CLINICAL LAB

A PROJECT SANTA FE FOUNDATION INITIATIVE

Opportunities with Clinical Lab 2.0

Adding Value and Creating Clinical and Operational Intelligence to Improve Health Care Delivery

James M Crawford, MD PhD jcrawford1@northwell.edu

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Disclosures

Chair, BOD, Project Santa Fe Foundation, LLC

Member, BOD, ClaraPath (robotic microtomy)

President, Northwell Health Genomics Alliance (genomic testing)

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Session Objectives:

- Principles of Laboratory Leadership → enhancing Population Health outcomes
- Strategic Objectives to promote efficient (and cost effective) health care delivery
- Real-life case studies that illustrate strategic and tactical laboratory successes

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Roots of the Clinical Lab 2.0 Movement:

- Patient Centered Medical Home: 1967 advocacy (American Academy of Pediatrics)
- → 2007 Joint Principles of PCMH (AAP, AAFP, American Osteopathic Association)
- → 2010 Affordable Care Act: emphasis on Primary Care, "health home", launch of Accountable Care Organization (ACO) model
- → CMS emphasis on Person-Centered Care with *longitudinal accountability*

****plus****

- 2006 "Value-Based Care" (Michael Porter and Elizabeth Olmstead Teisberg)
- → 2015 Medicare Access and CHIP Reauthorization Act (MACRA), establishing Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMS)
- → 2021 CMS goal that by 2030, *100% of Medicare beneficiaries and vast majority of Medicaid beneficiaries will be in a care relationship with accountability for quality and total cost of care*

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

(Deep) Roots of the Project Santa Fe Foundation:

- 1988: Clinical Laboratory Improvement Amendments (CLIA)
- 2/28/1992: Federal Register published first “test performance requirements”
- 7/31/1992: CMS Final Rule implementing accrediting provisions of CLIA; included granting deeming authority to qualified accreditation organizations*
- …..→ ca. 2014: “Six Sigma” quality in delivery of clinical laboratory test results**

PROBLEM: under the Value-Based Payment system, the Clinical Laboratory (Anatomic Pathology included) is a commodity

* Deemed: Joint Commission, CAP, COLA, AABB, Accreditation Commission for Health Care, American Society for Histocompatibility and Immunogenetics, American Association for Laboratory Accreditation

**Howanitz PJ, et al., *Arch Pathol Lab Med* 2014; 138: 1141-1149. DOI: 10.5858/arpa.2014-0150-OA

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Clinical Lab 2.0:

- 2016: Retreat in Santa Fe, NM: *Are clinical laboratory services strictly a commodity, or do laboratory services have a higher valuation that can drive better outcomes for patients, providers, and financial stakeholders?*

Regular Article

Academic Pathology
Volume 4: 1–8
© The Author(s) 2017
Reprints and permission:
sagepub.com/journalsPermissions.nav
DOI: 10.1177/2374289517701067
journals.sagepub.com/home/apc
SAGE

Improving American Healthcare Through "Clinical Lab 2.0": A Project Santa Fe Report

James M. Crawford, MD, PhD[1], Khosrow Shotorbani, MBA, MT(ASCP)[2], Gaurav Sharma, MD[3], Michael Crossey, MD, PhD[2], Tarush Kothari, MD, MPH[1], Thomas S. Lorey, MD[4], Jeffrey W. Prichard, DO[5], Myra Wilkerson, MD[5], and Nancy Fisher, MBA[2]

CLINICAL LAB 2.0

The Mission of Project Santa Fe

Create a disruptive value paradigm and explore alternative business models that expand the role of diagnostic services in the future healthcare ecosystem

Leverage Laboratory Medicine and Pathology domain knowledge to establish the standards and evidence for Clinical Lab 2.0. Facilitate diverse partner collaborations in order to guide policies, transfer knowledge and accelerate the Clinical Lab 2.0 movement across the laboratory industry.

The desired outcomes of CL1.0*

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Accuracy	**High precision, high “trueness”**
Reliability	**Overall consistency of a measure**
Safety	**Reduction in Systematic Error, Reduction in Random Error**
Timeliness	**Meeting/exceeding expectations/standards for Turnaround Time**
Expertise	**Technical, Professional**
Innovation	**"Science of Medicine”: Diagnostics/Prognostics/Theranostics**
Financials	**Revenue, Expense, Margin/Profit**

***Commodity**

The desired outcomes of CL2.0*

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Lab	**Valued as "an essential component of a high performance IDN"**
Consumers	**A key partner in their journey through Wellness and Illness**
Providers	**A key partner for their ability to *care for their Patients***
Health System	**Financial + Quality Performance *of the health system*** **Enhanced Patient Outcomes + Patient Experience** **Enhanced Brand Value, Strategic Clinical Program Growth**
Payers	**Lab as partner: *Data, Product Design/Delivery, Financial Outcomes*** **- and *Improved Population Outcomes***

***Asset**

Clinical Lab 2.0: A unifying concept

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Develop the Evidence Base for Valuation of Laboratory and Pathology Services

- **Optimize:** Time-to-Diagnosis; Time-to-Effective Care; Transitions-in-Care; Care Coordination; Actual Selection of Effective Care
- **Close:** Gaps-in-Care
- **Support & Lead:** Wellness Care; Screening; Monitoring; Chronic Disease Management
- **Translate into:** Quantifiable Measures of:
  - Population Outcomes
  - Economic Outcomes
- **Take advantage:** Health System consolidation
  Laboratory Integration across Health Systems
  Payer interest in innovative Managed Care programming

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

Lab is a “First Responder”*

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Touches more lives than any other clinical service

Time to Diagnoses–
lab has zero latency (actionable)

Diagnostic Optimization

Care Optimization

Therapeutic Optimization

Screening/ Surveillance

- **Each touch point is measured (scientifically) as value-structured data**
- **Each data point is clinically actionable**
- **Not only is Lab > 70% clinical data; Lab represents > 70% of clinical decisions**
  - **Lab can verify (or refute) physicians’ hypotheses**
  - **Lab can rule a condition IN**
  - **Lab can rule a condition OUT**
  - **Lab informs Pharmacy and Therapeutics**

***Christopher Barney, Kidney Transplant Recipient, NKF Patient Advocate; CLMA April 2019**

Lab is “Population Health”

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

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)

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” so as to optimize clinical pathways
- More importantly, the lab can help with the following clinical strategies of value-based healthcare…

INTERVENTION *PREVENTION* *COST AVOIDANCE* *RISK ADJUSTMENT*

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Clinical Lab 1.0 (transactional)

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

Clinical Lab 2.0 (integrative; diagnostic surveillance)

Health Optimization
- Proactively identify, test, and engage patients
- Precision Medicine
- Coordinate with providers

Risk Management
- Baseline /screen patients
- Health maintenance
- Prioritize clinical interventions
- Risk stratification
- Reduce negative outcomes

Care Coordination
- Diagnostic Management Teams
- Close care gaps
- Optimizing lab testing in clinical workflows
- Eliminate care variation
- Real time patient triage

Evidence-based Outcomes
- Diagnostic computation
- Predictive Analytics
- Data driven decisions

Economic & Payment Models
- Alternative payment models aligned to operational objectives
- Support quality metrics and reimbursement models

Data Analytics: Real time acquisition, standardization, longitudinal

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Clinical Lab 2.0: 2017 – present (selected):

- 2017-2019, 2021-2025ff: Clinical Lab 2.0 Annual Workshops (open)
- 2017-2024ff: Project Santa Fe Colloquia (by invitation)
- 2017,2018,2019,2023,2024: Executive War College workshops/presentations
- 2017 – present: PSFF-sponsored Demonstration Projects:
  - Acute Kidney Injury (published)
  - Chronic Kidney Disease (published)
  - Anemia (submitted)
  - Critical Values (submitted)
  - Sepsis (nearing completion)
  - Opioids (in progress)
  - Steatotic Liver Disease (being initiated)

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

SAVE THE DATE: March 3-4, 2025

8th Annual Clinical Lab 2.0 at Pendry Chicago*

Two days of transformative conversation, where population health, value-based care, and the diagnostics industry CONVERGE. Together, we will shape the transition from a business of volume to a business of value in sustainable healthcare. Limited seating (~120 attendees), so make sure to mark your calendar and join us in Chicago!

cl2lab.org

*One of only 33 "Michelin 2-key" hotels in U.S.

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Is “Clinical Lab 2.0” making any difference?

