

From a Test to a Value Based Care Model in Liver Disease

Aya Haghamaad, PharmD
Advisor, Pharmacy, Pathology Informatics, Northwell Health

Yachana Kataria, PhD, DABCC
Medical Director of Clinical Chemistry, Boston University

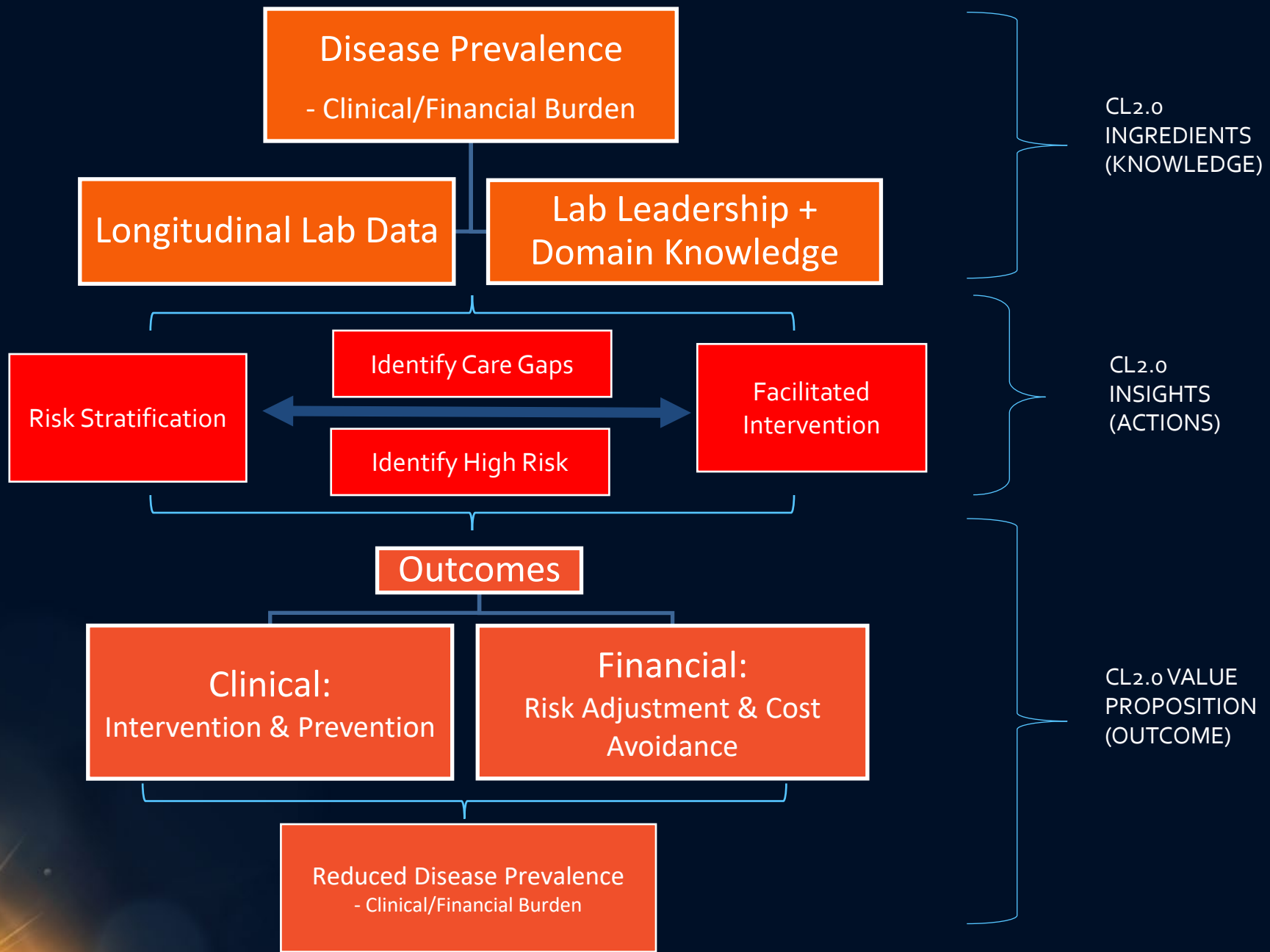
Ruth A. Lininger, MD, MPH
Associate Professor, Department of Pathology, Wake Forest University School of Medicine

Outcomes Matter!

