



# Principles of establishing a health-system wide care model for MASLD and metabolic health

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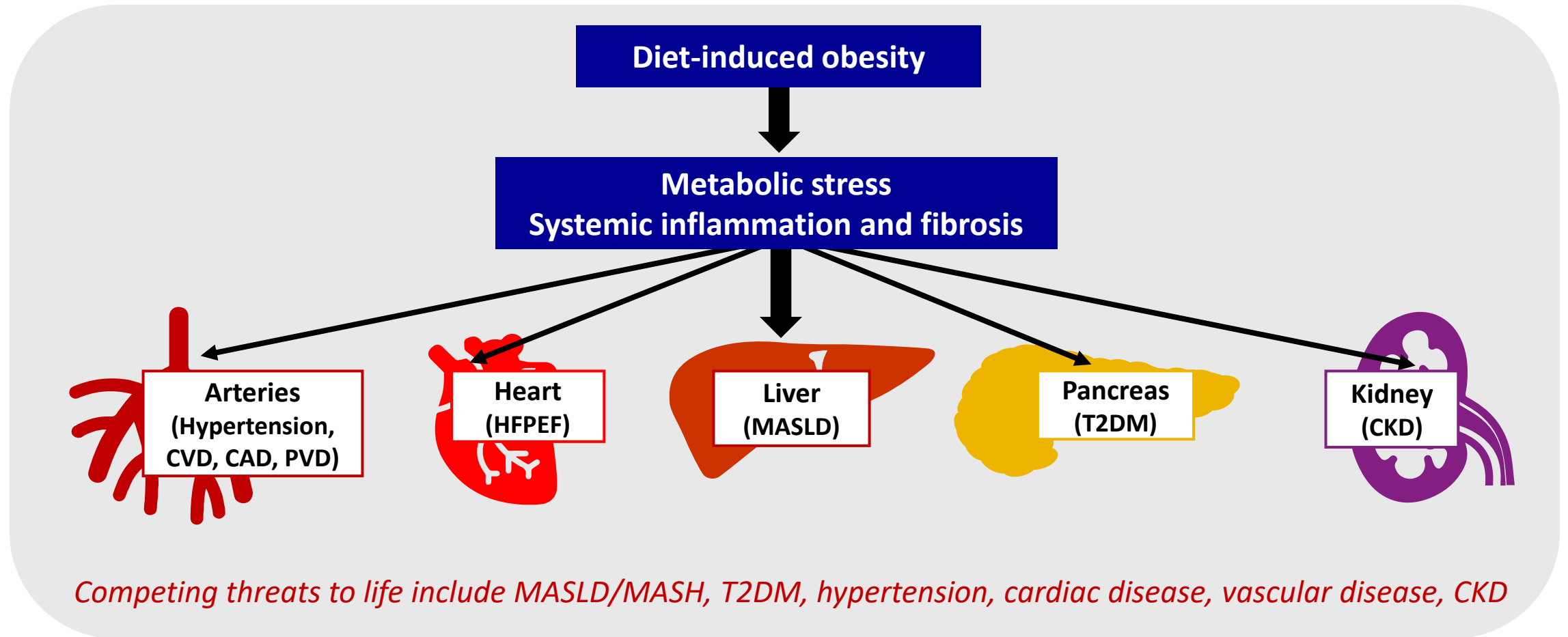
# Disclosures

## [Arun J. Sanyal]

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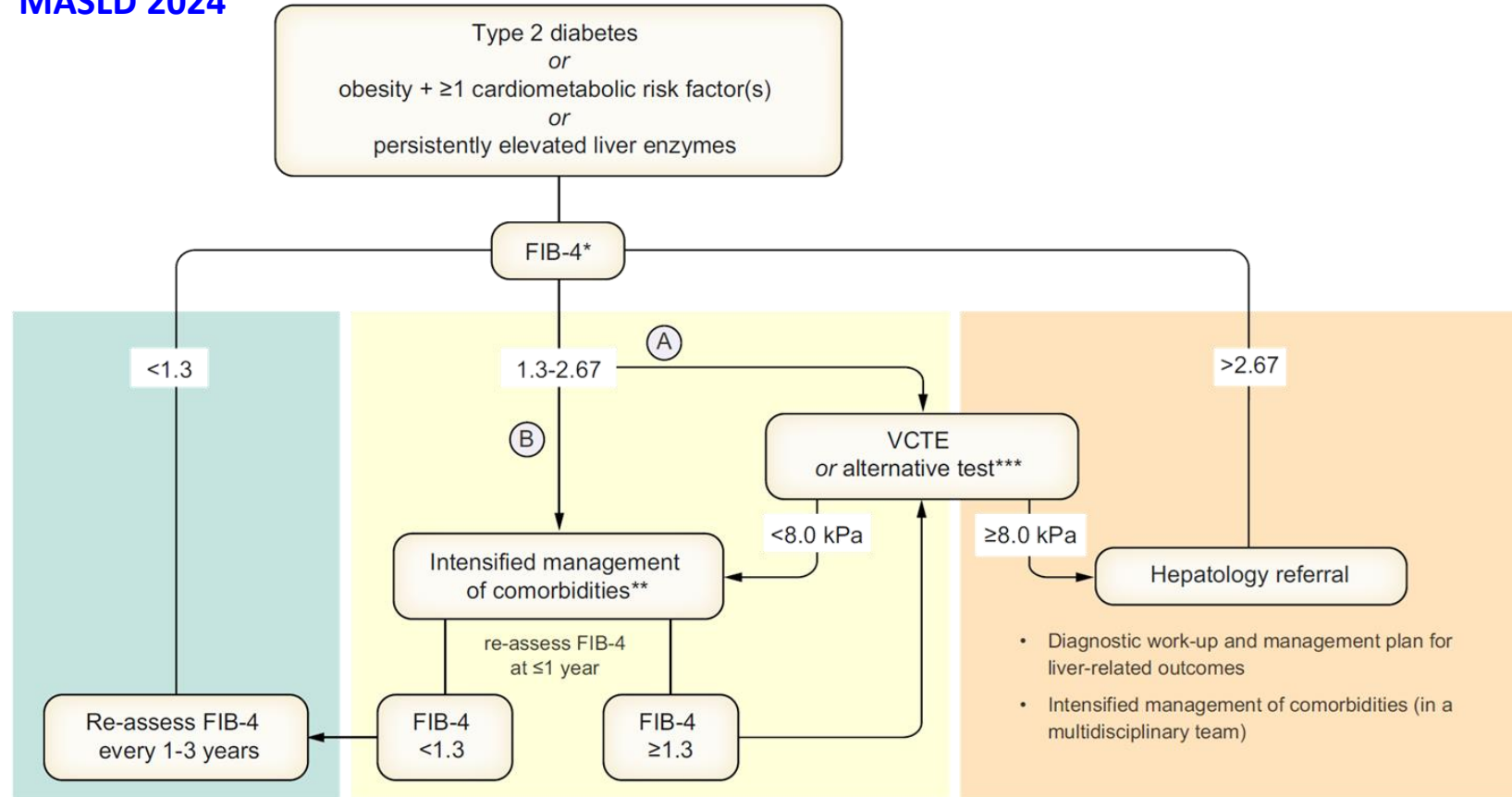
- Ownership interests: Durect, Tiziana, Genfit, Exhalenz, Northsea, Rivus, Inversago
- Consultant: Gilead, Intercept, Novartis, Novo Nordisk, Inventiva, Merck, Pfizer, Boehringer Ingelhiem, Bristol Myers Squibb, Eli Lilly, Genentech, Amgen, Alnylam, Regeneron, Thera Technologies, Madrigal, Salix, Malinckrodt, Gatehouse, Rivus, Siemens, Lipocine, 89 Bio, Astra Zeneca, Akero, Foresite, Mitopower, Histoindex, Path AI, Takeda
- Grant support to school: Gilead, Intercept, Novartis, Novo Nordisk, Inventiva, Eli Lilly, Genentech, Boehringer Ingelhiem, Bristol Myers Squibb

