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A PROJECT SANTA FE FOUNDATION INITIATIVE

Clinical Lab 2.0

Demonstration Projects In Action

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Acknowledgement

James Crawford, Mark Fung, Aya Haghamad, Yachana Kataria, Kathleen Swanson, Elizabeth Montgomery, Nkem Okoye, Myra Wilkerson, Ruth Lininger, Octavia Peck Palmer, Richard VanNess, Kimon Stathakos, David Allen, Vahid Azimi, Ulysses Balis, Jon Harol, Karen Heichman, Jaren Jaeger, Veena Joy, Kathy Kelley, Keith Laughman, Jackie Murray, Melissa Ryan Robert Tibbets, Donna Wolk, Khosrow Shotorbani, ***… and many others***

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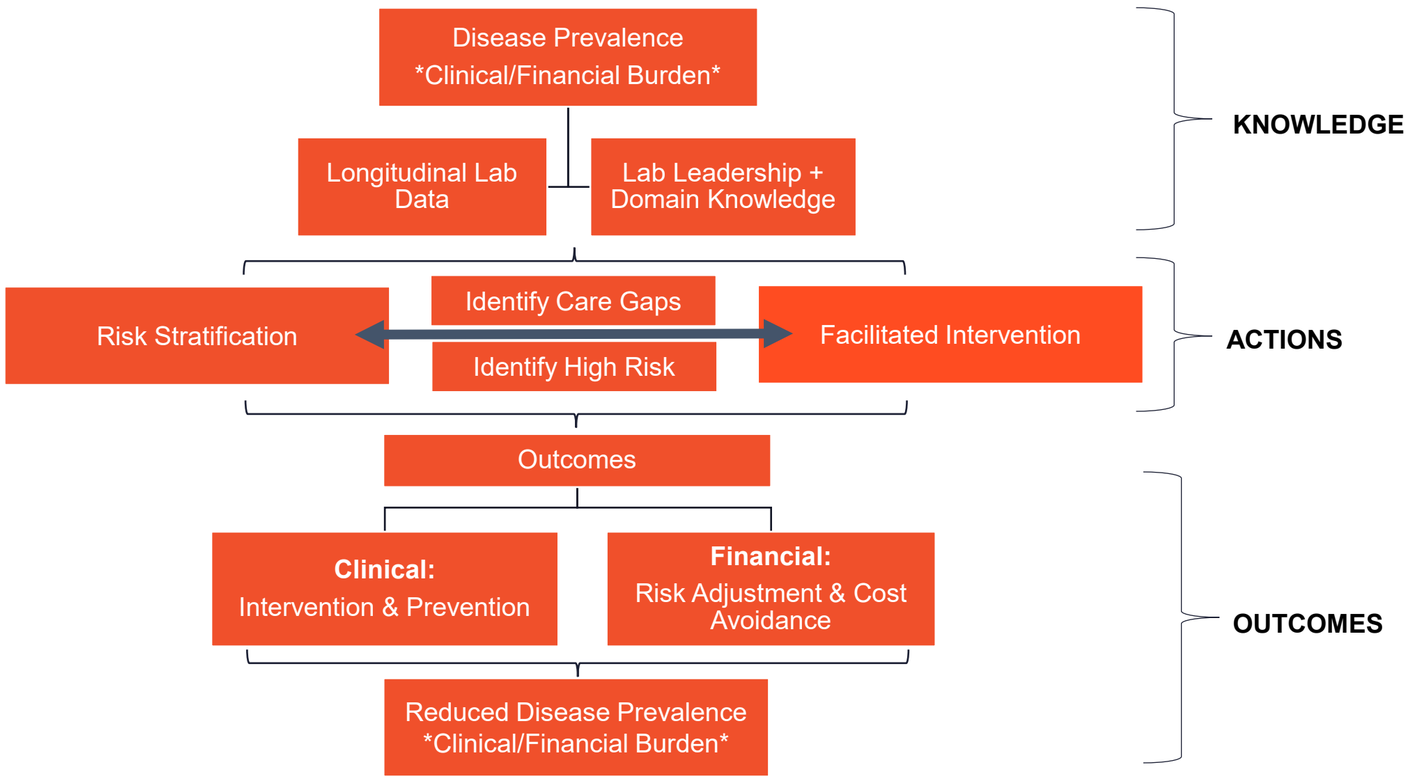
Why Demonstration Projects?