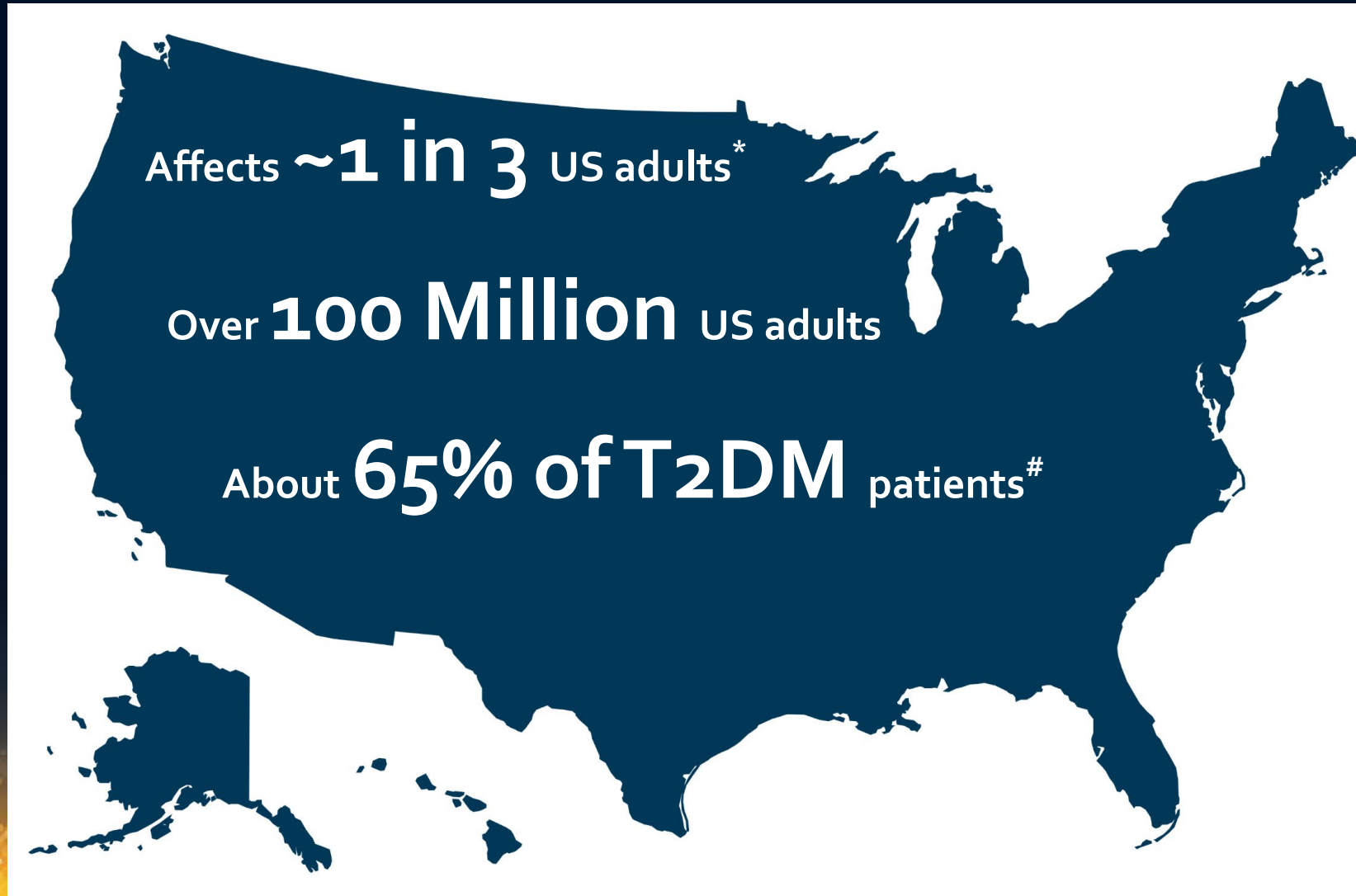
Creating the Foundation for CL2.0 Evidence