There is a strong rationale for therapies that attack multiple competing threats (CRM and liver) to life related to metabolic ill-health



CAD, coronary artery disease; CKD, chronic kidney disease; CVD, cerebrovascular disease; CVS, cardiovascular system; HFPEF, heart failure with preserved ejection fraction; PVD, peripheral vascular disease; T2DM, type 2 diabetes mellitus, MASLD= metabolic dysfunction associated steatotic liver disease.

# EASL-EASD-EASO Clinical Practice Guidelines MASLD 2024



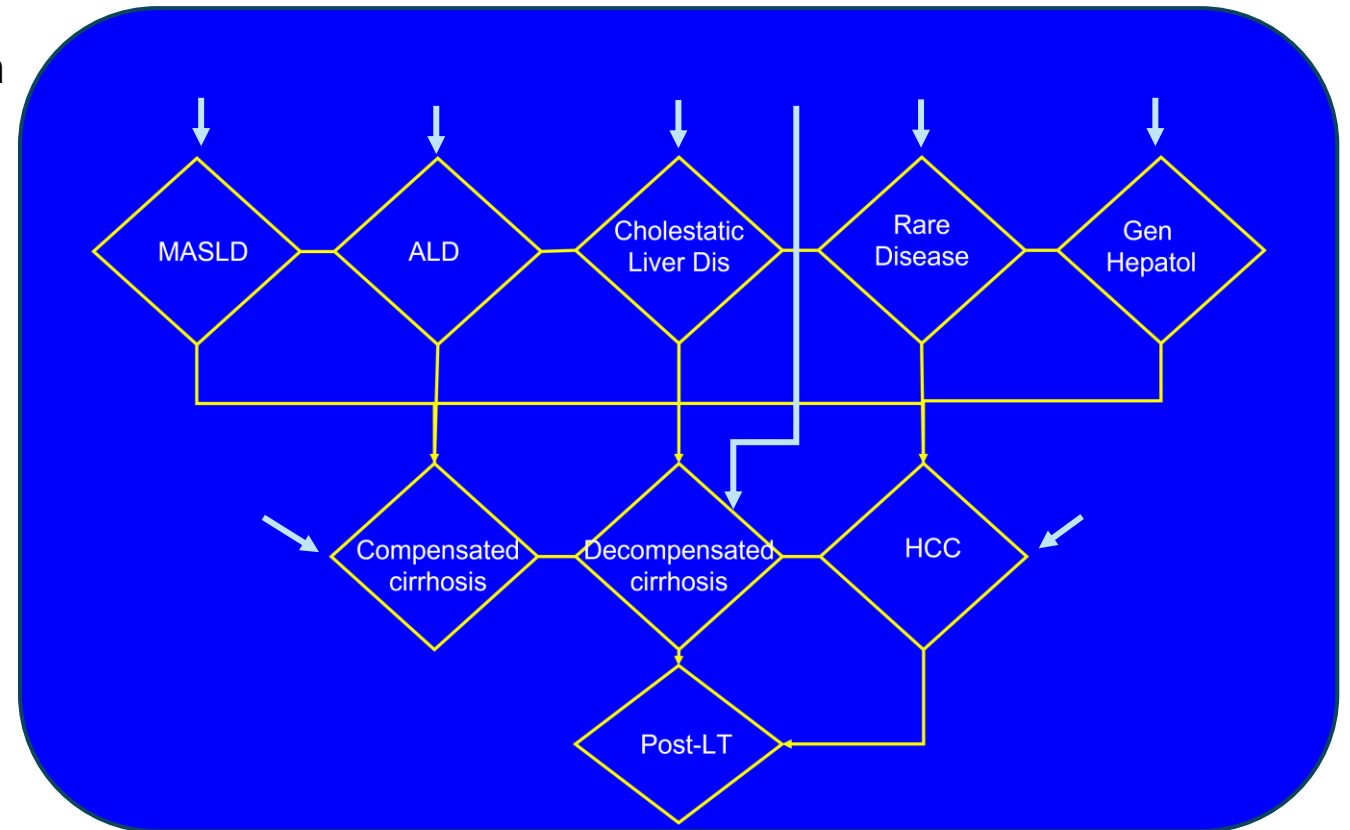
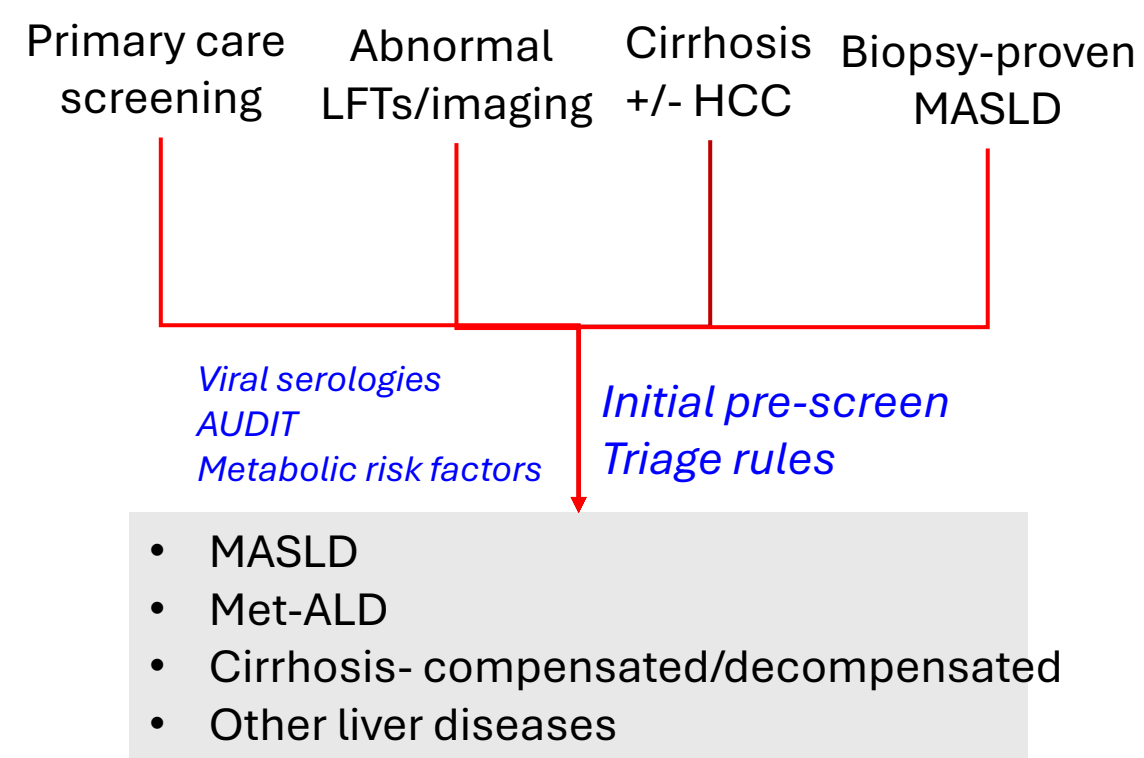
- \*FIB-4 thresholds valid for age ≤65 years (for age >65 years: lower FIB-4 cut-off is 2.0); \*\*e.g. lifestyles intervention, treatment of comorbidities (e.g. GLP-1RA), bariatric procedures; \*\*\* e.g. MRE, SWE, ELF, with adapted thresholds. A and B are options, depending on medical history, clinical context and local resources. EASD, European Association for the Study of Diabetes; EASL, European Association for the Study of the Liver; EASO, European Association for the Study of Obesity; ELF, Enhanced Liver Fibrosis test; GLP-1RA, glucose-like peptide-1 receptor agonist; NIT, non-invasive test; SWE, shear wave elastography; TE, transient elastography. EASL-EASD-EASO J Hepatol 2024;doi.org/10.1016/j.jhep.2024.04.031.