Mission Statement

Enable clinical laboratories to showcase their value across the healthcare ecosystem through reproducible, data driven initiatives that generate evidence, improve patient outcomes, deliver cost-effective solutions, and provide actionable insights to key stakeholders.



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Demonstration Projects In Action

Completed

✓ **Chronic Kidney Disease**

Examination of chronic kidney disease using longitudinal laboratory results to identify clinical and financial risk

Ongoing

✓ **Steatotic Liver Disease**

Real-world use of noninvasive testing in the assessment of pre-diabetic and diabetic patients with the comorbidity of steatotic liver disease

✓ **Sepsis**

SURVIVE Sepsis: Value of interdisciplinary interventions and evidence

Planning Phase

✓ **Anemia**

Amenia as a surrogate marker to improve colorectal cancer screening

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Demonstrating The Value of The Clinical Laboratory in CKD Management

Geisinger

The University of Vermont
LARNER COLLEGE OF MEDICINE

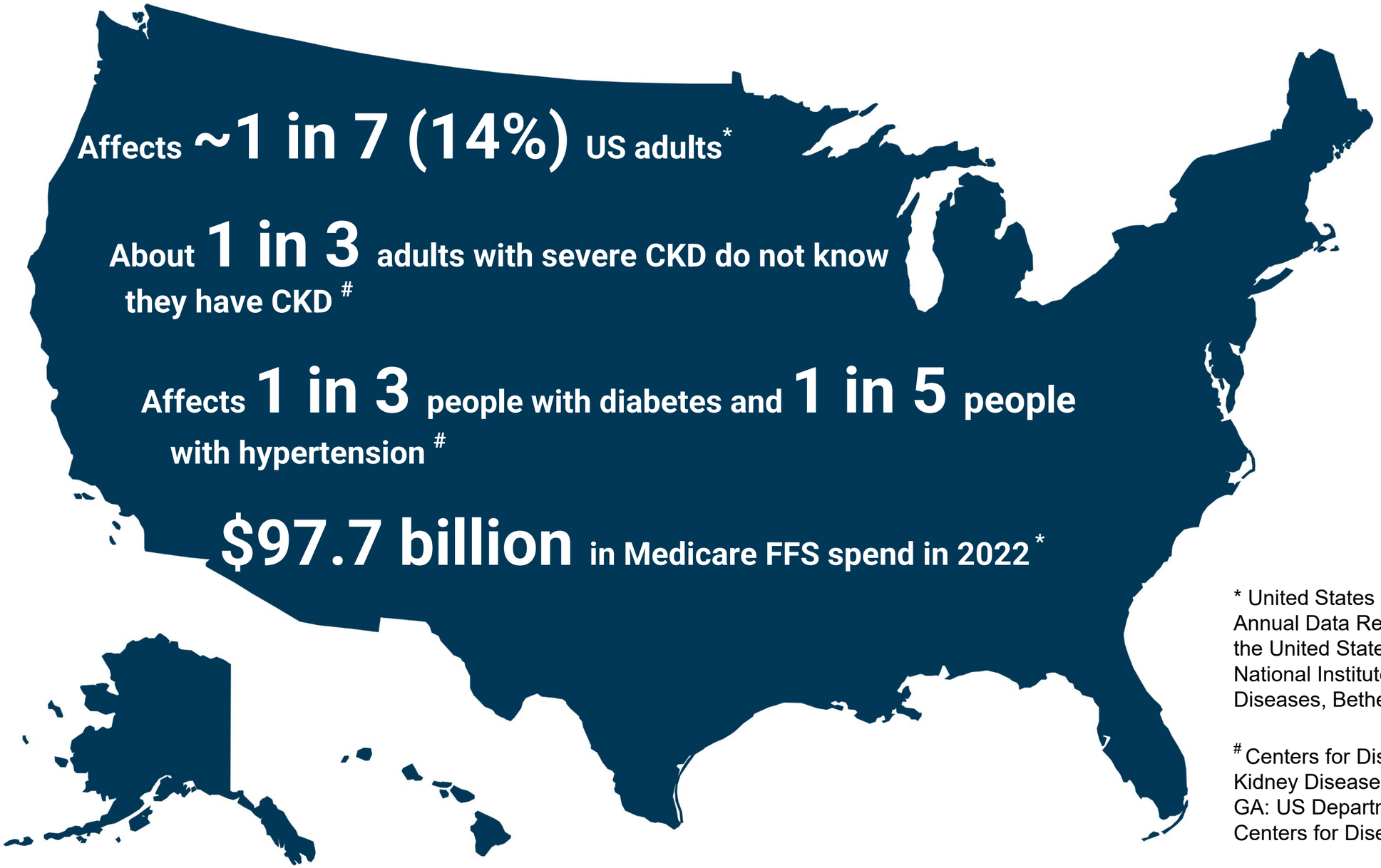
Northwell Health℠

in collaboration with

NATIONAL KIDNEY FOUNDATION®

Fung, M., et al. *BMC Nephrol* 25, 447 (2024). https://doi.org/10.1186/s12882-024-03869-4

Prevalence and Economic Burden of CKD



* United States Renal Data System. 2024 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024

Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2023. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2023

Results From CKD Demonstration Project

Research | Open access | Published: 06 December 2024

A retrospective multi-site examination of chronic kidney disease using longitudinal laboratory results and metadata to identify clinical and financial risk

Mark Fung, Aya Haghamad, Elizabeth Montgomery, Kathleen Swanson, Myra L. Wilkerson, Kimon Stathakos, Richard VanNess, Sarah A. Nowak, Clayton Wilburn, Haluk Kavus, Mohammed Amer Swid, Nkemakonam Okoye, Yonah C. Ziemba, Girish Ramrattan, Jonathan Macy, John McConnell, Mary Jane Lewis, Beth Bailey, Khosrow Shotorbani & James M. Crawford

BMC Nephrology **25**, Article number: 447 (2024) | Cite this article

Longitudinal laboratory results identified:

✓ **Substantial clinical gap**

- CKD patients with comorbid risk factors of diabetes and heart failure
- Up to 78% of patients with laboratory evidence of stage 3 or 4 CKD lacked corresponding ICD-10 or HCC code for CKD in their electronic medical record
- Up to 83% of diabetic patients had not undergone guideline-recommended screening for CKD

✓ **Significant financial risk**

- $2.85 million in unrealized reimbursement opportunity due to undocumented CKD

Fung, M., et al. *BMC Nephrol* 25, 447 (2024). https://doi.org/10.1186/s12882-024-03869-4

Call to Action

Research | Open access | Published: 06 December 2024

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BMC Nephrology **25**, Article number: 447 (2024) | Cite this article

How do we transition from reactive confirmation of "sick care" to proactive practice of "well care" ?

Fung, M., et al. *BMC Nephrol* 25, 447 (2024). https://doi.org/10.1186/s12882-024-03869-4

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Demonstrating The Value of The Clinical Laboratory in SLD Management