Criterion	Comment	Criterion	Comment
Disease Condition*	Prevalent; Recognizable early stage	Health Care Team*	Lab part of and potentially lead coalition
Health Care Setting*	It is feasible to deliver planned care	Funding*	Will need coalition and/or pilot funding
Diagnosis*	Suitable test; part of longitudinal care	Metrics*	Establish quantitative metrics ab initio
Management*	Accepted programmatic intervention	Value-based care*	Metrics should align with VBC measures
Cost-effectiveness*	Costs of diagnosis/care balanced by outcomes of medical care as a whole	Outcomes	Clinical/Economic outcomes must be realized, not imputed
Opportunity*	Gaps between prevalence and actual identification of condition	Attribution*	The lab's causal contribution to program must be established at outset
Prioritization*	Project must matter to Stakeholders	Reputation*	Do not be shy about claiming attribution

**true for the SLD-NIT project*



Prevalence of Metabolic Dysfunction Associated Steatotic Liver Disease (MASLD)

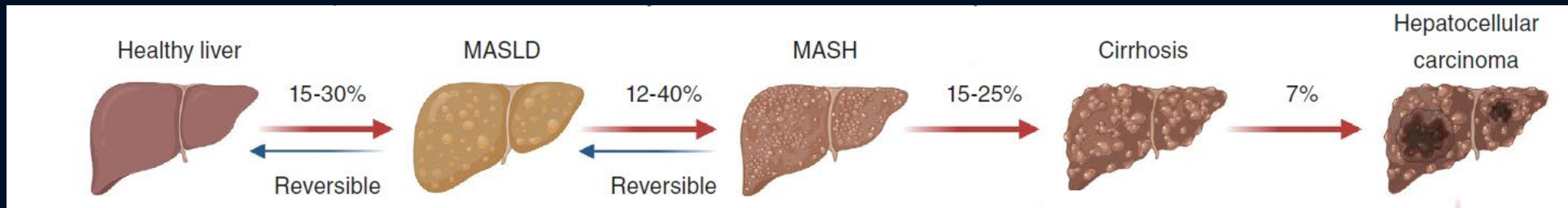


^{*}Hepatology 79(3):p 666-673, March 2024

^{*}Clin Gastroenterol Hepatol. 2024 Jun; 22(6): 1330-1332.e4

[#]En Li Cho E, et al. Gut 2023;72:2138-214

Clinical Burden Of MASLD



- Strong association between cardiometabolic risk factors (obesity, T2DM, hypertension, dyslipidemia) and the development of MASLD
- Rate of fibrosis progression is faster in MASH (~8.4 years) vs MASLD (~11.6 years) *
- Early identification allows for implementation of interventions that may prevent progression to cirrhosis and other hepatic complications #

Liver transplant or death

Eur J Intern Med. 2024 Apr;122:3-10



* Clin Gastroenterol Hepatol. 2023 May;21(5):1154-1168

Hepatology. 2022;75:1235-1246

Economic Burden

Research Article

Modeling the health and economic impact of pharmacologic therapies for MASLD in the United States

Carolyn Wallace¹, Ivane Gamkrelidze¹, Chris Estes¹, Homie Razavi¹  , Arun J. Sanyal²

Annual healthcare costs (2024 USD)	F2 (diagnosed)	\$528	60
	F3 (diagnosed)	\$651	60
	Compensated cirrhosis (prevalent)	\$3,431	61
	Decompensated cirrhosis (prevalent)	\$40,638	61
	Hepatocellular carcinoma (prevalent)	\$64,822	61
	Liver transplant (incident)	\$257,338	61
	Post-liver transplant (prevalent)	\$56,046	61
Diagnostic costs (2024 USD)	CBC (CPT 85025)	\$7	62
	Hepatic function panel (CPT 80076)	\$8	62
	Ultrasound, elastography (CPT 76981)	\$131	14