- Liver centric not patient centric
- Does not account for competing risks from other comorbid end organ disease
- Builds on health system wide inefficiencies in care delivery
- Ignores MASLD as a life-cycle disorder

# Key elements while establishing care pathway for health system

- MISSION ORIENTED- for profit vs not for profit patient care delivery vs academic
- Know referral patterns in to health system and reasons for referral-create infrastructure
- Patient-centric
  - Right patient
  - Right clinic
  - Right provider
  - Right care
  - Right amount of time
- Seamless
- Adaptive to changes in referral patterns, medical knowledge, new tools
- Business model to support sustainability
- Built in mechanisms to assess what works and what does not work- an active learning environment

# Principle # 1: know your referral basin

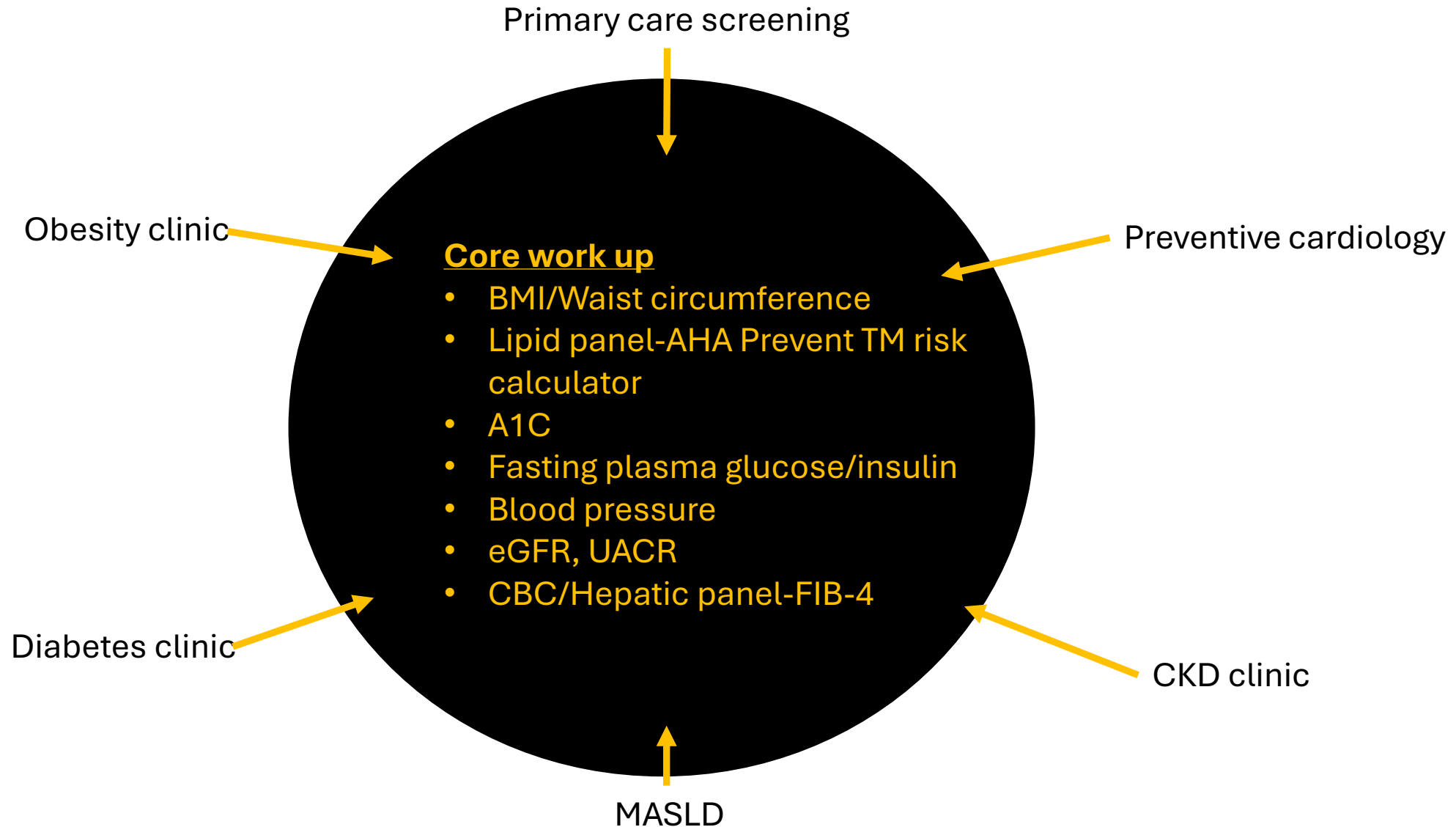


In some ways it is easier when a single provider provides all of the care!!

