

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



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.



<u>advertisers</u> - monitoring social media to learn about customer behavior, preferences, or responses to campaigns

financial services - predict risk

<u>hospitals</u> – predict readmission



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.

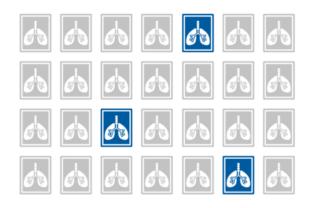






Real-time Insights

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:

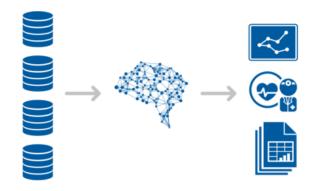






Retrospective Insights

'Real Peer Review': show 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
 - o Time of Day, Day of Week, Holidays
 - Service Provider

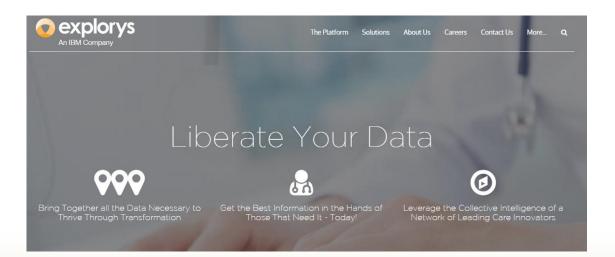


Healthcare Analytics



SOLUTIONS | EVENTS | BLOG | ABOUT | CONTACT

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









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





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.

Explorys 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

Explorys 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

Explorys *intra*-organization benchmarking provides direct comparisons of key performance indicators, helping to monitor, assess, and improve performance within an organization. Explorys also provides *inter*-organization benchmarks across those who participate in the

Explorys 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...

Leadership

- Care coordinators
- Providers
- Program Specific Measure Libraries & Scorecards

Value-Based Care

- Medicare Advantage
- Employee Health plan
- Physician-based HEDIS
- Inpatient quality and efficiency
- Utilization
- Pre-built Reports & Data Marts

onsistent and accu

Support for GPRO reporting

- Provider scorecards and performance plans
- · HCC and proper coding opportunities
- Contract performance





Big DataPopulation 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 burdens, utilization patterns, and per-member-permonth (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, model makes the most sense for their initia myriad of options, including 3rd-party comgeneration risk models.

- Population profiles including sex, ag stratification, and share-of-chart.
- Historical utilization including cost of utilizers, and E&M distribution acros
- Risk and projected utilization such a and condition.

The Explorys Risk Model

Explorys clients have an option to impleme analytic and population health managemer in-class performance (both the R2 and MAF analytics applied to a richer data set.



The Explorys Risk Model facilitates several key features when embedded within the Explorys Enterprise Performance Management (EPM) Suite, including the following:

 Risk adjustment and benchmarking of clinical outcomes and utilization to accurately compare performance across a variety of commercial and Medicare

Population Management

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

Big Data



THE AUTHORITATIVE SOURCE FOR THE CLINICAL LABORATORIAN

March 2014 Clinical Laboratory News: Volume 40, Number 3

The Rise of Big Data

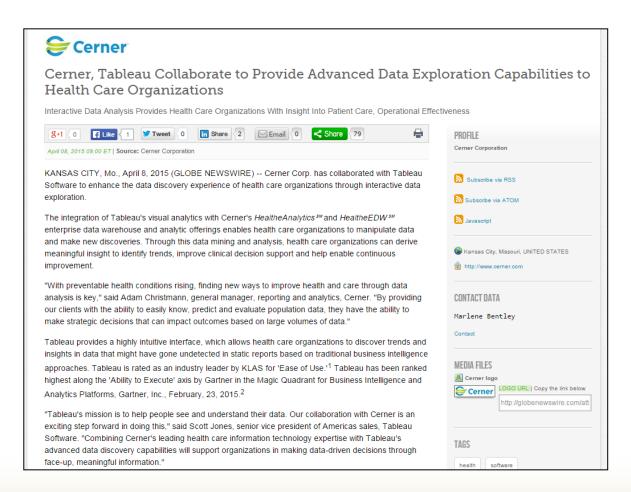
Trends and Opportunities for the Lab

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



Big Data Laboratory Medicine





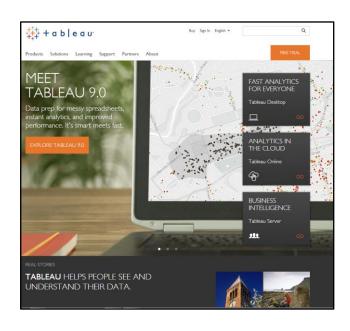
Pat Hanrahan
CANON Professor of Computer
Science and Electrical
Engineering at Stanford
University.