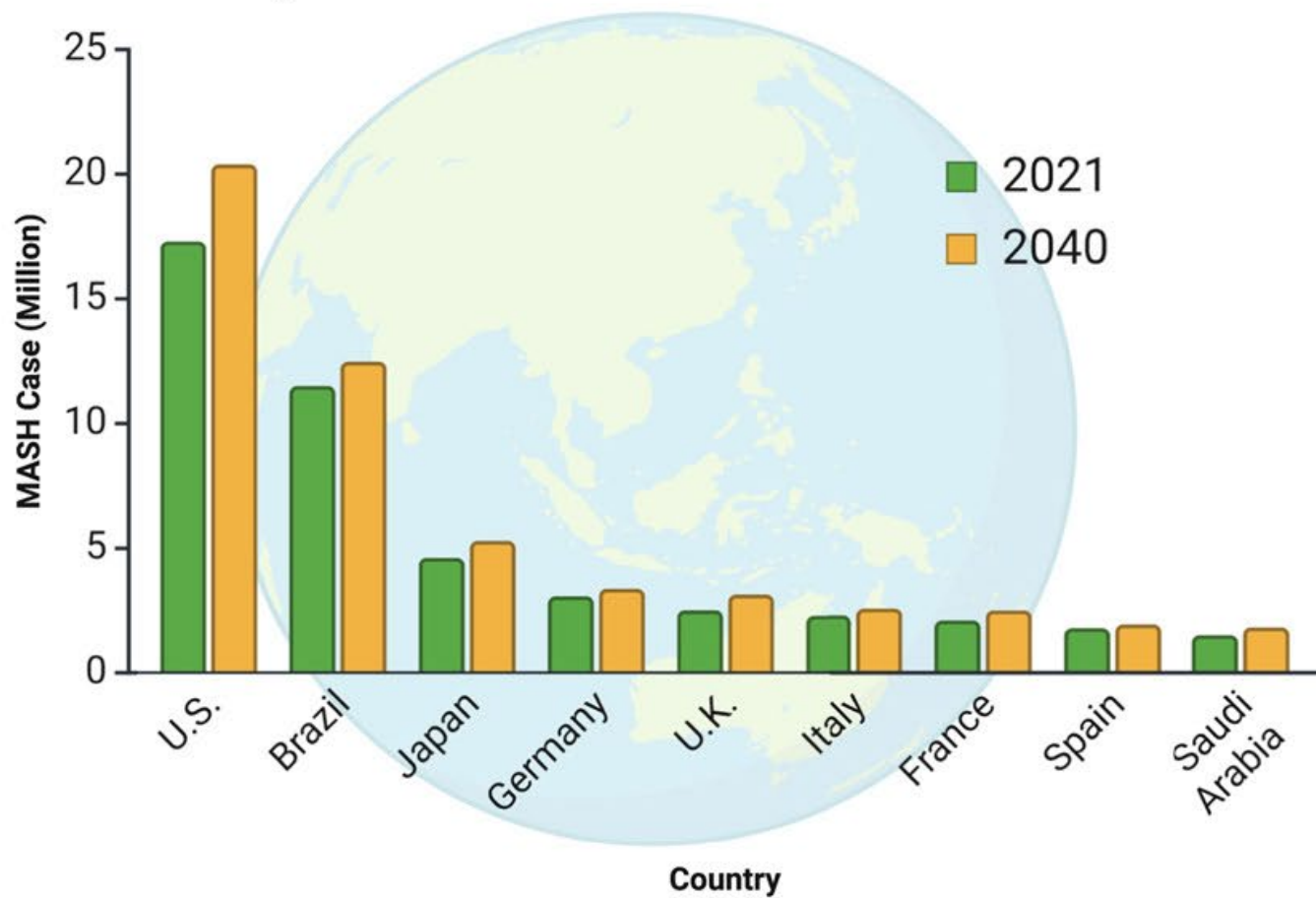
CBC, complete blood count; HCC, hepatocellular carcinoma; MASLD, metabolic dysfunction-associated steatotic liver disease; MASH, metabolic dysfunction-associated steatohepatitis.

Projected Global Clinical, Humanistic, and Economic Impact of Metabolic Dysfunction-Associated Steatohepatitis (MASH)

Cost of Inaction Scenario

Current Practices without accounting for potential cost-saving interventions or treatments

