</td>
<td>40 (1.0%)</td>
</tr>
<tr>
<td>1,000-5,000</td>
<td>7 (0.2%)</td>
<td>4 (0.8%)</td>
<td>11 (0.3%)</td>
</tr>
<tr>
<td>5,001-10,000</td>
<td>1 (&lt;0.1%)</td>
<td>1 (&lt;0.2%)</td>
<td>2 (&lt;0.1%)</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>4 (0.1%)</td>
<td>0 (0.0%)</td>
<td>4 (0.1%)</td>
</tr>
</tbody>
</table>
Evidence Based Best Practices

Probability of myoglobinuria (>1,000 µg/L)
- 0.4%

% of cases
- 51.7%

Small (1+)
- 2.4%

Moderate (2+)
- 9.6%

Large (3+)
- 20.8%

Clinical review
- 9.7%

Test
- 12.1%

Test
- 26.5%
Population Health

Patient Letters

Reminders & Results

Results
- PAP smear
- Fecal occult blood
- Hgb A1c

Reminders
- HgbA1c

Dear [Patient],

Your fecal occult blood test was done as part of routine care. This test is used as a tool for the early detection of colorectal cancer. This test is recommended to be done annually by the American Cancer Society and as directed by your healthcare provider.

This test is negative. You do not have colorectal cancer. However, this test can be made negative in the presence of blood in the stool. If you have a positive test, you will be contacted by your healthcare provider.

Thank you for keeping yourself healthy.

[Signature]

[Healthcare Provider]
Dear Veteran:

Southern Arizona VA Health Care System is introducing Health Promotion and Population Health Management Programs to improve the care and control of ongoing health problems. Our goal is to assist you, your primary care provider, and FACT Team, in ways to keep you as healthy and well-informed as possible. As part of a pilot project we are working to assist Veterans to have timely health screenings including annual laboratory testing.

Thank you for coming in for your HbA1c lab test! Your results are now available, see below. Please read the whole letter to learn what to do with this result.

Your results are as follows:

Your HbA1c result on Aug 15 2014 was 9.0. Goals for your HbA1c level should be discussed with your health care provider who has been notified about your results. Please call Cootillo Clinic at Southern Arizona VA Health Care System at (520) 234-4894, Monday through Friday between 8:00am and 4:00pm to schedule a time to discuss your recent HbA1c result.

Thank you,

PAP smear

Thank you for allowing Southern Arizona VA Health Care System to provide your care. Your recent PAP smear test was done as part of routine care. This test is used as a tool for early detection of cervical cancer.

PAP tests are repeated at regular times depending on your individual needs.

Per your Provider, your most recent PAP test was normal (negative for cancerous/negative for precancerous cells).

Please call your Patient Aligned Care Team (your Health Care Team) if you have any questions or concerns regarding this test. You can also go to our website at www.va.gov.

FOBT

Dear TEST 32,

Your fecal occult blood test was done as part of routine care.

This test is used as a tool for early detection of colon cancer.

This test is recommended to be done annually beginning at age 50 by the American Cancer Society and as directed by your healthcare provider.

Your most recent fecal occult blood test was:

NEGATIVE (No Blood Detected) Performed on: 10 Dec 2013

Please call me if you have any questions or concerns regarding this test.
Test result notification TIU notes are entered automatically via a rules based system, and printing and mailing is automated.
Viral Hepatitis C
VHA HIV, Hepatitis & Public Health Pathogens Program

Viral Hepatitis

Birth Cohort Testing
HEPATITIS C

Introduction

According to CDC, in the United States, a disproportionate number of people born between 1945 and 1965 have hepatitis C. Many are unaware they are infected, and thus do not receive treatment. This is why, all Veterans born between 1945 and 1965 were offered a test for hepatitis C. Risk factors are listed below.
To: TEST ZZ

Aug 28, 2015

I want to inform you about recent healthcare guidelines which recommend that individuals in your age group be screened for hepatitis C infection.

Since there is no record of you ever being evaluated for hepatitis C, I’d advise that you be tested. While it is unlikely that you have this infection, it is still worthwhile to check. This only requires a blood test.

The reason for doing this is because individuals who have hepatitis C infection usually do not feel sick or have any symptoms at first, but may eventually get severe liver disease or even cancer if not treated.