# Goals of first visit (MASLD clinic)

- CONFIRM STEATOSIS
- EVALUATE FOR OTHER ETIOLOGIES OF STEATOSIS
- EXCLUDE ADDITIONAL LIVER PATHOLOGIES
- ASSESS ACTIVITY
- **RISK ASSESSMENT**
  - LIVER
  - NON-HEPATIC
- IDENTIFY KEY FACTORS THAT WILL IMPACT DISEASE COURSE AND RESPONSE TO ANY INTERVENTIONS

# Principle # 2: Baseline Assessment: core work up applied consistently across health system that addresses all threats to life





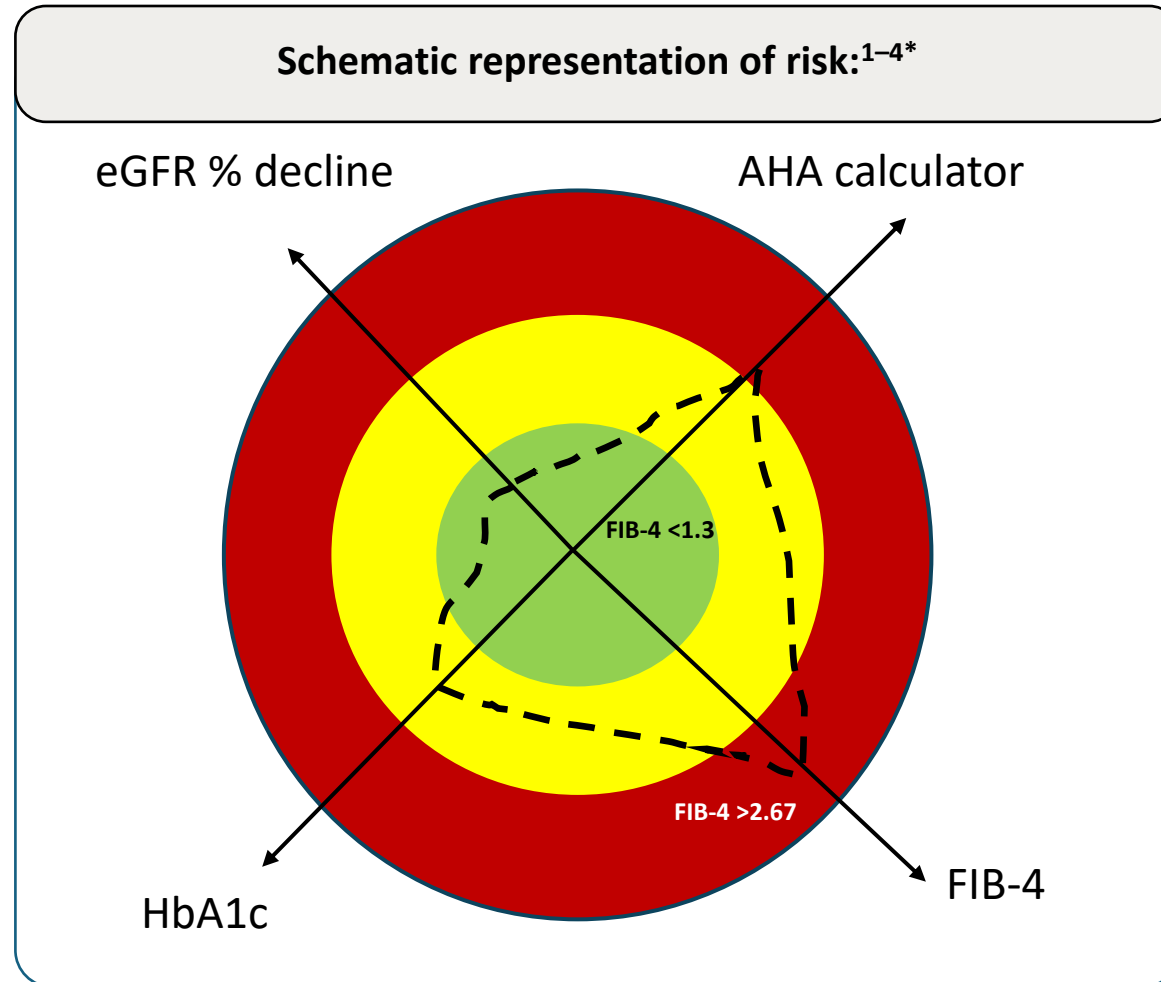
# Principle # 3: assess risk for patient and not for disease

## Renal

Low: eGFR > 60,  
UACR < 30  
Intermediate: eGFR  
30-60, UACR 30-300  
High: eGFR < 30,  
UACR > 300, > 40%  
decline

## Diabetes

Low: A1C < 5.6, FPG < 100  
Intermediate: 5.6-6.5,  
FPG 100-126  
High: > 6.5  
Poorly controlled: > 9.5