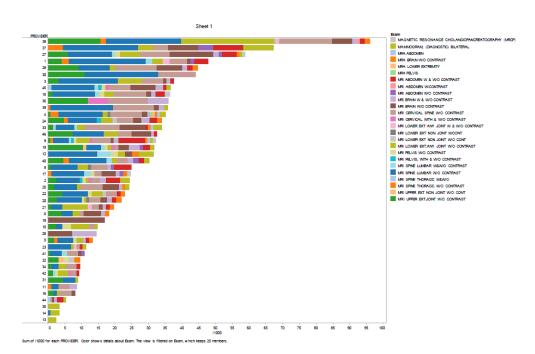




Tableau

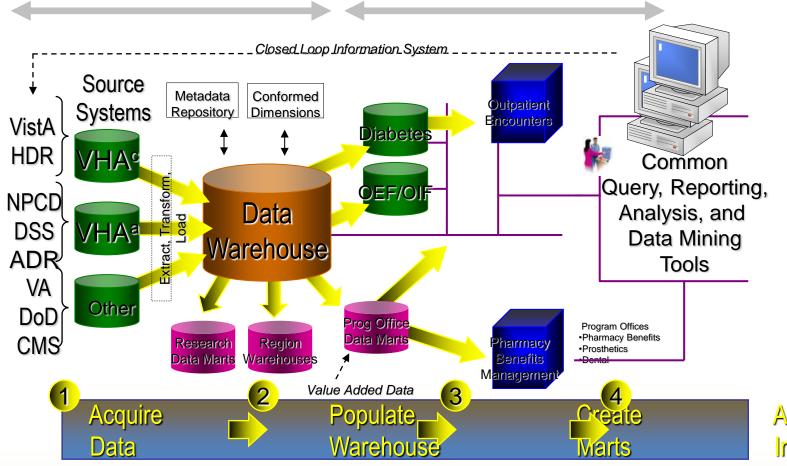
Healthcare Analytics







VHA Corporate Data Warehouse



VHA^c – VHA clinical systems VHA^a – VHA administrative and financial systems HDR – 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

Access Information



Test performance

Hemolysis (preanalytical)
Germline and phenotype testing (analytical)

Evidence-based laboratory practices Myoglobinuria Protein C

Poplulation 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. Howanitz, MD; Christopher M. Lehman, MD; Bruce A. Jones, MD; Frederick A. Meier, MD; Gary L. Horowitz, ML

• Context.—Hemolyzed specimens delay clinical laboratory results, proliferate unnecessary testing, complicate physician decisions, injure patients indirectly, and increase

Objective.—To determine quality improvement practichealth care costs.

Design.—We used the College of American Pathologists es when hemolysis occurs. (CAP) Survey Program to distribute a Q-Probes-type questionnaire about hemolysis practices to CAP Chemistry

Results.—Of 3495 participants sent the questionnaire, Survey participants. 846 (24%) responded. Although 85%, 69%, and 55% of participants had written hemolysis policies for potassium, lactate dehydrogenase, and glucose, respectively, only a few (46%, 40%, and 40%) had standardized hemolysis reports between their primary and secondary chemistry analyzers for these 3 analytes. Most participants (70%) had not attempted to validate the manufacturers' hemolysis data for these 3 analytes; however, essentially all who

taken corrective action to reduce hemolysis during the pas year and used, on average, 2.4 different actions, with collection and distribution of hemolysis data to admin trative leadership (57%), troubleshooting outliers (55%),

problem locat When asked 70% noted improvemen drogenase, pants used lipemia and

Conclusio increases th reporting, ment. (Arch Pa

1014-

retraining phlebotomist (53%), and establishment § quality improvement teams among the laboratory and

CLINICAL RESEARCH STUDY

Reducing Blood Sample Hemolysis at a Tertiary Hospital **Emergency Department**

Marcus Eng Hock Ong, MBBS, MPH, a Yiong Huak Chan, PhD, b Chin Siah Lim, MBBSa

^aDepartment of Emergency Medicine, Singapore General Hospital, Singapore; ^bYong Loo Lin School of Medicine, National University **a** of Singapore, Singapore.

PURPOSE: To determine the causes for sample hemolysis and measure the effect of an intervention to reduce sample hemolysis in the Emergency Department of a large hospital.

METHODS: We conducted a phased, prospective, interventional study. In phase 1, factors associated with urea and electrolyte sample lysis were studied. Based on these results and a literature review, an educational program consisting of a 15-minute presentation was implemented. In phase 2, questionnaires were distributed to the doctors and medical students conducting blood sampling, and outcome data were collected after the samples were processed.

RESULTS: In phase 1 (n = 227), the use of a vacutainer was associated with the highest rates of hemolysis Lysis rate was 35.8% with use of the vacutainer, compared with 11% without (adjusted odds ratio 6.0, 95% confidence interval, 2.3-15.2). In phase 2 (n = 204), the following significant changes were found: increased use of a syringe rather than vacutainer (before 64.3%; after 98.5%, P <.01), increased use of venipuncture for blood sampling (26%-36.8%, P = .02), reduced arterial sampling (3.1%-0%, P = .02), increased sample volume (4.5-5.2 mL, P <.01) and reduced interval from sampling to analysis (60.8-48.4 minutes, P < .01). We were able to attain a reduction in sample hemolysis from 19.8% (before) to 4.9% (after) (P < .001). This would translate to a cost savings of SGD\$834.40 (USD\$556.30) per day at the emergency department and SGD\$304,556 (USD\$203,037) per year.

CONCLUSIONS: Introduction of an educational program at a hospital Emergency Department was able to significantly reduce rates of sample hemolysis.

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Practices for Identifying and Rejecting Hemolyzed Specimens Are Highly Variable in Clinical Laboratories Peter J. Howanitz, MD; Christopher M. Lehman, MD; Bruce A. Jones, MD; Frederick A. Meier, MD; Cary L. Horowitz, MD

 Context.—Hemolysis is an important clinical laboratory quality attribute that influences result reliability panty aurioute mat innuences result renamity.