- 2017 *Academic Pathology* publication:
  - n = 47 citations (now about 6-8 per year)
  - Altmetric score 25 (>20 is considered excellent; reflects “traffic”)
  - n = 11,542 views/downloads
- “If your goal was to get the conversation started in the Lab Industry, you have succeeded (even if ‘hard data’ from Demonstration Projects has been slow in coming).” September 2022

PROBLEM: We are in our own echo chamber. Is anyone else listening?

e.g., Health System Leadership, Payers

Population Health leadership, Primary Care colleagues

CONSUMERS (aka, Patients)

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

A personal conclusion

- *“Clinical Lab 2.0” is a battle won-in-detail:*
  - Strategic and Tactical Objectives have to be of explicit (and realized) Value to specific Stakeholders
  - It is the cumulative (and un-ending) quantitative evidence of sustained Value that raises the clinical laboratory from “Commodity” to “Asset” status, for decision-making stakeholders

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Illustrative Case Studies	Stakeholders
• *Acute Kidney Injury (published)*	health system CMO, CQO, CFO
• *Bacteremia (published)*	health system CMO, CQO, CFO
• *COVID-19 (published)*	State, Municipality, Counties….
• *Prenatal Care (published)*	State Medicaid system
• *Chronic Kidney Disease (published)*	Payers, health system Risk Management

Kothari T, et al., *Acad Pathol* 2018; DOI: 10.1177/2374289518816502. PMID: 32733989
Khare R et al., *Clin Infect Dis* 2019 March 14; pii.ciz198; doi: 10.1093/cid/ciz198; PMID: 30873522
Reichberg SB, et al. *Clin Infect Dis,* 8 Jul 2020; DOI: 10.1093/cic/ciaa922. PMID: 32640030
VanNess R, et al., *Am J Managed Care* 2021 Feb; 27(2): 60-65. doi: 10.37765/ajmc.2021.88582. PMID: 33577153
Fung M, et al., *BMC Nephrology* (ePub 4 April 2024). DOI: 10.21203/rs.3.rs-4032702/v1

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

TriCore Laboratories/Rhodes Group

- Identify Members enrolled in Centennial Care (CC, New Mexico Medicaid Program)
- Identify CC Members who have a history of testing with TriCore
- Assess for Risk: Pregnancy + Diabetes; Hepatitis C
- Identify Gaps in Care; notify CC for proactive:
  - Prenatal Care
  - HCV screening/treatment

TRICORE

RHODES GROUP

ROI of Rhodes' FOCUS Platform (2021-2022)

Health Condition	Measure/Outcome	2021 Performance*	2022 Performance	ROI
Prenatal	Timeliness of Prenatal Care NMHSD PM #5	79%	86%	$2,480,038
	Post-Partum Care NMHSD PM #5	67%	75%	$2,480,038
	NICU Occupancy	10.7%	10.6%	$1,774,057
	Preterm Delivery Outcome	13.6%	13.2%	$5,026,098
Hepatitis C	NMHSD Risk Corridor			$3,065,044
			TOTAL	$14,825,275

***VanNess R, et al., *Am J Managed Care* 2021 Feb; 27(2): 60-65. doi: 10.37765/ajmc.2021.88582. PMID: 33577153**

A Laboratory Initiated Care Model: Chronic Kidney Disease

Geisinger

The University of Vermont
LARNER COLLEGE OF MEDICINE

Northwell Health℠

in collaboration with

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

NATIONAL KIDNEY FOUNDATION®

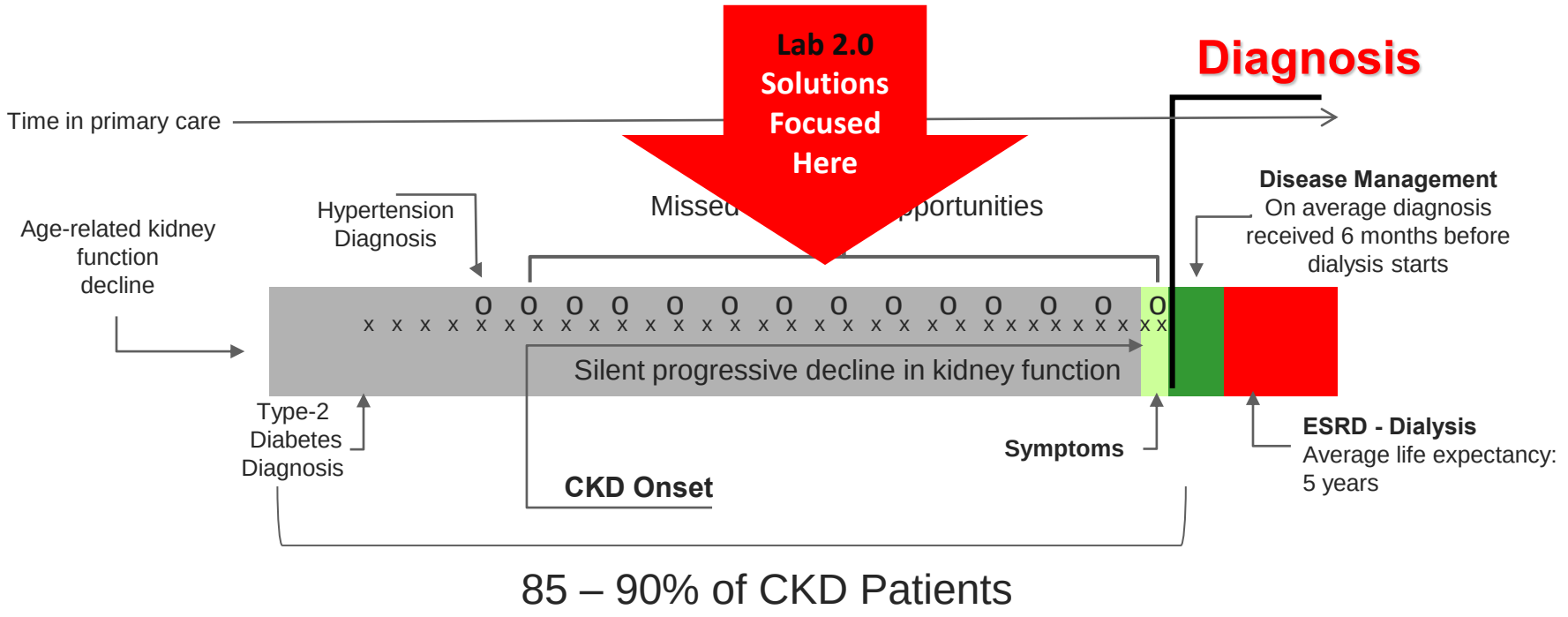
Fung M, et al. *BMC Nephrology* (ePub 4 April 2024). DOI: 10.21203/rs.3.rs-4032702/v1

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Chronic Kidney Disease (CDC numbers)

- About 37 million US adults with CKD, most are undiagnosed
  - 15% of adults
  - 1 in 3 adults with diabetes
  - 1 in 5 adults with hypertension
  - 1 in 2 patients aged 30-64 are expected to develop CKD in their lifetime
- 40% with severely reduced kidney function (CKD Stages 3,4; not on dialysis) are not aware of having CKD
- Treating Medicare beneficiaries with CKD costed $87 billion (2019)
- Treating patients with End-Stage Renal Disease (ESRD) costed additional $37 billion (2019)

https://www.cdc.gov/kidneydisease/basics.html



Szczech, Lynda A, et al. "Primary Care Detection of Chronic Kidney Disease in Adults with Type-2 Diabetes: The ADD-CKD Study (Awareness, Detection and Drug Therapy in Type-2 Diabetes and Chronic Kidney Disease)." *PLOS One* 9(11); 2014:e110535 .

Tuot, Delphine S, et al. "Chronic Kidney Disease Awareness Among Individuals with Clinical Markers of Kidney Dysfunction." *Clin J Am Soc Nephrol* 6 (2011): 1838-1844.

