The Golden Age of Clinical Labs Global Movement- from Volume to Value

RESHAPING THE WAY CARE IS DELIVERED

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Founder, CEO, Lab 2.0 Strategic Services LLC

5/27/2020

Disclaimers

Today's comments are reflective of:

- My 4-year tenure as CEO of TriCore Reference Laboratories (2014-2017)
- The collective body of knowledge from Project Santa Fe Foundation & Clinical Lab 2.0 movement
- My own personal thoughts

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Blog: over past 48 hours

Khosrow Shotorbani
Lab 2.0- Thought leadership, Speaker, strategy facilitation, strategic planning
1d · Edited · ⊕

As you think about Covid-19, know this;
Labs are the first to know!
Labs are the first responders
Labs are the epicenter of Informatics.
Lab folks are the ones make this happen!
24/7-365 days/ year
Labs are the unsung heroes AMERICAN SOCIETY OF CLINICAL PATHOLOGY
College of American Pathologists (CAP)
 #labmedicine
#ASCP
#CAP
#patientsafety
Clinical Lab 2.0 #clinicallab2movement

Ever wonder who are behind the Coronavirus testing?

Definitely NOT doctors and nurses!

1:16 ⏀   ⫶⫶ LTE ▭

‹ Your post on March 16, 2020

It's your not-so-known   1,599 Reactions

43,310   104 Comments
views
Also known and perceived as: lab nerds,
boring lab techs, nerdy   472 Reshares
technologists, squinty clinical laboratory

🏢 559 people from Abbott viewed your post

More views from:

Roche	328
Siemens Healthineers	263
LabCorp	247

1:17 ⏀   ⫶⫶ LTE ▭

‹ Your post on March 16, 2020

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technologists, squinty clinical laboratory

💼 2,336 people who have the title Salesperson vie...

More views from:
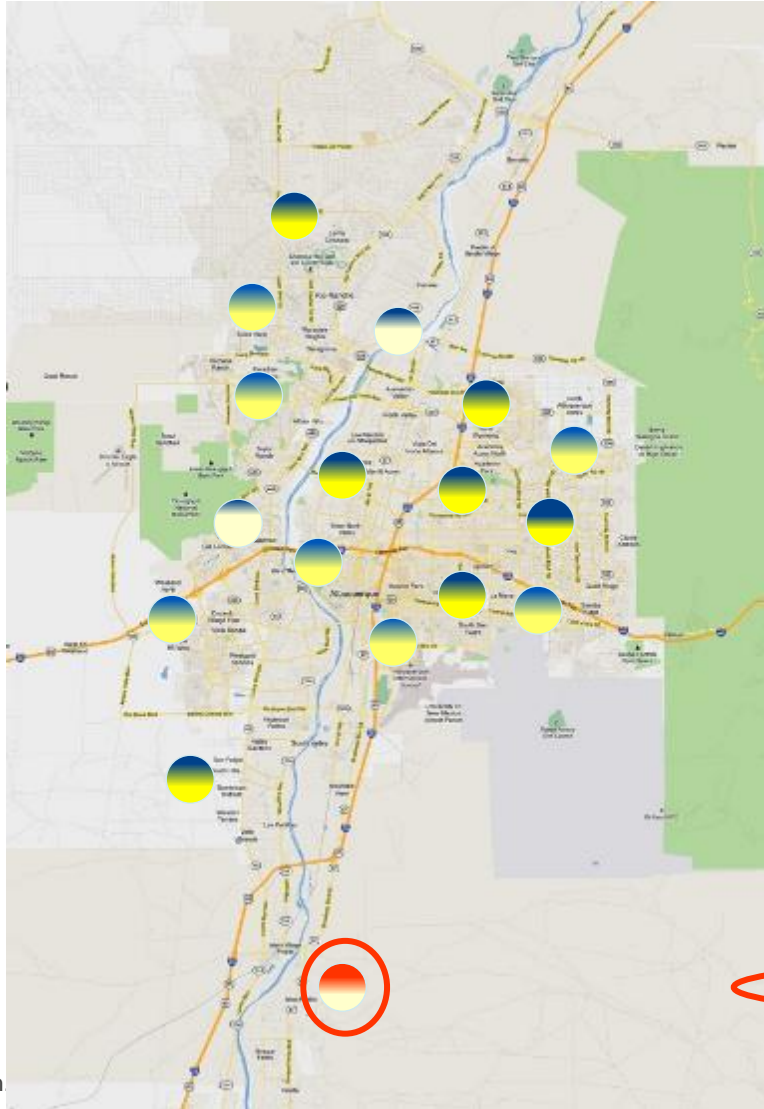
| Laboratory Technician | 1,934 |
| Laboratory Scientist | 1,169 |
| Medical Assistant | 994 |

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Albuquerque Metro Area (FLURSV)

Zip	Positive	Tests	Rate
87102	26	210	12%
87104	5	64	8%
87105	79	558	14%
87106	17	172	10%
87107	33	250	13%
87108	53	390	14%
87109	34	254	13%
87110	34	230	13%
87111	34	280	12%
87112	43	293	15%
87113	9	82	11%
87114	37	269	12%
87120	41	334	12%
87121	87	713	12%
87122	9	68	13%
87123	49	338	14%
87068	9	30	30%

Suspected

Confirmed
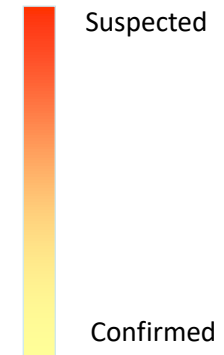
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[Stay Home, Catch Up on your Movies]
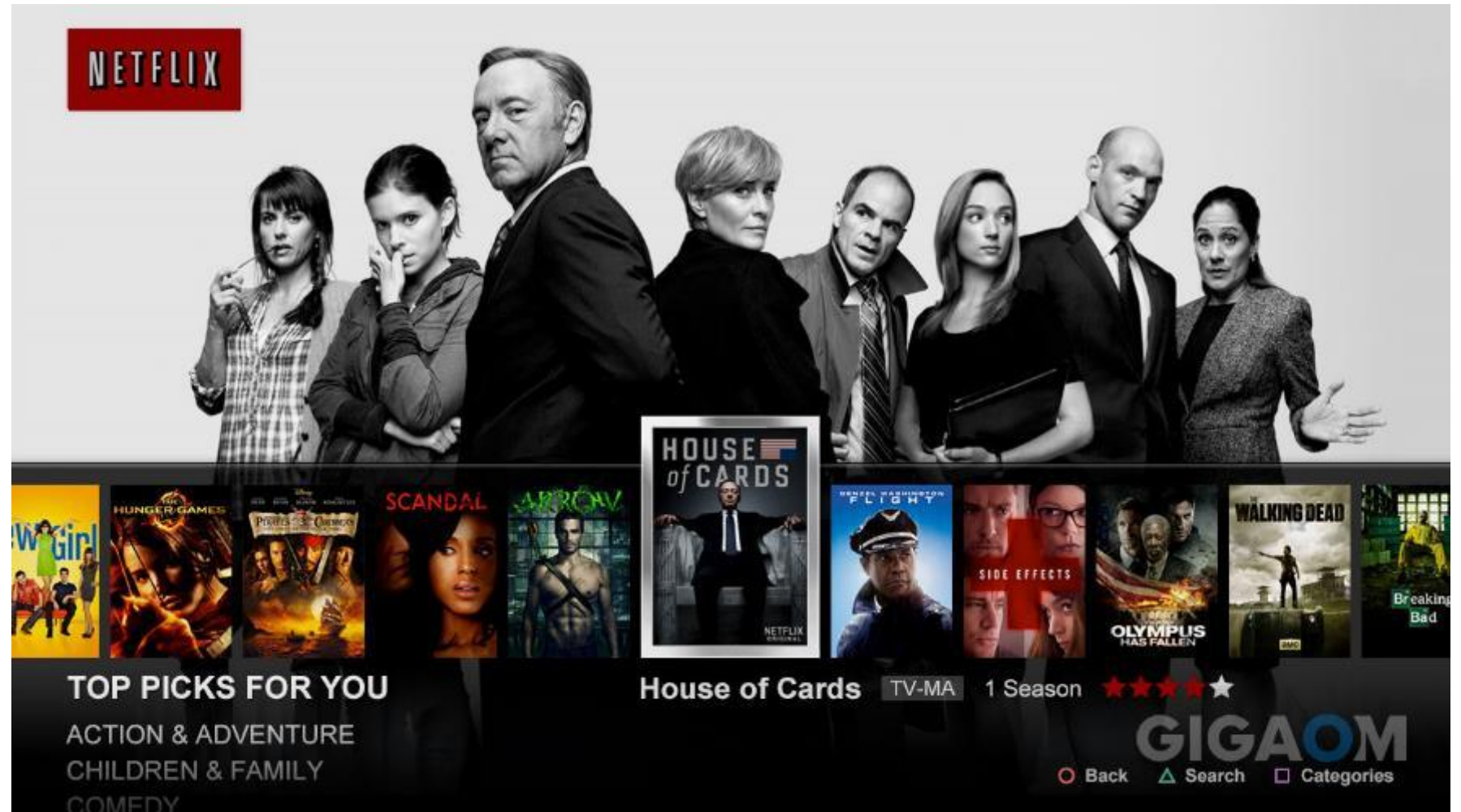
March 17, 2020

Where cases have been reported

COVID-19
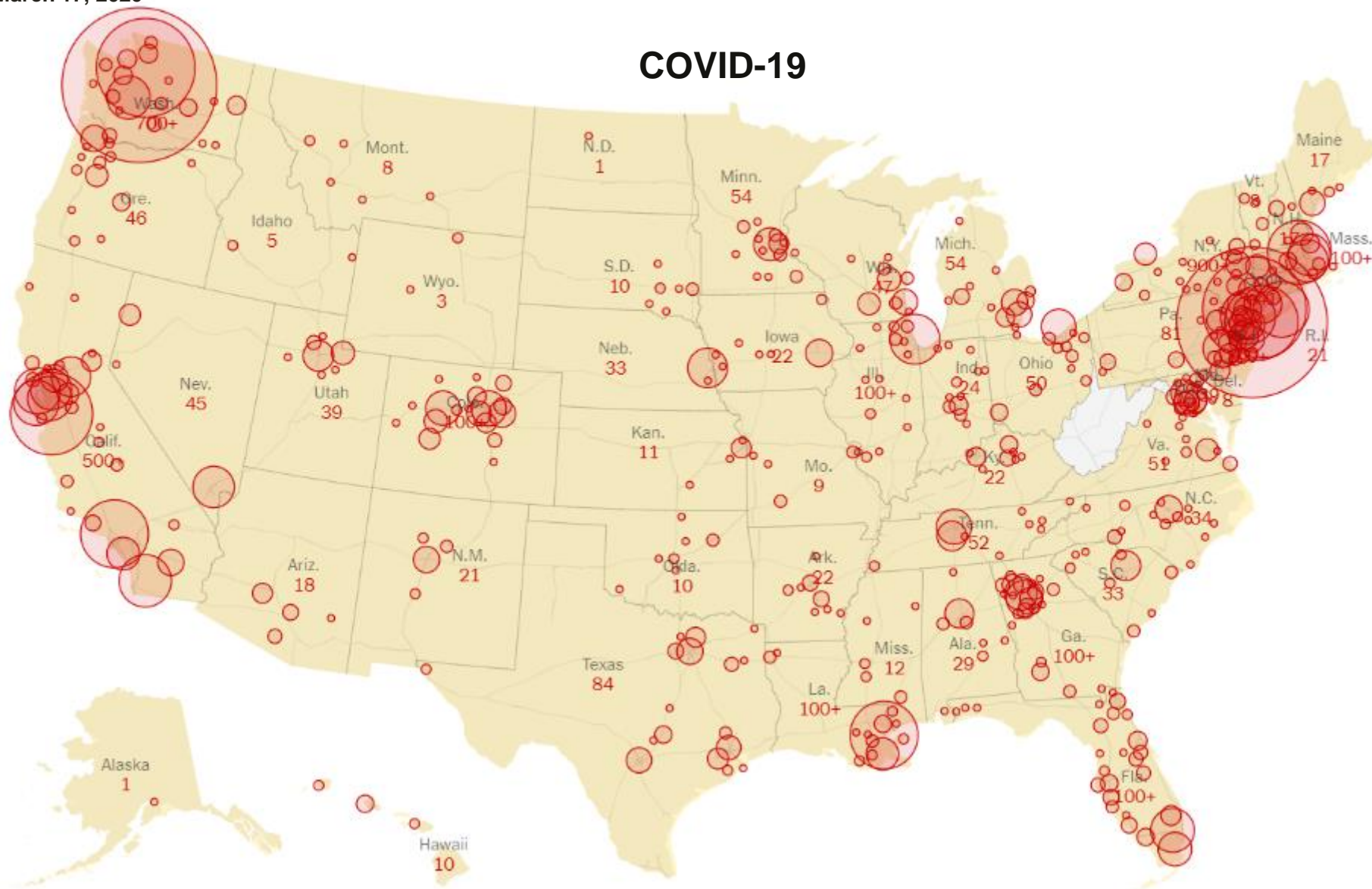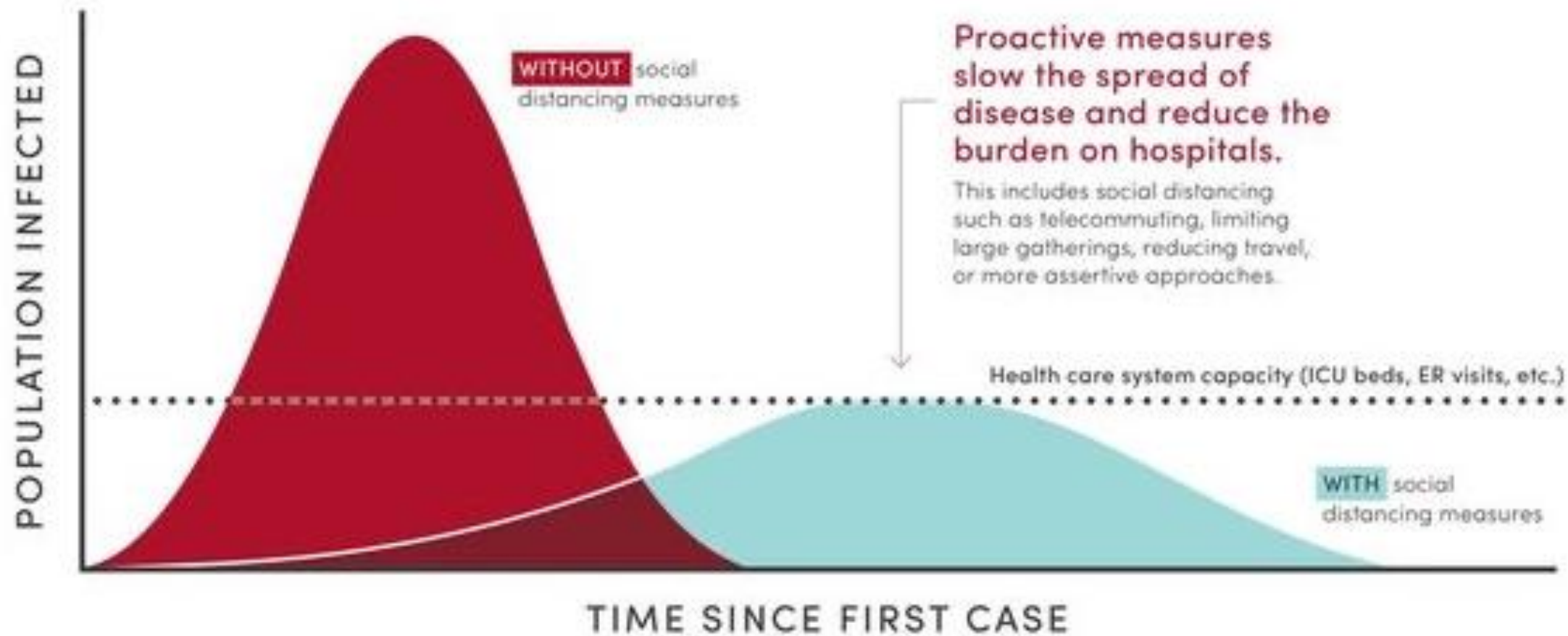
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"Patient Engagement Is The Blockbuster   Drug Of The Century," *- DAVID CHASE-FORBES*

-**Access**
-**Population Screening**
-**Aligned Incentives**
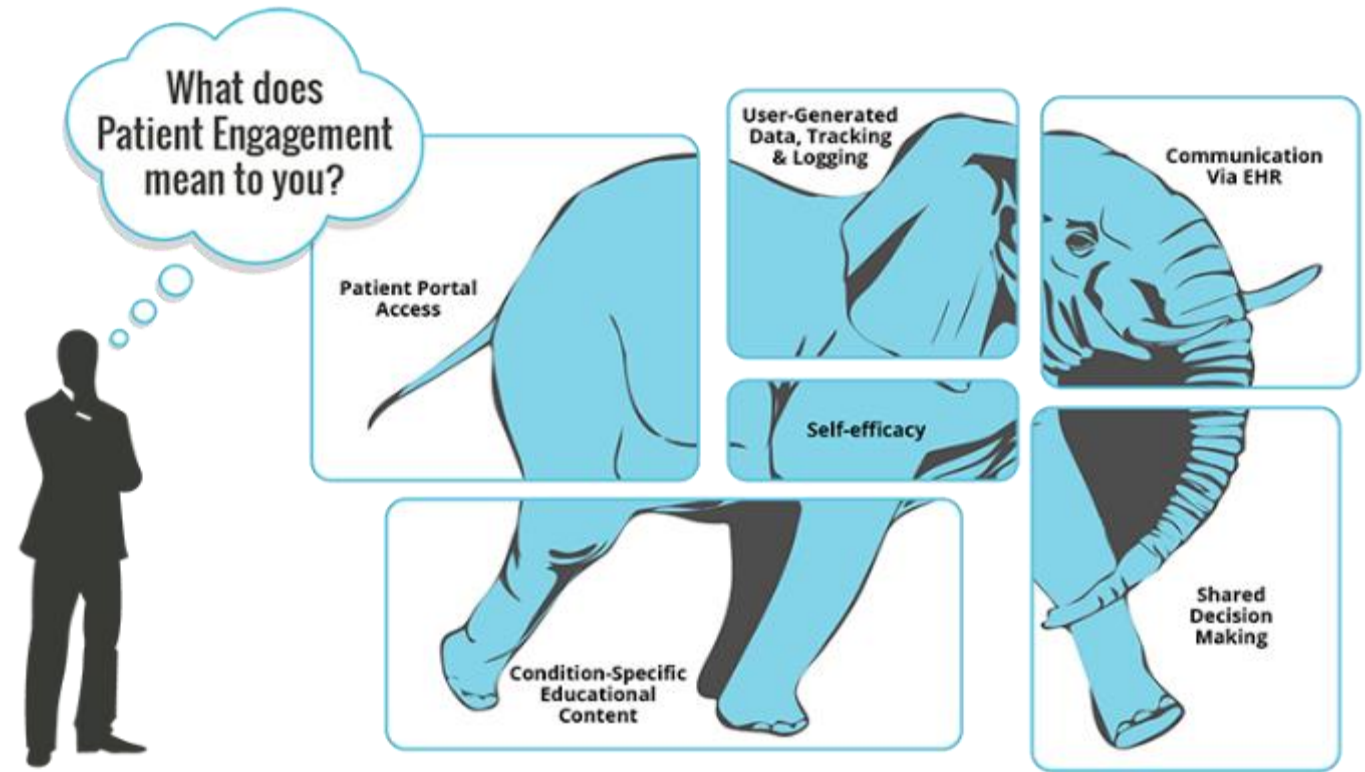
$2.1B Acquisition

ROLE OF LAB DATA…

AT THE POINT OF CARE?