Projected MASH Cases from 2021 to 2040



Direct Cost

2021

2040



\$35.0 Billion **\$78.6** Billion



\$3.4 Billion **\$9.8** Billion



\$2.2 Billion **\$5.3** Billion



\$1.7 Billion **\$4.0** Billion



\$1.5 Billion **\$3.5** Billion



\$1.3 Billion **\$3.0** Billion



\$1.3 Billion **\$2.9** Billion

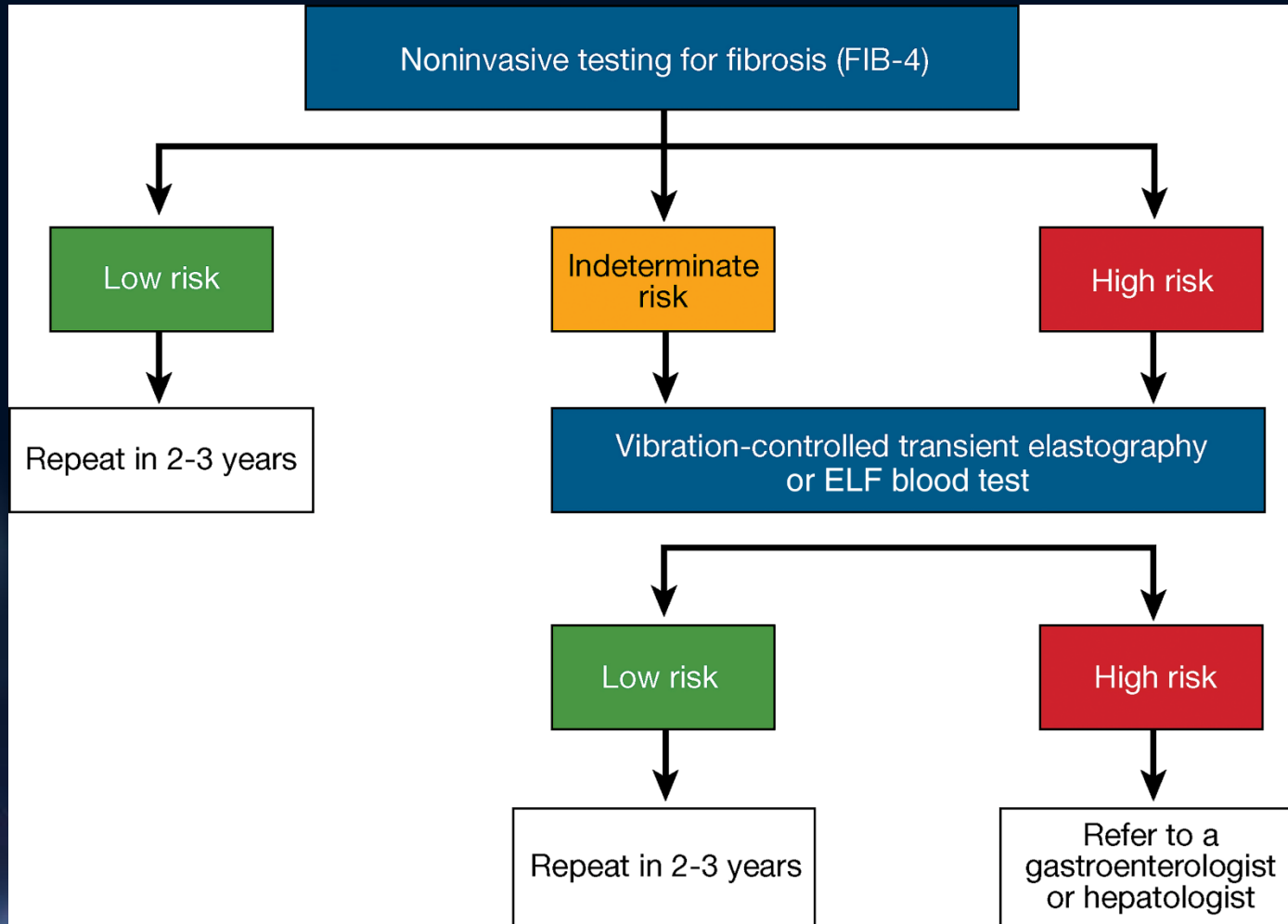


\$1.2 Billion **\$2.3** Billion



\$0.8 Billion **\$1.8** Billion

ADA Clinical Practice Guideline for MASLD



Adults with type 2 diabetes or prediabetes, particularly those with obesity or cardiometabolic risk factors or established cardiovascular disease, should be screened/risk stratified for clinically significant liver fibrosis

Why Now?



FDA Approves Treatment for Serious Liver Disease Known as 'MASH'

Action Will Provide New Therapy for Growing Public Health Issue

Action

The U.S. Food and Drug Administration has approved [Wegovy \(semaglutide\) injection](#) to treat metabolic-associated steatohepatitis (MASH) in adults with moderate-to-advanced fibrosis (excessive scar tissue in the liver). MASH, also known as nonalcoholic steatohepatitis, is a serious liver disease. Wegovy, which was first approved in 2017, is also approved for obesity or overweight and to reduce cardiovascular events, such as heart attacks, in individuals at high risk of these events. Approximately 6% of U.S. adults (14.9 million people) have MASH, and its prevalence is expanding.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