Objective.—To determine hemolysis identification and

rejection practices occurring in clinical laboratories. Jection practices occurring in chincal laborate Design.—We used the College of American Survey program to distribute naire about hemol

JOURNAL of MEDICINE ®

Conclusions.—Hemolysis practices vary widely. Stan-

ries, no hemolyzed specimens were rejected; and in 88% of laboratories, some specimens were rejected; and in 00 % specimens were rejected depending of laboratories. or raboratories, some specimens were rejected depending on hemolysis levels. Participants used 69 different terms to on nemotysis levels, rariicipants used by different terms to describe hemolysis scales, with 21 terms used in more than nescribe nemotysis scates, with 21 terms used in more than 10 laboratories. Slight and moderate were the terms used 10 laboratories, Sugar and moderate were the terms used most commonly. Of 16 different cutoffs used to reject most commonly. Or to universit cutous used to reject hemolyzed specimens, moderate was the most common, nemotyzeu specimens, mouerate was me most common, occurring in 30% of laboratories. For whole blood electrolyte measurements performed in 86 laboratories, etectrolyte measurements performed in on anotationes, 57% did not evaluate the presence of hemolysis, but for 5/70 did not evaluate the presence of nemotysis, but for those that did, the most common practice in 21 laborato. tries (24%) was centrifuging and visually determining the presence of hemolysis in all specimens.

dard assessment and consistent reporting are the first steps part assessment and consistent reporting are the mass in reducing interlaboratory variability among results. A retuting micriatoratory variability among results.

(Arch Pathol Lab Med. 2015;139:1014–1019; doi: 10.5858/arpa.2014-0161-CP)



Benchmarking Test performance (preanalytical)

Hemolysis

LocationName	▼ LabChemTestNa ▼	LabCh *	COMMENTS
ABQ VA EMERGENCY DEPT/WK-X	POTASSIUM	3.8	~ ~STAT SPECIMEN SLIGHTLY HEMOLYZED. Interpr
ABQ VA EMERGENCY DEPT/WK-X	POTASSIUM	4.2	[™] SPECIMEN IS SLIGHTLY HEMOLYZED.
ABQ VA EMERGENCY DEPT/WK-X	POTASSIUM	3	~ "STAT SPECIMEN SLIGHTLY HEMOLYZED. Interpr
ABQ VA EMERGENCY DEPT/WK-X	POTASSIUM	5.1	~ SPECIMEN IS MODERATELY HEMOLYZED.
ABQ VA EMERGENCY DEPT/WK-X	POTASSIUM	canc	~ CHEM Specimen hemolyzed, Called RN SARAH N

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

			Emei	rgenc	y Depart	ment				Non-Emergency Department					ED/Non-ED		
Facility	N				Hemoly	zed			N		Hemolyzed				Hemolyzed		
	IN	Re	ported	Car	nceled	C/R	Tota	al (%)	IN	Repor	ted	Cance	led (%)	C/R	Tota	I (%)	nemoryzeu
1	2,403	67	2.8%	47	2.0%	0.7	114	4.7%	15,305	53	0.3%	72	0.5%	1.4	125	0.8%	5.8
2	2,162	11	0.5%	0	0.0%	0.0	11	0.5%	17,396	20	0.1%	1	0.0%	0.1	21	0.1%	4.2
3	2,096	3	0.1%	106	5.1%	35.3	109	5.2%	16,370	5	0.0%	212	1.3%	42.4	217	1.3%	3.9
4	2,015	55	2.7%	39	1.9%	0.7	94	4.7%	15,527	80	0.5%	38	0.2%	0.5	118	0.8%	6.1
5	1,809	3	0.2%	1	0.1%	0.3	4	0.2%	11,935	1	0.0%	2	0.0%	2.0	3	0.0%	8.8
6	1,723	84	4.9%	4	0.2%	0.0	88	5.1%	20,780	84	0.4%	8	0.0%	0.1	92	0.4%	11.5
7	1,638	9	0.5%	74	4.5%	8.2	83	5.1%	14,240	102	0.7%	262	1.8%	2.6	364	2.6%	2.0
8	1,453	4	0.3%	11	0.8%	2.8	15	1.0%	12,194	32	0.3%	32	0.3%	1.0	64	0.5%	2.0
9	1,440	9	0.6%	48	3.3%	5.3	57	4.0%	5,949	11	0.2%	120	2.0%	10.9	131	2.2%	1.8
10	1,212	190	15.7%	1	0.1%	0.0	191	15.8%	11,408	760	6.7%	0	0.0%	0.0	760	6.7%	2.4
11	1,158	8	0.7%	0	0.0%	0.0	8	0.7%	14,558	22	0.2%	4	0.0%	0.2	26	0.2%	3.9
12	1,109	44	4.0%	1	0.1%	0.0	45	4.1%	11,859	196	1.7%	6	0.1%	0.0	202	1.7%	2.4
13	646	13	2.0%	0	0.0%	0.0	13	2.0%	6,607	26	0.4%	0	0.0%	0.0	26	0.4%	5.1
14	563	12	2.1%	0	0.0%	0.0	12	2.1%	4,200	14	0.3%	0	0.0%	0.0	14	0.3%	6.4
15	511	14	2.7%	1	0.2%	0.1	15	2.9%	16,201	123	0.8%	6	0.0%	0.0	129	0.8%	3.7
16	504	4	0.8%	7	1.4%	1.8	11	2.2%	3,625	2	0.1%	8	0.2%	4.0	10	0.3%	7.9
Total	22,442	530	2.4%	340	1.5%	0.6	870	3.9%	198,154	1,531	0.8%	771	0.4%	0.5	2,302	1.2%	3.3
		_															



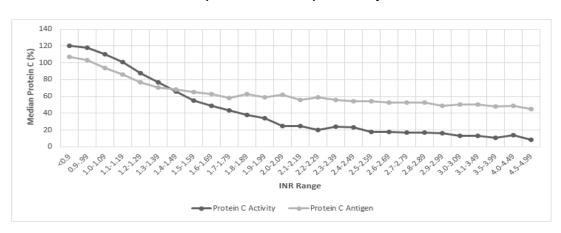
Effect of vitamin K deficiency (INR) on protein C activity and antigen values

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.