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Our lens of the Clinical Lab

An <u>ancillary</u> cost center, managing <u>3 </u>cents

Or?

<u>Triage</u> of Well-Care, managing <u>97</u> cents?

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# Clinical Lab with a new lens

- ✓ Lab is the first to know- real time actionable data

- ✓ Lab is the first responder

- ✓ Lab is the "epicenter of informatics"

- ✓ Labs should be the "Command Center"

If so, what is our measurable value?!

Center For Diagnostics
Meteorology of Chronic Conditions

✓ First key responders

✓ Lab as the clinical "Triage"

✓ Integrated

    - Physicians workflow

    - Care manager workflow
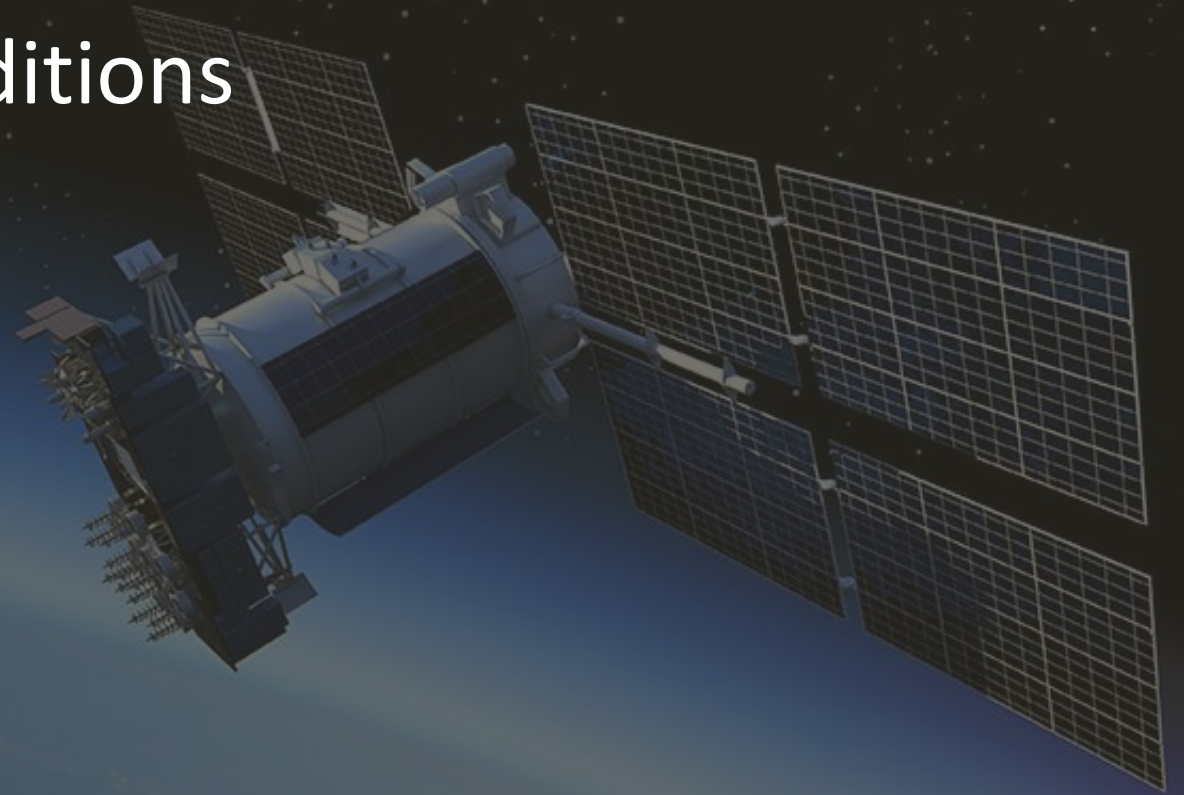
C2 CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE
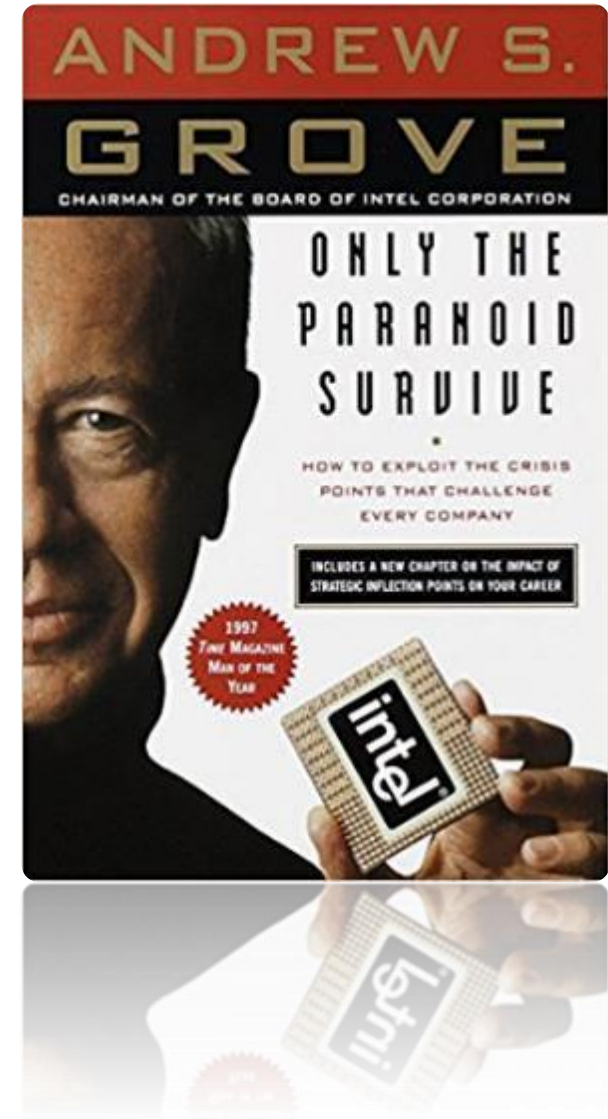
What Is a Strategic Inflection Point?

"a strategic inflection point is a time in the life of business when its fundamentals are about to change. That change can mean an opportunity to rise to new heights. But it may just as likely signal the beginning of the end"

Andy Grove, Intel

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"Lab 2.0 is <u>NOT</u> about selling or sharing patient data, its not ours to do so…..Lab 2.0 is about leveraging longitudinal patient data for a proactive clinical actionable insight to improve outcome and reduce overall cost."

"Patient owns their data and its all about portability, clinical stewardship"

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"Our imagination is the only limit to what we can hope to have in the future"

Franklin Kettering (1876-1985)

Clinical Lab 2.0 Movement

➢Leadership

➢Standards OKRs

➢Evidence
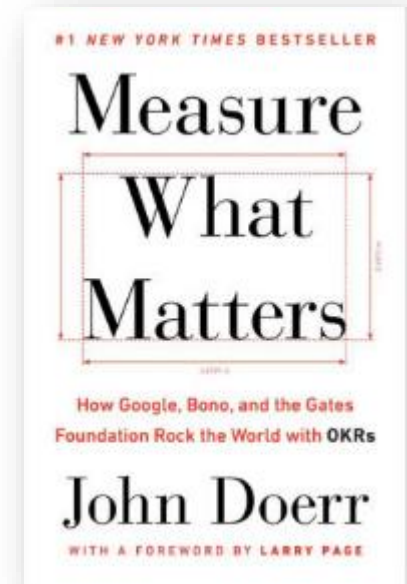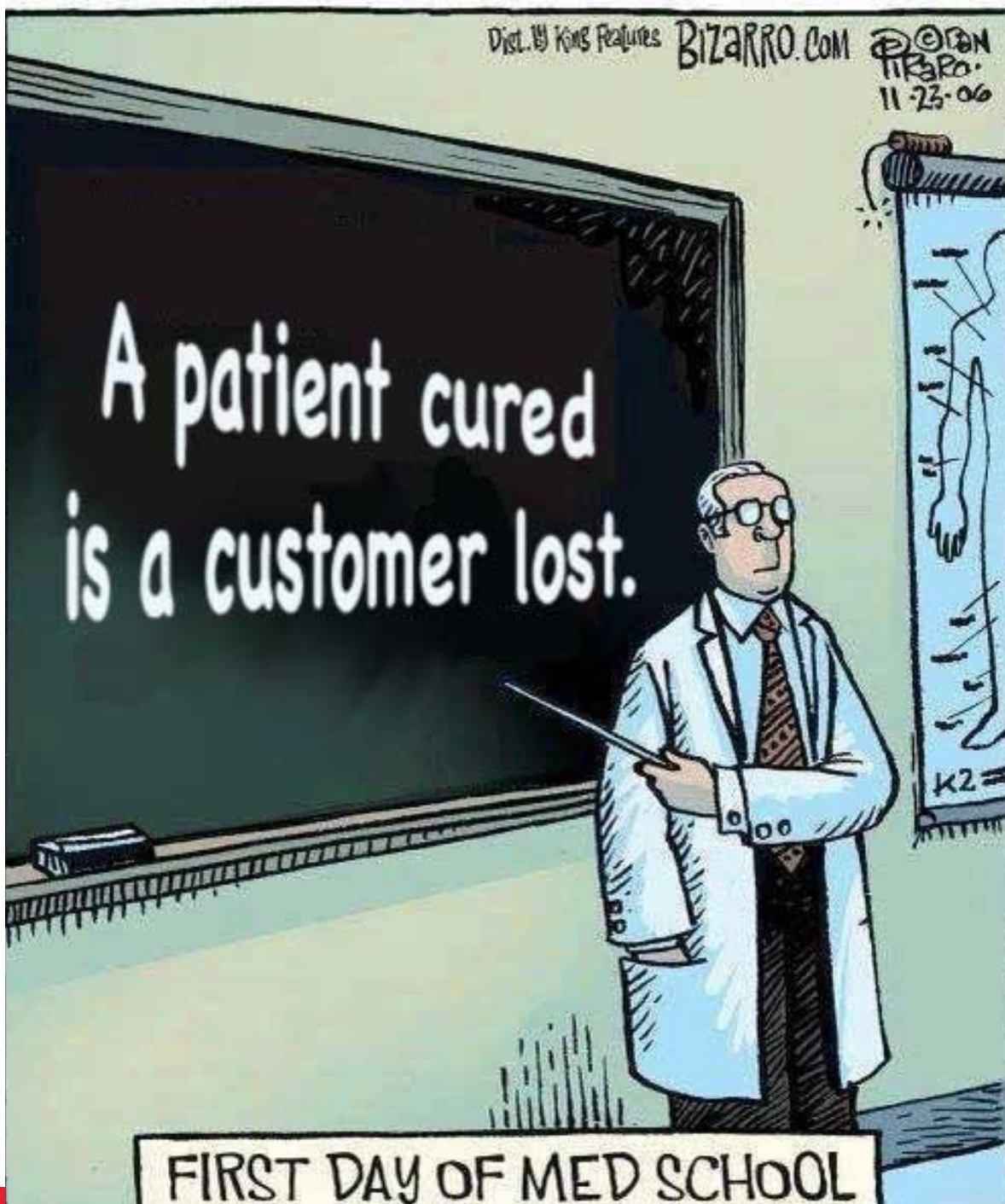
Seriously?!

**Latin definition of patient:
"the one who suffers"**

Lab 1.0 - Transactional

SCr
1.1

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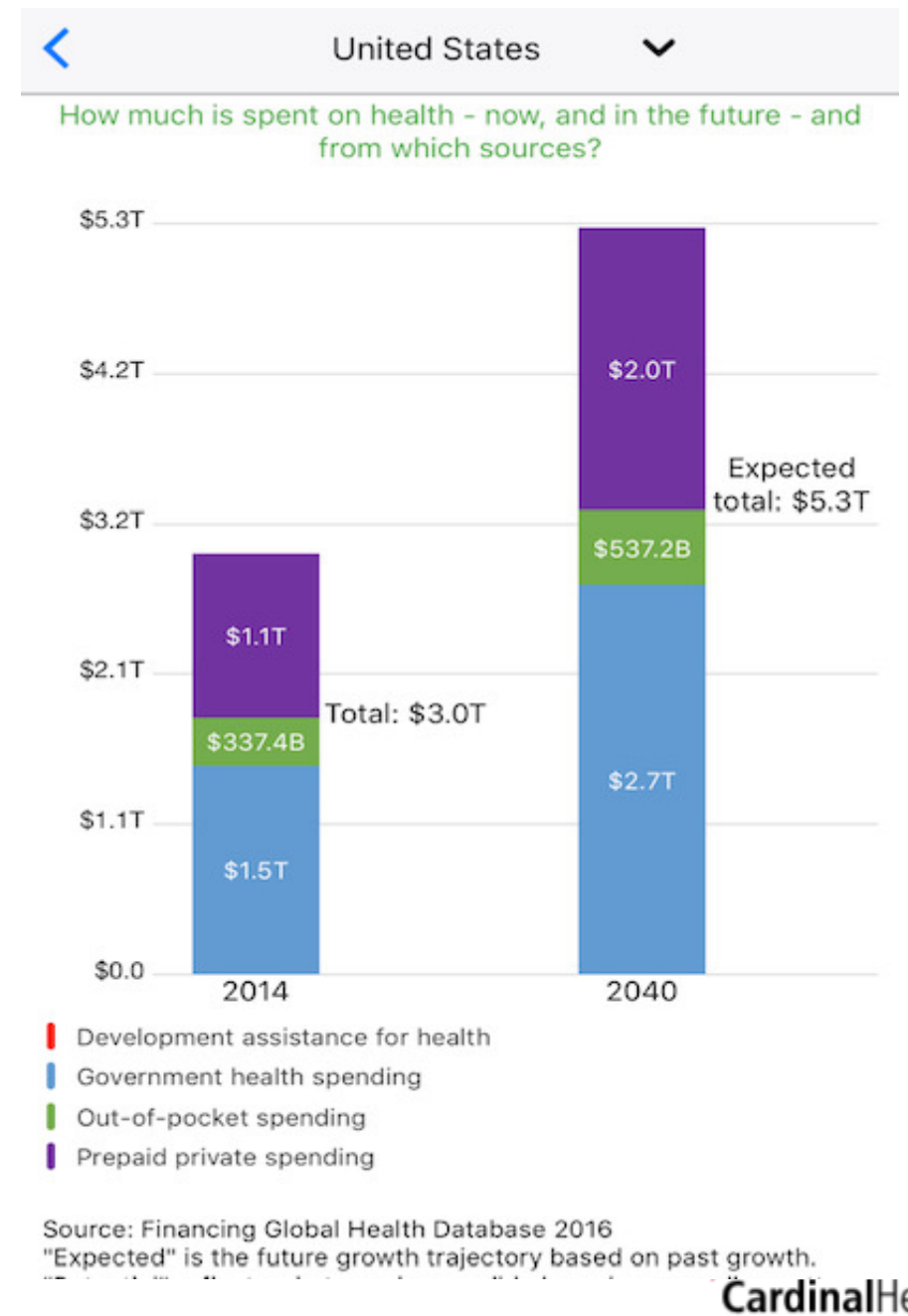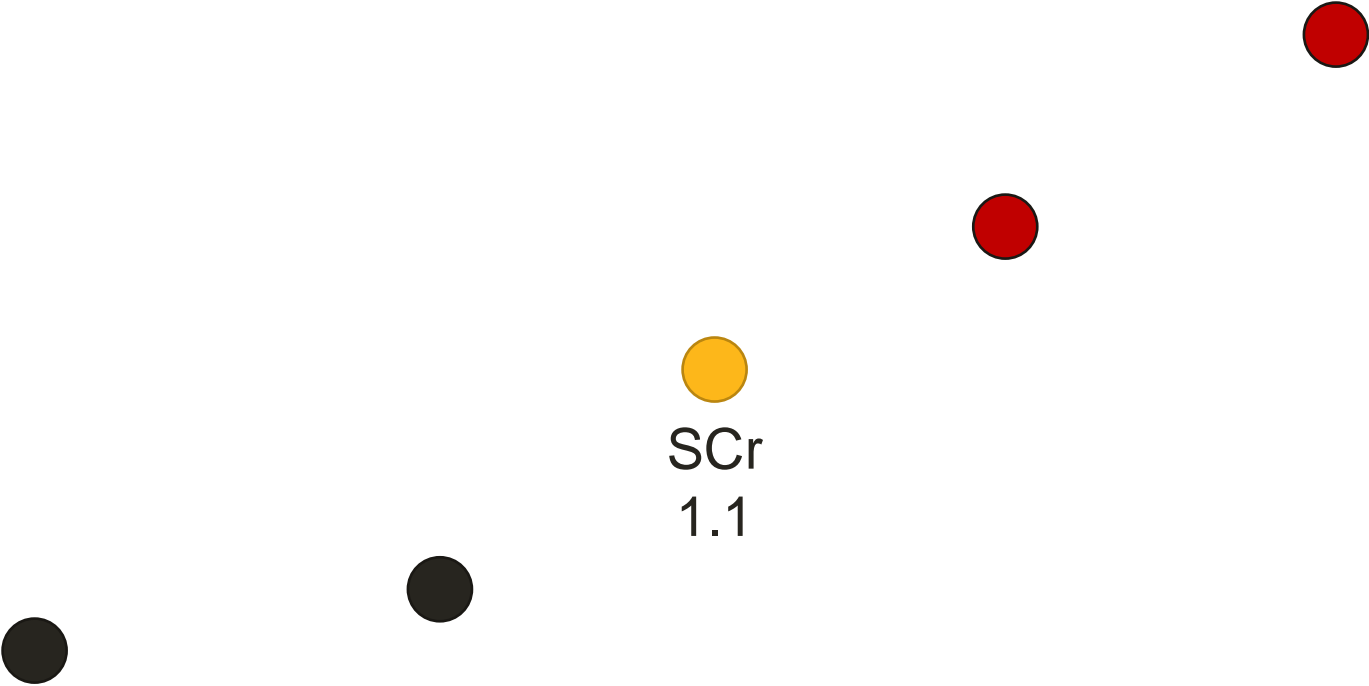
Lab 1.5 - Longitudinal