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Kaplan-Meier survival curves of CKD

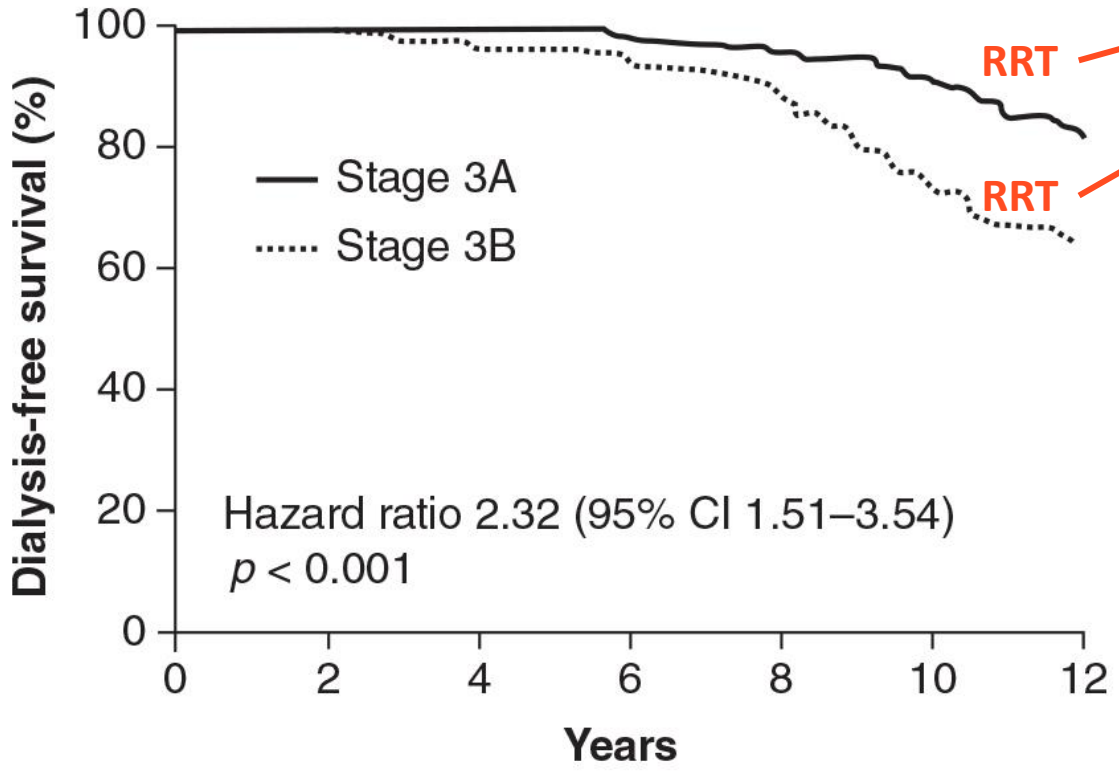


Figure 2. Dialysis-free survival in groups of patients with stage 3A and 3B chronic kidney disease at baseline.

Baek SD, et al., Scand J Urol Nephrol 2012; 46: 232-238

RRT

RRT

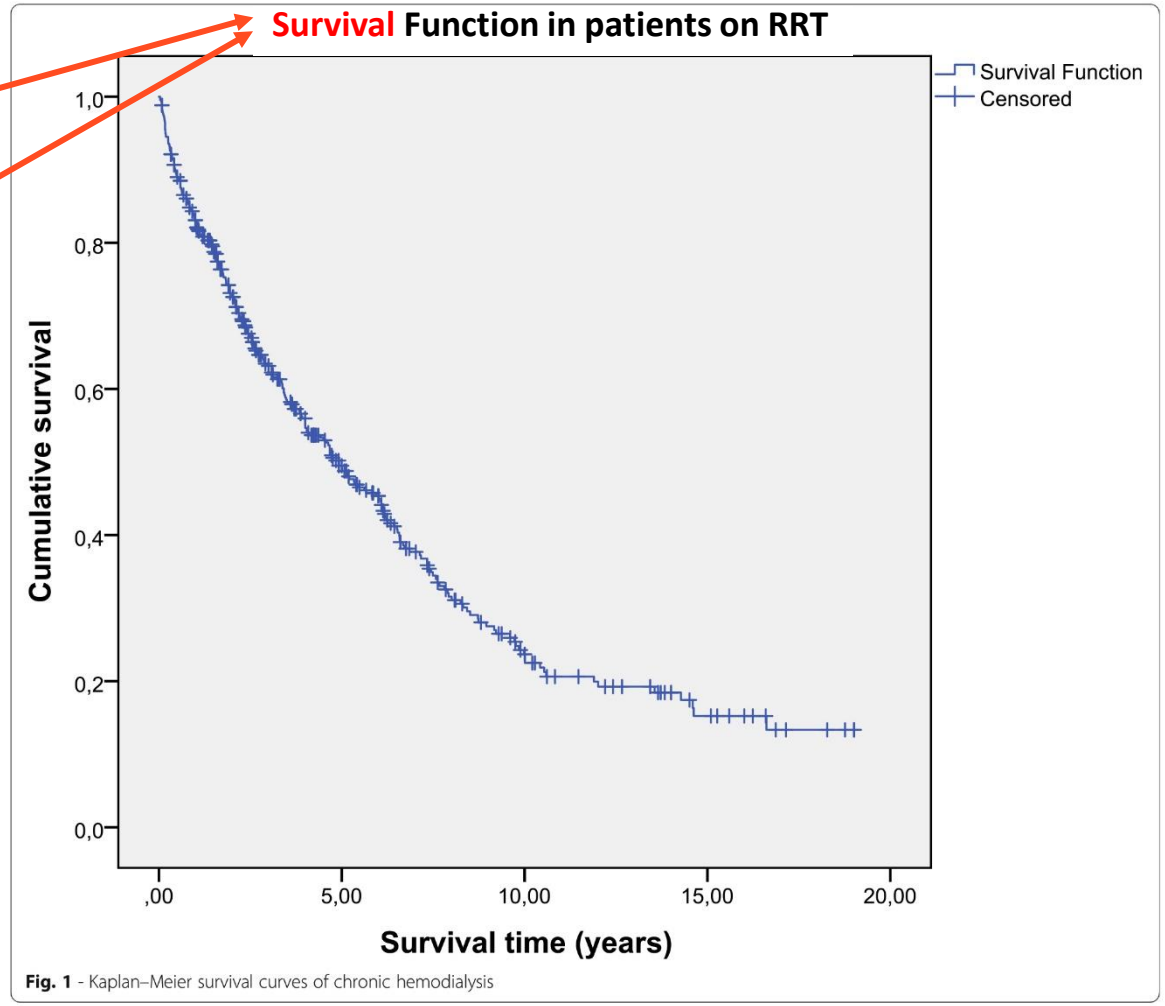


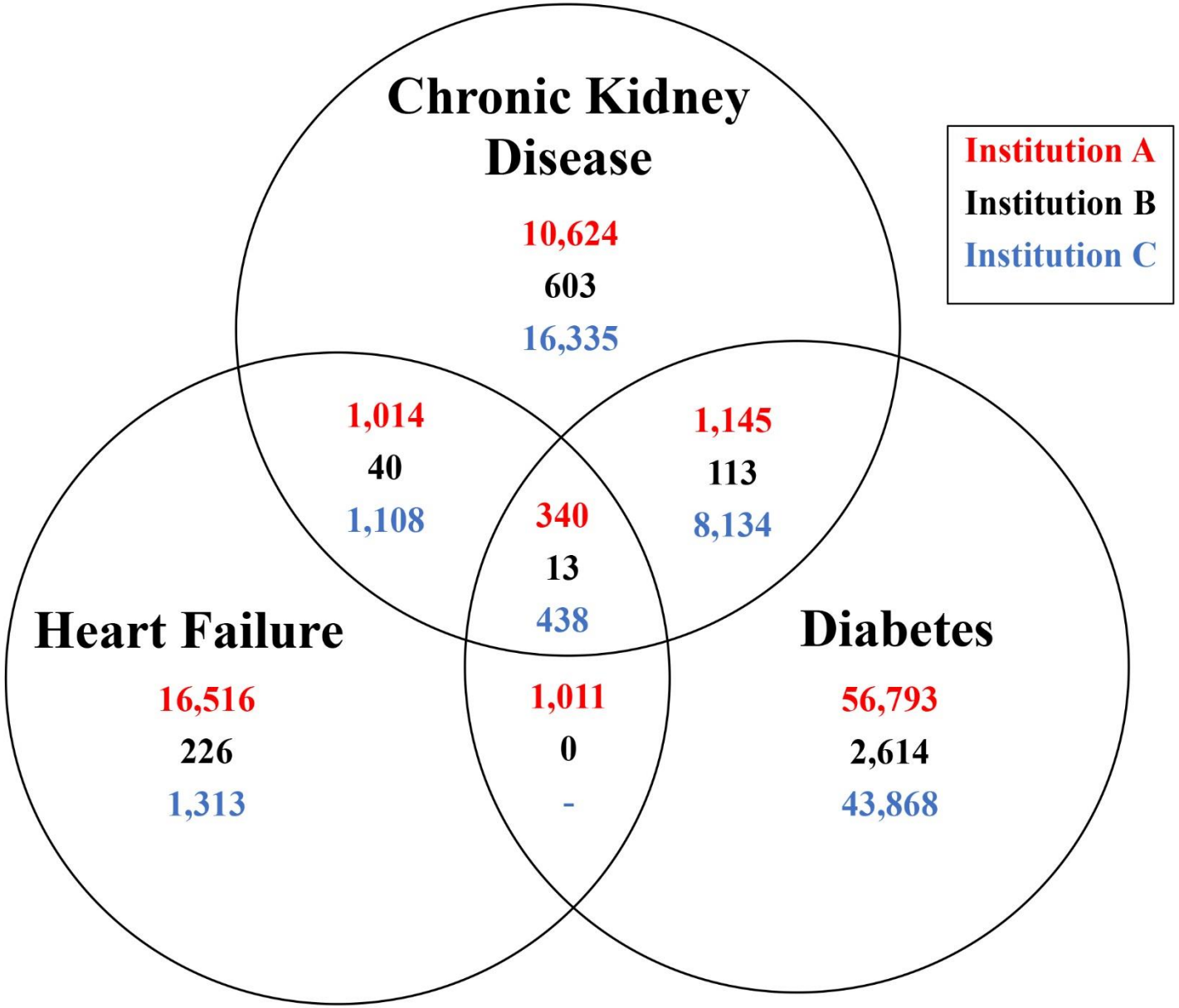
Fig. 1 - Kaplan–Meier survival curves of chronic hemodialysis