	Functional Protein C			Ant	igen Prot	ein C
INR Range		Method			Method	
	N			N	PC ≤54%	% low
<0.9	289	7	2.4%	108	1	0.9%
0.999	3049	69	2.3%	887	12	1.4%
1.0-1.09	6231	201	3.2%	1878	78	4.2%
1.1-1.19	3390	187	5.5%	1087	88	8.1%
1.2-1.29	1465	195	13.3%	535	87	16.3%
1.3-1.39	710	170	23.9%	306	79	25.8%
1.4-1.49	442	170	38.5%	185	55	29.7%
1.5-1.59	340	168	49.4%	159	48	30.2%
1.6-1.69	280	160	57.1%	133	41	30.8%
1.7-1.79	205	135	65.9%	116	43	37.1%
1.8-1.89	221	155	70.1%	100	33	33.0%
1.9-1.99	196	147	75.0%	110	46	41.8%
2.0-2.09	177	145	81.9%	98	28	28.6%
2.1-2.19	189	158	83.6%	119	57	47.9%
2.2-2.29	132	116	87.9%	90	35	38.9%
2.3-2.39	169	144	85.2%	95	43	45.3%
2.4-2.49	148	126	85.1%	82	41	50.0%
2.5-2.59	128	117	91.4%	90	45	50.0%
2.6-2.69	123	107	87.0%	77	42	54.5%
2.7-2.79	137	118	86.1%	67	35	52.2%
2.8-2.89	94	86	91.5%	51	29	56.9%
2.9-2.99	79	65	82.3%	42	26	61.9%
3.0-3.09	77	72	93.5%	46	28	60.9%
3.1-3.49	204	188	92.2%	117	73	62.4%
3.5-3.99	142	129	90.8%	73	46	63.0%
4.0-4.49	82	72	87.8%	46	32	69.6%
4.5-4.99	44	40	90.9%	21	15	71.4%



Protein C Method Selection

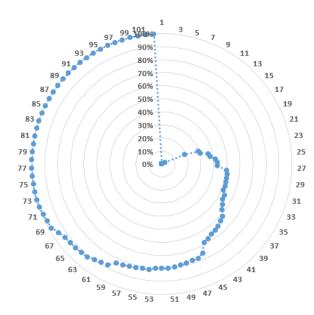
Protein C – Functional vs Antigenic Testing

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

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

	Percentile						
	10th	25th	50th	75th	90th		
% functional	00/	42.9%	80.0%	100%	100%		
protein C	U/0			100%	100%		

Distribution among 102 VA laboratories of all protein C tests as % measured by functional assay

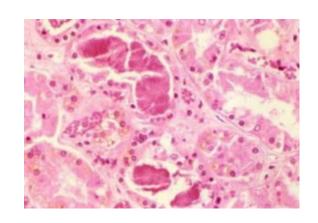




Evidence Based Best Practices Myoglobinuria

Performance of urine dipstick blood test for detecting myoglobinuria

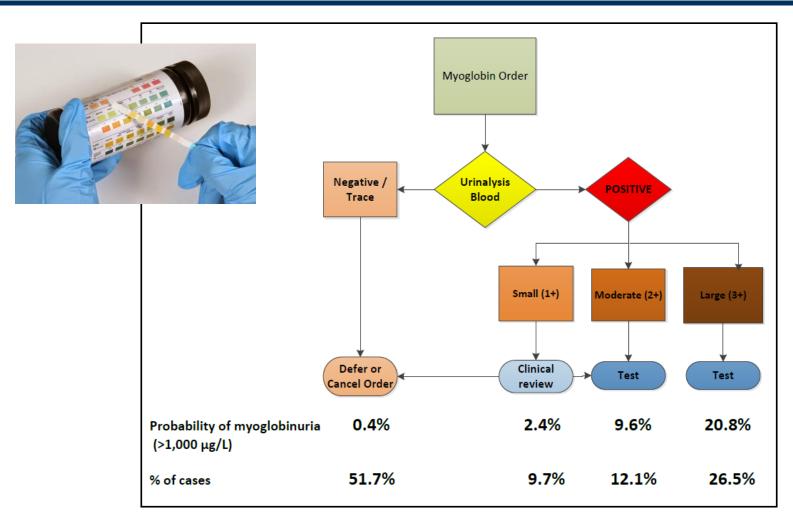
81 facilities7,579 cases



Urine	Negative	and trace dipst	tick blood		Positive dipstick blood			Total		
Myoglobin	Negative	Trace	ALL	Small (1+)	Mod (2+)	Large (3+)	ALL	No. (%)		
μg/L	No. (%)	No. (%)	NEGATIVE	No. (%)	No. (%)	No. (%)	POSITIVE	NO. (%)		
μg/ L	3,421 (45.1%)	494 (6.5%)	3,915 (51.7%)	738 (9.7%)	920 (12.1%)	2,006 (26.5%)	3,664 (48.3%)	7,579		
~ E0	3,310 (96.8%)	A24 (97 20/)	3,741 (95.6%)	632 (85.6%)	662 [74 09/)	1.020 (51.0%)	2,333 (63.7%)	6,069 (80.1%)		
₹30	3,310 (30.6%)	431 (67.3%)	3,741 (33.0%)	032 (63.0%)	002 (71.5%)	1,035 (31.6%)	2,000 (00.7%)	0,009 (60.1%)		
50-99	42 (1.2%)	18 (3.6%)	60 (1.5%)	26 (3.5%)	44 (4.8%)	131 (6.5%	201 (5.5%)	261 (3.4%)		
100-249	30 (0.9%)	27 (5.5%)	57 (1.5%)	30 (4.1%)	52 (5.7%)	180 (9.0%)	262 (7.2%)	319 (4.2%)		
250-999	27 (0.8%)	13 (2.6%)	40 (1.0%)	32 (4.3%)	74 (8.0%)	239 (11.9%)	345 (9.4%)	385 (5.1%)		
1,000-5,000	7 (0.2%)	4 (0.8%)	11 (0.3%)	14 (1.9%)	69 (7.5%)	148 (7.4%)	231 (6.3%)	242 (3.2%)		
5,001-10,000	1 (<.0.1%)	1 (0.2%)	2 (<0.1%)	2 (0.3%)	8 (0.9%)	73 (3.6%)	83 (2.3%)	85 (1.1%)		
>10,000	4 (0.1%)	0 (0.0%)	4 (0.1%)	2 (0.3%)	11 (1.2%)	196 (9.8%)	209 (5.7%)	213 (2.8%)		