SCr
1.1

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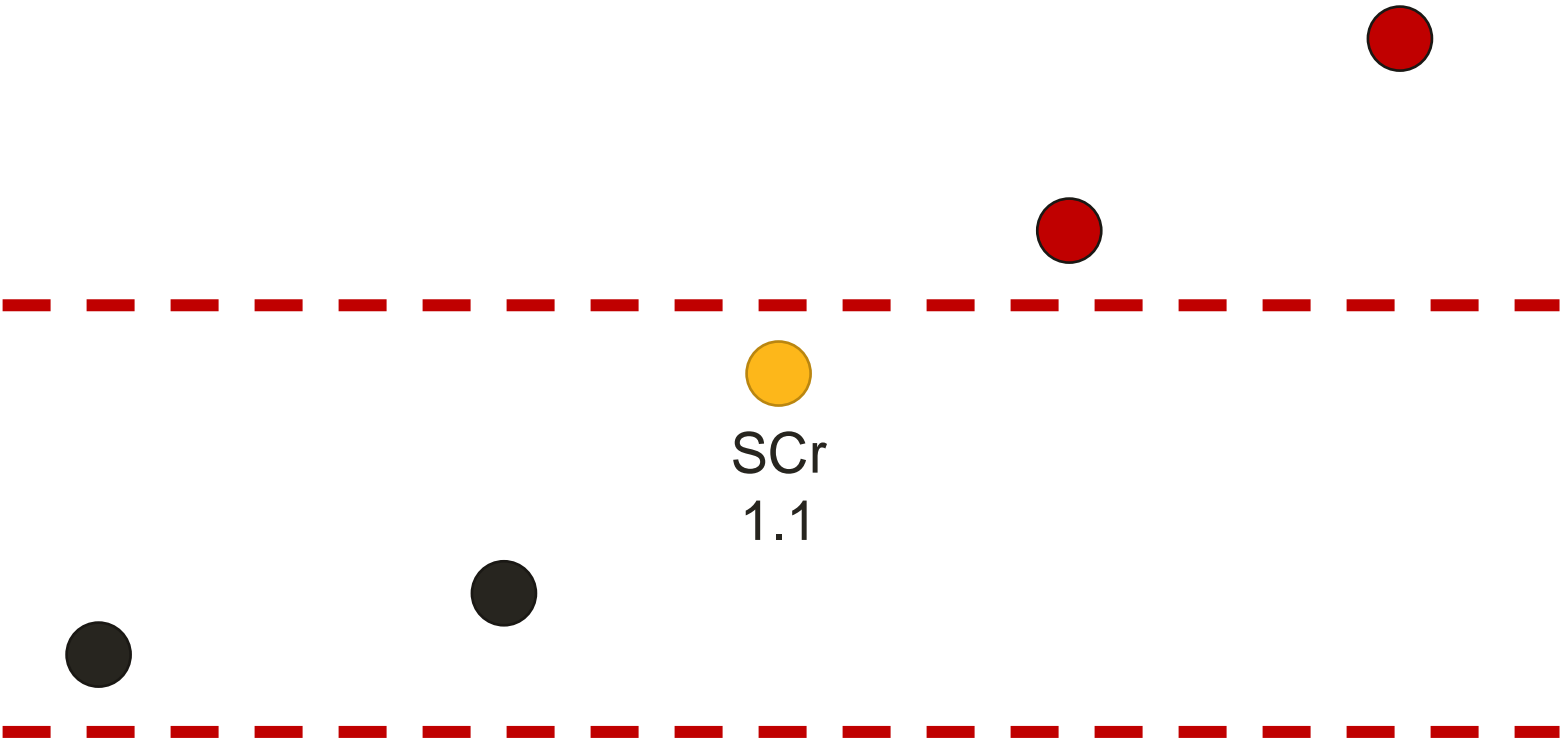
Cross-Industry Comparison of Size, Productivity and Efficiency
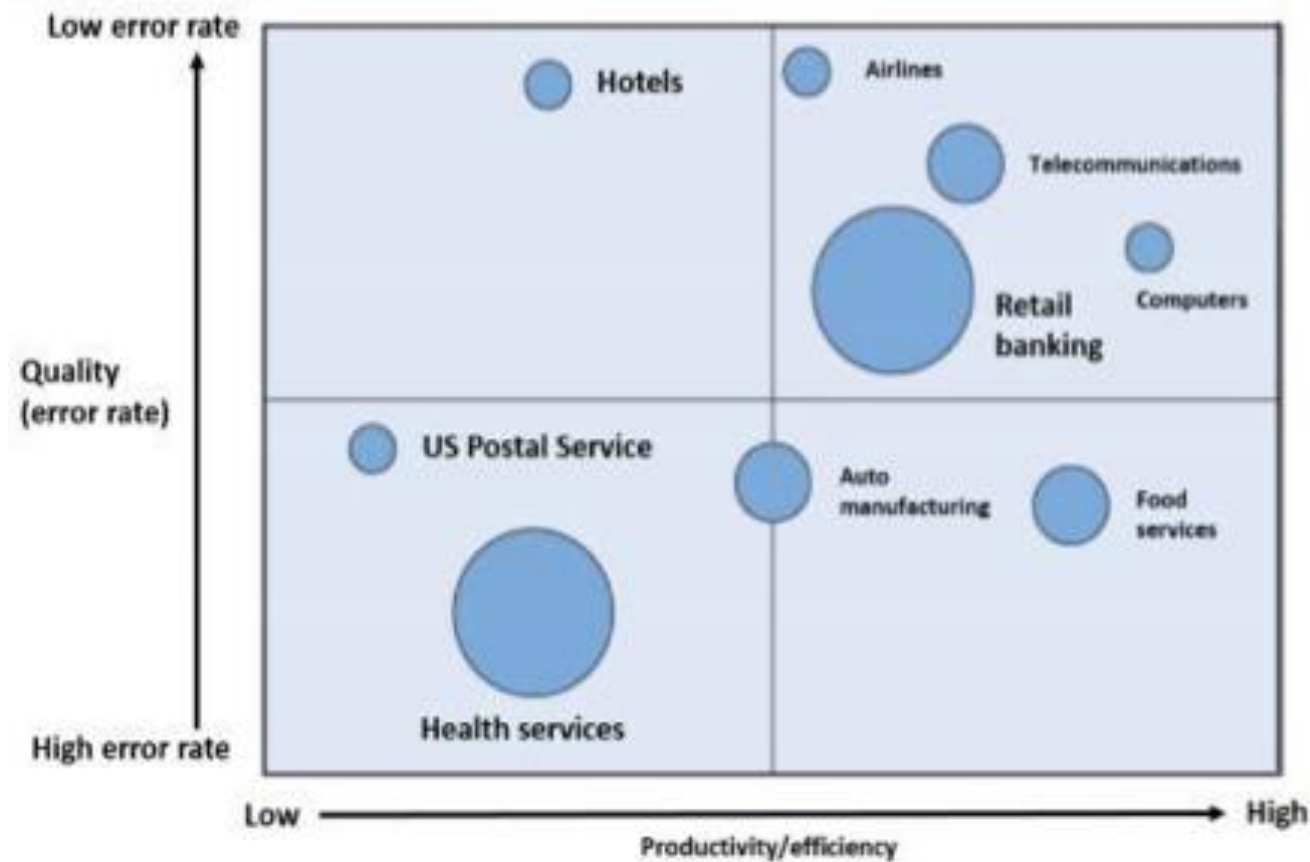
What is the role of molecular diagnostics in optimizing variation?

6 Sigma analytical performance ....Yet

Over-utilization

Miss-utilization

Under-utilization

REMAIN OUR CHALLENGES… OR OPPORTUNITIES

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Lab 1.0 Business Model Is <u>Not</u> Sustainable

$$\text{VOLUME} \times \text{REIMBURSEMENT} - \text{COST} = \boxed{\text{? Lab 1.0 Economics}}$$

$$\text{PAMA Bundled Payment} + \text{FDA LDT} + \text{PHYSICIAN EMPLOYMENT} + \text{INDUSTRY CONSOLID-ATION} =$$

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PAMA Impact

1% decrease in MCLFS

10% decrease in MCLFS
2018 - 2020

15% decrease in MCLFS
2021 - 2023

Net Revenue

Base Year = 2014

2014　2015　2016　2017　2018　2019　2020　2021　2022　2023
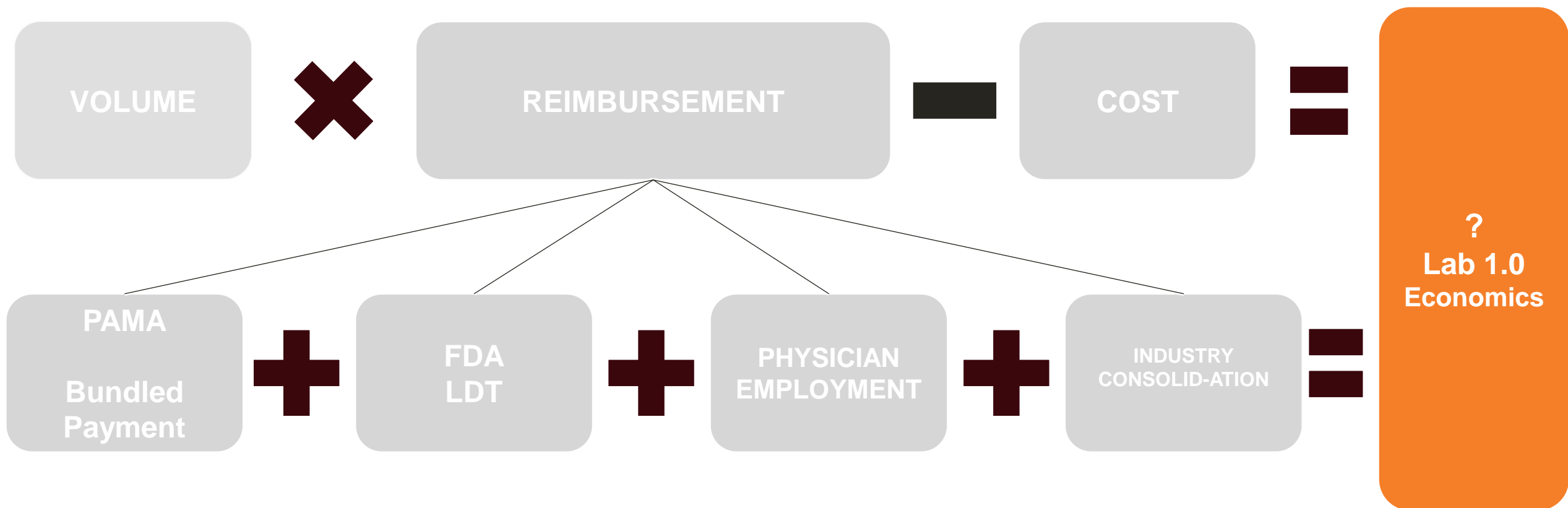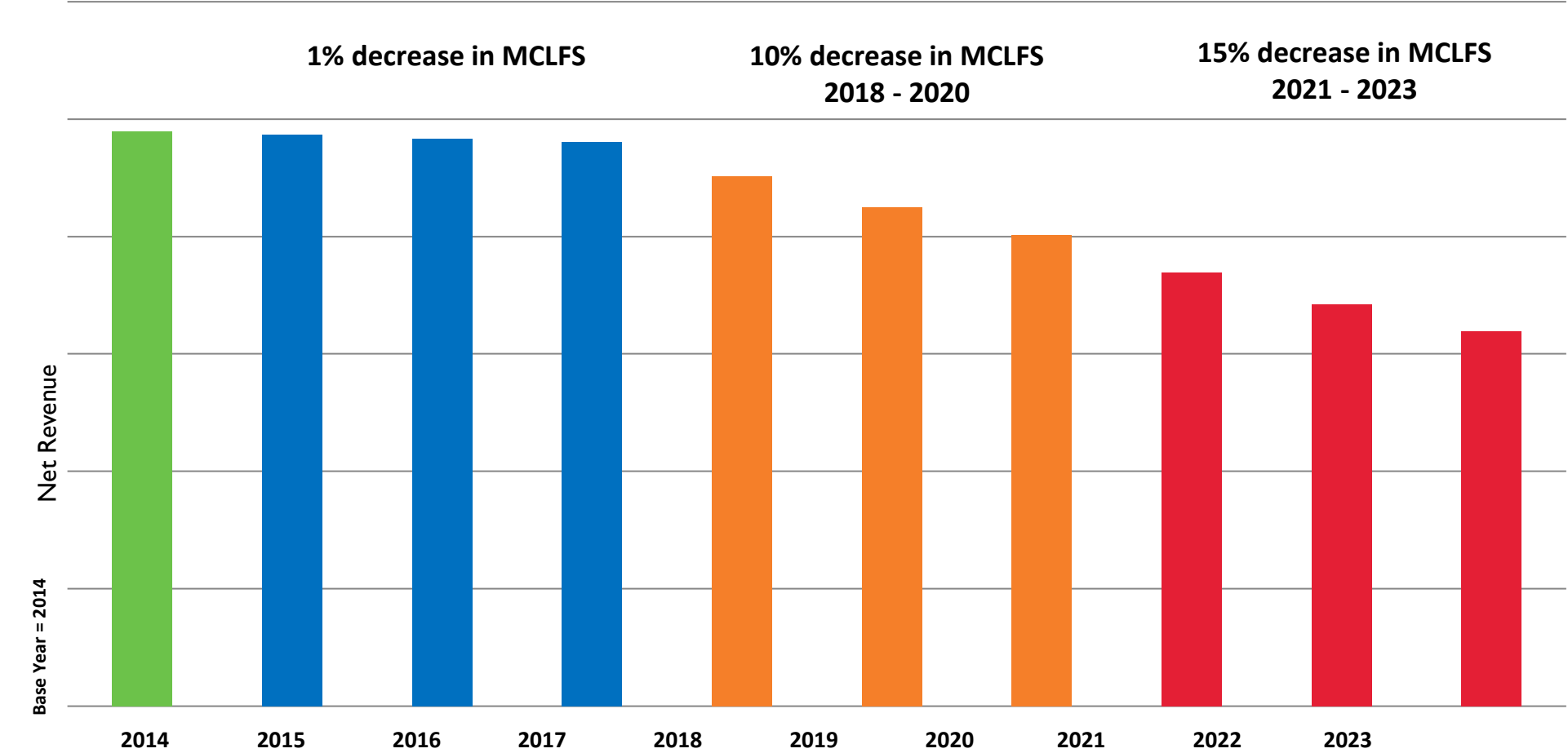
Prepared by TriCore

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"When the size of the pie shrinks, it changes the table manners."