If you wish to be tested for hepatitis C infection, simply bring this letter to the phlebotomy (blood collection) section, tell the phlebotomist that you received screening blood test for hepatitis C.

Once testing is completed, you will receive a letter about test results or advice for further steps.

If you are unsure or have any questions about infection at this time, please contact information to assist with making a decision for your next visit.

Sincerely,

To: TEST ZZ

Aug 28, 2015

I am pleased to inform you that your recent test for hepatitis C was completed and results were NEGATIVE.

This means that you DO NOT have any evidence of hepatitis C infection and no further evaluation is needed.

Thank you,

Department of Veterans Affairs
Hepatitis C Birth Cohort Screening

Birth Cohort Screening (Oct 2015-March 2016)
Percent of Patients Tested Who Received Letters

3,390 letters and 605 (17.9%) tested to date

Week and number of letters sent
- Tested
- Untested

Cases | Tested (%) | Anti-HCV POS (%) | HCV RNA POS (%)
---|---|---|---
3,390 | 605 (17.8%) | 12 (2.0%) | 5 (0.8%)
Use of automated algorithm and HCV registry to screen for occult HCV infection among high risk population

...at risk for HCV infection (ICD-9 code)
.....no history of anti-HCV testing
.....not in HCV registry
.....blood specimen in lab

<table>
<thead>
<tr>
<th>High Risk Patient Not Tested (N=38)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to contact</td>
<td>20 (52.6%)</td>
</tr>
<tr>
<td>Deferred for clinical, technical or administrative reasons</td>
<td>9 (23.7%)</td>
</tr>
<tr>
<td>Refused testing</td>
<td>6 (15.8%)</td>
</tr>
<tr>
<td>Specimen not available</td>
<td>3 (7.9%)</td>
</tr>
</tbody>
</table>

High Risk Patients Tested

<table>
<thead>
<tr>
<th>Cases</th>
<th>Tested (%)</th>
<th>Anti-HCV POS (%)</th>
<th>HCV RNA POS (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>166</td>
<td>128 (77.1%)</td>
<td>16 (12.5%)</td>
<td>8 (6.3%)*</td>
</tr>
</tbody>
</table>

*One not tested for HCV RNA.
*All HCV RNA pos born between 1945-1965
Viral Hepatitis C
High risk vs low risk screening

<table>
<thead>
<tr>
<th>Screening Method</th>
<th>Cases</th>
<th>Tested (%)</th>
<th>Anti-HCV POS (%)</th>
<th>HCV RNA POS (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth cohort</td>
<td>3,390</td>
<td>605 (17.8%)</td>
<td>12 (2.0%)</td>
<td>5 (0.8%)</td>
</tr>
<tr>
<td>High Risk</td>
<td>166</td>
<td>128 (77.1%)</td>
<td>16 (12.5%)</td>
<td>8 (6.3%)*</td>
</tr>
</tbody>
</table>

**Annals of Internal Medicine**

The Cost-Effectiveness of Birth-Cohort Screening for Hepatitis C Antibody in U.S. Primary Care Settings

- **Results of Base-Case Analysis:** Compared with the status quo, birth-cohort screening identified 890 (520-1300) patients with chronic HCV infection at a screening cost of $2874 per case identified. Assuming that birth-cohort screening was followed by peginterferon and ribavirin (PEG-IFN + R) for treated patients, screening increased QALYs by 348 and costs by $5.5 million, for an ICER of $15,700 per QALY gained. Assuming that birth-cohort screening was followed by direct-acting antivirals plus PEG-IFN + R treatment for treated patients, screening increased QALYs by 532 and costs by $19.0 million, for an ICER of $35,700 per QALY saved.

- **Results of Sensitivity Analysis:** The ICER of birth-cohort screening was most sensitive to sustained viral response of antiviral therapy, the cost of therapy, the discount rate, and the QALY losses assigned to disease states.

**Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965**

- Primary measures: numbers of cases that were identified and treated, and that achieved sustained virologic response; liver disease and death from HCV; medical and productivity costs; quality-adjusted life-years (QALYs); incremental cost-effectiveness ratio (ICER).
Duplicate Germline Genetic & Phenotype Testing

- Reliability of Test Results
- Test Utilization

The incidence of duplicate genetic testing

Douglas L. Kegert-Johnson, MD, Daniela Macaya, MOC, Timothy W. Heffron, PhD, and Lisa A. Boardman, MD

**Purpose:** Duplicate genetic testing (DGT) should give the same results as the initial genetic test. Therefore, DGT is indicated only in rare instances where the initial results require confirmation. The objective of this study was to determine the incidence of DGT by reviewing TPMT, HFE, and CYP2C19 polymorphism testing performed in our institution’s laboratories in 2006. A secondary objective was to determine the savings in charges that resulted from a system in place to limit HFE DGT.

**Methods:** A retrospective analysis was performed by a medical director at an academic medical center. The percentage of patients having the same genetic test more than twice in 2006 was 3.3% (25/7719) for TPMT, 0.3% for HFE (24/7782), and 0.3% (43/3) for CYP2C19 DGT. Retail laboratory charges for the DGT identified in 2006 were $78,728. To estimate the incidence of DGT over a longer period of time before 2006, an electronic records review was performed on a subset of internal patients and found the all-time incidence of DGT for TPMT, HFE, and CYP2C19 DGT to be 6.3%, 1.5%, and 0.9%, respectively. No case of DGT with an appropriate indication for duplicate testing was found. A system in place to decrease HFE DGT is estimated to have saved $77,479 in charges for 2006 (95% CI, $35,512–$128,015).

**Conclusions:** Indicated DGT is rare and decreasing DGT could result in significant savings. Institutions should consider implementing a systems-based process to limit DGT.


**Key Words:** genetic testing, molecular diagnostic techniques, duplicate genetic testing, laboratory techniques and processes.
HLA-B *5701 Phenotype (Abacavir Hypersensitivity)
Factor V Leiden testing
120 facilities

### PATIENT TEST RESULTS

<table>
<thead>
<tr>
<th>DIAGNOSIS</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>WILD</td>
<td>40,457 87.4%</td>
</tr>
<tr>
<td>HETE</td>
<td>5,601 12.1%</td>
</tr>
<tr>
<td>HOMO</td>
<td>197 0.43%</td>
</tr>
<tr>
<td>DISCREPANCY</td>
<td>18 0.04%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>46,273 98.3%</td>
</tr>
</tbody>
</table>

**OTHER**

<table>
<thead>
<tr>
<th>MUTATION</th>
<th>103</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT REPORTED</td>
<td>674</td>
</tr>
<tr>
<td>TOTAL</td>
<td>777</td>
</tr>
</tbody>
</table>

**GRAND TOTAL** 47,050

**MUTA** – Mutation, not otherwise specified
**NOTR** – Not reported in test results or comments (e.g. comment reads “see scanned report,” etc.)

**Patients with repeated tests** 3,762
**Patient with discrepant results** 24

<table>
<thead>
<tr>
<th>Percent discrepancies</th>
<th>0.64%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interpretive discrepancies*</td>
<td>0.48%</td>
</tr>
</tbody>
</table>

**Test Result(s)**

<table>
<thead>
<tr>
<th>N</th>
<th>Test Result(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>37,251</td>
<td>WILD</td>
</tr>
<tr>
<td>5,108</td>
<td>HETE</td>
</tr>
<tr>
<td>2,815</td>
<td>WILD,WILD</td>
</tr>
<tr>
<td>657</td>
<td>NOTR</td>
</tr>
<tr>
<td>414</td>
<td>HETE,HETE</td>
</tr>
<tr>
<td>276</td>
<td>WILD,WILD,WILD</td>
</tr>
<tr>
<td>175</td>
<td>HOMO</td>
</tr>
<tr>
<td>97</td>
<td>MUTA</td>
</tr>
<tr>
<td>39</td>
<td>NOTR,WILD</td>
</tr>
<tr>
<td>31</td>
<td>HETE,HETE,HETE</td>
</tr>
<tr>
<td>27</td>
<td>WILD,NOTR</td>
</tr>
<tr>
<td>20</td>
<td>HOMO,HOMO</td>
</tr>
<tr>
<td>15</td>
<td>NOTR,NOTR</td>
</tr>
<tr>
<td>14</td>
<td>MUTA,HETE</td>
</tr>
<tr>
<td>13</td>
<td>HETE,NOTR</td>
</tr>
<tr>
<td>8</td>
<td>WILD,HETE</td>
</tr>
<tr>
<td>7</td>
<td>HETE,WILD</td>
</tr>
<tr>
<td>6</td>
<td>NOTR,HETE</td>
</tr>
<tr>
<td>5</td>
<td>NOTR,WILD,WILD</td>
</tr>
<tr>
<td>4</td>
<td>HETE,MUTA</td>
</tr>
<tr>
<td>4</td>
<td>WILD,NOTR,WILD</td>
</tr>
<tr>
<td>3</td>
<td>MUTA,MUTA</td>
</tr>
<tr>
<td>2</td>
<td>HOMO,HETE</td>
</tr>
<tr>
<td>2</td>
<td>MUTA,NOTR</td>
</tr>
</tbody>
</table>

* ≥ 2 of 3 concordance
Repeat factor V Leiden testing
120 facilities

<table>
<thead>
<tr>
<th>Time Between Repeat Tests</th>
<th>Percentile</th>
<th>5</th>
<th>10</th>
<th>25</th>
<th>Median</th>
<th>75</th>
<th>90</th>
<th>95</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days</td>
<td></td>
<td>2</td>
<td>8</td>
<td>59</td>
<td>331</td>
<td>1,081</td>
<td>2,800</td>
<td>3,379</td>
</tr>
<tr>
<td>Months</td>
<td></td>
<td>2</td>
<td>11</td>
<td>36</td>
<td>93</td>
<td>113</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.9</td>
<td>3.0</td>
<td>7.7</td>
<td>9.3</td>
</tr>
</tbody>
</table>

Factor V Leiden Test Volume

<table>
<thead>
<tr>
<th>Year</th>
<th>New Patient</th>
<th>Retested Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>1,262</td>
<td>51</td>
</tr>
<tr>
<td>2001</td>
<td>1,548</td>
<td>80</td>
</tr>
<tr>
<td>2002</td>
<td>1,945</td>
<td>102</td>
</tr>
<tr>
<td>2003</td>
<td>2,451</td>
<td>183</td>
</tr>
<tr>
<td>2004</td>
<td>2,703</td>
<td>206</td>
</tr>
<tr>
<td>2005</td>
<td>2,898</td>
<td>213</td>
</tr>
<tr>
<td>2006</td>
<td>3,145</td>
<td>271</td>
</tr>
<tr>
<td>2007</td>
<td>3,146</td>
<td>277</td>
</tr>
<tr>
<td>2008</td>
<td>3,297</td>
<td>358</td>
</tr>
<tr>
<td>2009</td>
<td>3,600</td>
<td>365</td>
</tr>
<tr>
<td>2010</td>
<td>3,912</td>
<td>370</td>
</tr>
<tr>
<td>2011</td>
<td>4,052</td>
<td>380</td>
</tr>
<tr>
<td>2012</td>
<td>4,114</td>
<td>390</td>
</tr>
<tr>
<td>2013</td>
<td>4,258</td>
<td>432</td>
</tr>
</tbody>
</table>
Repeat factor V Leiden testing
120 facilities

20% retested at different facility
Effect of genotype/phenotype on repeat testing

<table>
<thead>
<tr>
<th>Mutation</th>
<th>Duplicate Testing No./total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hemochromatosis</strong></td>
<td></td>
</tr>
<tr>
<td>$P = &lt;.001$</td>
<td></td>
</tr>
<tr>
<td>C282Y/C282Y</td>
<td>283/2,608 (10.9%)</td>
</tr>
<tr>
<td>H63D/H63D</td>
<td>93/1,099 (8.5%)</td>
</tr>
<tr>
<td>C282Y/H63D</td>
<td>135/1,758 (7.7%)</td>
</tr>
<tr>
<td>C282Y/w</td>
<td>301/4,477 (6.7%)</td>
</tr>
<tr>
<td>H63D/w</td>
<td>467/7,506 (6.2%)</td>
</tr>
<tr>
<td>w/w</td>
<td>505/22,626 (6.7%)</td>
</tr>
<tr>
<td><strong>Factor V Leiden</strong></td>
<td></td>
</tr>
<tr>
<td>$P = .032$</td>
<td></td>
</tr>
<tr>
<td>Homozygous</td>
<td>22/197 (11.2%)</td>
</tr>
<tr>
<td>Heterozygous</td>
<td>488/5,596 (8.7%)</td>
</tr>
<tr>
<td>Wild</td>
<td>3,205/40,456 (7.9%)</td>
</tr>
<tr>
<td><strong>HLA-B*57:01</strong></td>
<td></td>
</tr>
<tr>
<td>$P = .16$</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>23/410 (5.6%)</td>
</tr>
<tr>
<td>Negative</td>
<td>680/8,767 (7.8%)</td>
</tr>
</tbody>
</table>
## Genetic Test Patient Registry