ADVOCATE HEALTH

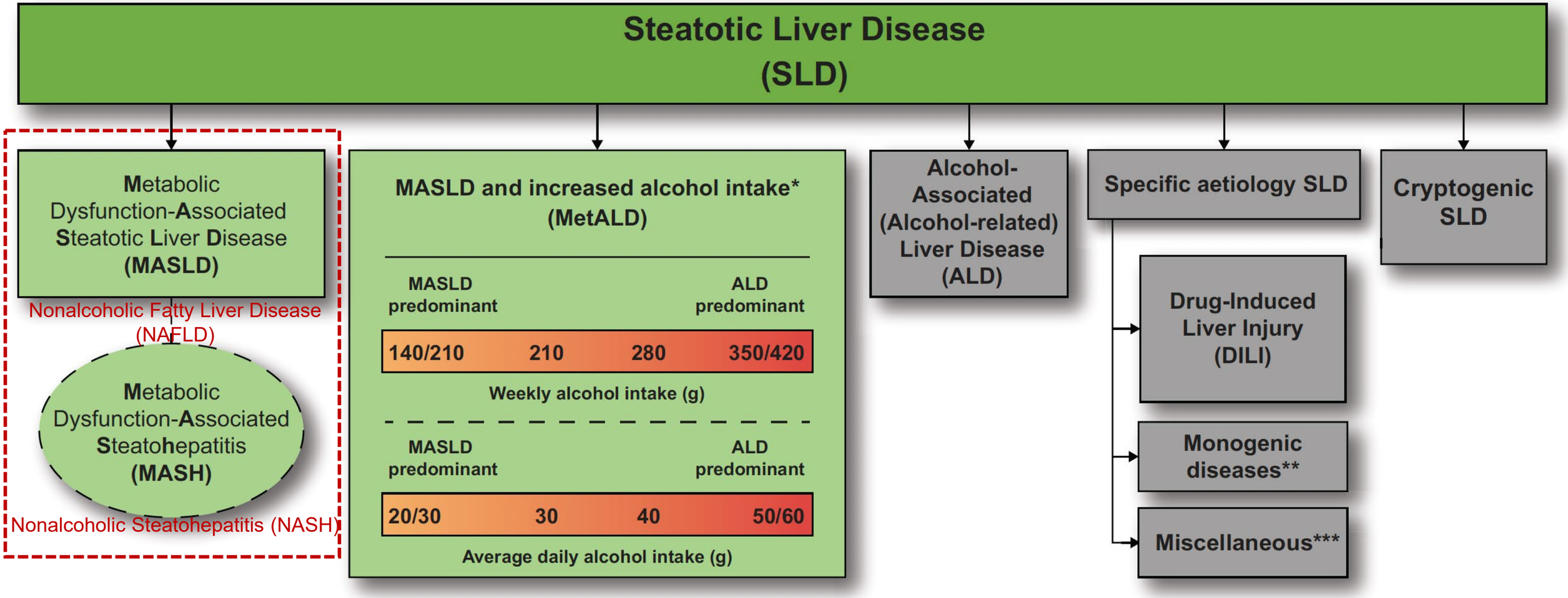
Wake Forest University School of Medicine