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Healthcare is on the move

FUTURE IS HERE

Sick Care	→	Well Care
Heads in Beds	→	Prevention
Volume	→	Value
Sample Centric	→	Patient Centric
CPT F4S per/test	→	Bundled Payment

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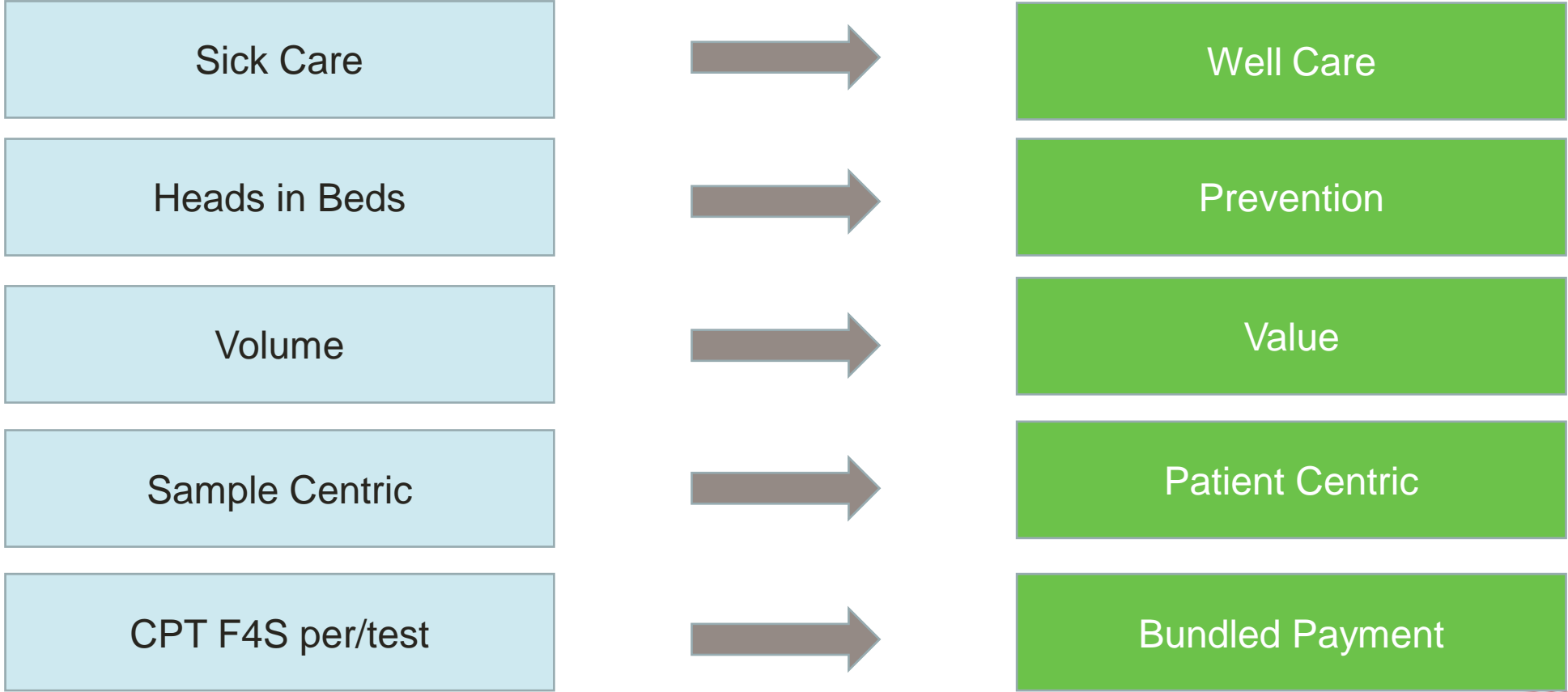
Healthcare is on the move

✓ *Intervention*
✓ *Prevention*
✓ *Cost Avoidance*

Lab becomes the best bargain, predictor

"We are working to use technology [lab data] to predict and provide treatment before becomes a problem," - **Intermountain Healthcare.**

Managing the Transition
'Dynamic Tension' of business models

CURRENT STATE

Clinical Lab 1.0

FUTURE STATE

Clinical Lab 2.0

Fee-for-Service Reimbursement

Value-based Reimbursement

Managing Transition

Inflection Point

DANGER ZONE

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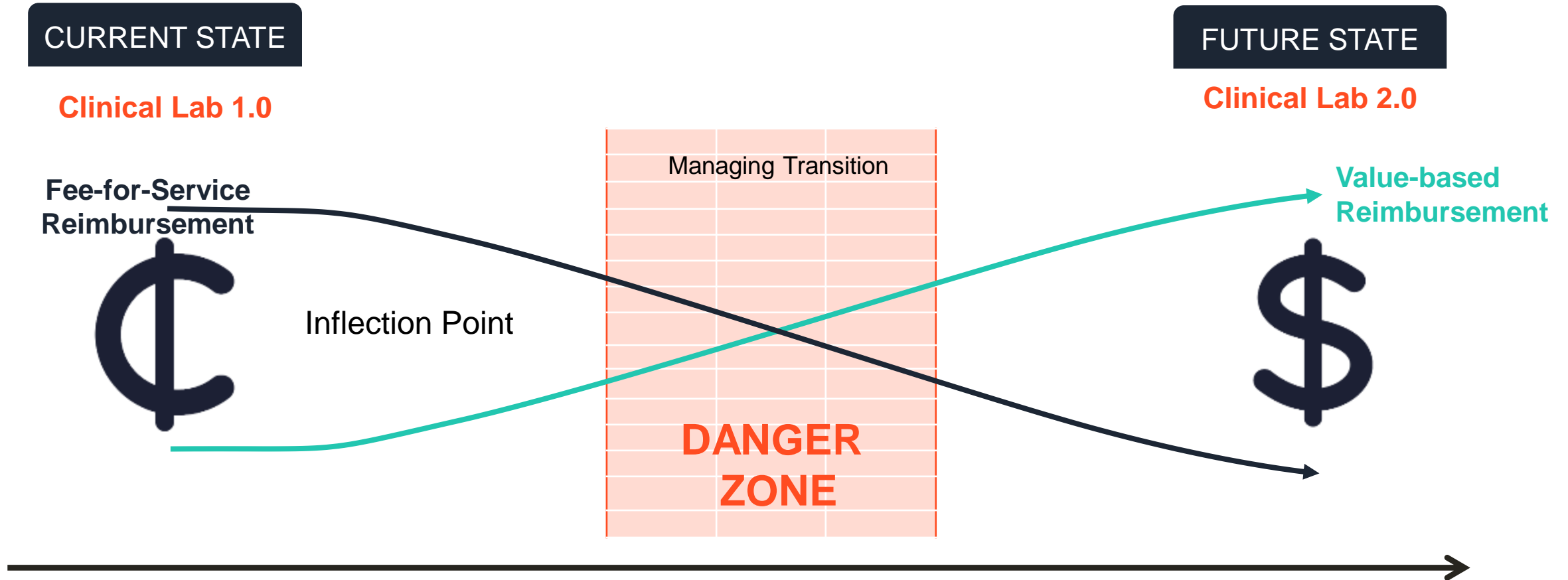
Insanity: doing the same thing over and over again and expecting different results.

Automating

– Albert Einstein
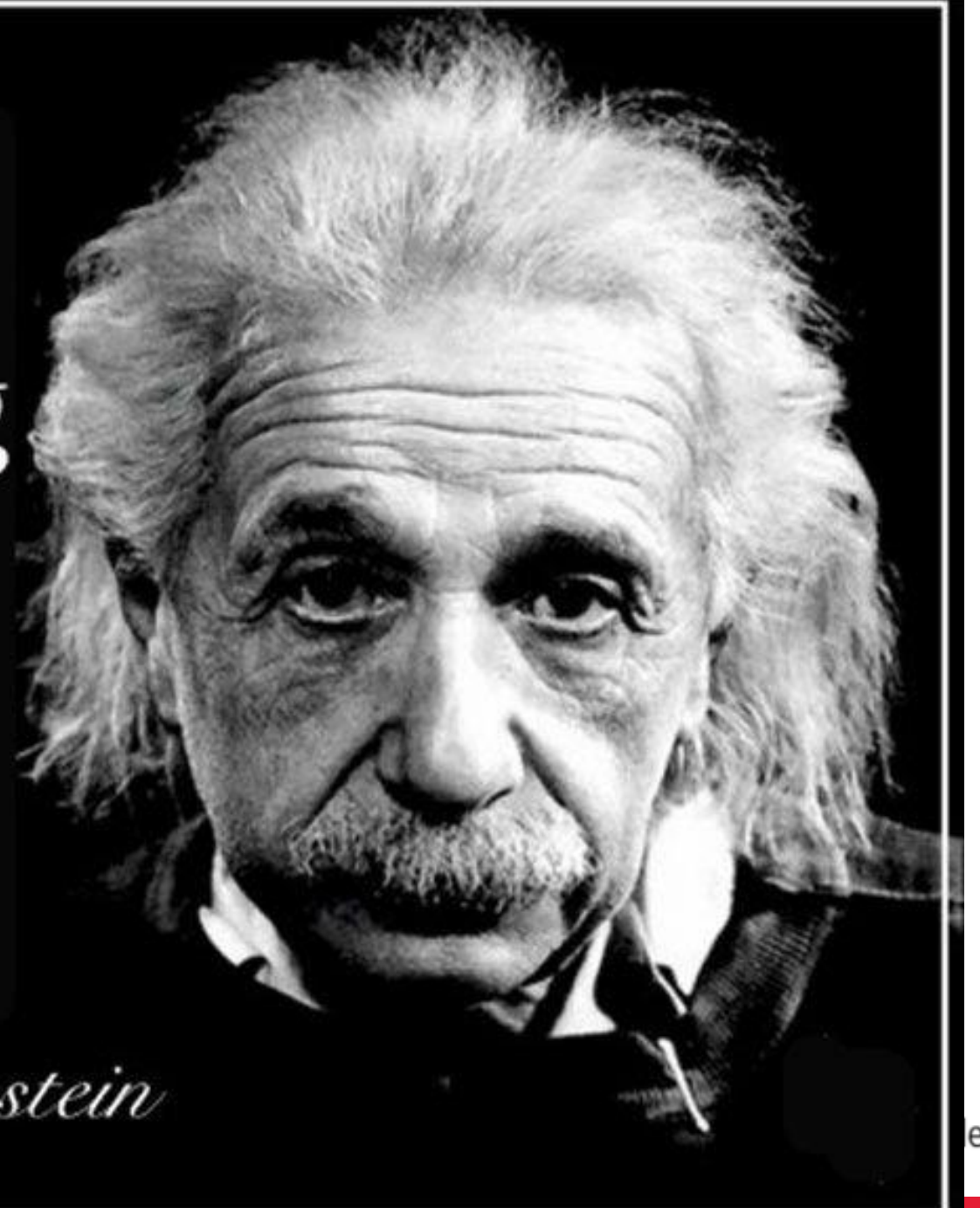
ealth

"Let me know when the **change** is passed"

Health System Lab Acquisitions **2007-2019**

Clincal Lab Strategic Acquisitions & Partnerships
2008 - 2018

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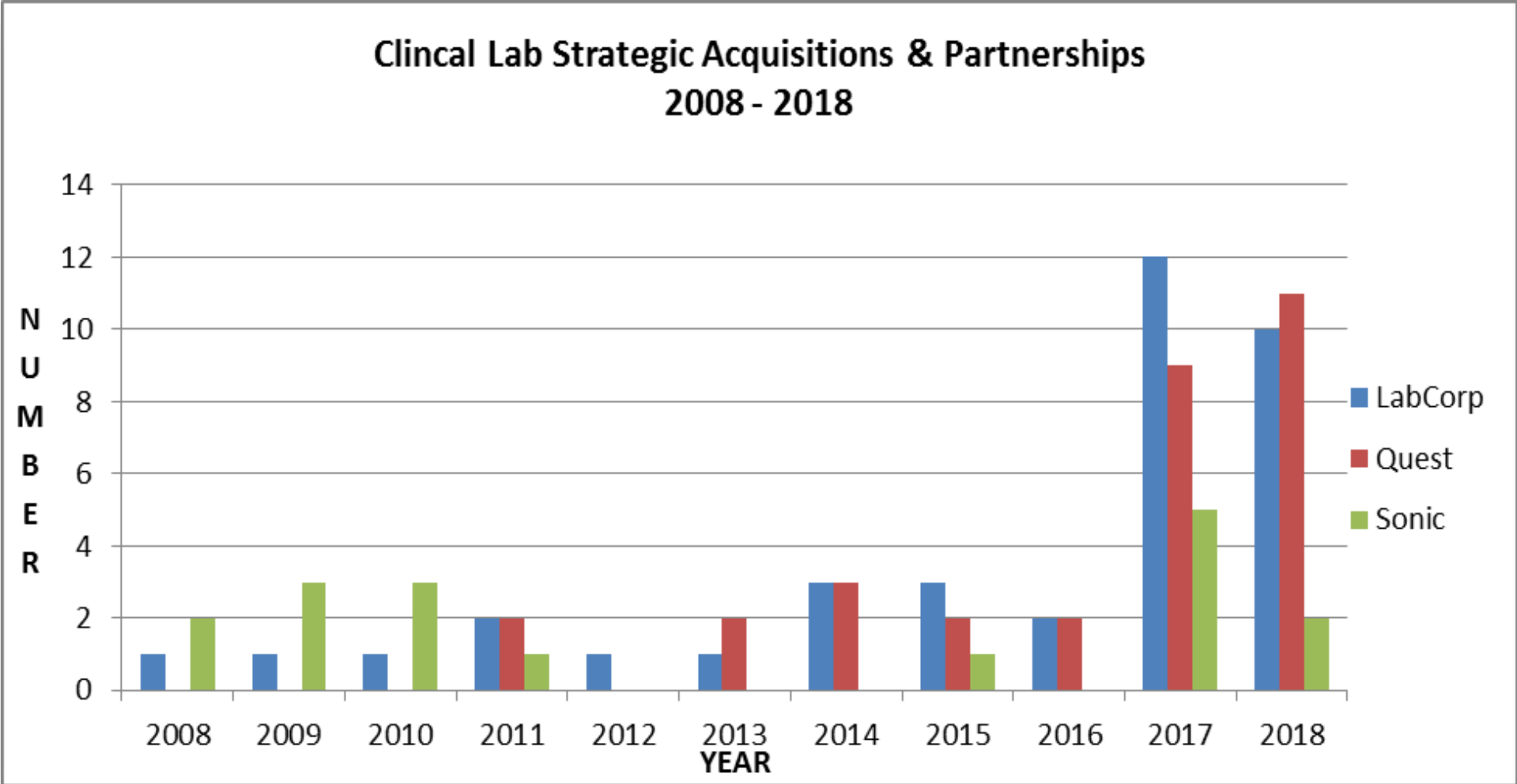
"Farmer trying to survive tough times ends up selling parts of his land to agribusiness, and soon realizes it wasn't the Corn that had value but the land it was grown on.

He started his own death spiral.

– Michael Crossey, MD, PhD

" If you don't have a seat at the table, you will be on the menu..."

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A PROJECT SANTA FE FOUNDATION INITIATIVE

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Northwell Health Laboratories

The 10-Year Outcomes After Deciding to Keep the Lab

Kendal J. Jensen, MD, PhD; Robert Stallone, BA; Michael Eller, MBA; Joseph Castagnaro, MBA; Hannah Poczter, MS, MBA; Richard Tesoriero, MBA; Jeanne Balzano-Kane, MS; Cari Gusman, BS; Tawfiqul Bhuiya, MD; Dwayne Breining, MD; James M. Crawford, MD, PhD

● *Context.*—Northwell Health Laboratories were established in 1997, serving the Northwell Health system. In 2008, the health system considered minority entry into a joint venture with a commercial laboratory. Based on arguments made by Northwell laboratory leadership, the decision was made to retain full ownership of the laboratory.

Objective.—To evaluate the 10-year outcomes of the 2008 decision and assess the value of a fully integrated laboratory service line for a regional health network.

Design.—Ten-year outcomes were analyzed including financial, volume, and value-based activities.

Results.—First, a fully integrated laboratory service line was created, with unified medical and managerial leadership. Second, Core Laboratory volumes and revenues grew at annualized rates of 4.5% and 16.0%, respectively. Third, hospital-based laboratory costs were held either constant, or grew in accordance with strategic clinical programs. Fourth, laboratory services were able to provide leadership in innovative system clinical programming and value-based payment programs. Fifth, the laboratories became a regional asset, forming a joint venture affiliation with New York City Health + Hospitals, and supporting distressed hospitals in Brooklyn, New York. Lastly, Northwell Health Laboratories have become a reputational asset through leadership in 2 consortia: The Compass Group and Project Santa Fe.