Evidence Based Best Practices

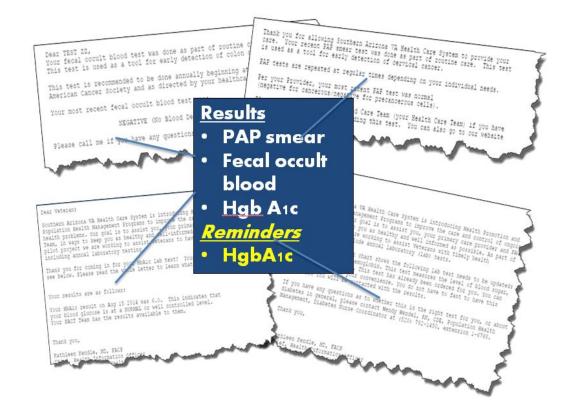




Population Health



Patient Letters Reminders & Results





Patient Results Letters



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 PACT 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.

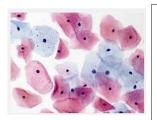
Thank you for coming in for your HbAlc lab test! Your results are now available, see below. Please read the whole letter to learn what to do with this result.

Your results are as follows:

Your HbAlc result on Aug 15 2014 was 9.0. Goals for your HbAlc level should be discussed with your health care provider who has been notified about your results. Please call Ocotillo Clinic at Southern Arizona VA Health Care System at (520) 629-4881, Monday though Friday between 8:00am and 4:00pm to schedule a time to discuss your recent HbAlc 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

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 ZZ

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:

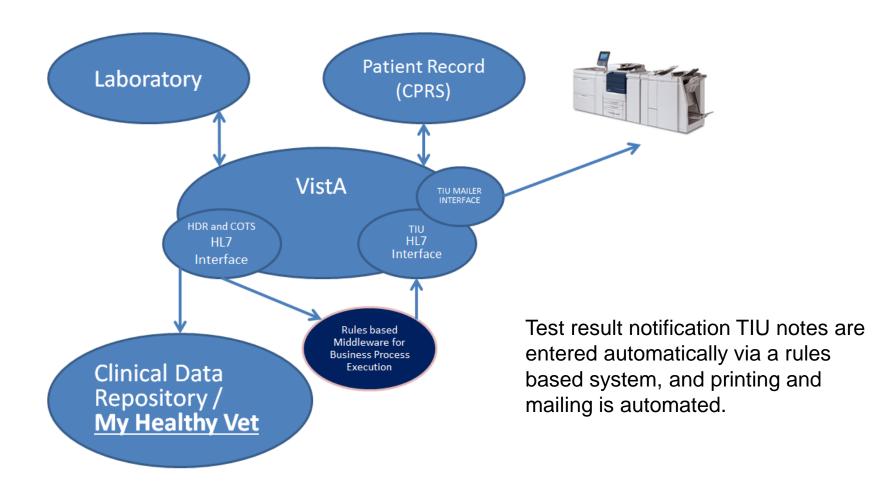
NEGATIVE (No Blood Detected) Performed on: 10 Dec 2013

Please call me if you have any questions or concerns regarding this test.





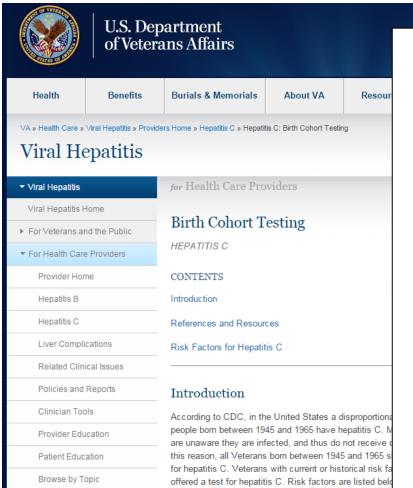
Automated Patient Letters





Viral Hepatitis C

VHA HIV, Hepatitis & Public Health Pathogens Program





Morbidity and Mortality Weekly Report
August 17, 2012

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





Patient Result Letters Initiative Hepatitis C birth-cohort screening



Aug 28, 2015~

To: TEST ZZ

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 reabout test results or advice for further