## Cardiac risk strata (10 yr risk)

Low: < 7.5%  
Intermediate: 7.7-10%  
High: > 10%

## BP

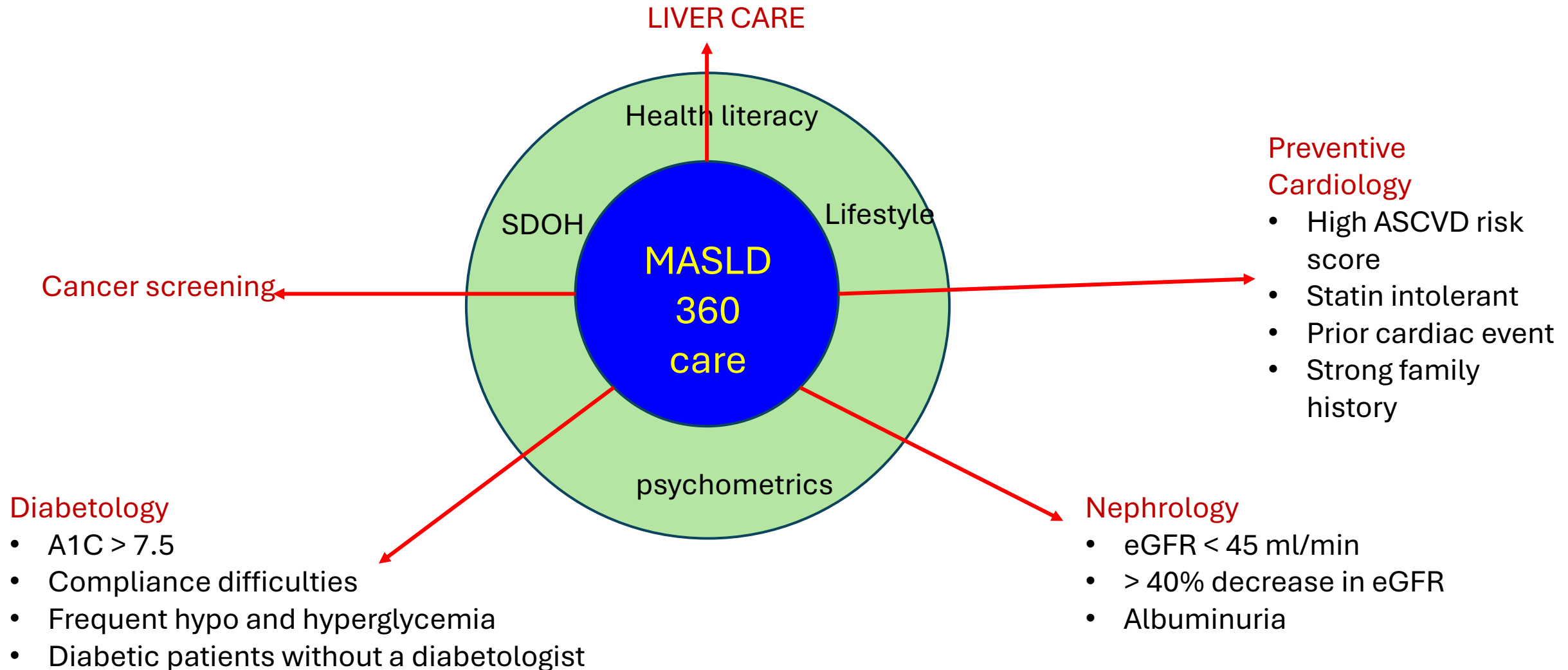
Low: normotensive (with/without Rx)  
Intermediate: BP > 140 < 160 syst > 90 < 120 diast  
High: > 160 systolic, > 120 diastolic

## Liver risk strata:

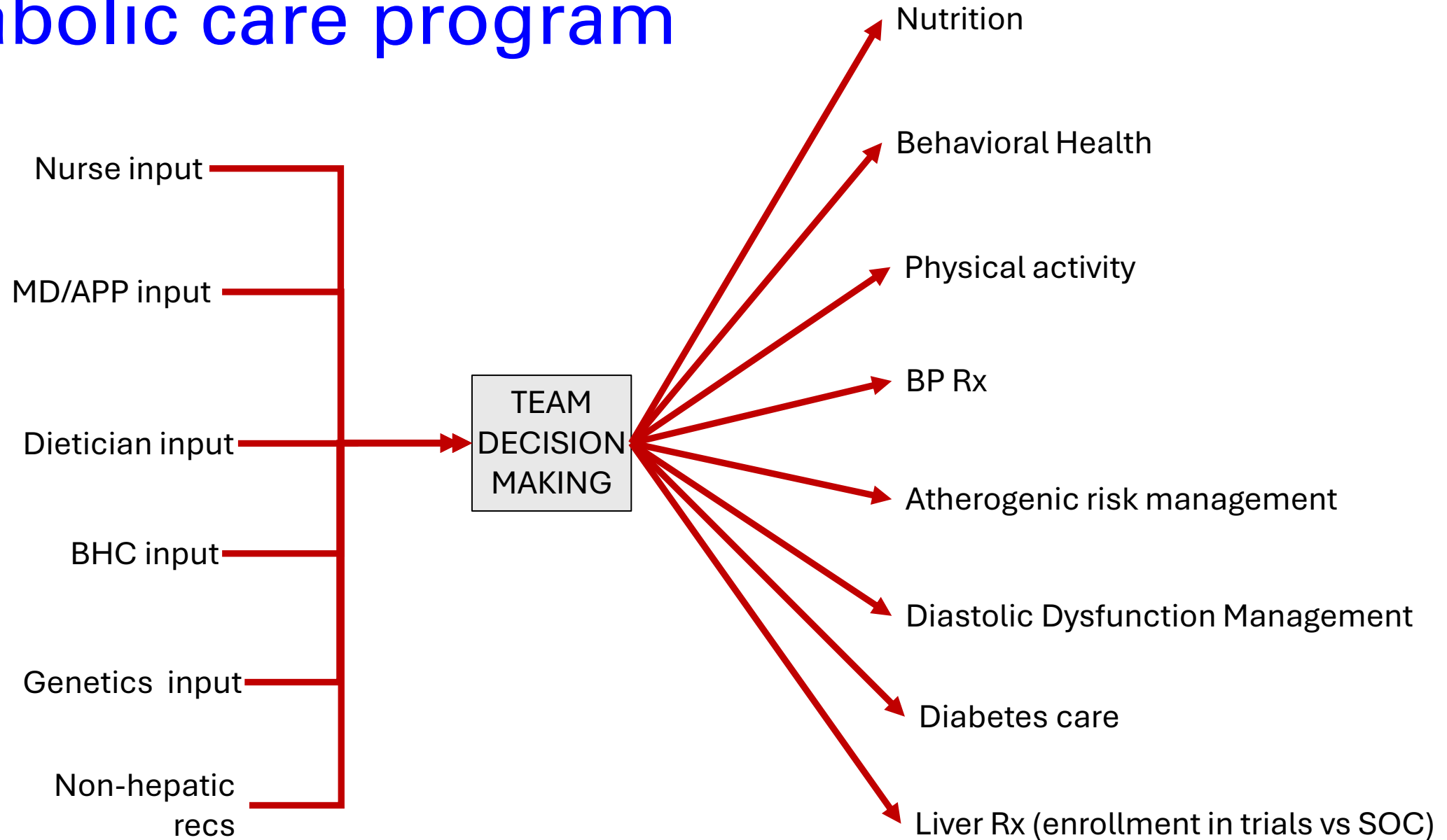
Low: FIB4 < 1.3  
Intermediate: 1.3-2.6  
High: > 2.6

- \*Measures are not comprehensive and have been selected as examples. AHA, American Heart Association; eGFR, estimated glomerular filtration rate; FAST, FibroScan AST; HbA1c, glycosylated haemoglobin; LSM, liver steatosis measurement. 1. Cen et al. Front Nutr 2022; 9:916704; 2. Khan et al. Circulation 2023;148:1982; 3. Masroor et al. JCTH 2019; 9:15; 4. Stern et al. Clin Mol Hepatol 2023;29:S196;