Conclusions.—The 10-year outcomes have exceeded projections made in 2008, validating the decision to retain the laboratories as a wholly owned system asset. The laboratories are now well positioned for leading innovation in patient care and for helping to drive a favorable posture for the health system under new payment models for health care.

(*Arch Pathol Lab Med.* doi: 10.5858/arpa.2018-0569-SA)

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Laboratory Business Decisions

✅ Sell part or all lab services

❑ Partnership with commercial laboratory

❑ Maintain ownership and optimize lab services

cost/test

Volume to Value[4]

❑ Total cost-of-care leveraging laboratory data

❑ Population surveillance

❑ Risk management/Care gaps

Pre-Analytical	Analytical	Post-Analytical

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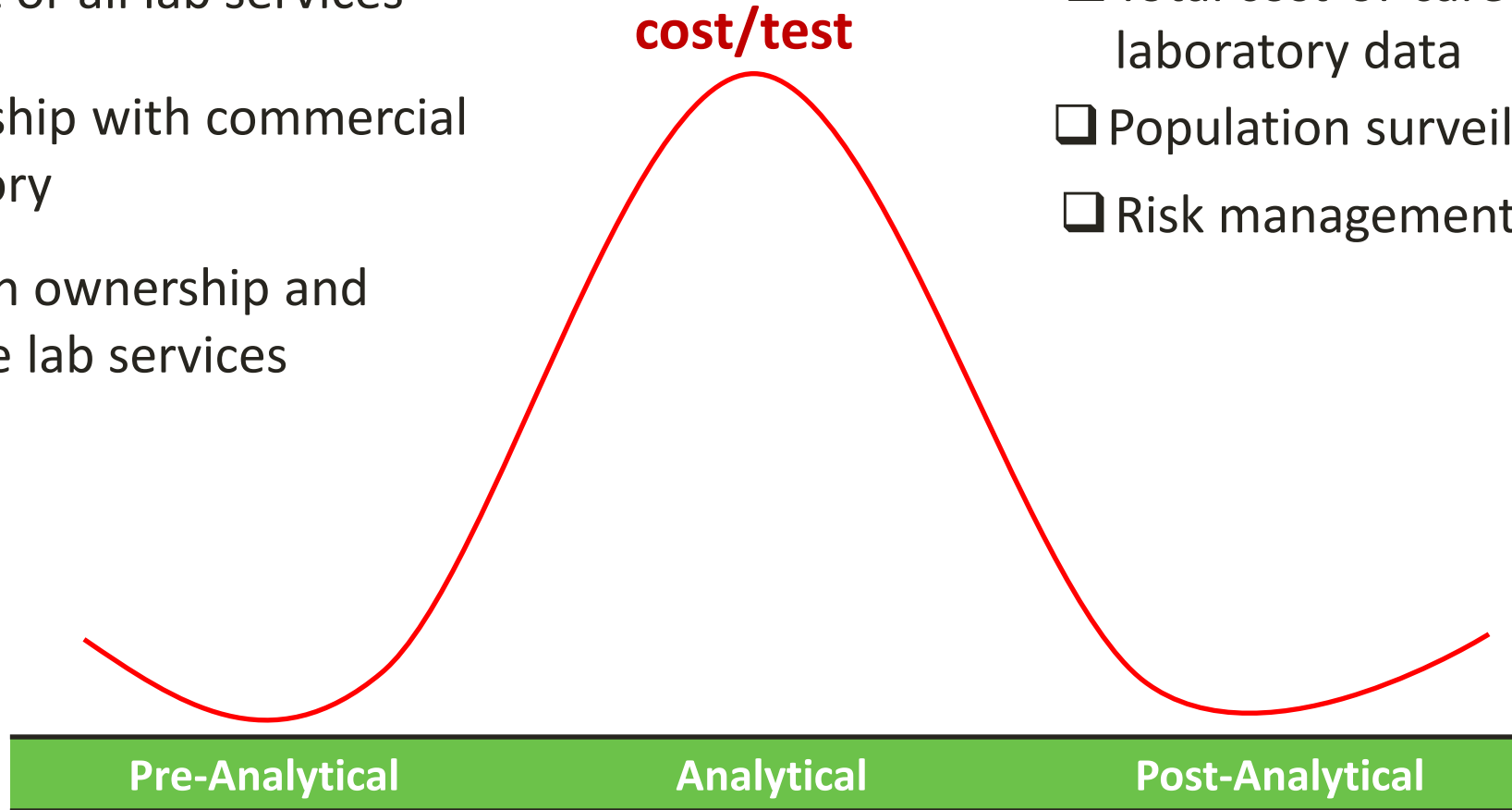
Winnable position for Labs

3
Critical
Strategic Steps

✔ **Optimize** current model, Reengineer, Eliminate waste
- Consolidation, automation
- POCT

✔ **Diversify**

✔ **Transform**, "stepping into clinical Lab 2.0 Frontiers " = *New Value*

Strategic Inflection Point
Risk Stratification

Increased Risk of Complication(s)

Increased Risk of Complication(s) & Care Gaps

$ associated with care

Optimal

Care Gaps

Risk created from patient risk factors

Risk created from gaps in health care

$ Patient Harm

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PRENATAL CARE GAPS

Prenatal Care in 1st Trimester by Year[1]

1. Complete Health Indicator Report of Prenatal Care in the First Trimester. New Mexico's Indicator-Based Information System (NM-IBIS). *New Mexico Department of Health.* https://ibis.health.state.nm.us/indicator/complete_profile/PrenCare.html (Accessed: October 18, 2018)

Example: Prenatal care in New Mexico

- 72% of New Mexico's births are Medicare funded[2]

- New Mexico's timeliness[3]
  - 20% of births received care in the 2nd trimester
  - 8.5% received no prenatal care

- 30% of live births were to women receiving intermediate or inadequate care[4]

Average Cost of Newborns for New Mexico MCOs[1]

	FY 10	FY 11
Cost of Newborns with Complications	$13,668	$14,175
Cost of Normal Newborns	$815	$827

1. New Mexico Legislative Finance Committee Report. Human Services Department. September 2012. http://www.nmlegis.gov/lcs/lfc/lfcdocs/perfaudit/Human%20Services%20Department%200Improving%20Outcomes%20for%20Pregnant%20Women%20and%20Infants%20Through%20Medicaid.pdf (Accessed October 7, 2015)
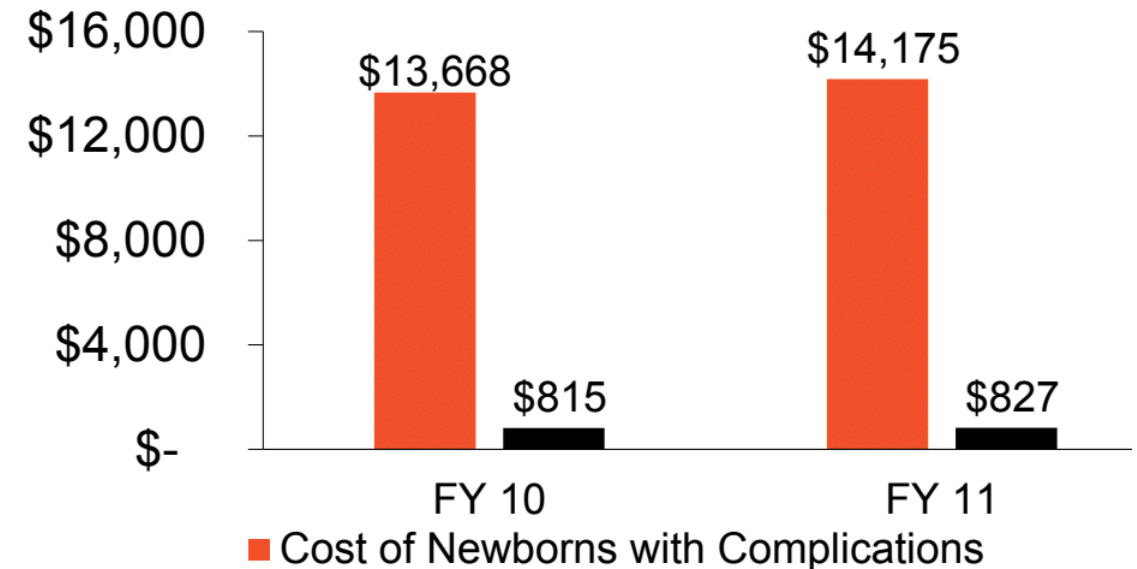2. Medicaid Funds 70% of NM Births. *Albuquerque Journal.* January 27, 2013. Available at: http://www.abqjournal.com/163829/news/medicaid-funds-70-of-births-in-nm.html [Accessed July 20, 2015]
3. Perinatal Care in Medicaid and CHIP. (February 2015) http://www.medicaid.gov/midicaid-chip-program-information/by-topics/quality-of-care/downloads/secretarys-report-perinatal-excerpt.pdf. (Accessed October 10, 2015)
4. Institute of Medicine (US) Committee on the Consequences of Uninsurance. Washington (DC): National Academies Press (US): 2002

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Prenatal Care

The United States is the most dangerous place in the developed world to give birth

The *USA Today* report mirrors the findings of an [NPR and ProPublica](#) investigation on maternal mortality in the U.S., which concluded a "hodgepodge" of hospital protocols for dealing with potentially deadly but easily treatable complications is putting women in danger. Hospitals were also found to be unprepared for maternal emergencies.

From 1990 to 2015, the number of maternal deaths per 100,000 births in most developed nations has been flat or dropping. In the U.S., the rate has risen sharply.
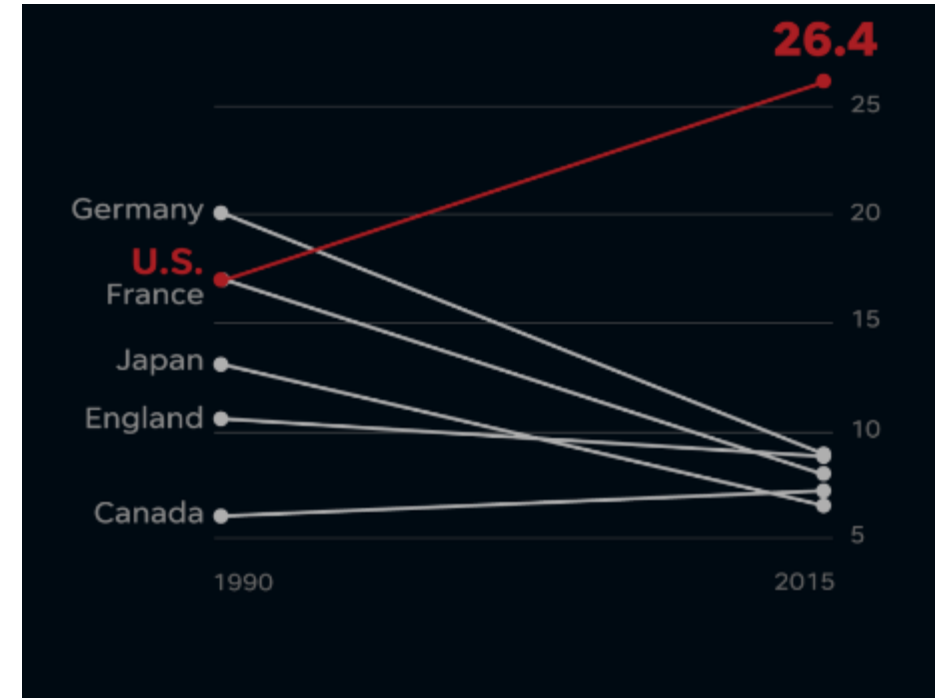
SOURCE: The Global Burden of Disease 2015 Maternal Mortality study as published in The Lancet medical journal.

Prenatal Care

LAB 2.0

- ✓ Align patient with national treatment guidelines
- ✓ Risk stratify upon condition identification
- ✓ Determine missed care for patient righting
- ✓ Alert for abnormal result(s)
- ✓ Assure final visit is on target

- ✓ HCGT/UPREG
- ✓ First Trimester Screen
  - FSTSEQ
  - FFSTSCR
- ✓ Second Trimester Screen
  - AFPMM4
  - SECSEQ
  - SECINT
- ✓ Gestational Diabetes Screen
- ✓ Group B Strep

A la carte

| Increased Risk of Complication(s) | Increased Risk of Complication(s) & Care Gaps |
| Optimal | Care Gaps |

Care Gap

Abnormal Result

Due

HCGT UPREG

First Trimester Screen

Second Trimester Screen

Gestational Diabetes Screen

Group B Strep

| 0-13 weeks | 14-26 weeks | 27-40 weeks |

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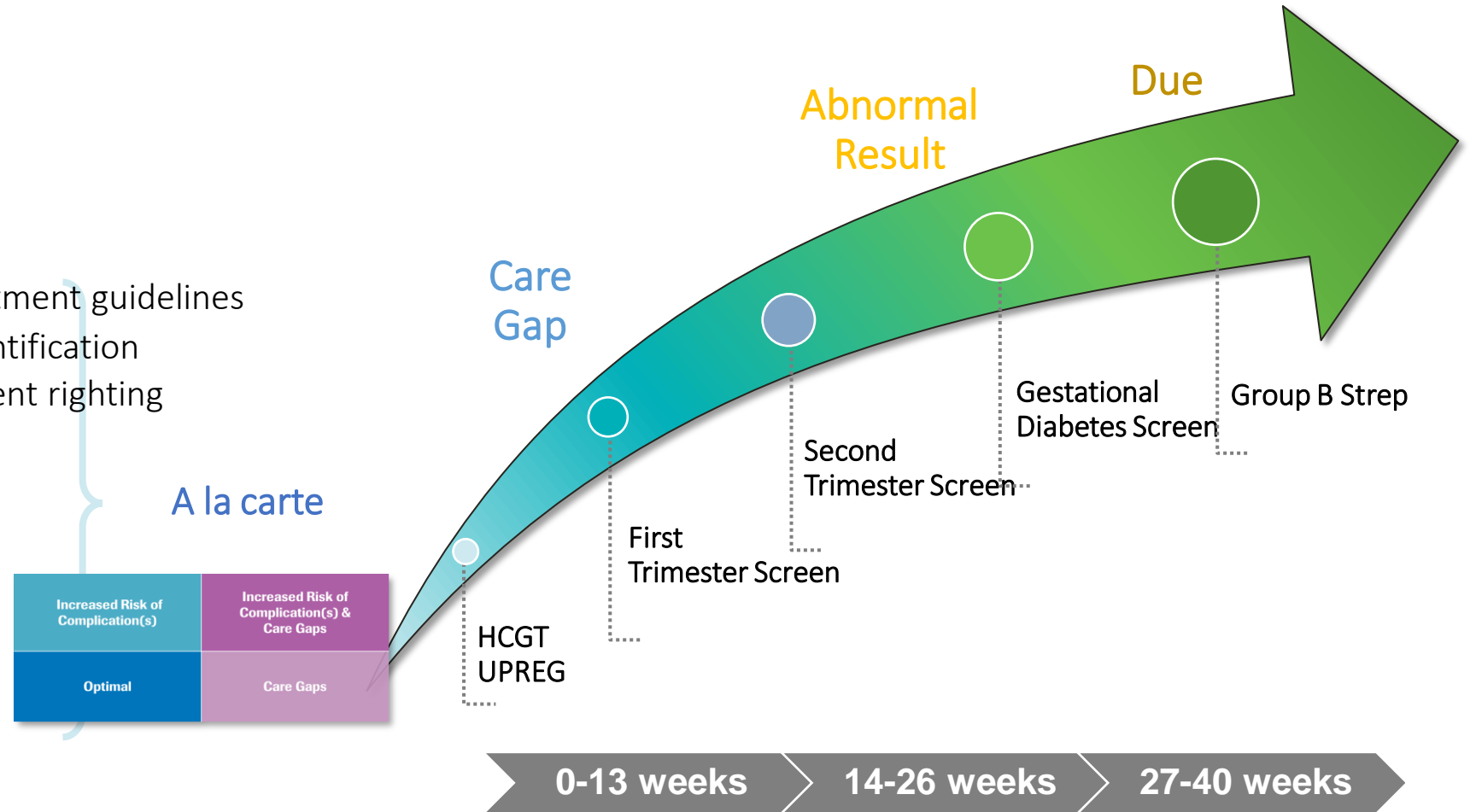
Objectives of MCO Pilot: **Prenatal**

	Clinical	Financial
Risk stratify members for better care coordination	✓	✓
Identify prenatal patients early	✓	✓
Close Gaps in Care	✓	✓
Impact NICU days LOS	✓	✓
Impact Preterm Delivery Rate	✓	✓
Identify prenatal patients accessing ER	✓	✓