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

~Sincerely.~



Aug 28, 2015~

To: TEST ZZ

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, ~

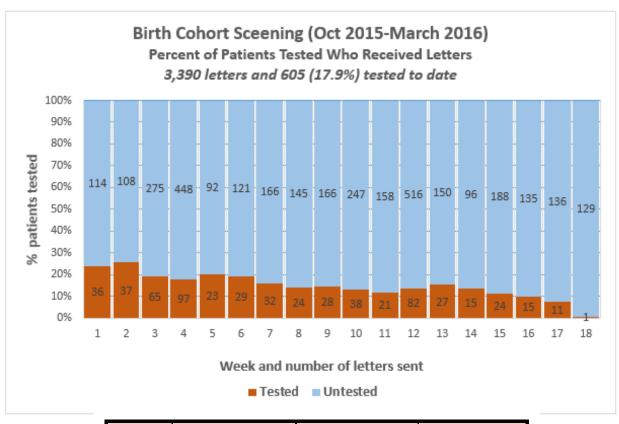








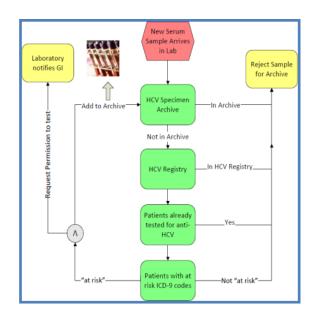
Hepatitis C Birth Cohort Screening



Cases	Tested (%)	Anti-HCV POS (%)	HCV RNA POS (%)
3,390	605 (17.8%)	12 (2.0%)	5 (0.8%)



Viral Hepatitis C High Risk Screening



High Risk Patients Tested							
Cases	Tested (%)	Anti-HCV	HCV RNA				
		POS (%)	POS (%)				
166	128 (77.1%)	16 (12.5%)	8 (6.3%)*				

^{*}One not tested for HCV RNA.

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

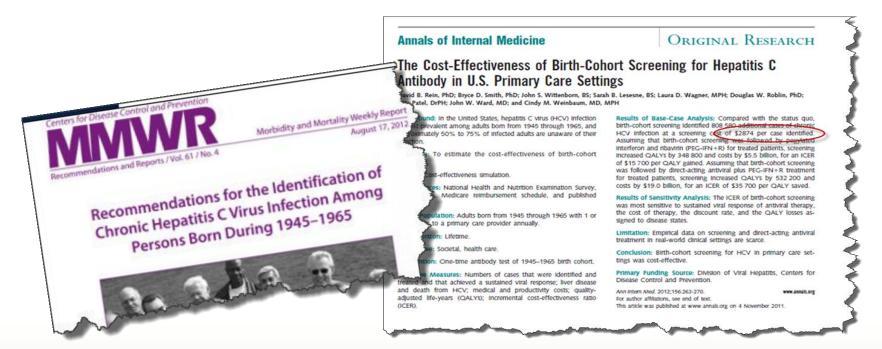
High Risk Patient Not Tested	(N=38)
Reasons for not testing	N (%)
Unable to contact	20 (52.6%)
Deferred for clinical, technical	9 (23.7%)
or administrative reasons	3 (23.770)
Refused testing	6 (15.8%)
Specimen not available	3 (7.9%)

^{*}All HCV RNA pos born between 1945-1965



Viral Hepatitis C High risk vs low risk screening

Screening Method	Cases	Tested (%)	Anti-HCV POS (%)	HCV RNA POS (%)
Birth cohort	3,390	605 (17.8%)	12 (2.0%)	5 (0.8%)
High Risk	166	128 (77.1%)	16 (12.5%)	8 (6.3%)*





Duplicate Germline Genetic & Phenotype Testing

article

February 2008 · Vol. 10 ·

The incidence of duplicate genetic testing

Douglas L. Riegert-Johnson, MD¹, Daniela Macaya, MQC², Timothy W. Hefferon, PhD³, and Lisa A. Boardman, MD⁴

Purpose: Duplicate genetic testing (DGT) should give the same results as the initial genetic test. Therefore, DGT is indicated only in the 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 CYP450 2D6 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 records review at an academic medical center. Results: The percentage of patients having the same genetic test more than once in 2006 was 3.3% (253/7710) for TPMT, 0.3% for HFE (24/7851), and 0.9% (4/433) for CYP450 2D6 testing. Retail laboratory charges for the DGT identified in 2006 were \$76,728. To estimate the incidence of DGT over a longer period of time than 2006, an all-time records review was performed on a subset of internal patients and found the all-time incidence of DGT for TPMT, HFE, and CYP450 2D6 testing to be 6.9%, 1.9%, 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, \$35,512-184,015). Conclusions: Indicated DGT is rare and decreasing DGT could result in significant savings. Institutions should consider implementing a systems-based

Key Words: genetic testing, molecular diagnostic techniques, duplicate genetic testing, laboratory techniques and

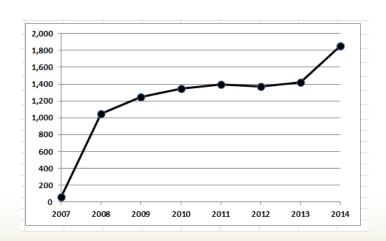
- Reliability of **Test Results**
- □ Test Utilization



HLA-B *5701 Phenotype (Abacavir Hypersensitivity)