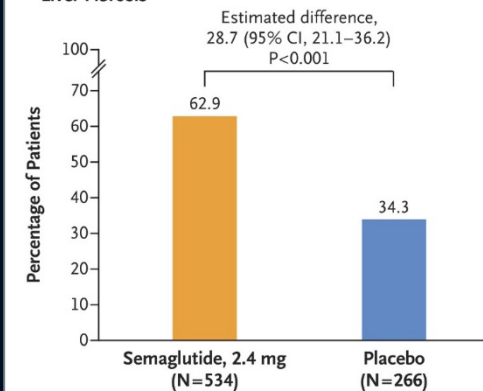
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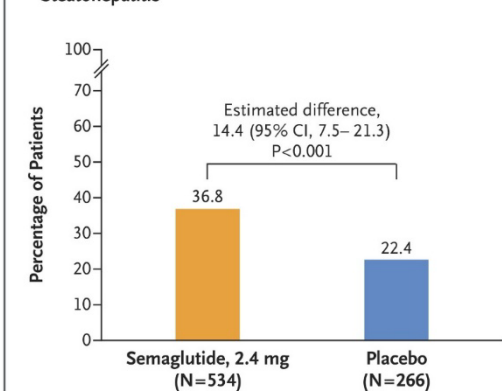
Phase 3 Trial of Semaglutide in Metabolic Dysfunction-Associated Steatohepatitis

Arun J. Sanyal, M.D.,¹ Philip N. Newsome, M.B., Ch.B., Ph.D.,^{2,3} Iris Kliiers, M.D.,⁴ Laura Harms Østergaard, M.Sc.,⁴ Michelle T. Long, M.D.,⁴ Mette Skalshøj Kjær, M.D., Ph.D.,⁴ Anna M.G. Cali, M.D.,⁴ Elisabetta Bugianesi, M.D., Ph.D.,⁵ Mary E. Rinella, M.D.,⁶ Michael Roden, M.D.,^{7,9} and Vlad Ratziu, M.D., Ph.D.,¹⁰ for the ESSENCE Study Group*

A Resolution of Steatohepatitis with No Worsening of Liver Fibrosis



B Reduction in Liver Fibrosis with No Worsening of Steatohepatitis



2025 Jun 5;392(21):2089-2099. doi: 10.1056/NEJMoa2413258. Epub 2025 Apr 30.

Hypothesis

Noninvasive test (NIT) results for SLD, available through clinical laboratory data, can provide population health information on the risk stratification and gaps in care for pre-diabetic and diabetic patients when evaluated against the ADA treatment guidelines

Participating Institutions



Ruth Lininger, MD, MPH
Julie Cooper MS
Clinnis Adams, MBA
Liz Dahlgren MBA
Sara Cooper MD



Aya Haghmad, PharmD
James Crawford, MD, PHD
Jason Wong, Ph.D
Jennifer Onwochei, MD
Nkemakonam Okoye, Ph.D
Yonah Ziemba, MD
Girish Ramrattan, MS



Yachana Kataria, PhD, DABCC

Industry Partner



Study Objectives

- Risk stratify steatotic liver disease in prediabetic and diabetic patients through use of NIT based on 2023 ADA guidelines.
- Identify gaps in care for screening fatty liver disease in pre-diabetic and diabetic patients based on 2023 ADA guidelines.
- Examine the use and potential cost implications of using NIT as a mechanism to guide patient referrals from primary care and endocrinology settings to specialist management of steatotic liver disease.

Methods: Study Cohorts

Timepoint 1

- Prior to ADA guidelines
- (7/1/2021-6/30/2022)