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TriCore 2.0 Analytics – Total Patients
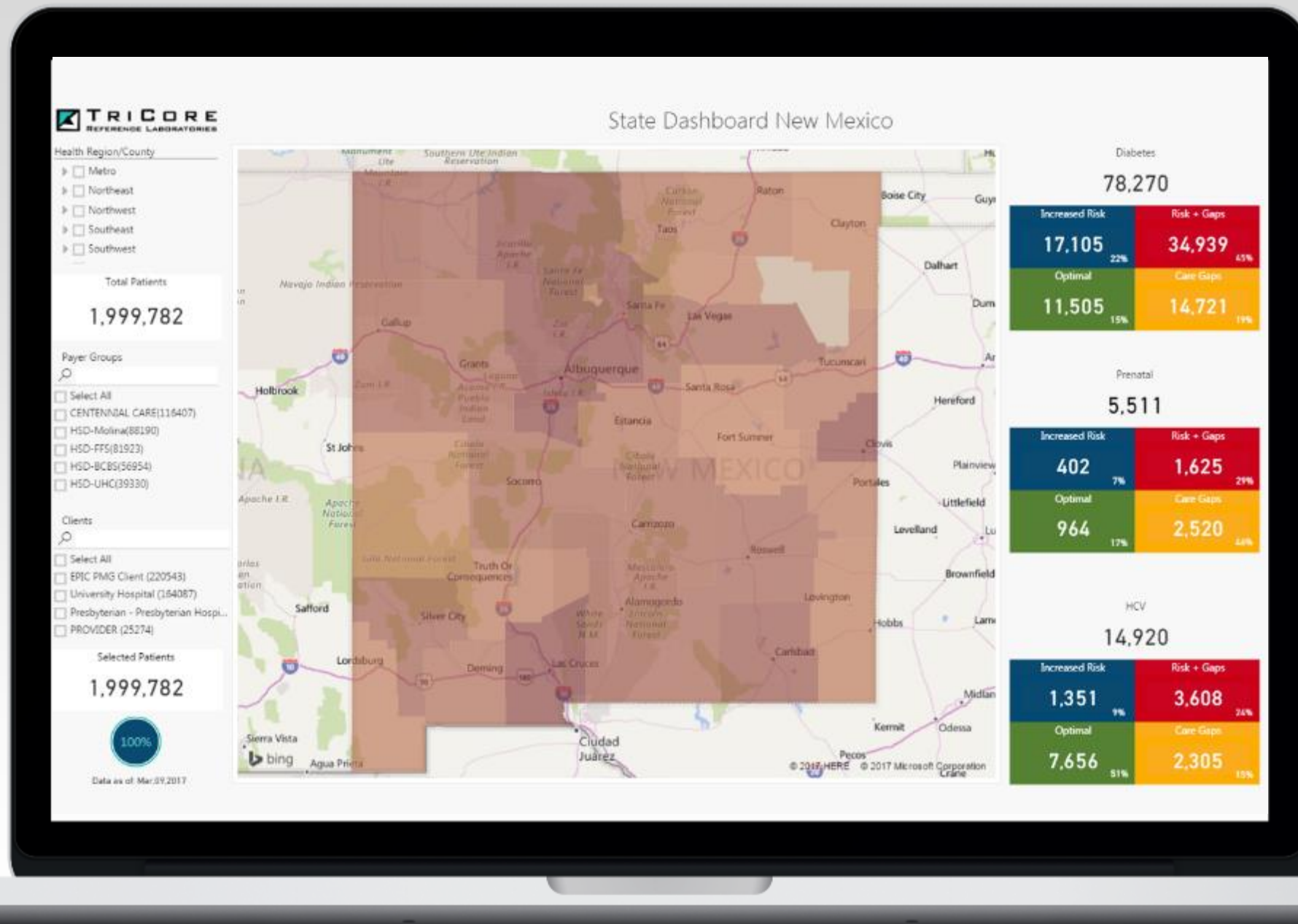
Prenatal Patients
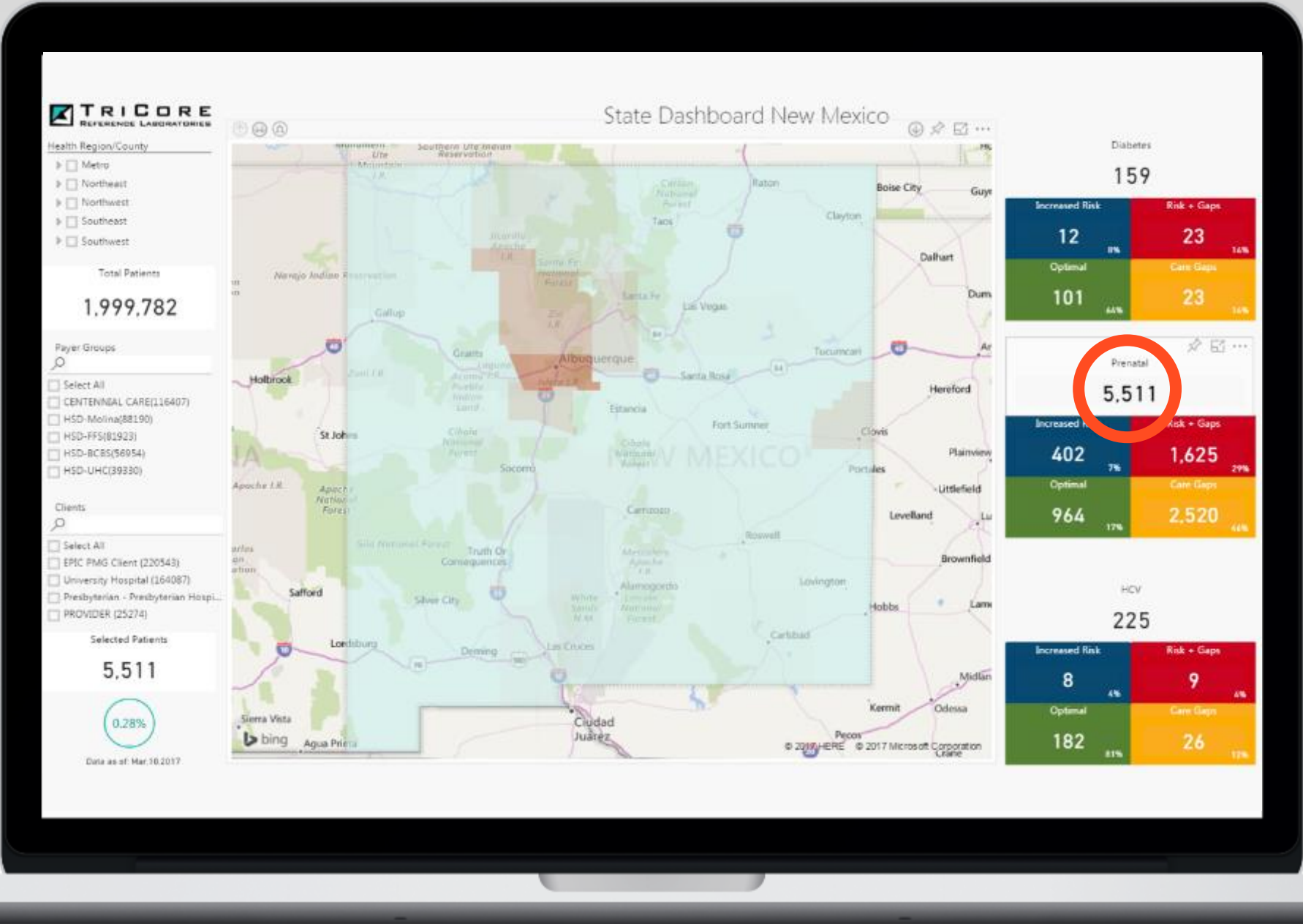
Prenatal Patients with High Risk and Care Gaps

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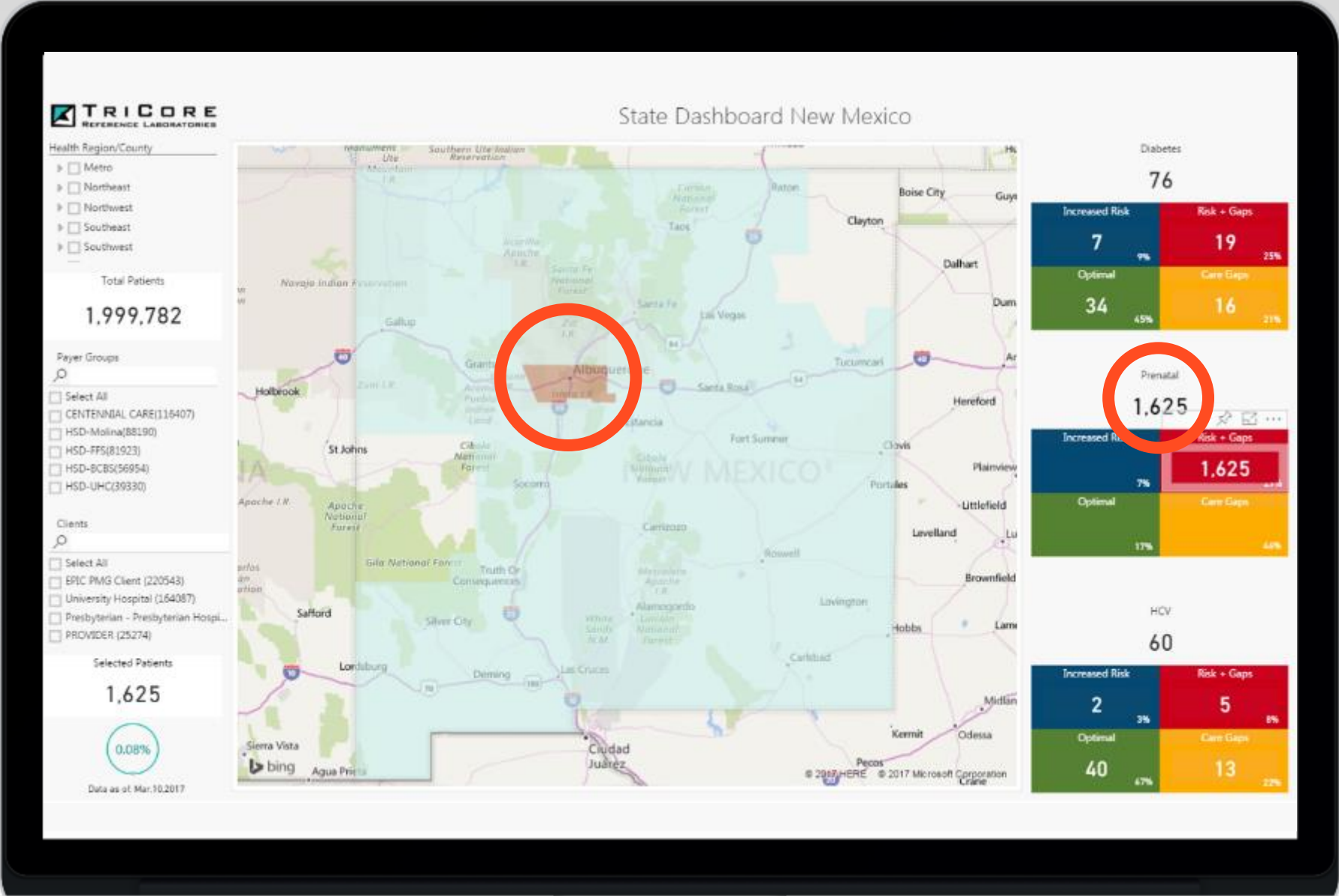
Prenatal Patients with High Risk and Care Gaps and Insured by Medicaid
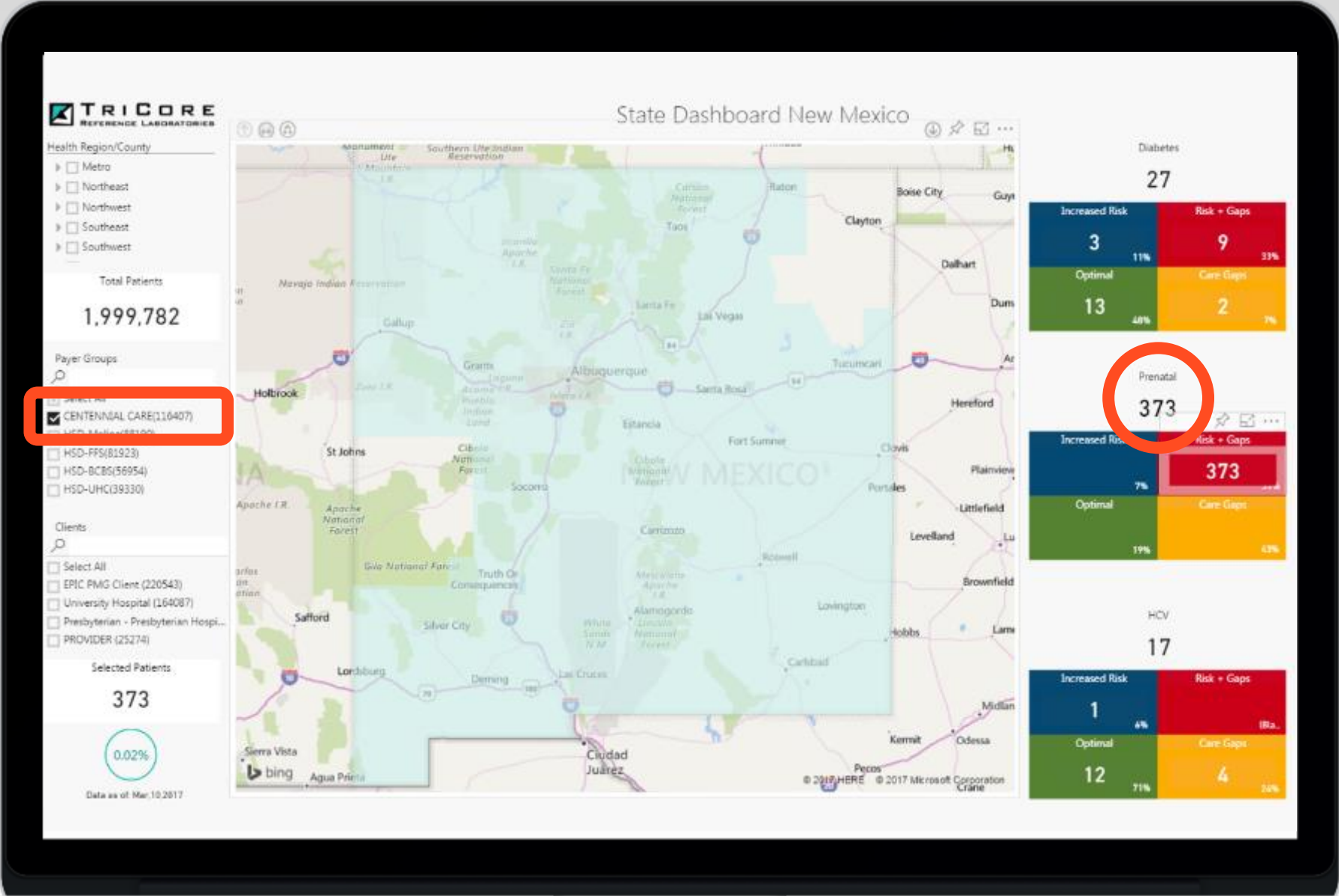
Prenatal Patients with High Risk and Care Gaps and Insured by Medicaid in Bernalillo
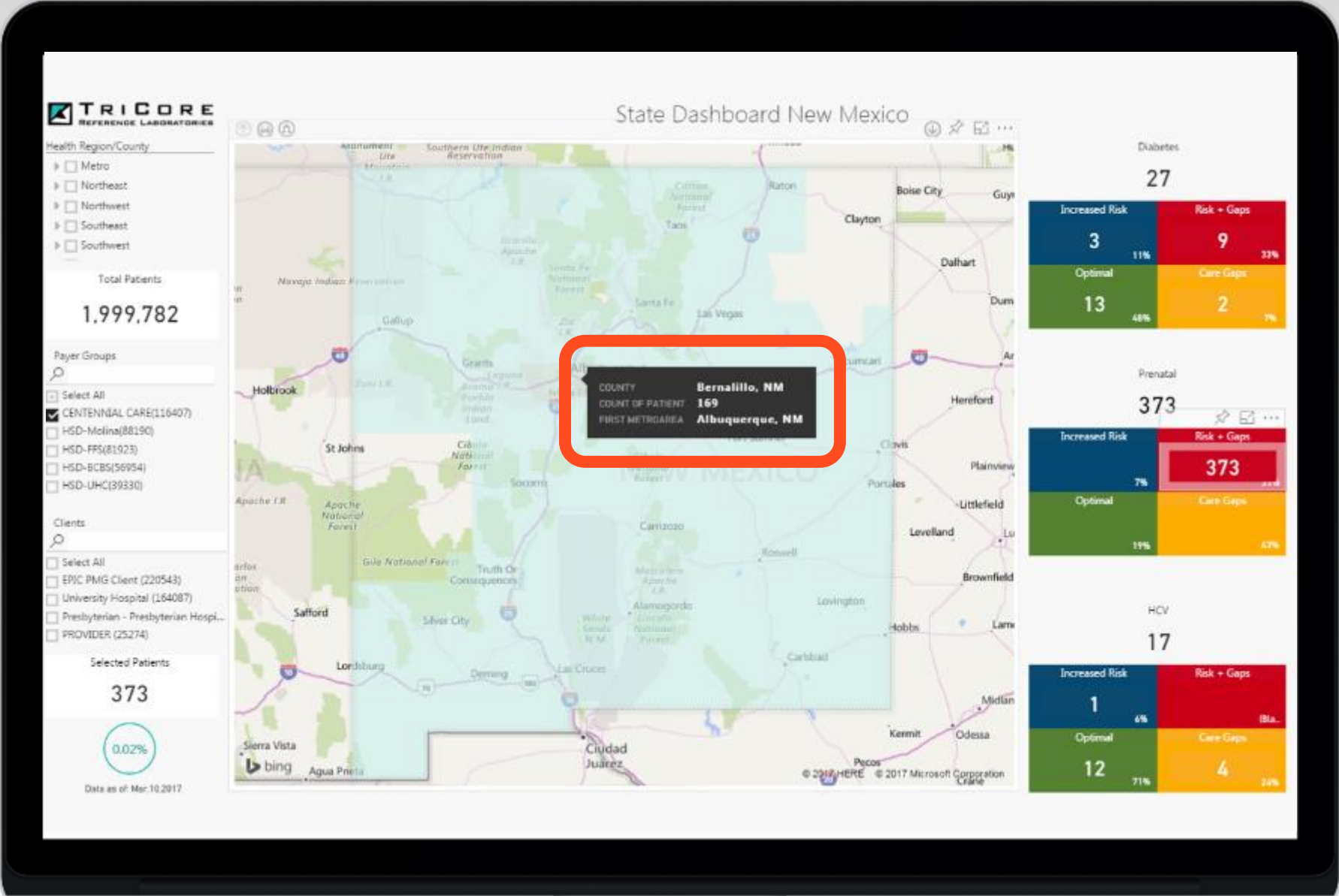
Prenatal Patients with High Risk and Care Gaps and Insured by Medicaid (Workable List)