Northwell Health℠

BOSTON MEDICAL CENTER

sponsored by

SIEMENS Healthineers

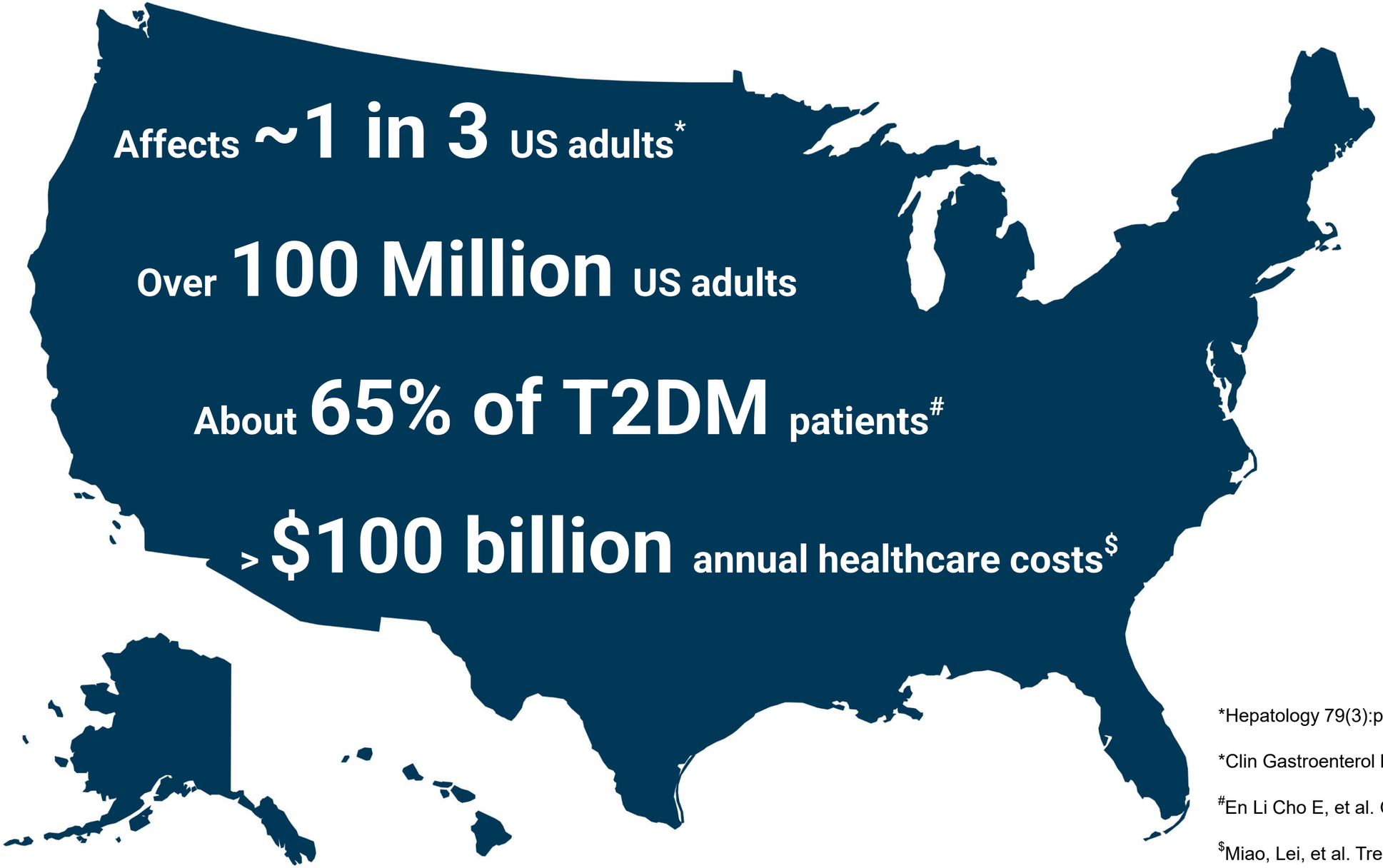


*Weekly intake 140-350g female, 210-420g male (average daily 20-50g female, 30-60g male)
**e.g. Lysosomal Acid Lipase Deficiency (LALD), Wilson disease, hypobetalipoproteinemia, inborn errors of metabolism
***e.g. Hepatitis C virus (HCV), malnutrition, celiac disease, human immunodeficiency virus (HIV)

AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

Hepatology 78(6):p 1966-1986, December 2023

Prevalence and Economic Burden of MASLD



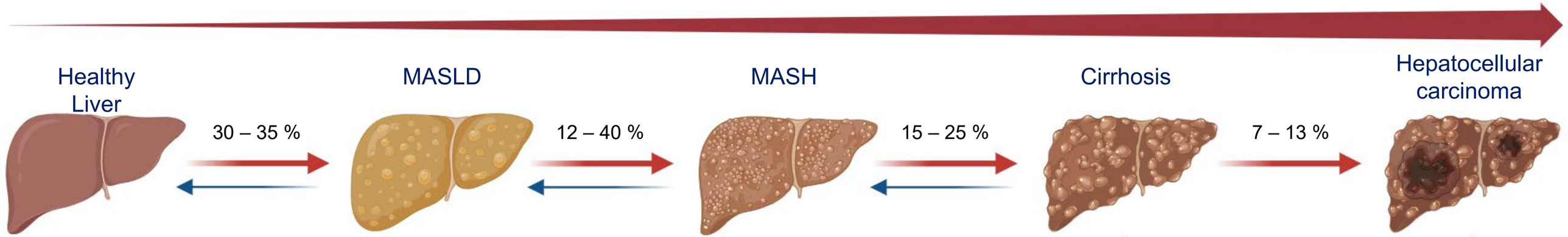