# Principle # 4: establish post visit care coordination and triggers for care escalation



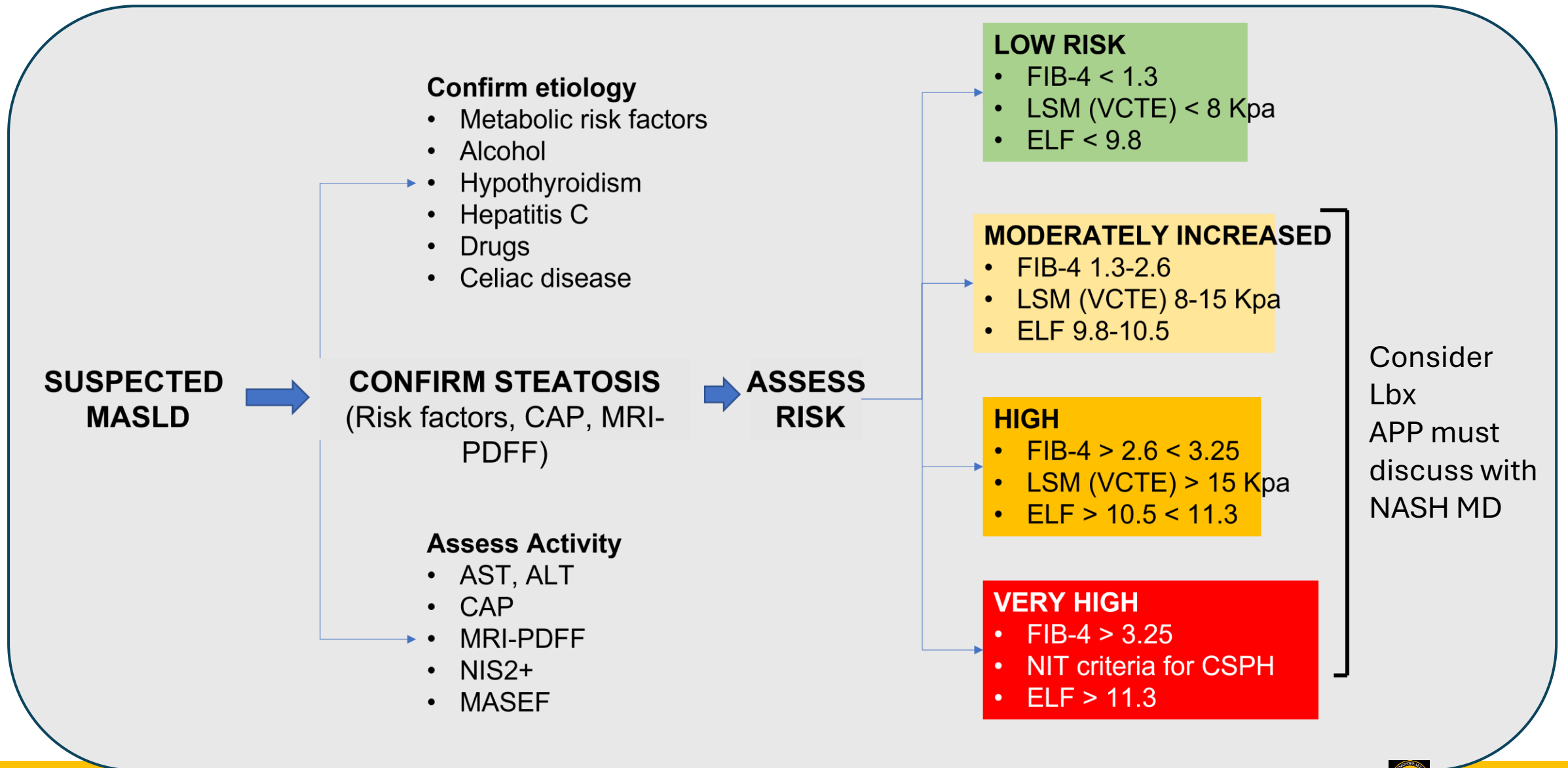
# Principle # 5: Develop a patient centered metabolic care program



## Principle # 6: Link core approach to care within the health care eco system

- **Statins**- as AHA Prevent guidance
- **GLP1**- Sema vs Tirzepatide
  - For BMI > 28, CVS risk > low, T2DM
  - For BMI > 35 no liver or systemic end organ disease
- **Metformin**- for T2DM or FPG > 100 mg/dl
- **SGLT2i**- Empagliflozin or Dapagliflozin
  - UACR > 300 in any patient
  - UACR > 30 in T2DM
- **Insulin**- consultation with diabetologist, consider CGM
- **ARBs**- first-line for BP, alternate ACE inhibitors