County	Zip Code	MetroArea	Patient	Gender	Age Category	Current Payer	Payer Group	Payer Type	Payer Effective Date	City
Bernalillo, NM	87120,NM, USA	Albuquerque, NM		F	18-24 years	Presbyterian	CENTENNIAL CARE	Medicaid	02-01-2017	Albuquerque, NM
Bernalillo, NM	87107,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	09-01-2016	Albuquerque, NM
Bernalillo, NM	87106,NM, USA	Albuquerque, NM		F	06-17 years	Presbyterian	CENTENNIAL CARE	Medicaid	03-01-2017	Albuquerque, NM
Bernalillo, NM	87109,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	10-01-2016	Albuquerque, NM
Bernalillo, NM	87120,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	09-01-2015	Albuquerque, NM
Bernalillo, NM	87105,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	07-01-2016	Albuquerque, NM
Bernalillo, NM	87121,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	07-01-2016	Albuquerque, NM
Bernalillo, NM	87105,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	01-01-2014	Albuquerque, NM
Bernalillo, NM	87121,NM, USA	Albuquerque, NM		F	18-24 years	Presbyterian	CENTENNIAL CARE	Medicaid	10-01-2016	Albuquerque, NM
Bernalillo, NM	87121,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	11-01-2016	Albuquerque, NM
Bernalillo, NM	87114,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	05-01-2016	Albuquerque, NM
Bernalillo, NM	87104,NM, USA	Albuquerque, NM		F	18-24 years	Presbyterian	CENTENNIAL CARE	Medicaid	01-01-2014	Albuquerque, NM
Bernalillo, NM	87114,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	01-01-2014	Albuquerque, NM
Bernalillo, NM	87114,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	03-01-2017	Albuquerque, NM
Bernalillo, NM	87110,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	09-01-2015	Albuquerque, NM
Bernalillo, NM	87112,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	06-01-2016	Albuquerque, NM
Bernalillo, NM	87121,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	07-01-2014	Albuquerque, NM
Bernalillo, NM	87102,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	04-01-2015	Albuquerque, NM
Bernalillo, NM	87123,NM, USA	Albuquerque, NM		F	06-17 years	Presbyterian	CENTENNIAL CARE	Medicaid	01-01-2014	Albuquerque, NM
Bernalillo, NM	87112,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	10-01-2016	Albuquerque, NM
Bernalillo, NM	87022,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	11-01-2015	Isleta, NM
Bernalillo, NM	87120,NM, USA	Albuquerque, NM		F	06-17 years	Presbyterian	CENTENNIAL CARE	Medicaid	01-01-2014	Albuquerque, NM
Bernalillo, NM	87121,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	10-01-2016	Albuquerque, NM
Bernalillo, NM	87123,NM, USA	Albuquerque, NM		F	06-17 years	Presbyterian	CENTENNIAL CARE	Medicaid	10-01-2016	Albuquerque, NM
Bernalillo, NM	87105,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	11-01-2014	Albuquerque, NM
Bernalillo, NM	87111,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	08-01-2014	Albuquerque, NM
Bernalillo, NM	87114,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	10-01-2015	Albuquerque, NM
Bernalillo, NM	87123,NM, USA	Albuquerque, NM		F	25-34 years	Presbyterian	CENTENNIAL CARE	Medicaid	04-01-2014	Albuquerque, NM
Bernalillo, NM	87109,NM, USA	Albuquerque, NM		F	06-17 years	Presbyterian	CENTENNIAL CARE	Medicaid	01-01-2014	Albuquerque, NM
Bernalillo, NM	87121,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	01-01-2014	Albuquerque, NM
Bernalillo, NM	87121,NM, USA	Albuquerque, NM		F	35-49 years	Presbyterian	CENTENNIAL CARE	Medicaid	12-01-2015	Albuquerque, NM

Back to Report

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

METHOD: PATIENT TAILORED INSIGHTS

Prescriptive Care for Each Patient

Measurable Definition of Value……Value Chain

➢ Value

➢ Value Based Care

➢ Value Based Partnership

➢ Value Based Purchasing

➢ Value Based Payment

➢ Value Based Payment Primer

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Measurable Definition of Value…..Value Chain

The Old Way

Lab 2.0 Definition

Quality

Cost

Outcome

Measurable Action

Cost

Value-based Healthcare
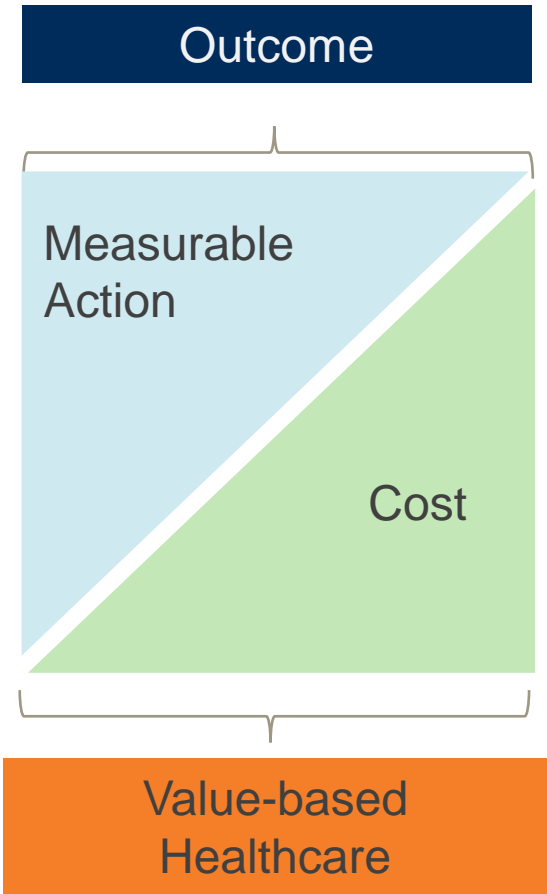
Measurable action/Time bound

- ➢ Risk Stratification
- ➢ Care-Gaps
- ➢ High Risk
- ➢ Facilitated Intervention
  - ❑ Intervention
  - ❑ Prevention
  - ❑ Cost avoidance
  - ❑ Financial Risk Adjustment

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Key Pilot Results

$734,130	**73%**	**33%**	**30%**	**10%**	**=$4.4M**
total savings	of care gaps closed	NICU reduction	Pre-Term Delivery	reduction in ER visits	Anticipated 1 Year Savings

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

ONE MCO PILOT AND PROJECTION

Health Condition	Measure/Outcome	2016 MCO Performance[1]	TRL Clinical Analytics Result[2]	ROI
Prenatal	Timeliness of Prenatal Care NMHSD PM #5	75%	77%	$766,766[3,4]
	Post-Partum Care NMHSD PM #5	58%	60%	$766,766[3,4]
	Frequency of Prenatal Care NMHSD PM #6	56%	73%	$766,766[3,4]
	NICU Occupancy	19%	11%	$1,184,851[3]
	Preterm Delivery Outcome	20%	11%	$1,367,009[2,5]
	ER Utilization (Prenatal Members Only)	33 visits per month	30 visits per month	$46,250[2,6]
Diabetes	Hemoglobin A1c Testing PM #4	82%	92%	$766,766[3,4]
	Nephropathy Screening PM #4	87%	91%	$766,766[3,4]
	ER Utilization (Diabetic Members Only)	54 visits per month	38 visits per month	$240,000[2,6]
Hepatitis C	NMHSD Hepatitis C DSIM	350 members	1,577 members	$1,610,208[4]
			TOTAL	**$8,282,188**

1. BCBSNM Audit Review Table. http://www.hsd.state.nm.us/uploads/FileLinks/485263ae1ad040ea9d52673aef6109b4/2016_HEDIS_BCBS.pdf (Accessed: March 21, 2018)
2. Results projected from pilot performed with BCBSNM Special Beginnings September 2017 through April 2018
3. Assumes BCBSNM's revenue for Centennial Care is approx. $536,736,096. Health Notes. Program Evaluation Unite. Legislative Finance Committee. January 13, 2017 https://www.nmlegis.gov/Entity/LFC/Documents/Health_Notes/Health%20Notes%20-%20Medicaid%20managed%20care%20rates.pdf
4. New Mexico Human Services Department. Request for Proposals. RFP#13-630-8000-0001 Centennial Care http://www.hsd.state.nm.us/uploads/FileLinks/c06b4701fbc84ea3938e646301d8c950/Centennial_Care_RFP_and_Contract__8_28_12__FINAL_.pdf (Accessed: August 11, 2017)
5. Thanh NX et al. Health Service Use and Costs Associated with Low Birth Weight-A Population Level Analysis. (2015) *J Pediatr.* 167(3): 551-556
6. Center for Disease Control and Prevention. Health, United States, 2016. https://www.cdc.gov/nchs/data/hus/hus16.pdf#093 (Accessed: August 29, 2017)

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PROPOSAL TO MCO

Health Condition	Measure/Outcome	2017 MCO Performance[1]	TRL Clinical Analytics Result[2]	ROI
Prenatal	Timeliness of Prenatal Care NMHSD PM #5	75%	77%	$1,999,874[3,4]
	Post-Partum Care NMHSD PM #5	58%	(35%)	-
	Frequency of Prenatal Care NMHSD PM #6	56%	73%	$1,999,874[3,4]
	NICU Occupancy	19%	11%	$1,470,555[3]
	Preterm Delivery Outcome	20%	11%	$5,708,892[2,5]
Diabetes	Hemoglobin A1c Testing PM #4	82%	92%	$1,999,874[3,4]
	Nephropathy Screening PM #4	87%	91%	$1,999,874[3,4]
Hepatitis C	NMHSD Hepatitis C DSIM	350 members	1,577 members	$4,199,735[4]
			TOTAL	**$19,378,676**

1. BCBSNM Audit Review Table. http://www.hsd.state.nm.us/uploads/FileLinks/485263ae1ad040ea9d52673aef6109b4/2016_HEDIS_BCBS.pdf (Accessed: March 21, 2018)
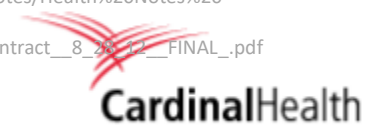
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4. New Mexico Human Services Department. Request for Proposals. RFP#13-630-8000-0001 Centennial Care http://www.hsd.state.nm.us/uploads/FileLinks/c06b4701fbc84ea3938e646301d8c950/Centennial_Care_RFP_and_Contract__8_28_12__FINAL_.pdf (Accessed: August 11, 2017)

5. Thanh NX et al. Health Service Use and Costs Associated with Low Birth Weight-A Population Level Analysis. (2015) *J Pediatr*. 167(3): 551-556

6. Center for Disease Control and Prevention. Health, United States, 2016. https://www.cdc.gov/nchs/data/hus/hus16.pdf#093 (Accessed: August 29, 2017)

CardinalHealth

Lab 1.0	Lab 2.0
Volume-based	Value-based

Pre-analytical	Analytical	Post-analytical	
Transactional			Integrative Post Diagnostic Computation

- ✓ Cost/Unit
- ✓ Accurate test results
- ✓ Rapid turnaround times
- ✓ Clinical Menu
- ✓ Clinical Utility (Lab Formulary)
- ✓ Test Utilization Management
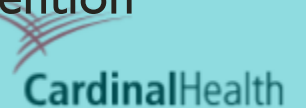
Sick Care
De-escalation

Reactionary
Fee for Service
Commoditized
Reimbursement
Rewards Waste

Health Care
Early escalation

Proactive
Risk Management
Wellness Programming
Payment on Value
Rewards Efficiency & Outcomes

- ✓ Cost/Life or Cost/Population
- ✓ Risk Stratification
- ✓ Identify Care Gaps
- ✓ Care Coordination
- ✓ Facilitated Intervention

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1.0 Clinical Lab: Volume-based

Sick Care
- Receive and result tests
- Passive engagement

Disease Screening
- Scheduled by treating physician
- Disease Surveillance

Wellness Program
- Result-driven
- Blanket approach to testing

Consensus-based
- Protocol/guideline driven

Payment Models
- Cost per test
- Fee for Service
- Laboratory a commodity

2.0 Clinical Lab: Outcomes-based

Health Optimization
- Proactive engagement
- Precision Medicine

Risk Management
- Identification & real-time tracking of risk
- Driving care intervention
- Reducing negative outcomes

Care Coordination
- Diagnostic Management Teams
- Care gaps closed using data
- Optimizing lab testing in clinical workflows
- Eliminate care variation

Evidence-based
- Predictive Analytics
- Data driven decisions

Payment Models
- Value-based (Per member per month)
- Impact to total cost-of-care

J. Olsen, MD. Geisinger Health System

CLINICAL LAB 2.0

Sick care vs. Healthcare

LAB 2.0   IDENTIFYING CHRONIC KIDNEY DISEASE

eMPI

Targeted Intervention

Chem7 Order

Risk Stratify

LIS

Result Interface

GFR Analysis

Billing System

Patient Wellness

Payment

Last 12 months 24,430

Kidney damage and normal or ↑ GFR	Kidney damage and mild ↓ GFR	Moderate ↓ GFR	Severe ↓ GFR	Kidney Failure
Stage 1	**Stage 2**	**Stage 3**	**Stage 4**	**Stage 5**
≥90	60	30	15	

Zeroing in on Diagnostic Latency

Rate of Progression

CardinalHealth

Why Clinical Lab? Why Pathology?

"I am a physician first and a laboratory specialist second!"

James Crawford, MD, PhD- Chair of Board, PSFF

Clinical Lab…….Practice of medicine

- Practice of Laboratory Medicine
- Field of Pathology
- An essential <u>seat</u> at the table

CardinalHealth

1- LAB IS THE FIRST RESPONDER

Lab is the CATALYST- Population Health

Time to Diagnoses–
lab has zero latency (actionable)

Diagnostic Optimization

Care Optimization

Therapeutic Optimization

Screening/Surveillance

CardinalHealth

2 – LAB IS THE LARGEST TOUCH POINT

Touches more lives than any other ancillary
(home health, ER, Out/PT, in/PT)

- Each touch point is measured (scientifically) in a value-structured data
- Each data point is clinically actionable
- It represents **> 70% clinical data**
- It represents **> 70% of the clinical decisions**
- It can verify physicians' hypotheses
- Rules a condition **IN**
- Rules a condition **OUT**

CardinalHealth

Lab can do "Real Time" population health surveillance

3 – LAB IS REAL TIME

Become real time chronic/acute care surveillance

- By **expanding surveillance** to chronic conditions and others

- When a **patient-centric** longitudinal repository ID is established and normalized

- Measuring changes in a patient for early-stage detection or **"precision medicine"**

CardinalHealth

Lab can help improve outcome and reduce overall cost – far above and beyond cost/unit

4 - LAB IS THE FIRST TO KNOW

Based on the aggregated longitudinal data…

- Lab can **risk stratify** population for known chronic conditions
- Lab can **identify care gaps** for conditions with comorbidity and help close gaps in care
- Lab can **identify high-risk patients early** before hospitalization, or ER visits
- Lab can **act as a facilitated intervention** at the point of care (patient/Consumer)

CardinalHealth

What if…

Lab data could be used to identify a health condition within a population?

RISK STRATIFICATION

What if…

Lab data could help those patients into care?

IDENTIFY CARE GAPS

What if…

Lab data could help find the patients *at risk* for comorbidity?

HIGH RISK

What if…

Lab data could help intervene before the disease experiences a comorbidity?