Ferreira E, et al., BMC Nephrol; 2020: 21:502

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Chronic disease distribution based on 2021 *Lab* results

- Interprofessional collaboration between 3 Project Santa Fe Foundation (PSFF) members and the National Kidney Foundation (NKF)
- Purpose of study: identify potential value of the clinical laboratory to: stratify risk, identify gaps in care, and capture missing billing and reimbursement opportunities for CKD patients (with comorbidities of diabetes and heart failure)



Fung M, et al. *BMC Nephrology* (ePub 4 April 2024). DOI: 10.21203/rs.3.rs-4032702/v1

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

2021 data: 3 institutions

	Institution A	Institution B	Institution C
Patients with HbA1c >/= 6.5 and *no screening for CKD*	**59%** (34,384/58,278)	**82%** (2,274/2,740)	**77%** 40,378/52,440

How was CKD (Stage 3 or 4) identified?	Institution A	Institution B	Institution C
Lab Results Only	**78%** (12,478/16,063)	**32%** (487/1511)	**66%** (19,433/29,277)
Both Lab + Dx Code	**4%** (645/16,063)	**19%** (282/1511)	**22%** (6,582/29,277)
Dx Code Only	**18%** (2,940/16,063)	**49%** (742/1511)	**11%** (3,262/29,277)

Fung M, et al. *BMC Nephrology* (ePub 4 April 2024). DOI: 10.21203/rs.3.rs-4032702/v1

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

2021 Estimated Lost Opportunity for undocumented CKD (3 institutions); Medicare Advantage alone

	*Medicare Advantage Patients (total CKD by Lab only)	Unrealized HCC Risk Adjustment
Medicare CKD Stage 3	3,531* (36,385)	$2,051,376†
Medicare CKD Stage 4	332* (3,522)	$658,881†
ACA CKD Stage 4	55 (3,522)	$616,203

***3,863 MA patients not Dx'd by ICD10; †$2.71M RA not captured for patient care**

Assumptions:

- % insured enrollment in MA, *2021* HCC Risk Adjusted rates for Medicare Advantage/ACA
- Gaps in CKD identification/documentation from NKF/PSFF CKD study for 3 sites

Extrapolates to 3.3M MA patients in U.S., and $2.1B not used for MA patient care

Johnson KL, et al., US Renal Data System 2022 Annual Data Report: Epidemiology of Kidney Disease in the United States. Am J Kidney Disease, 2023 Mar; 81(351):A8:A11. DOI: 10.1053/j.ajkd.2022.12.001

*e.g., Medicare estimated at 19% of total insured population; Medicare Advantage at 50% of Medicare (New York) (ergo, 9% of total insured individuals); https://www.kff.org/medicare/state-indicator/

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

NKF:Project Santa Fe Study: No ICD10 Code

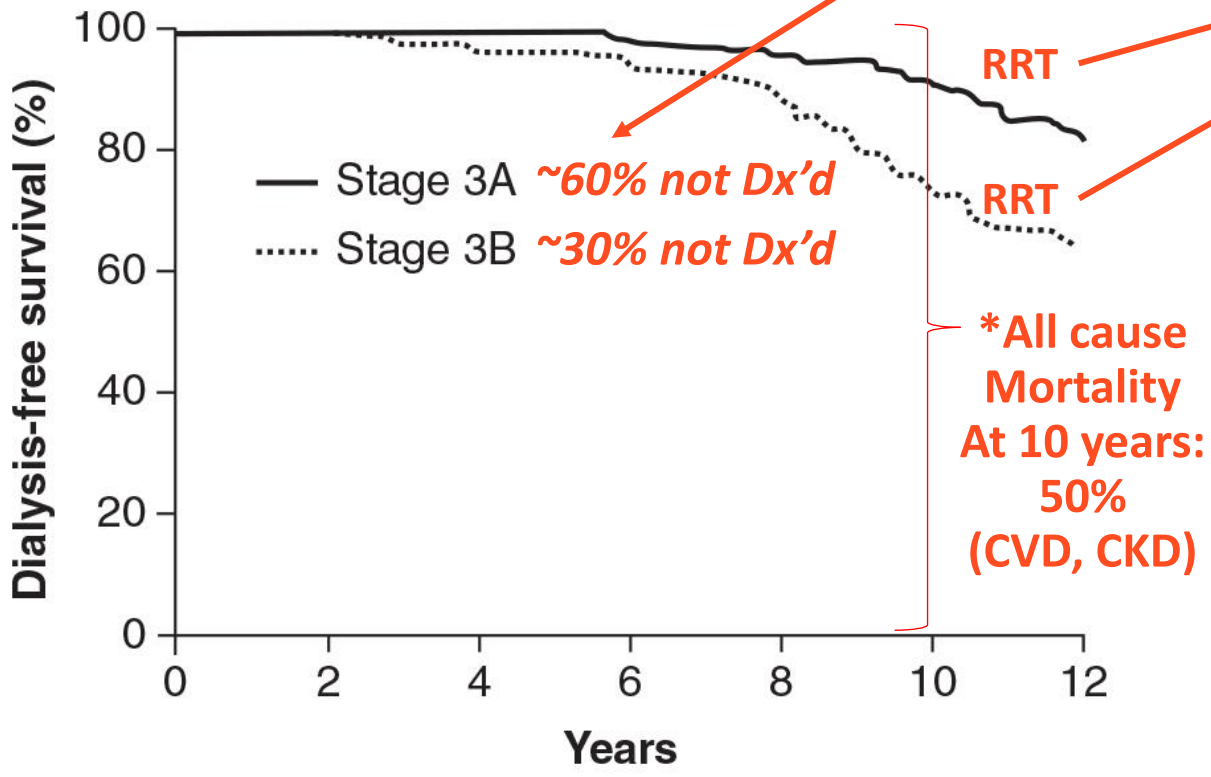


Figure 2. Dialysis-free survival in groups of patients with stage 3A and 3B chronic kidney disease at baseline.