# Initial work up in MASLD clinic

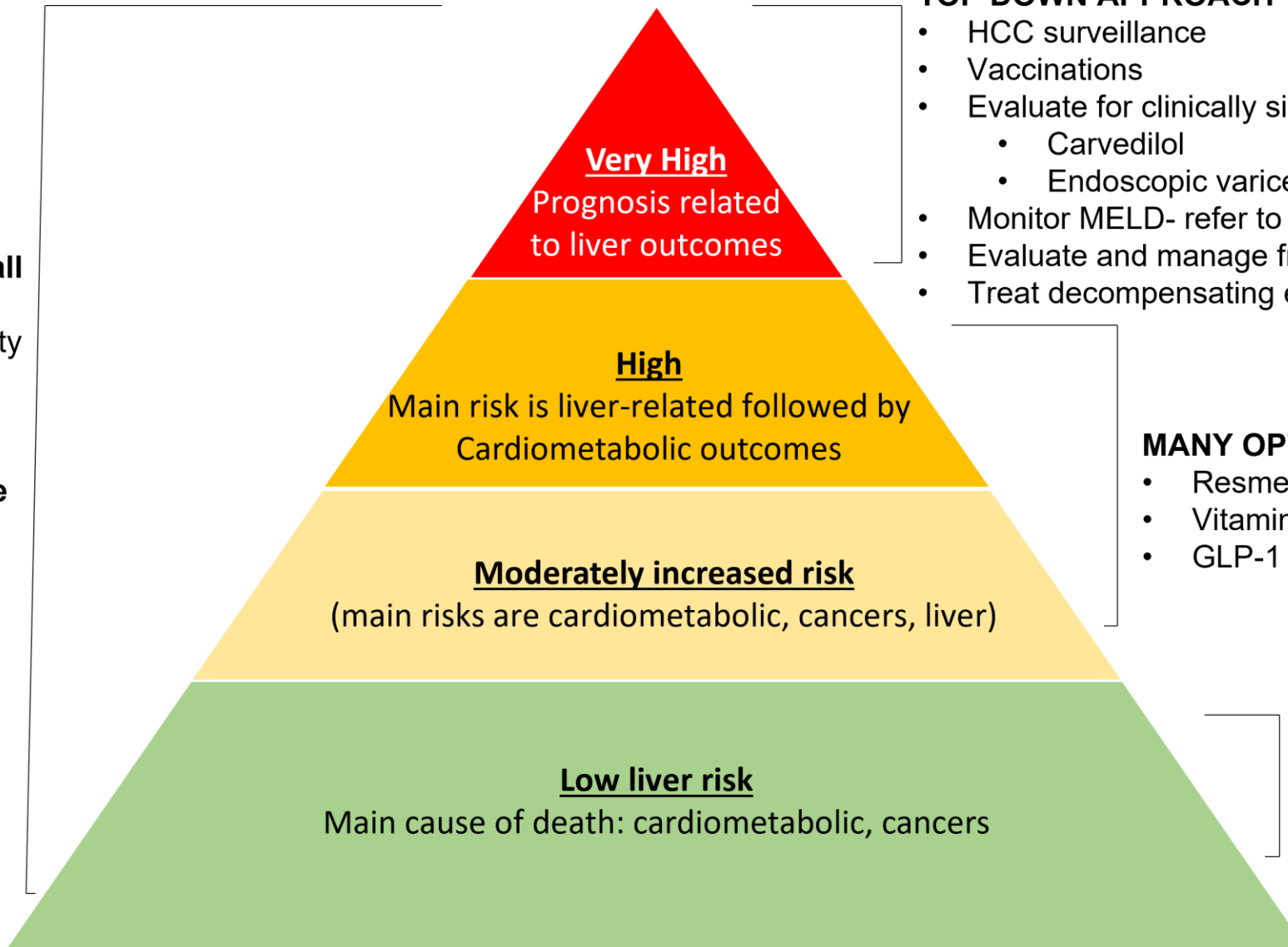


**Lifestyle intervention for all**

- Diet
- Physical activity
- Sleep
- Mental health

**Comorbidity care for all**

- Obesity
- T2DM
- Heart disease
- Vascular disease
- Cancer screening



**TOP DOWN APPROACH**

- HCC surveillance
- Vaccinations
- Evaluate for clinically significant portal hypertension
  - Carvedilol
  - Endoscopic variceal ligation as indicated
- Monitor MELD- refer to transplant center
- Evaluate and manage frailty/sarcopenia
- Treat decompensating events

**MANY OPTIONS FOR MID LEVEL RISK STRATA**

- Resmetirom (thyroxine  $\beta$  receptor agonists)
- Vitamin E and pioglitazone
- GLP-1 based Rx

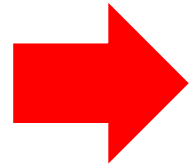
**BOTTOM UP APPROACH**

- Rx underlying obesity, T2DM and cardiac risks

# Principle # 7: protocolize care modification with increasing disease severity

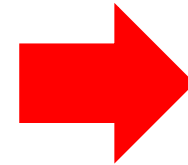
## ASSESSMENT:

- ☐ Cardiovascular Disease
- ☐ Diabetes
- ☐ Sarcopenia
- ☐ Renal function
- ☐ Psychiatric disorders
- ☐ Monitor for CSPH
- ☐ HCC surveillance
- ☐ HCC surveillance
- ☐ Hepatic encephalopathy



## INTERVENTIONS:

- ☐ Management of comorbidities
- ☐ Medications
- ☐ Lifestyle- enhancing adoption
- ☐ Risk based therapeutic recs
- ☐ Vaccines/Variceal prophylaxis



Rx competing risks

Maintain compensation

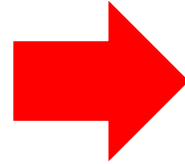
HCC early detection

Maintain quality of life

# Principle # 8: create care pathways linked to resources available- paradigms for resources constrained areas

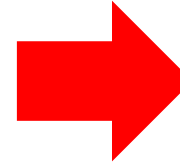
## TEAM:

- Physician extender
- Primary care MD
- Specialty MD
  - Liver
  - Diabetes
  - Cardiology
  - Renal



## ASSESSMENT:

- ☐ Family Hx
- ☐ AUDIT
- ☐ Labs- FIB-4,
- ☐ ASCVD/AHA score
- ☐ eGFR
- ☐ Vaccines
- ☐ CA screening
- ☐ Outcomes assessment
  - ☐ Risk stratification
  - ☐ SSLI Risk Profile
  - ☐ Health literacy
  - ☐ SDOH assessments