	HLA B5701
	HLA-B*5701 W/RFL HLA-B HIGH
	(HLA B*5701 .HLA-B*5701 GENOTY ABACAVIR SENS
	ABACAVIR HYPERSENSITIVITY
	ABACAVIR HYPERSENSITIVITY (006926)
	B*5701-HLA
	B5701
	HLA B 5701 HLA B*5701
	HLA B*5701 LC
	HLA B*5701 TYPING
	HLA B5701
	HLA B5701 (D/C 8/1/13)
	HLA B5701 (LABCORP)
	HLA B5701 (LC006926)QQQ HLA B5701 (OUTPUT)
	HLA B5701 (V2)
	HLA B5701 ANTIGEN
	HLA B5701(PRE 8/1/2013)
	HLA B5701*
	HLA B5701/SEND OUT HLA-B 5701
	HLA-B 5701 (2002429)
	HLA-B 5701 TYPING
	HLA-B 5701 TYPING RT
	HLA-B 5701 TYPING(STL)
	HLA-B*5701 HLA-B*5701
	HLA-B*5701 -
	HLA-B*5701 (Dcd 3-30-12)
	HLA-B*5701 (dc'd 5/6/14)
	HLA-B*5701 (PCR)
	HLA-B*5701 Buccal Swab
	HLA-B*5701 REPORT,blood HLA-B*5701 Test
	HLA-B*5701 TYPING
	HLA-B*5701 TYPING (Q)
	HLA-B*5701 TYPING (QU)
	HLA-B*5701 TYPING 19774
	HLA-B*5701 TYPING SPL
	HLA-B*5701 TYPING(Q) HLA-B*5701 TYPING,blood
	HLA-B*5701(DC'D 10/24/14)
	HLA-B*5701.
	HLA-B5701
	HLA-B5701 (19774)
	HLA-B5701 (REF LAB) HLA-B5701 TEST
	HLA-B5701 TEST (LC)
	HLA-B5701 TYPING
	HLA-B5701(Mayo91833)
	HLA-B5701(o)
	HLA-B5701, ABACAVIR HYPERSENSITIVITY
	ID***HLA-B5701 zzHLA B*5701 TYPING
	ZZ-HLA-B*5701
	ZZHLA-B5701 TYPING
١	ZZZHLA-B*5701

YEAR	NEG	POS	UNK	Total	%POS*	%UNK
2006	1			1	0.0%	0.0%
2007	58	4		62	6.5%	0.0%
2008	1,004	46	1	1,051	4.4%	0.1%
2009	1,184	46	17	1,247	3.7%	1.4%
2010	1,185	47	116	1,348	3.8%	8.6%
2011	1,297	71	30	1,398	5.2%	2.1%
2012	1,301	64	8	1,373	4.7%	0.6%
2013	1,356	58	9	1,423	4.1%	0.6%
2014	1,738	90	29	1,852	4.9%	1.6%
2015**	361	9	3	370	2.4%	0.8%
*UNK excl						



Test results per patient	No.
NEG	8,094
NEGNEG	593
NEGNEGNEG	51
NEGNEGNEG	5
NEGNEGNEGNEG	1
UNKNEGNEG	1
NEGUNKUNK	1
Subtotal	8,746
POS	387
POSPOS	22
POSPOSPOSPOS	1
Subtotal	410
UNK	180
UNKUNK	23



Factor V Leiden testing 120 facilities

PATIENT TEST RESUTS					
DIAGNOS	DIAGNOSIS				
WILD	40,457	87.4%			
HETE	5,601	12.1%			
номо	197	0.43%			
DISCREPANCY	18	0.04%			
TOTAL			46,273	98.3%	
OTHER					
MUTATION	103				
NOT REPORTED	674				
TOTAL	777		777	1.7%	
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.)

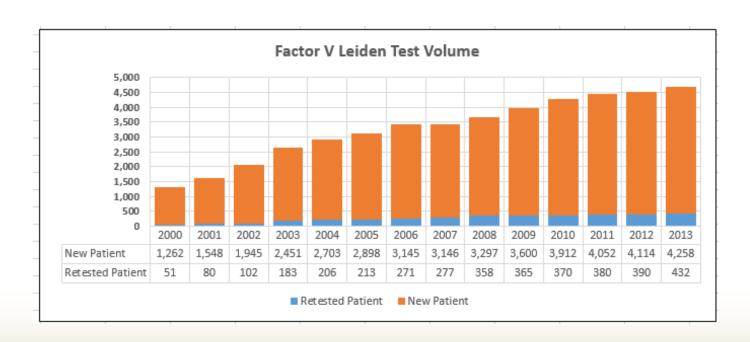
3,762
24
0.64%
0.48%

Test Result(s)	N	Test Result(s)	N
WILD	37,251	NOTR.NOTR.NOTR	2
HETE	5,108	WILD,WILD	2
WILD.WILD	2,815	WILD.WILD.NOTR	2
NOTR	657	HETE.HETE.HETE	1
HETE.HETE	414	HETE.HETE.HETE.HETE.HETE	1
WILD.WILD.WILD	276	HETE.HETE.NOTR	1
номо	175	HETE.HETE.WILD.HETE	1
MUTA	97	HETE.HETE.WILD.HETE.HETE	1
NOTR.WILD	39	HETE.MUTA.HETE.HETE	1
НЕТЕ.НЕТЕ.НЕТЕ	31	HETE.NOTR.HETE	1
WILD.WILD.WILD	30	HETE.WILD.HETE	1
WILD.NOTR	27	номо.номо.номо	1
номо.номо	20	мита.номо.номо	1
NOTR.NOTR	15	MUTA.WILD	1
MUTA.HETE	14	NOTR.HETE.HETE.HETE	1
HETE.NOTR	13	NOTR.MUTA	1
WILD.HETE	8	NOTR.NOTR.WILD	1
HETE.WILD	7	NOTR.WILD.NOTR	1
NOTR.HETE	6	NOTR.WILD.WILD.WILD	1
NOTR.WILD.WILD	5	WILD.HETE.HETE	1
HETE.MUTA	4	WILD.HETE.MUTA.HETE	1
WILD.NOTR.WILD	4	WILD.HETE.WILD	1
MUTA.MUTA	3	WILD.NOTR.NOTR.NOTR	1
HOMO.HETE	2	WILD.WILD.WILD.WILD	1
MUTA.NOTR	2		