Baek SD, et al., Scand J Urol Nephrol 2012; 46: 232-238

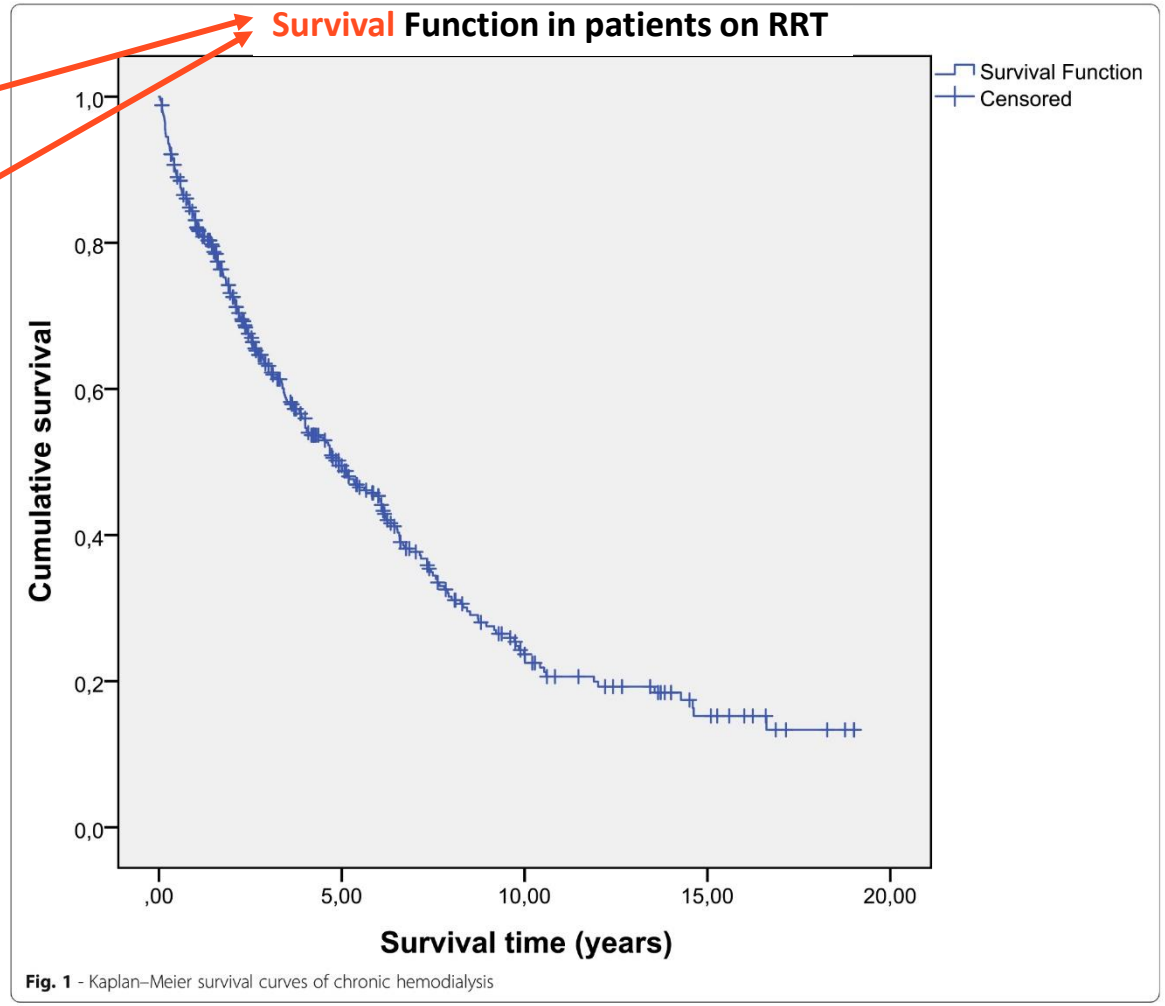


Fig. 1 - Kaplan–Meier survival curves of chronic hemodialysis

Ferreira E, et al., BMC Nephrol; 2020: 21:502

*Sharma P, et al., Br J Gen Practice; 2010 June

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Comparison of CKD with Breast Cancer Survival

Breast cancer-specific survival for patients with early breast cancer

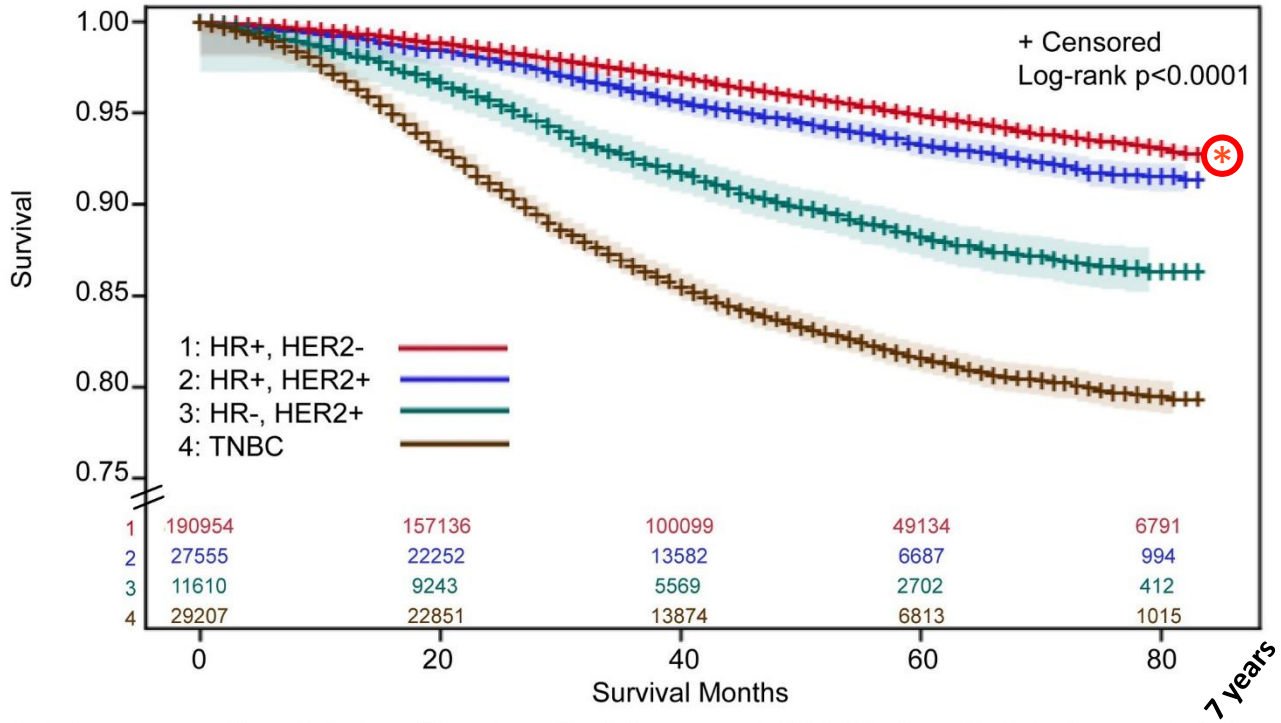


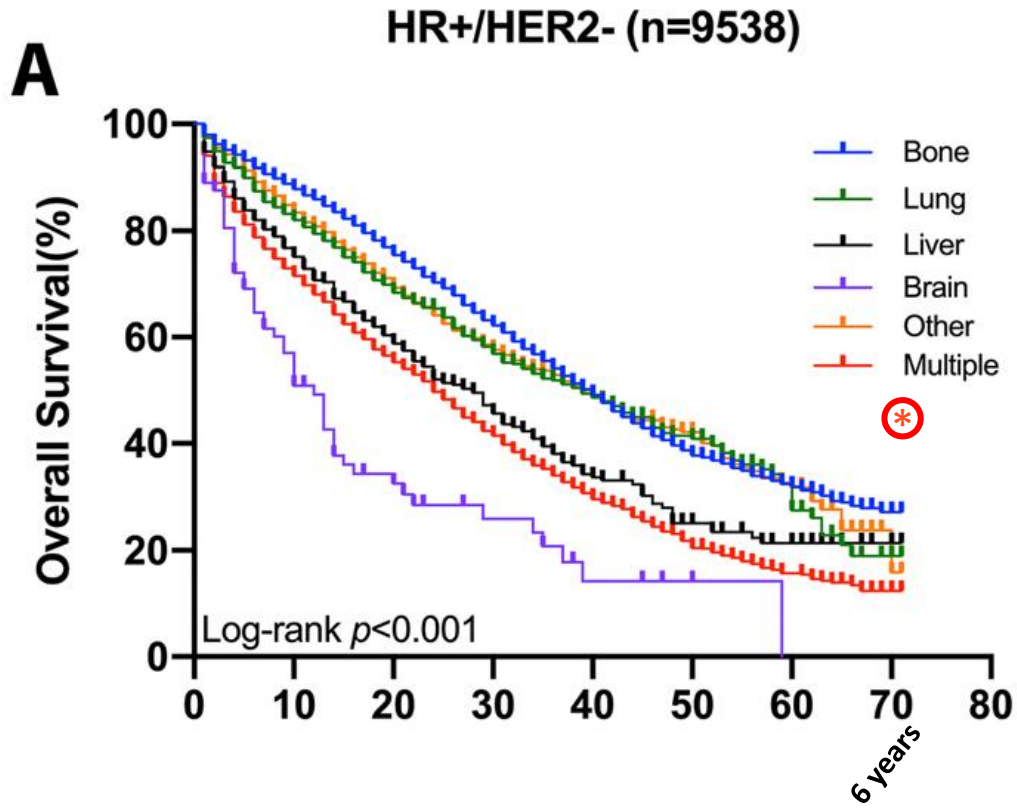
Fig 2. Breast cancer-specific survival estimates[1] for patients with early breast cancer, by HR, HER2 subtype. [1]Survival estimates were derived using Kaplan-Meier methods with 95% Hall-Wellner confidence bands. SEER does not provide cancer-specific survival status for patients with a previous tumor, so those patients were excluded. ⌐ Indicates y-axis was truncated to 0.75–1.00. Abbreviations: HER, human epidermal growth factor receptor; HR, hormone receptor; SEER, Surveillance, Epidemiology, and End Results; TNBC, triple negative breast cancer.

https://doi.org/10.1371/journal.pone.0264637.g002

Nelson DR, et al., PLoS One 2022; 17(2):e0264637

⊛93%: Dialysis-free survival of CKD Stage 3B at 7 years

Metastatic breast cancer survival by metastatic site



Wang R, et al. BMC Cancer; 2019: 19:1091

⊛Survival of Patients on RRT at 6 years

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

250 Causes of Death (2016), 195 countries

Condition	Life Years Lost (000s)	Deaths (000s)
Neoplasms	208,041	8,927
Breast	14,369	546
CVD	319,639	17,646
CKD	26,261	1,187
CKD-DM	10,965	501
CKD-HTN	4,927	300