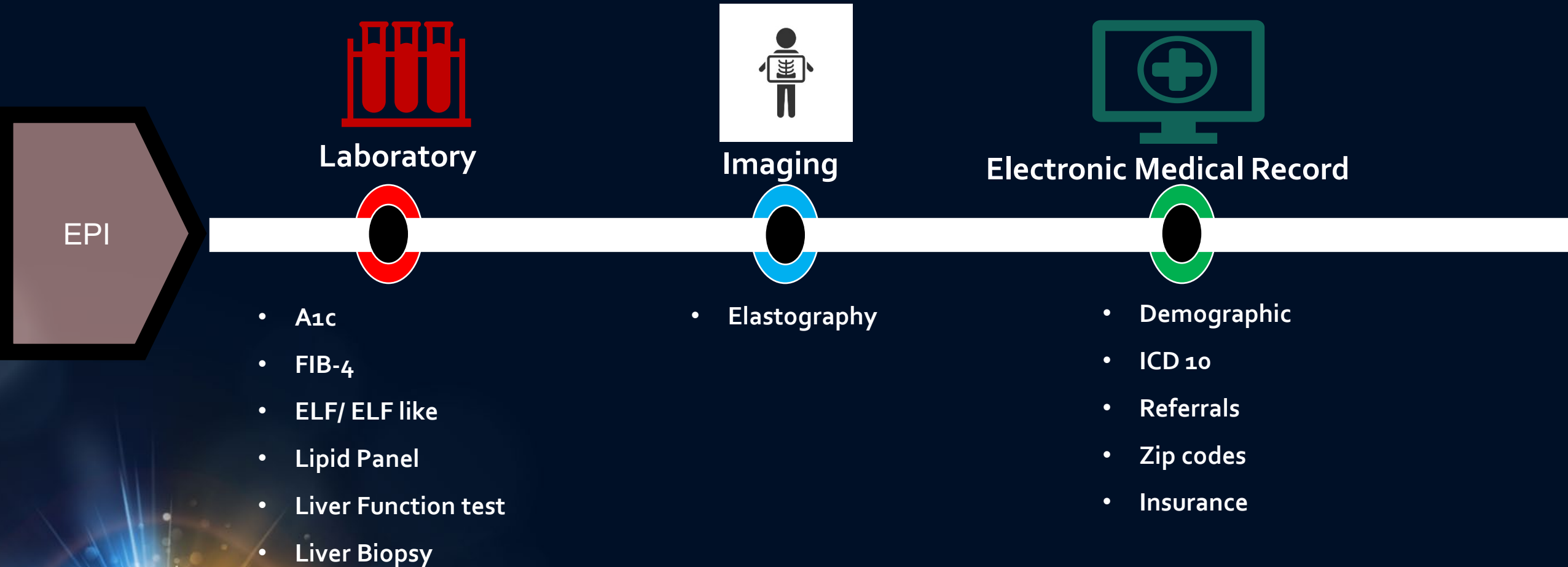
Timepoint 2

- Before introduction of 2023 ADA guidelines (7/1/2022-6/30/2023)

Timepoint 3

- After introduction of ADA guidelines (7/1/2023-6/30/2024)

Longitudinal Data (>80 data parameters)



Methods: Data Management & Processes



Current Status

- ✓ Project Planning
- ✓ Hypothesis and Objectives
- ✓ Project Lead(s)
- ✓ Participating Sites Identified
- ✓ Regulatory/Compliance Requirements
- ✓ Data Collection and Management
- Data Analysis
- Results Dissemination
- Presentation(s)
- Publication
- Lab initiated Care Model

The Challenge: A Historic First



Conducting the first enterprise-wide research study following the Atrium Health and Advocate Health merger

1

No Unified IRB

Separate institutional review processes across merged entities

2

Data Silos

SE-MW enterprise lacked research data sharing frameworks

3

System Access

No enterprise-wide Epic access for research co-investigators



What We Learned: A Reality Check

Conducting this enterprise-wide statotic liver disease study revealed critical gaps in data infrastructure, informatics support, and institutional knowledge that have broad implications for Clinical Lab 2.0 research.



**Validating
Missing Data**



**Where Data
Actually Lives**



**Bioinformatics
Support Gaps**



**Data Beyond
the LIS**



**Pathology
Informatics Skills**



**Take-Home
Pearls**



Take-Home Pearls



Invest in Specialty-Trained Bioinformatics & Pathology Informatics Personnel

This expertise is invaluable and currently scarce. Without it, CL2.0 studies face significant delays, data quality issues, and knowledge translation failures.



Curate Datasets with Improved Data Governance

Map lab data to common interoperable standards. Include metadata that currently exists and metadata not yet considered — such as instrument and user metadata.



National Interoperable Standards Are the Path to Precision Medicine

Lab data interoperability with comprehensive metadata mapping will take us to the next level. Clinical Lab 2.0 can lead this transformation.

Questions?

Yachana.kataria@bmc.org
Ahaghamad1@northwell.edu
Ruth.Lininger@advocatehealth.org
Kathy.Swanson@cl2lab.org

THANK YOU!