*Hepatology 79(3):p 666-673, March 2024

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

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

$Miao, Lei, et al. Trends in Endocrinology & Metabolism (2024).

Progression of MASLD

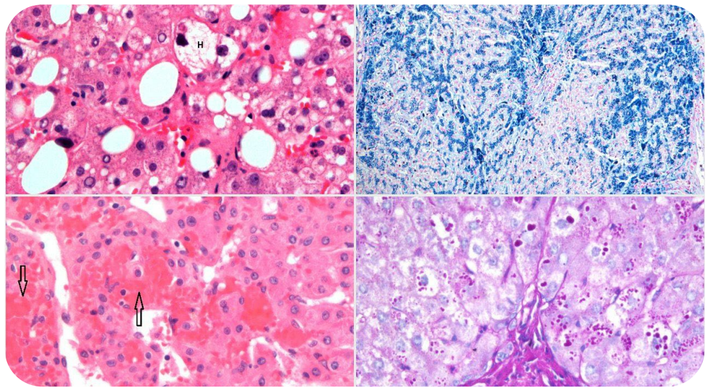


- Strong association between cardiometabolic risk factors (obesity, T2DM, hypertension, dyslipidemia) and the development of MASDL
- Rate of fibrosis progression is faster in MASH (~8.4 years) vs MASLD (~11.6 years) *
- Early identification allows for implementation of interventions that may prevent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