*CVD, Cardiovascular Disease; CKD, Chronic Kidney Disease; DM, Diabetes Mellitus; HTN, Hypertension

Foreman KJ, et al., Lancet 2018; 392: 2052-2090

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Chronic Kidney Disease: Next Steps: Nephrology, Endocrinology, Primary Care Providers Risk Management, C-suite

- Partnership with Primary Care, Nephrology, Endocrinology
  - To identify most effective use of reports identifying gaps on a regular basis
  - To develop care pathways that Lab can help provide to primary care offices
  - To develop criteria for when referral to Nephrology is warranted
- Goals of tri-partite partnership (Primary Care, Subspecialty, Lab)
  - Empower primary care with necessary reports and tools from Lab to continue management of early chronic disease
  - Reassure content experts (subspecialist) that Lab is providing vetted guidance
  - Minimize chronic disease progression while assuring timely referrals
  - Identification of Lab as a facilitator of faster, more standardized effective care

CLINICAL LAB 2.0

Lessons Learned from Demonstration Projects

Institutional receptivity to a Lab-initiated project varies widely, as does institutional need

One institution's "Clinical Lab 2.0" may not be another's. *The Valuation is local.*

Building the Real-World Evidence base for the Value-added of a Laboratory project is hard (and takes time)

Value-added activities are not resourced by the laboratory Cost-per-Test Revenue Cycle

Economic Outcomes must be "realized", not "imputed", and Lab's contribution must be causally-linked

CLINICAL LAB 2.0

Maxims

Your Laboratory-led projects must matter to your health system's: CEO, COO, CFO, CQO, CMO, CNO, CIO….

If your projects don't, you are not thinking big enough

And your projects should also matter to your: Payers, Treating Physicians, Patients/Consumers

CLINICAL LAB 2.0

The Mission of Project Santa Fe

Create a disruptive value paradigm and explore alternative business models that expand the role of diagnostic services in the future healthcare ecosystem

Leverage Laboratory Medicine and Pathology domain knowledge to establish the standards and evidence for Clinical Lab 2.0. Facilitate diverse partner collaborations in order to guide policies, transfer knowledge and accelerate the Clinical Lab 2.0 movement across the laboratory industry.

CLINICAL LAB 2.0

The Pillars of Project Santa Fe Work

Create a disruptive value paradigm and explore alternative business models that expand the role of diagnostic services in the future healthcare ecosystem

CL2.0 Leadership
Foundation

- What is Leadership in Value-based Healthcare?
- Outside the lab
- CL2.0 Skillset
- CL2.0 Knowledge set
- Know Self; Know Terrain
- Communication is key

CL2.0 Business Model
Standards

- CL2.0 Objectives & Key Results
- Measure what matters – Quad Aim
  - Clinical
  - Business/Financial
  - IT/Data
  - Product (MVP)
- Health Economics, Population Health, Value based Care

CL2.0 Evidence
Demonstration

- CL2.0 Multi-Institutional Demonstration Projects
- Outcome focused – Clinical & Economic
- Case studies, best practices & lessons learned
- Publish – peer review & skunkworks

CL2.0 Partnerships

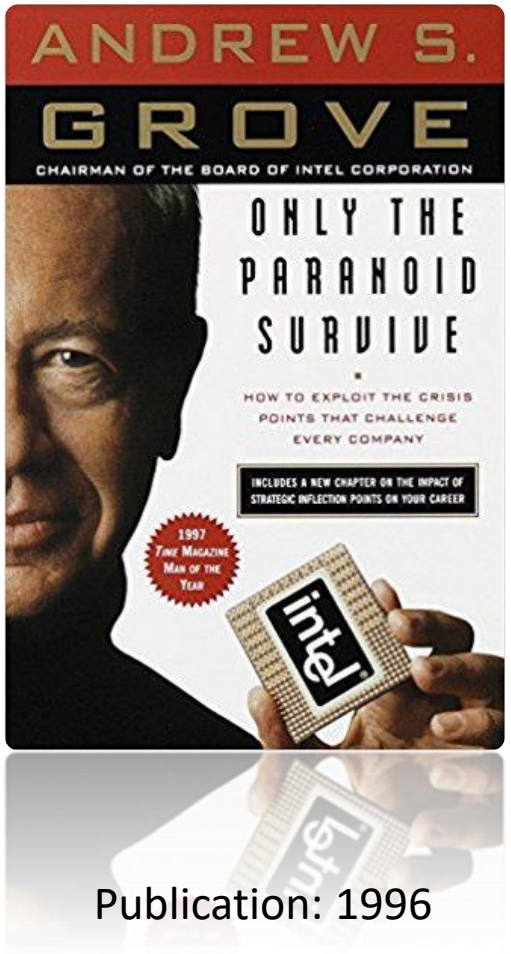
Question:

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.

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Has the current lab business model reached a ***'Strategic Inflection Point'****?*



Publication: 1996

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

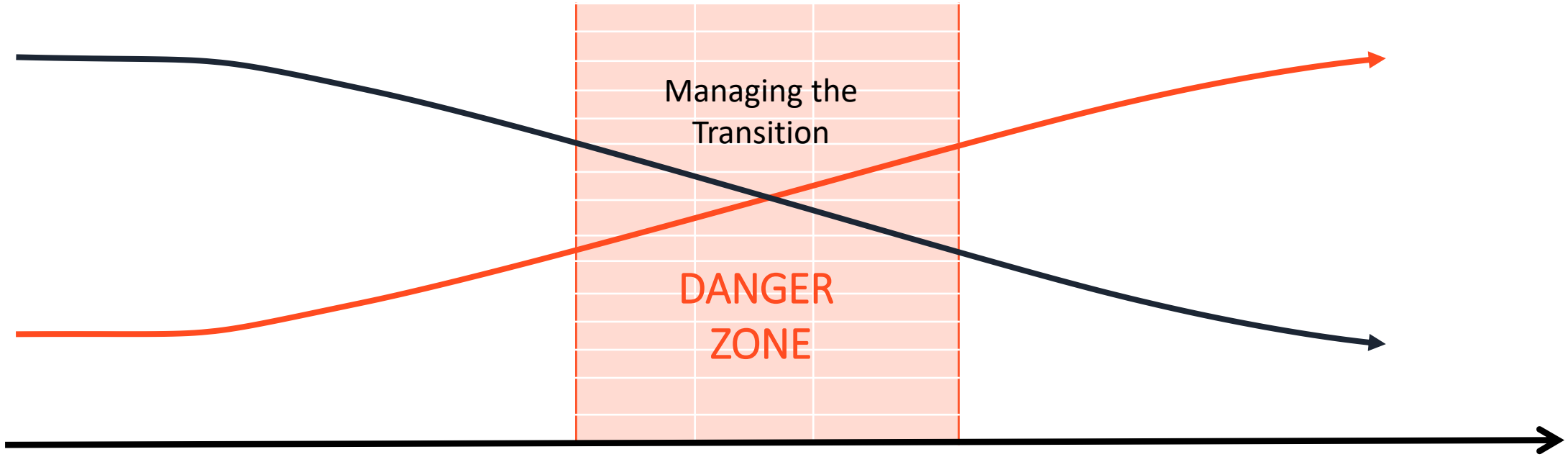
Strategic Inflection Point

CURRENT STATE
Sick-Care

Fee-for-Service Reimbursement
Business of Volume

FUTURE STATE
Well-Care

Value-based Reimbursement
Business of Outcome & Risk



CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Future State - Why do we feel bullish?

If we are moving from business of “heads in bed” to business of “we don’t want you in the hospital” model……..

Lab becomes highest yield asset to drive:

- *Risk Adjustment* and *Quality Ratings*
  - e.g., HCC, HEDIS, STAR ratings
- *Risk Management*
  - Clinical Intervention
  - Clinical Prevention

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Future State - Why do we feel bullish?

If we are moving from business of “heads in bed” to business of “we don’t want you in the hospital” model……..

Lab becomes highest yield asset to drive:

- *Risk Adjustment* and *Quality Ratings* → *Realized Revenue*
  - e.g., HCC, HEDIS, STAR ratings
- *Risk Management* → *Cost Avoidance*
  - Clinical Intervention
  - Clinical Prevention

The Lab has the opportunity to drive:

- **Better Population Outcomes**
- **Reduced Total Cost-of-Care**
- **Avoidance of Cost**
- **Decreased Economic Burden to Patient**

CLINICAL LAB 2.0

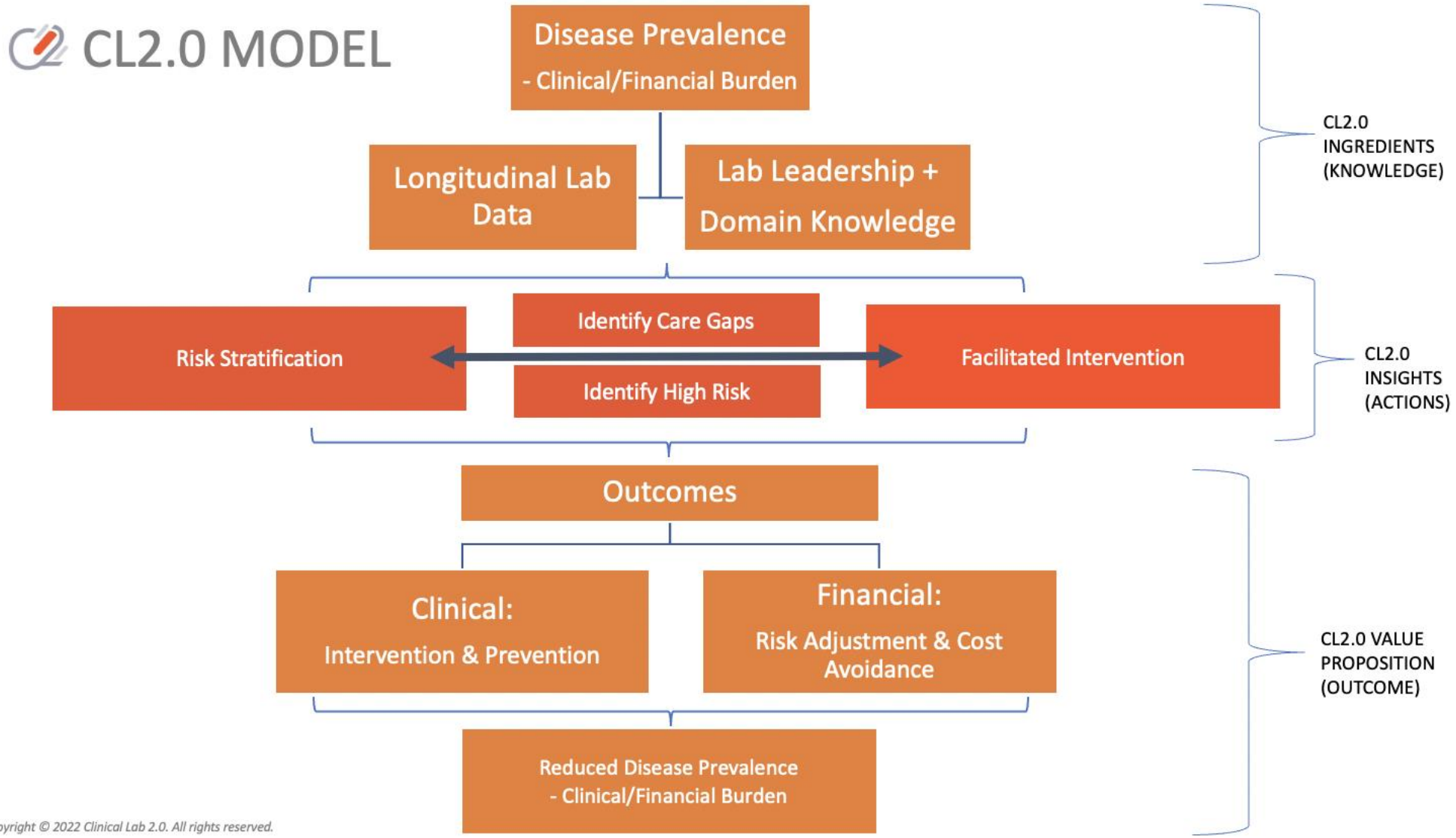
A PROJECT SANTA FE FOUNDATION INITIATIVE

CL2.0 Customer: A healthcare entity which will:

- be at a financial *risk* for improved outcomes for a defined population and therefore be “on the hook” for value-based payment.
- have influence or authority on ‘*Quadruple Aim*’ *policies* impacting clinical protocols, clinical workflow, practice pathways.
- have the ability to use risk stratification guide changes in Provider and Patient *behavior* to improve care delivery and *outcomes.*

→ *Lab-Initiated Care Models*

Lab-Initiated Care Models

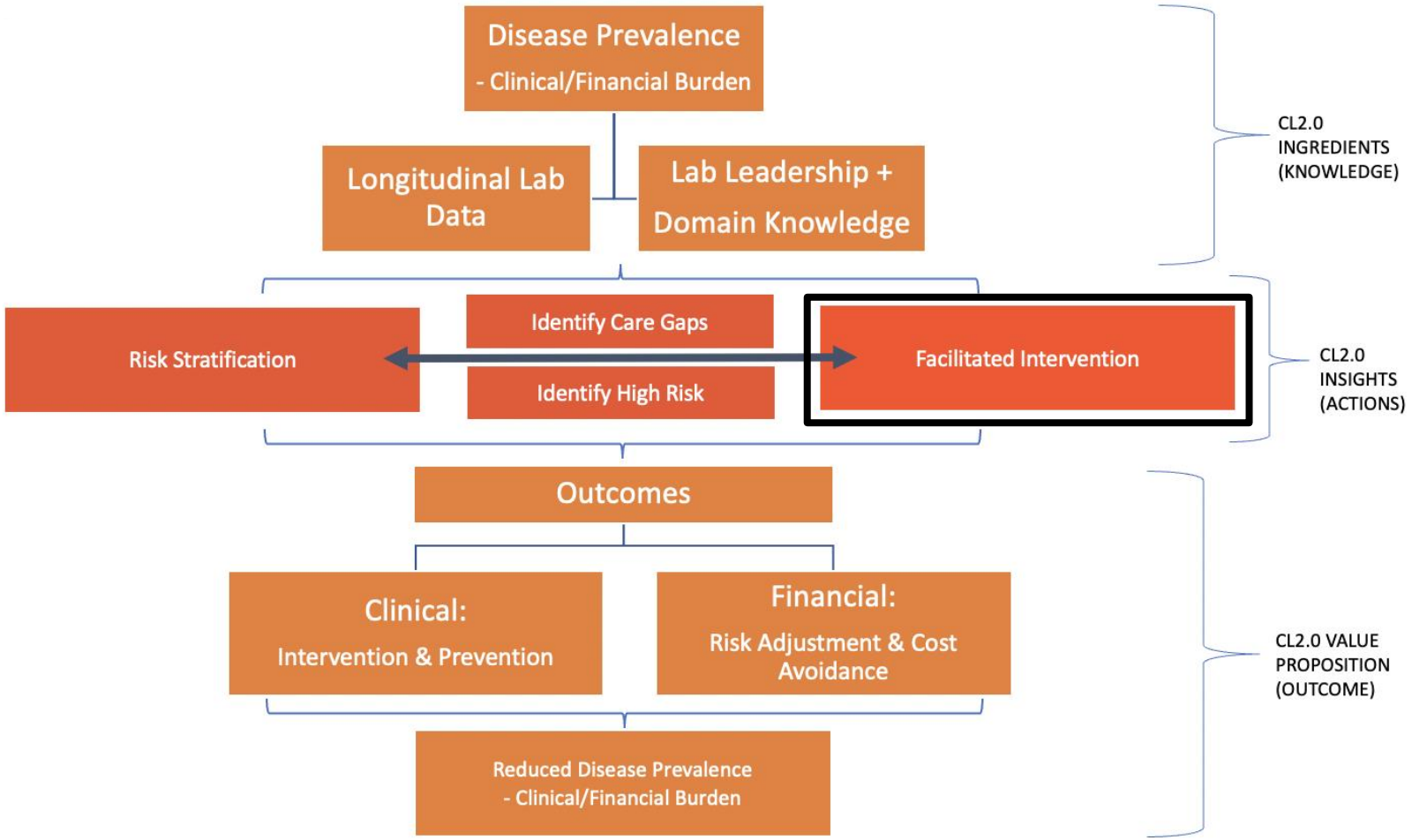


- High prevalence conditions
- Laboratory Leadership
- Key Partnerships
  - Physician, Administrative, Payer champion
- Clinical Protocols
  - Testing cascade; diagnostic pathway
- Workflow & facilitated interventions
- Shared accountability
- Measurable and attributable outcomes
- Policy impacting clinical protocols & workflow

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

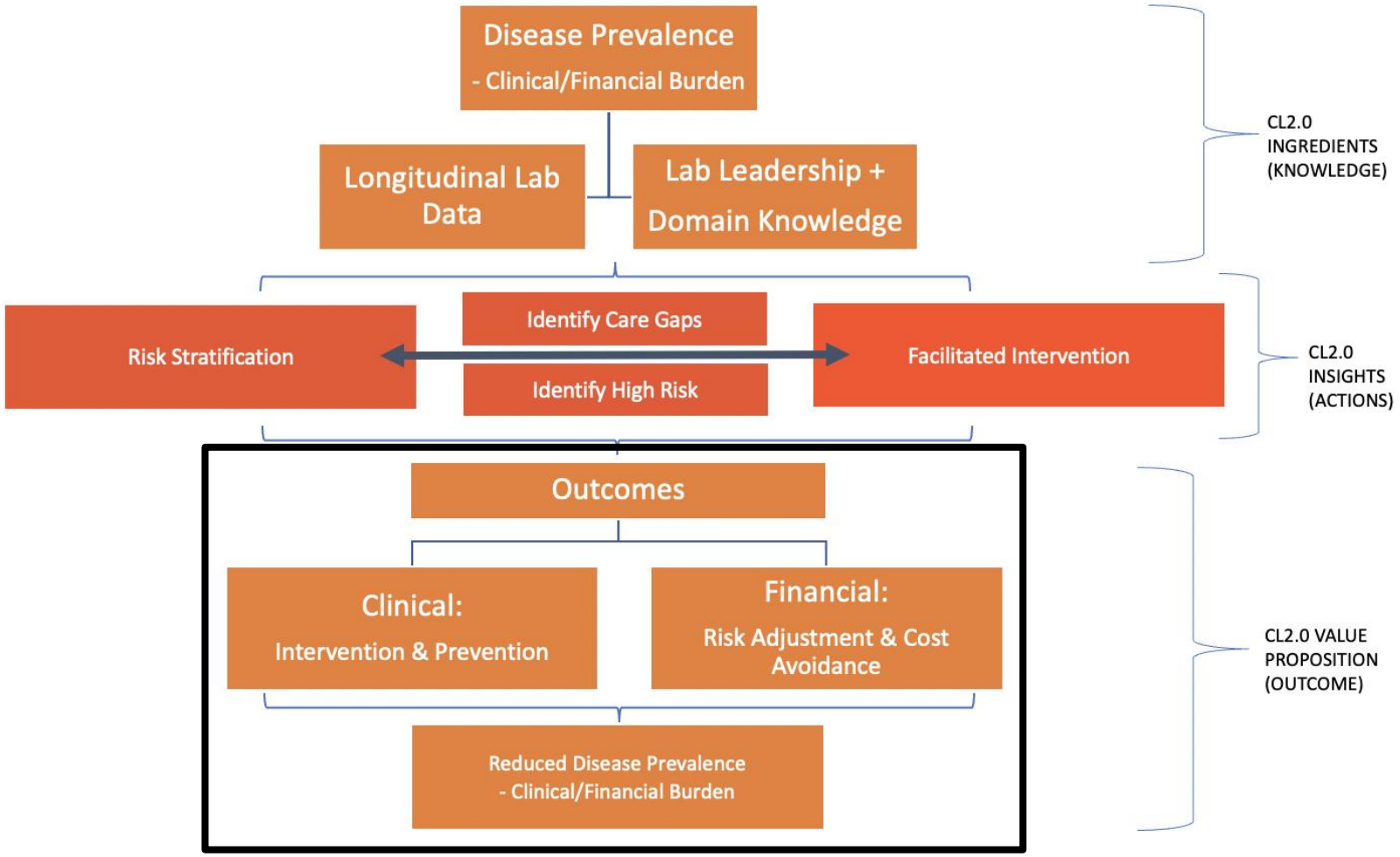
What now needs to happen (1)



CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

What now needs to happen (2)



CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

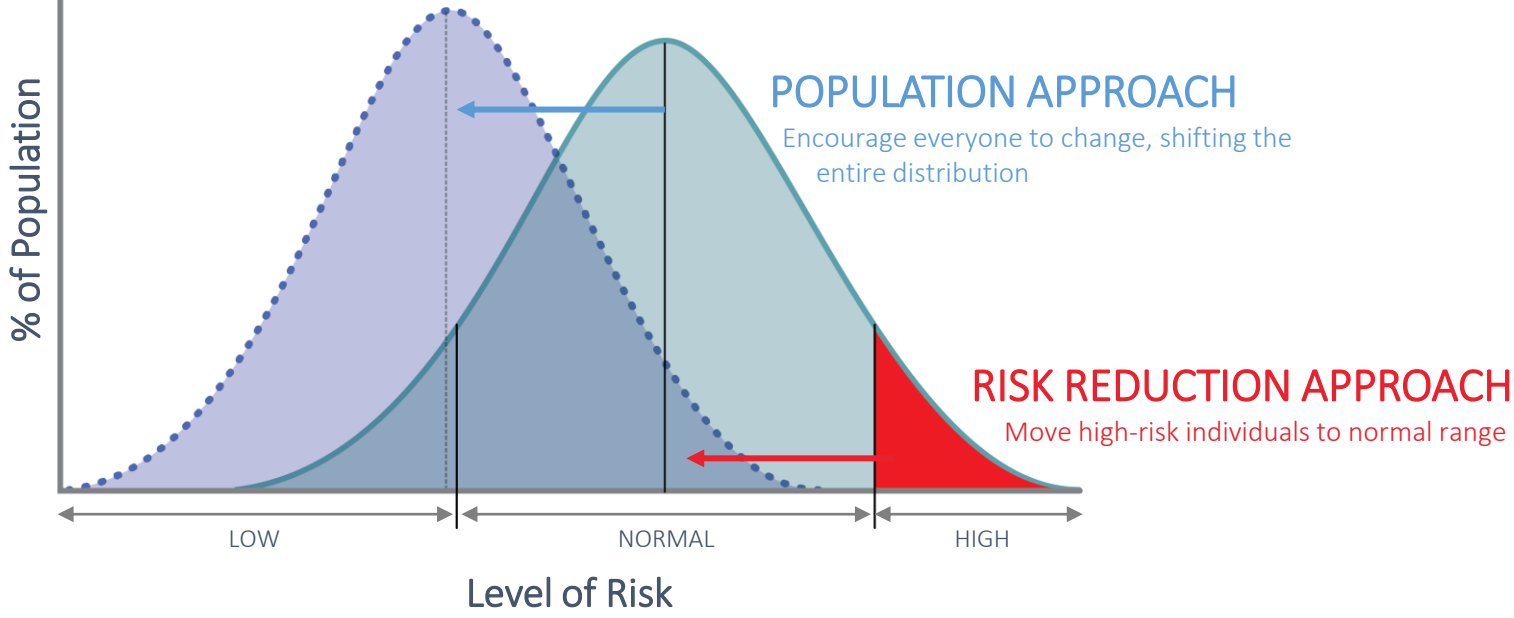
If we (lab) wait, by the time we label someone a "Patient," we have failed that person.

Clinical Lab 2.0 is a cornerstone of:

- Pre-patient
- Pre-care
- Consumer well-care

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



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

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

Laboratory Leadership needs to:

- Form the institutional/regional teams to implement programs, based on:
  - Identification of “at risk” individuals, track their longitudinal trends/gaps-in-care
  - Define the service model of delivering best practice care, Deploy
  - Measure-what-matters (operational metrics, health care/cost outcomes), making sure to track the attributable contribution from clinical laboratory leadership
- *Operate within existing (and future) Value-Based Payment* paradigms
- Constantly strive to identify new opportunities, new markets
  - Health system products
  - Payer products

“Go Vertical” in your learning

CLINICAL LAB 2.0
A PROJECT SANTA FE FOUNDATION INITIATIVE

Health Care Policy
Health Care Payments
Health Care Market Trends
Laboratory Market Trends
Laboratory Regulation
Payer initiatives
Data Science
Medical Science
Disruptors in the Marketplace
Consumerism

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

The opportunities abound:

- Chronic Disease management, including confounding comorbidities
- Address the clinical programmatic “pain points” of your immediate Stakeholders
- Improving specific Quality metrics of Value-Based Payment systems
- Direct partnership with Risk Management/Managed Care programs
- Working with Payers for Benefits and Product design/delivery
- Amplification of your effort through Industry partnership

CLINICAL LAB 2.0

A PROJECT SANTA FE FOUNDATION INITIATIVE

The biggest barrier:

- The Business Model of U.S. health care is based on Lab as a commodity
- At the current time, the business model for Clinical Lab 2.0 does not exist
- Therefore, “winning the battle in detail” means providing realized, attributable Value to your immediate Stakeholders
- The Return-on-Investment for costs of CL2.0 programming must be in clear view
- Advocacy and, potentially, Policy change will be needed to establish the revenue streams that support Clinical Lab 2.0 activities, over-and-above commodity payment

Do your health system’s (or Payer’s) patients do better for you being their laboratory? PROVE IT!

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

CLINICAL LAB 2.0

A **PROJECT SANTA FE FOUNDATION** INITIATIVE

CLINICAL LAB

A PROJECT SANTA FE FOUNDATION INITIATIVE

Acknowledgement

The founders and thought leaders of Project Santa Fe (Clinical Lab 2.0) 2016-present

James M Crawford, MD PhD jcrawford1@northwell.edu