### Reliability of Test Results

<table>
<thead>
<tr>
<th>Genetic Test Patient Registry</th>
<th>Hemochromatosis</th>
<th>Factor V Leiden</th>
<th>HLA-B*57:01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities No.</td>
<td>118</td>
<td>120</td>
<td>94</td>
</tr>
<tr>
<td>Patients No.</td>
<td>46,929</td>
<td>47,050</td>
<td>9,358</td>
</tr>
<tr>
<td>Patients with one or more duplicate tests No. (%)</td>
<td>3,530 (7.5%)</td>
<td>3,762 (8.0%)</td>
<td>704 ((7.5%)</td>
</tr>
<tr>
<td>Patients retested at another facility No. (%)</td>
<td>712 (20.2%)</td>
<td>753 (20.0%)</td>
<td>282 (40.1%)</td>
</tr>
<tr>
<td>Discrepant test results No. / total duplicates (%)</td>
<td>27/2,827 (0.96%)</td>
<td>24/3,786 (0.63%)</td>
<td>0/675 (0.0%)</td>
</tr>
</tbody>
</table>

*among cases with complete information*
Duplicate Germline Genetic Test Utilization Program

Process for detection and notification of laboratories about new orders for duplicate germline and phenotype orders

- Factor V Leiden
- Prothrombin gene mutation
- Hemochromatosis
- IL28B genotype
- HLA B*5701
- HLA B27
Improving utilization of genetic tests
National automated notification system

Diagram:
- New CPRS Order
  - Duplicate test?
    - Yes: Notify facility
    - No: Stop

Table: Current Order and Previous Test(s)
Duplicate Genetic Testing Program
February 2015 – January 2016

**Intervention**
- 22 facilities
- 232 duplicates
- 142 (61.2%) cancellations

**Control**
- 101 facilities
- 949 duplicates
- 32 (3.4%) cancellations

Previous testing performed at a different facility in 87 (37.5%) cases

Previous testing performed at a different facility in 280 (29.5%) of cases
# Duplicate Germline Genetic Test Utilization Program

## Duplicate orders Feb 2015-Jan 2016*

<table>
<thead>
<tr>
<th>Test</th>
<th>Intervention (N=22 facilities)</th>
<th>No intervention (N=101 facilities)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Notifications</td>
<td>Cancellations</td>
</tr>
<tr>
<td>HFE</td>
<td>39</td>
<td>30 (76.9%)</td>
</tr>
<tr>
<td>FVL</td>
<td>53</td>
<td>35 (66.0%)</td>
</tr>
<tr>
<td>PGM</td>
<td>14</td>
<td>9 (64.3%)</td>
</tr>
<tr>
<td>HLA-B27</td>
<td>56</td>
<td>23 (51.8%)</td>
</tr>
<tr>
<td>HLA-B5701</td>
<td>70</td>
<td>39 (55.7%)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>232</td>
<td>142 (61.2%)</td>
</tr>
</tbody>
</table>

* 367 of 1,181 (31.1%) duplicates were performed at different facility

## Percentile range of cancellations by facility (%)

<table>
<thead>
<tr>
<th>Action (N facilities)</th>
<th>10th</th>
<th>Median</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention (N=22)</td>
<td>22.8%</td>
<td>66.7%</td>
<td>100.0%</td>
</tr>
<tr>
<td>No intervention (N=101)</td>
<td>0.0%</td>
<td>0.0%</td>
<td>14.2%</td>
</tr>
</tbody>
</table>
Duplicate Germline Genetic Test Utilization Program
“Whoa—way too much information.”
‘Big Data’ Team

Danny Luevano  Evelyn Harrison  Cindy Barger