FACILITATED INTERVENTION

CardinalHealth
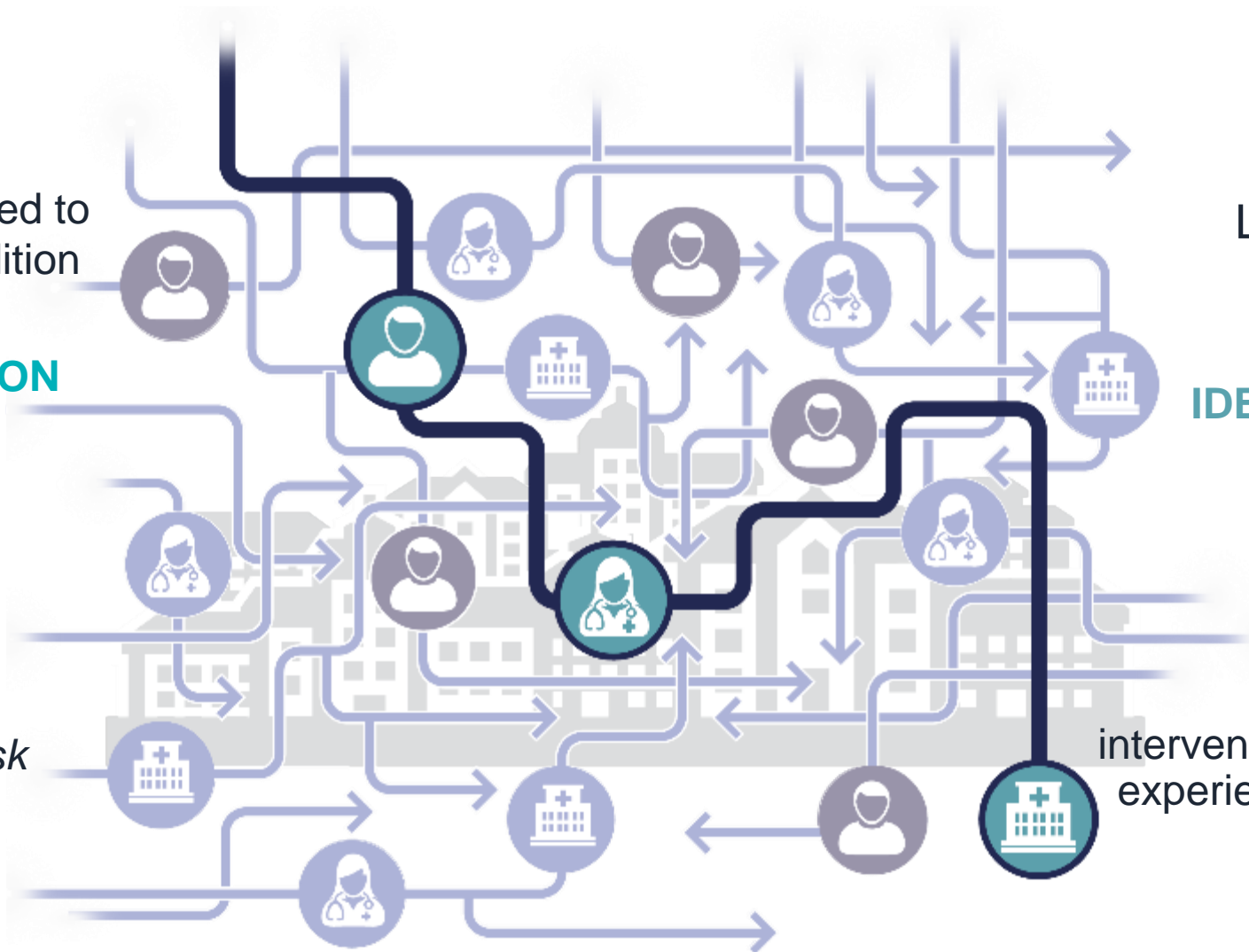
Lab is an under-leveraged asset and a subspecialty of medicine

5-LAB: BEST BARGAIN

Highest yield/return on investment

- For every dollar we spend on healthcare, **three cents is spent on diagnostics**
- The diagnostic lab investment gives us the most clinically **actionable data**
- Diagnostic labs help to manage "sick care" to and optimize **reduce LOS**
- More importantly, lab can help with these clinical strategies of **value-based healthcare…**

INTERVENTION   PREVENTION   COST AVOIDANCE   RISK ADJUSTMENT

CardinalHealth

Harnessing the power
Lab cannot do this ALONE!

Laboratory Data

CLINICAL CARE

Social Determinants of Health
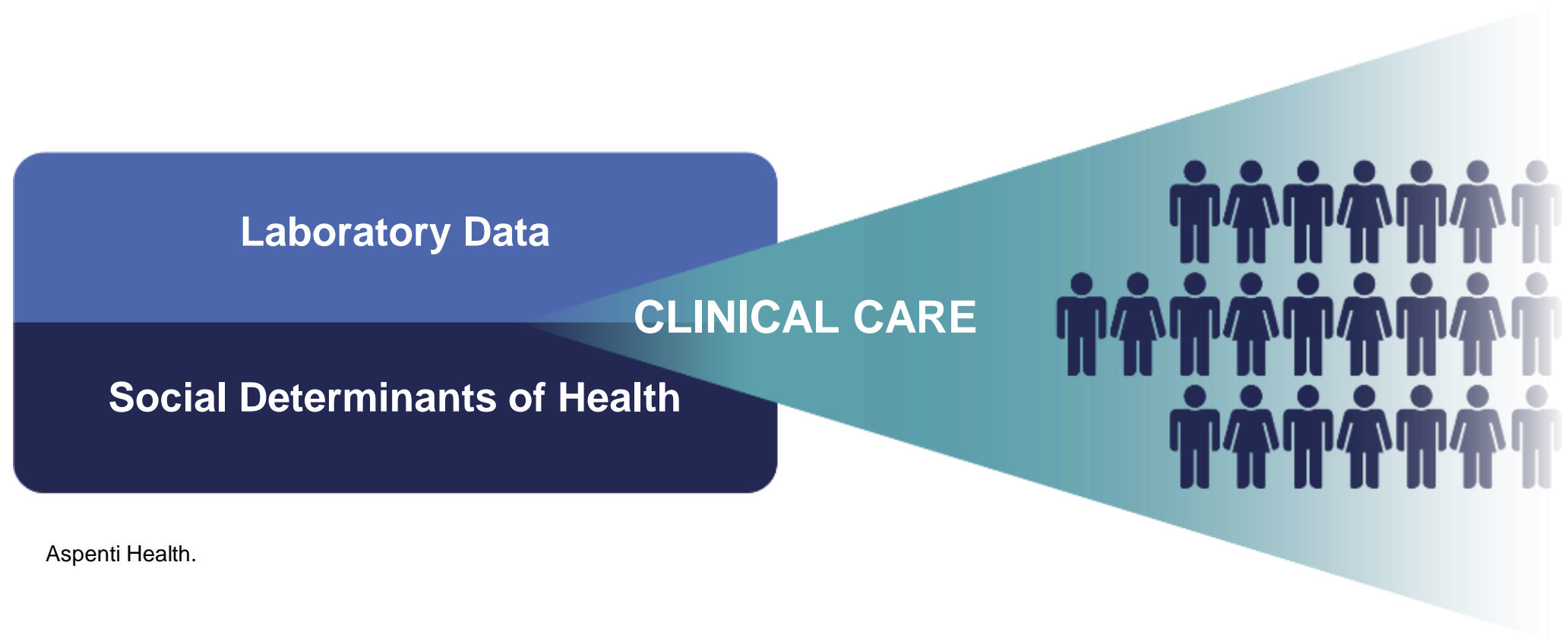
Aspenti Health.

~~Laboratory 1.0 to 2.0 Transition~~
Laboratory 2.0 Focus

Laboratory 1.0

> **Doesn't go away!**

> **May be more important than ever**

> **Needs to run like it 'always has'**

Laboratory 2.0

> **Needs to be something that we do 'on top of' Laboratory 1.0**

> **Needs to be complementary to Laboratory 1.0 activities**

> **Needs to focus on outcomes, and the patient**

Lab 1.0 *transactional*	Lab 2.0 *integrative*

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
	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

Clinical Lab 2.0 (2017)

Crawford JM et al., *Academic Pathology* 2017; DOI: 10.1177/2374289517701067

November 1999

INSTITUTE OF MEDICINE

Shaping the Future for Health

TO ERR IS HUMAN:
BUILDING A SAFER HEALTH SYSTEM

ealth care in the United States is not as safe as it should be--and can be. At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented, according to estimates from two major studies. Even using the lower estimate, preventable medical errors in hospitals exceed attributable deaths to such feared threats as motor-vehicle wrecks, breast cancer, and AIDS.

Types of Errors

Diagnostic
Error or delay in diagnosis
Failure to employ indicated tests
Use of outmoded tests or therapy
Failure to act on results of monitoring or testing

Treatment
Error in the performance of an operation, procedure, or test
Error in administering the treatment
Error in the dose or method of using a drug
Avoidable delay in treatment or in responding to an abnormal test
Inappropriate (not indicated) care

Preventive
Failure to provide prophylactic treatment
Inadequate monitoring or follow-up of treatment

Other
Failure of communication
Equipment failure
Other system failure

SOURCE: Leape, Lucian; Lawthers, Ann G.; Brennan, Troyen A., et al. Pre-venting Medical Injury. Qual Rev Bull. 19(5):144–149, 1993.

Crawford JM et al., *Academic Pathology* 2017; DOI: 10.1177/2374289517701067

Clinical Lab 2.0 (2017)

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transactional

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  Receive Test Sample
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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
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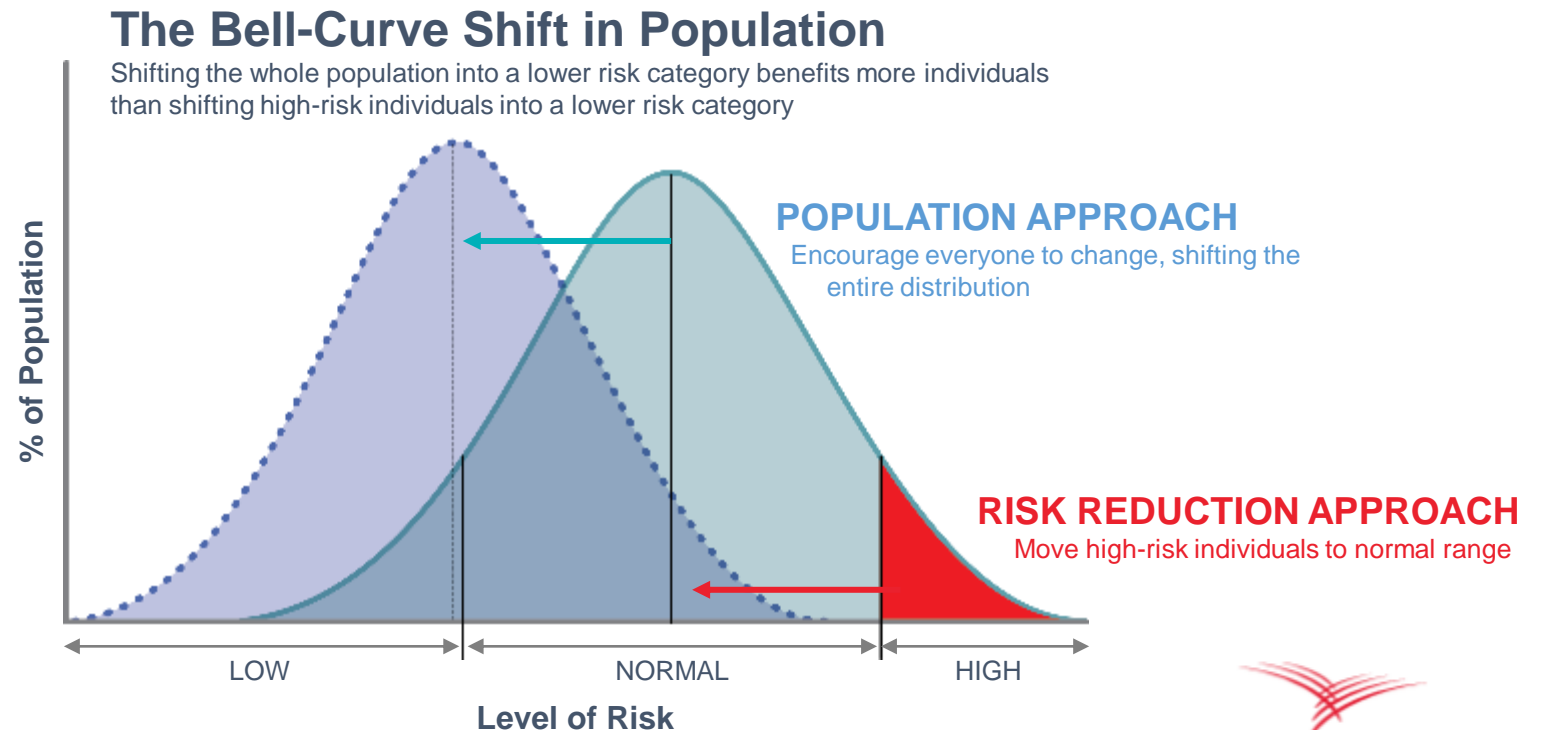 Equipment failure
  Other system failure

SOURCE: Leape, Lucian; Lawthers, Ann G.; Brennan, Troyen A., et al. Preventing Medical Injury. Qual Rev Bull. 19(5):144–149, 1993.

IOM 1999

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"If we (lab) wait, by the time we label a person "patient," we have failed that person."

Lab 2.0 a cornerstone of:
- **Pre-patient**
- **Pre-care**
- **Consumer wellness**

The Bell-Curve Shift in Population
Shifting the whole population into a lower risk category benefits more individuals than shifting high-risk individuals into a lower risk category

POPULATION APPROACH
Encourage everyone to change, shifting the entire distribution

RISK REDUCTION APPROACH
Move high-risk individuals to normal range

% of Population

Level of Risk

LOW   NORMAL   HIGH

SOURCE: Rose G. Sick individuals and sick populations. *Int J Epidemiol.* 1985;14(1):32-38.

Key Takeaways

✓Lab is the first to know- real time actionable data

✓Lab is the first responder

✓Lab is the "epicenter of informatics"

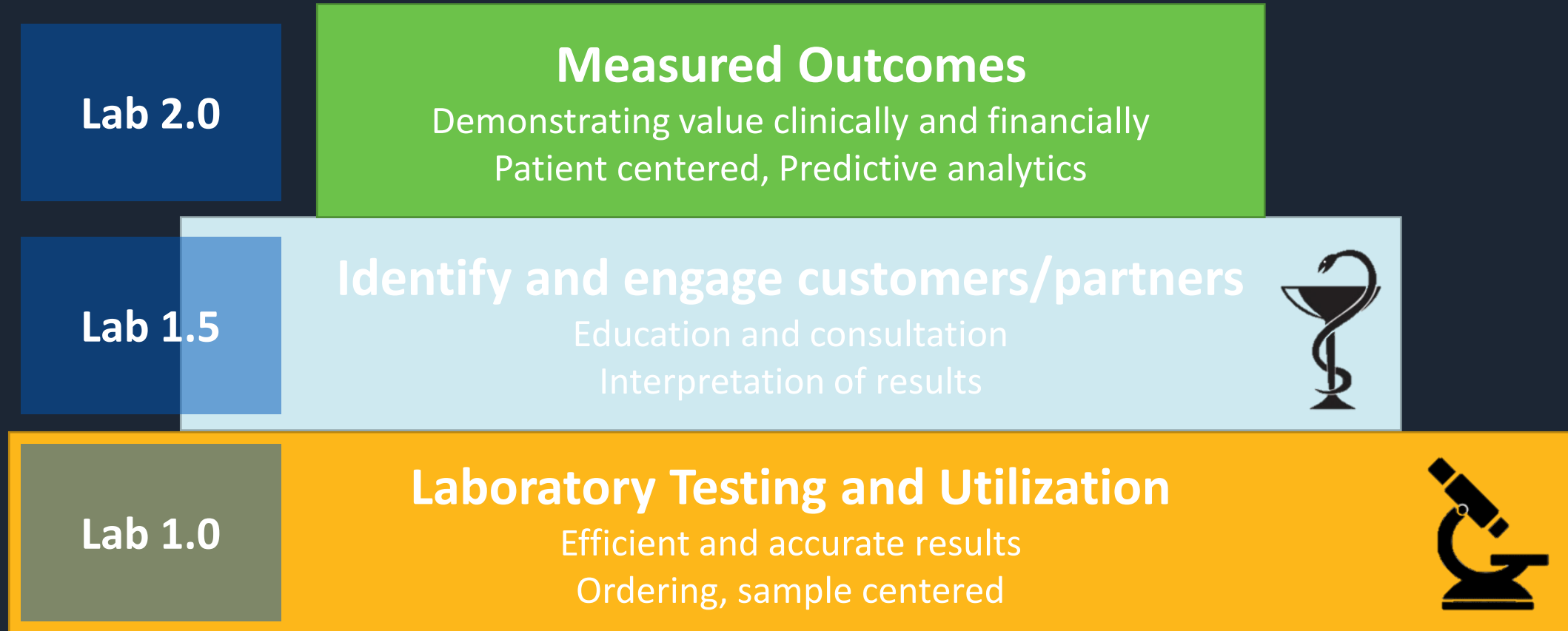✓Labs should be the "Command Center"

The work is before us!

The lab's potential impact doesn't end when we release a result; rather, that's where it begins!

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DO WE HAVE A SEAT AT THE TABLE?

MEETING SHOULD <u>NOT</u> START IF LAB IS NOT PRESENT

Thank you!

What Defines a lab 2.0 project?

Value Based

Outcomes Based

Patient Centered

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE