The New Game in Healthcare: Keeping Patients Healthy and Out-of-Hospital Precision Medicine; the Role Of Lab Testing

James M Crawford, MD, PhD jcrawford1@northwell.edu

Executive Director and Senior Vice President for Laboratory Services, Northwell Health Professor and Chair, Pathology/Lab Medicine Hofstra Northwell School of Medicine Manhasset, NY

Northwell Health™

Disclosures

- ClaraPath (start up from Cold Spring Harbor Laboratories)*
 - Scientific Advisory Committee
- Northwell Health Genomics Alliance (with OPKO Health)
 - President of LLC



Northwell Health



- Reference laboratory (9% of ambulatory market)
- 21 Hospitals (27% of regional market)
- Free-standing Emergency Room

450+ practice locations
 >4M patient encounters per year
 Network of SNFs, AmbSurg, UrgiCenters
 >28M billable lab tests per year



Outreach

Plus: 32 Patient Service Centers, in-office phlebotomy, home draw, network support of PQLs



Northwell: Hospital Laboratory Costs (\$M)



Core Lab Growth



Since 2008, revenue has increased by 224% and total tests have increased by 117%

*Total tests includes hospital reference testing, HHC testing and outreach/other testing

Northwell Health



Q: When is a Laboratory not a Laboratory?

A: When it is a leader in providing information. When it provides programmatic leadership.



Diabetes Wellness Care

A Successful Employer-Endorsed Program for Employees

Cynthia C. Bevis, JD, MBA, MS, June M. Nogle, PhD, Barbara Forges, MD, Philip C. Chen, MD, PhD, Deborah Sievers, MSN, RN, CDE, Karlene Ranghell Lucas, MBA, RRT, John J. Mahoney, MD, MPH, and James M. Crawford, MD, PhD

- A Pathology-led Diabetes Wellness program in Orlando, FL
 - Recruitment, Screening, Intervention (1y) = Education, Testing
 - Close coordination with PCPs, program Endocrinologists
 - 73 employees enrolled with pre-diabetes; 151 with diabetes
- Outcomes

rthwell Health*

- Pre-diabetes: mean HbA1c decreased 6.1% to 5.4% (p<0.0001)
- Diabetes: mean HbA1c decreased 9.0% to 7.5% (p<0.0001)
- 12m before: 27 hospitalizations; 12m during/15; 12m after/27
- Total PMPM costs: 1.2% rise year-of program; 8.3% rise yr after
- Conclusion: *Pathology* can provide leadership in wellness care

Establishing an Evidence Base for Critical Laboratory Value Thresholds

Travis A. Doering,¹ Frederick Plapp, MD, PhD,² and James M. Crawford, MD, PhD ^{1, 3}

From the ¹Hofstra North Shore-LIJ School of Medicine, Hempstead, NY; ²St Luke's Hospital, Kansas City, MO; and ³Department of Pathology and Laboratory Medicine, North Shore-LIJ Health System, Manhasset, NY.

- Five years of inpatient admissions examined
 - Total admissions = 165,066
 - Total "critical value" test results = 872,503
 - K⁺, Na⁺, Hct, Hb, Glucose, Lactate, APTT, INR (high, low)
 - Mortality as a function of time after test result
- Outcomes (selected)

orthwell Health*

- Current thresholds identified patients at risk for death: K⁺
- Current thresholds too conservative: elevated Hct, Hb
- Current thresholds not conservative enough: elevated lactate

Conclusion: Pathology really can save lives (measured in minutes)

High Lactate Plot: Survival in the first 48 hours after lab test





Chronic Kidney Disease Management*





Gastrointestinal and Hepatobiliary Pathology

Acute Kidney Injury

Northwell

Health™

- AKI affects 5-7 % of all hospitalized patients; Majority of patients are cared for by non-nephrologists
- AKI is under-recognized and under-diagnosed:
 - 6 to 30 fold increase in in-hospital mortality
 - Average LOS is increased by 3 to 7 days
 - Hospitalization costs increased by \$4,000 to \$10,000/day/patient
 - \$10B in annualized costs throughout the U.S.
- Lab instituted a "delta creatinine" Alert pilot program:*
 - 50% relative rise OR 0.3 mg/dl rise: detects 99.8% of AKI patients
 - 7:00 AM daily notification to CMO \rightarrow distributed to units
 - Pilot initiated at Forest Hills Hospital (250 beds) Jan 1, 2014
 - Alert triggered 5,185 times in 6m = 40 times per day
 - Clinical rounding identified 20 pts per day = 8% of admissions

*Tarush Kothari, MD, MPH
 LQF Oct 20 Breakout Session – 1:10 – 2:00 PM

System-wide Identification of AKI



Q: What does this teach us?

A: Any clinical problem is fair game. High-volume, high-impact problems are good. So are high-acuity (high or low volume). You have to work with clinical champions. You have to leverage *your* lab information.



Payer Use of Laboratory Data (ca. 2016)

- Laboratory Utilization Management (LUM)
 - Payment (may) require Evidence Base for test utilization
 - Laboratories not engaging in LUM are less desirable than those who are (e.g., esoterics/molecular)
- Laboratory Test Data Portability
 - Transmission of data to Payer
 - Fulfillment of HEDIS* requirements
- Patient Access to Laboratory Testing
 - "Patient Service Centers" (blood draw sites)
 - Physician Practice access to in-network lab draws



What Payers are Doing with Laboratory Data

- Risk Stratification of Covered Populations
- Supporting Actuarial Analysis of Total Cost of Care
- Reducing Leakage of Lab Testing to out-of-network Labs
- Assessment of Provider Performance on Quality Metrics
- Aiming to:
 - Work with Providers to support Coordinated Care
 - Close "Care Gaps"
 - Reduce/Manage Laboratory Test Utilization
 - Increase exclusivity of Laboratory Network(s)
 - Manage Costs
 - Manage Costs



Data Across the Continuum of Care



Northwell "Division" of Pathology Informatics

- Est. in 2013; a "group", not "division" (n = 9 and growing)
- Works intimately with LIS team (n = 50 and growing)
- CMIO and CIO for Laboratory Service Line
 - CMIO: works with clinical stakeholders throughout system
 - CIO: accountable to enterprise IT (CIO, OCIO)
- Design and build LDW*:

orthwell

Health™

- architecture, programmers, analysts, project manager
- Data integration from multiple systems throughout enterprise – "Owning" deliverables from laboratory environment
- Delivery platforms, both as internal and external builds
- Return-on-Investment: within first year but to health
- system. (Benefit does not derive to Laboratory Service Line)

Northwell "Division" of Pathology Informatics

- Business Analytics*
 - Financial*
 - Operational*
 - Service*
- Clinical Analytics
 - Utilization Management*
 - Clinical Decision Support*
 - Physician Practices*
 - Hospitals –Inpatient/Outpatient*
 - Patient Outcomes[†]

*All from Laboratory Data Warehouse [†]Requires data pulls from EDW or HIE





Northwell Health HHC Quality Metrics

January - December 2015



Laboratory Test Utilization (inpatient or ambulatory)

Reference Hospital Utilization Heatmap by Site Utilization Index = (provider test volume/provider total volume) / (total test volume/total volume)

e.g. for a given provider, Vitamin D 25 Hydroxy's would be expected to constitute 12.0% of their overall test

#	Test	Total	Test %	Cumalative %	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6	Hospital 7	Hospital 8	Hospital 9	Hospital 10	Hospital 11	Hospital 12	Hospital 13
	Total	377,526	-		69,696	57,512	46,606	37,584	33,366	31,526	26,276	25,681	18,892	18,336	8,701	2,085	1,265
1	Glycosylated Hemoglobin	59,787	15.8%	27.8%	2.49	0.00	2.17	0.00	2.86	0.00	0.00	0.00	0.00	0.00	0.00	2.36	1.93
2	Vitamin D 25 Hydroxy	45,212	12.0%	12.0%	0.87	2.28	1.04	0.00	1.24	1.92	0.84	0.43	0.00	0.00	0.00	0.46	0.69
3	LEAD	43,204	11.4%	23.4%	0.00	0.55	0.78	1.64	0.63	0.71	1.04	1.66	2.31	3.52	3.07	0.00	0.00
4	Quantiferon-TB Gold	39,205	10.4%	33.8%	0.61	0.69	1.53	1.85	0.06	1.04	2.02	1.68	0.55	0.00	0.35	3.67	1.93
5	HIV AG/AB Screen by CMIA	10,362	2.7%	36.5%	1.25	0.00	0.16	5.77	0.11	0.16	0.02	2.19	0.00	0.00	0.00	0.07	0.00
6	HPVHR MRNA	10,276	2.7%	39.3%	0.53	0.24	0.00	1.07	0.00	0.00	1.48	1.17	6.76	0.00	10.26	0.00	0.00
7	Viral Load	7,847	2.1%	41.3%	0.00	2.23	0.00	3.27	0.00	0.02	1.18	3.68	0.00	0.00	0.00	0.00	0.00
9	Benzo QuaNT Ur Confirm	6,760	1.8%	43.1%	0.00	6.56	0.00	0.00	0.00	0.00	0.00	0.01	0.00	0.00	0.00	0.03	0.00
8	Antinuclear AB	6,312	1.7%	44.8%	1.50	0.00	1.67	0.00	2.08	1.06	1.88	0.03	1.54	0.00	1.30	0.32	0.95
10	Vitamin D 1,25 Dihydroxy	5,528	1.5%	46.3%	0.68	0.85	0.32	0.46	0.35	3.25	0.90	2.06	0.05	3.03	0.01	0.33	0.76
11	Vitamin B1	4,604	1.2%	47.5%	3.48	0.10	0.04	0.01	0.00	2.87	0.05	0.00	1.42	0.30	0.37	0.00	0.06
12	Blood Culture	4,008	1.1%	48.6%	0.00	6.56	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
14	Hepatitis C RNA Quant	3,868	1.0%	49.6%	0.00	2.40	0.00	1.83	0.02	0.01	2.95	1.48	0.00	2.95	0.00	0.00	0.00
15	H.Pylori AG Stool	3,685	1.0%	50.6%	0.00	2.07	0.00	4.08	0.00	0.00	1.25	1.59	0.00	1.70	0.00	0.00	0.00
17	Vitamin B6	3,319	0.9%	51.4%	4.76	0.06	0.01	0.01	0.03	1.09	0.03	0.00	0.13	0.09	0.09	0.00	0.00
13	HPV GENO	3,272	0.9%	52.3%	1.39	0.00	0.00	0.00	1.23	7.61	0.00	0.00	0.00	0.00	0.00	0.00	0.00
16	Testosterone Free and Total	3,002	0.8%	53.1%	0.39	1.33	1.16	0.56	1.43	1.60	1.36	0.84	1.19	0.03	2.38	0.00	0.00
18	HLX CFTR Results	2,863	0.8%	53.9%	0.00	3.47	0.01	0.07	0.44	2.56	3.00	0.03	0.00	0.00	0.00	0.00	0.00
19	Hepatitis B Surface Antibody, Quant	2,789	0.7%	54.6%	0.83	0.80	3.38	0.00	2.02	1.18	0.43	0.01	0.00	0.00	0.00	0.13	0.00
20	Cyclic Citrullinated Peptide AB	2,410	0.6%	55.2%	0.91	0.52	1.11	1.11	1.13	0.88	0.73	2.39	1.24	0.79	0.76	0.00	0.25



Utilization Index = (provider test volume/provider total volume) / (total test volume/total volume)

e.g. for a given provider, Vitamin D 25 Hydroxy's would be expected to constitute 22.7% of their overall test volume

#	Test	Total	Test %	Cumalative %	From Hospital HM	Provider 1	Provider 2	Provider 3	Provider 4	Provider 5	Provider 6	Provider 7	Provider 8	Provider 9	Provider 10	Provider 11
	Total	31952				4913	1596	1028	839	728	568	554	554	528	506	471
0	%					15.4%	5.0%	3.2%	2.6%	2.3%	1.8%	1.7%	17%	1.7%	1.6%	1.5%
1	Vitamin D 25 Hydroxy	7261	22.7%	22.7%	1.92	0.60	0.91	0.00	2.40	0.57	0.22	0.00	3.20	0.01	0.00	0.84
2	Quantiferon-TB Gold	3408	10.7%	33.4%	1.04	0.00	0.00	9.33	2.10	0.00	2.06	1.81	0.20	7.78	2.08	0.00
3	LEAD	2548	8.0%	41.4%	0.71	0.00	0.00	0.00	0.00	0.00	3.00	2.38	0.00	0.05	3.20	0.00
4	HPVGENO	2079	6.5%	47.9%	7.61	0.00	0.00	0.00	0.00	0.00	3.60	4.83	0.00	0.00	3.28	0.00
5	Vitamin D 1,25 Dihydroxy	1502	4.7%	52.6%	3.25	2.88	1.61	0.00	0.03	2.69	0.00	0.15	0.04	0.00	0.08	2.35
6	Copper	1166	3.6%	56.2%	9.56	3.68	2.99	0.00	0.00	3.50	0.00	0.00	0.00	0.00	0.00	4.42
7	Vitamin A	1146	3.6%	59.8%	10.80	3.71	3.16	0.00	0.00	3.49	0.00	0.00	0.00	0.00	0.00	3.26
8	Vitamin B1	1105	3.5%	63.3%	2.87	3.90	3.22	0.00	0.00	3.65	0.00	0.00	0.00	0.00	0.00	1.35
9	Vitamin E	1063	3.3%	66.6%	10.87	3.98	2.64	0.00	0.00	3.76	0.00	0.00	0.00	0.00	0.00	3.45
10	HLX CFTR Results	628	2.0%	68.6%	2.56	0.00	0.00	0.00	0.00	0.00	8.87	9.28	0.00	0.10	8.04	0.00
11	Antinuclear AB	560	1.8%	70.3%	1.06	0.00	0.00	0.00	0.27	0.00	0.10	0.10	5.97	0.00	0.00	0.00
12	Hepatitis Be AG	532	1.7%	72.0%	5.34	1.89	2.41	0.06	3.79	2.39	0.32	0.00	0.87	0.23	0.00	2.55
13	Hepatitis Be AB	514	1.6%	73.6%	5.27	1.96	2.49	0.00	3.93	2.48	0.33	0.00	0.90	0.24	0.00	2.64
14	Testosterone Free and Total	400	1.3%	74.8%	1.60	0.00	0.00	0.00	2.48	0.00	0.70	3.17	0.14	0.30	2.68	0.00
15	Selenium Serum	388	1.2%	76.1%	10.26	2.61	5.47	0.00	0.00	3.28	0.00	0.00	0.00	0.00	0.00	4.20
16	Vitamin C	343	1.1%	77.1%	10.70	3.15	4.49	0.00	0.00	3.97	0.00	0.00	0.00	0.00	0.00	3.76
17	Vitamin B2	312	1.0%	78.1%	11.15	3.19	4.04	0.00	0.00	4.08	0.00	0.00	0.00	0.00	0.20	3.91
18	Vitamin B6	302	0.9%	79.0%	1.09	3.23	3.84	0.00	0.00	4.07	0.19	0.00	0.00	0.00	0.00	4.27
19	Hepatitis B Surface Antibody, Quant	274	0.9%	79.9%	1.18	0.00	0.00	0.11	0.00	0.00	0.41	0.21	0.21	1.33	0.00	0.00
20	KEPPRA	242	0.8%	80.7%	2.04	0.03	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Health™

Adherence to Quality Standards

Blood Culture Fill Volume



Fill volume:

Optimal is 8 – 10 mL

Maximum is 10 mL Minimum is 3 mL

Northwell Health System Quality Initiative Blood Culture Fill Volumes



Northwell Health System Quality Initiative Blood Culture Fill Volumes



Health™

Northwell Health System Quality Initiative Blood Culture Fill Volumes

BLOOD VOLUME DISTRIBUTION HISTOGRAM: HOSPITAL S	SERVICE
--	---------

For Period: Hospital:	08/01/2016 - 08/31/2016 11:59:59 PM
Report Generated:	09/06/2016 03:13:36PM



Northwell Health: Enterprise "Precision Medicine"

- Cancer: ~ 19,000 newly diagnosed cancer patients per year; >1% of United States (1.7M); 16,000 patients care for per year
 - Cancer Genomics: "actionable" gene variants
 - Cancer Genetics: screening and counseling
- **Prenatal Diagnosis**: 42,000 live births per year; >1% of all live births in the United States (3.96M)
 - Non-invasive perinatal screening (NIPS)
 - Carrier screening
- Pediatric & Adult Genetics



Genomics: Key Elements

The Clinical Team: disciplined, coordinated care

Patient identification

- Genetic counseling: test selection, patient selection
- Risk stratification
- Timing

Test resulting

- Genetic counseling: test interpretation
- Clinical management: action on the basis of test results
- Genetic counseling: family of proband
- Knowledge generation
 - Was clinical care actually influenced by test results?
 - What were patient outcomes? Cost of delivering care?
- How will such knowledge influence future care design? Northwell **Health**[™]

Genomics: Key Elements

The Laboratory:

- State-of-the-art technologies
- State-of-the-art "Bioinformatics Pipeline": data interpretation
- Genetic counseling: the role of the laboratory
- Informatics
 - Granular data: "good gene/bad gene" vs. detailed info
 - Linkage of [test results] to [clinical pre- and post- data]



Northwell Health Genomics Alliance: The Goal

- Enterprise-wide access to Precision Medicine
- Disciplined program of utilization and "action" upon results
- Prospective aggregation of [lab data] and [clinical data]
- Build the system Evidence Base for Genomic testing



Northwell Health partnerships



But we are not yet done: "Risk Assessment"

Patients ("members") are attributed to Risk-based programs
Actuarial Analysis of Risk: estimate cost of delivering care
Deliver Care: and document conditions-of-interest (HCCs)
The documentation determines premium rate on HIE (and hence, whether there is "up-side" or "down-side")



March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting

Discussion Paper

March 24, 2016



Centers for Medicare & Medicaid Services

Center for Consumer Information & Insurance Oversight



Figure 2.1 **Hierarchical Condition Categories Aggregations of Diagnosis Codes**



Identify attributed patients on the basis of Lab data

Determine gaps-in-care for attributed patients The key: "Conditions of Interest" (HCCs) Insert patients into Coordinated Care pathways Document disease conditions properly!

2016 YTD opportunity at Northwell Health: ~1% of risk* * It is only "early days" in this effort.



PROJECT SANTA FE





Lab 1.0 transactional

Sick Care

Receive Test Sample Result Test Sample Disease Screening

Protocol-driven Scheduled by Treating Physician Lab is derivative

Wellness Programming

Managed by Treating Physician Lab is derivative

Payment Models

Lab is a Commodity Value is Cost-per-Test

Lab 2.0 integrative

Health Care

Population Health using Lab data Total Cost-of-Care leveraging Lab data Time-to-Diagnosis **Diagnostic Optimization Care Optimization Therapeutic Optimization** Monitoring Optimization **Screening Optimization Risk Management** Identification of Risk Real-time tracking of Risk Escalation/De-escalation of Acuity Wellness Programming Gaps-in-Care closed using Lab data Outcomes of program using Lab data **Predictive Analytics** What will happen? When? Why? **Payment Models** Value of Lab for Total Cost-of-Care

PROJECT SANTA FE

© 2016



jcrawford1@northwell.edu