Eur J Intern Med. 2024 Apr:122:3-10
*Clin Gastroenterol Hepatol. 2023 May;21(5):1154-1168
#Hepatology. 2022;75:1235–1246

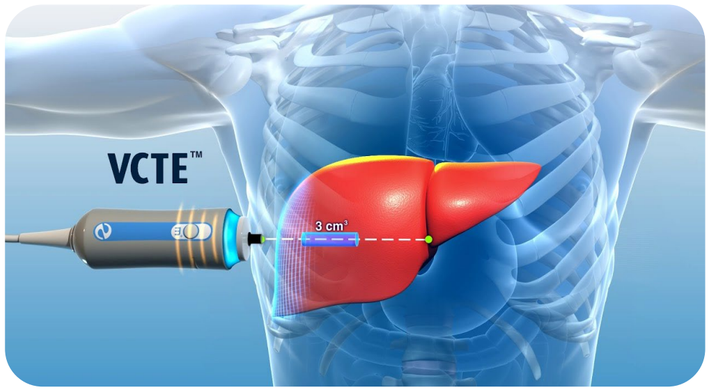
Diagnostic Evaluation of MASLD

Liver Biopsy



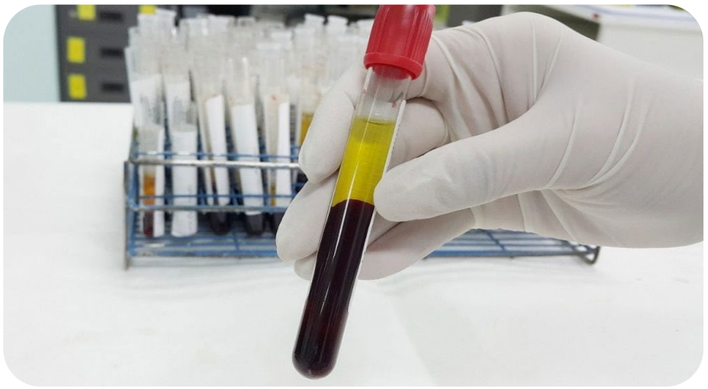
- Reference standard for fibrosis grading and staging
- METAVIR score
  - F0 = no fibrosis
  - F1 = portal fibrosis w/o septa
  - F2 = few septa
  - F3 = numerous septa without cirrhosis
  - F4 = cirrhosis