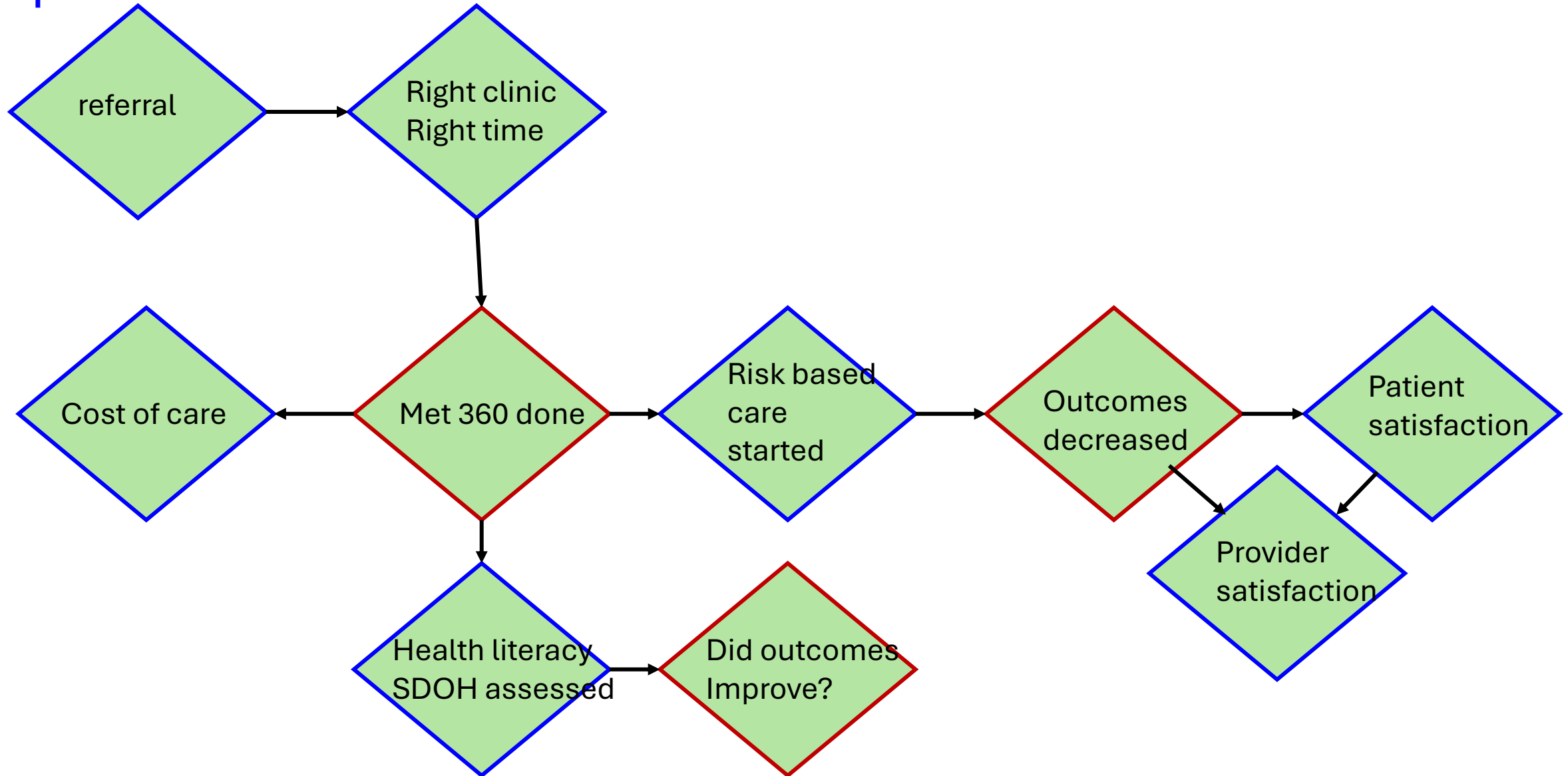


## INTERVENTIONS (focus on early detection and prevention):

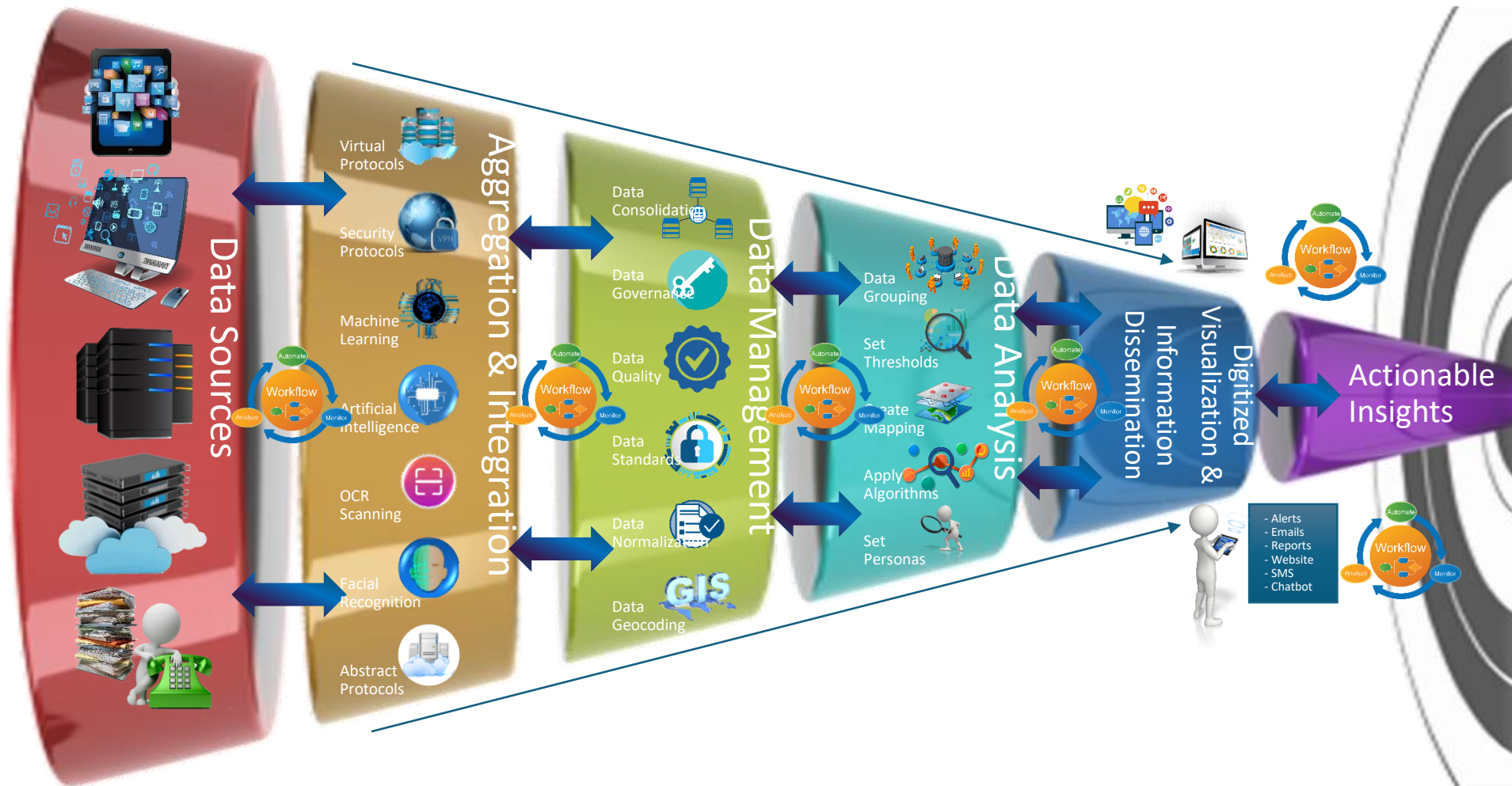
- ☐ Medications
- ☐ Lifestyle- enhancing adoption
- ☐ Risk based therapeutic recs
- ☐ Brief intervention for alcohol as needed



## Principle # 9: care pathways should allow audits and performance assessment



# Principle # 10: Without data- systems put in place to assess efficiencies, care pathways are likely to fail



# Summary

- Care pathways are ideally optimized for local environment
- The key goals are to improve:
  - burden of testing/therapeutics
  - care fragmentation and mixed messaging
  - patient outcomes at any given cost
  - provider satisfaction
- Using integrated approaches and selected use of care extenders, it is largely feasible even in resource constrained areas
- Economic models for care and benefit need to be developed to promote wider adoption



# Thank you for your attention



**VCU**

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School of Medicine