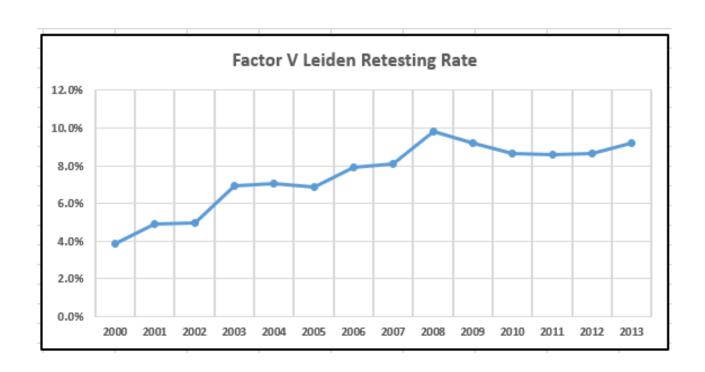
Repeat factor V Leiden testing 120 facilities

Time Between Repeat Tests							
	Percentile						
	5	10	25	Median	75	90	95
Days	2	8	59	331	1,081	2,800	3,379
Months			2	11	36	93	113
Years				0.9	3.0	7.7	9.3





Repeat factor V Leiden testing 120 facilities



20% retested at different facility



Effect of genotype/phenotype on repeat testing

Frequency of repeat testing by genotype or phenotype				
Mutation		Duplicate Testing		
		No./total (%)		
	C282Y/C282Y	283/2,608 (10.9%)		
	H63D/H63D	93/1,099 (8.5%)		
Hemochromatotis	C282Y/H63D	135/1,758 (7.7%)		
P=<.001	C282Y/w	301/4,477 (6.7%)		
	H63D/w	467/7,506 (6.2%)		
	w/w	505/22,626 (6.7%)		
	Homozygous	22/197 (11.2%)		
Factor V Leiden P=.032	Heterozygous	488/5,596 (8.7%)		
	Wild	3,205/40,456 (7.9%)		
HLA-B*57:01	Positive	23/410 (5.6%)		
P=.16	Negative	680/8,767 (7.8%)		



Genetic Test Patient Registry Reliability of Test Results

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

^{*}among cases with complete information



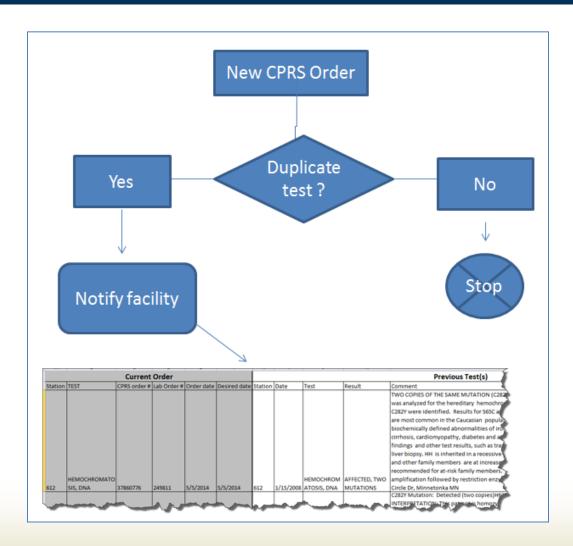
Duplicate Germline Genetic Test Utilization Program

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



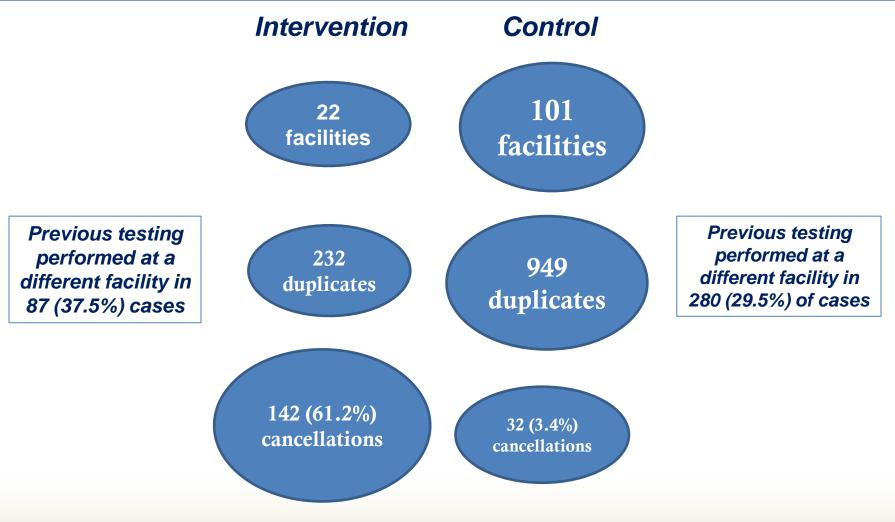
Improving utilization of genetic tests National automated notification system





Duplicate Genetic Testing Program

February 2015 - January 2016





Duplicate Germline Genetic Test Utilization Program

Duplicate orders Feb 2015-Jan 2016*						
Tort	Intervention (Intervention (N=22 facilities)		No intervention (N=101 facilities)		
Test	Notifications	Cancellations	None	Cancellations		
HFE	39	30 (76.9%)	313	3 (1.0%)		
FVL	53	35 (66.0%)	202	12 (8.3%)		
PGM	14	9 (64.3%)	94	10 (10.6%)		
HLA-B27	56	23 (51.8%)	164	3 (1.8%)		
HLA-B5701	70	39 (55.7%)	176	4 (2.3%)		
TOTAL	232	142 (61.2%)	949	32 (3.4%)		

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

Percentile range of cancellations by facility (%)					
Action (N facilities) 10th Median 90th					
Intervention (N=22)	22.8%	66.7%	100.0%		
No intervention (N=101)	0.0%	0.0%	14.2%		



Duplicate Germline Genetic Test Utilization Program









"Whoa-way too much information."



'Big Data' Team



Danny Luevano

Evelyn Harrison

Cindy Barger





The End