Imaging



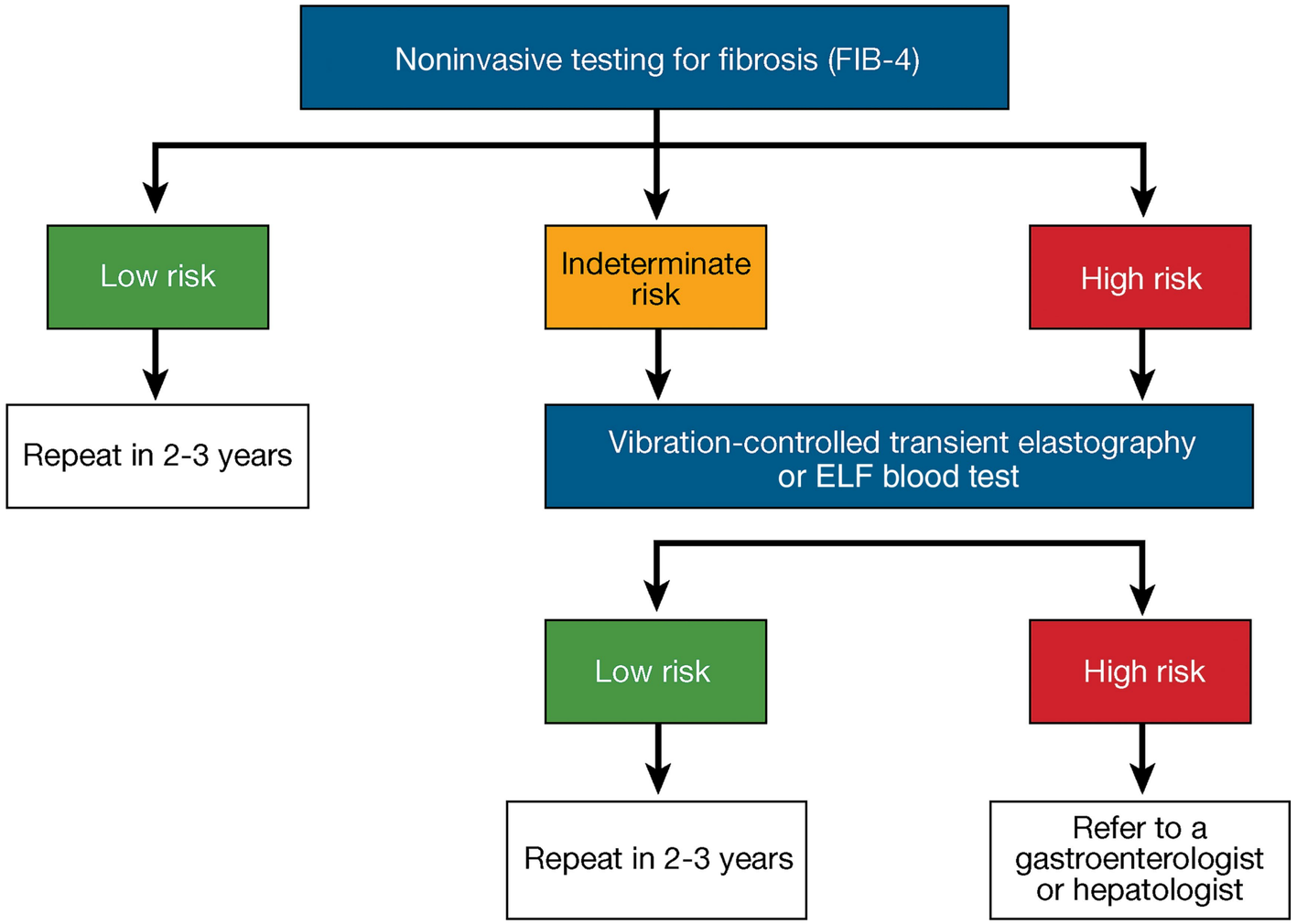
- Elastography (vibration-controlled or magnetic resonance)
- Ultrasound-based (e.g., controlled attenuation parameter)
- MRI–proton density fat fraction (PDFF)

Biomarkers



- Liver enzymes (ALT and AST)
- Fibrosis-4 index (FIB-4)
- Enhanced liver fibrosis (ELF)
- Other risk scores
  - AST-to-Platelet Ratio Index
  - FibroSURE
  - FibroMeter
  - NAFLD fibrosis score
  - Agile FibroScan-based score
  - FIBROSpect

ADA Clinical Practice Guideline for MASLD



American Diabetes Association®

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

Standards of Care in Diabetes 2024. Diabetes Care 2024;47(Supplement_1):S52–S76

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SLD Project Hypothesis and Objectives

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

Objectives:

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

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SLD Project Status Update

- ✓ IRBs submitted and approved by all 3 participating institutions
- ✓ DUAs completed at 2 out of 3 participating institutions
- ✓ Data collection template finalized
  - All participating institutions have met with their data analytics team to discuss data extraction
- ✓ Health economist and statistician contracted

Upcoming Deliverables

- ✓ Data extraction and validation anticipated to be completed by summer 2025
- ✓ Data analysis anticipated in fall 2025
- ✓ Publication and results dissemination in fall/winter 2025

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Lessons Learned

- ✓ Collaboration is essential in demonstrating the real-world value of longitudinal laboratory data
- ✓ Attributing economic value to outcomes due to clinical laboratory involvement is complex and requires rigorous project design
  - Who takes credit for what?
- ✓ We (the clinical lab) can't do this alone
  - Partnerships with clinicians, payers, patient advocacy groups, health care administrators, C-suite, policymakers

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Get In Touch!

If you are interested in sponsoring or participating in a multi-site demonstration project

Contact

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Yachana: Yachana.kataria@bmc.org

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“There is nothing so useless as doing efficiently that which should not be done at all”

- Peter Drucker

Thank you!

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