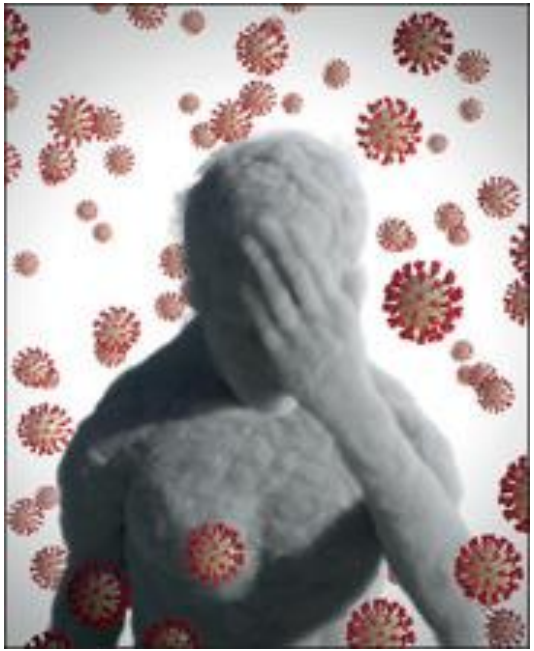
# Update on Long-COVID

## Post-Acute Sequelae of SARS-COV2 (PASC)

- Frank Sciurba, MD



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**NIH - RECOVER Cohort Pulmonary Reading Center (PI)**
**NIH - RECOVER Clinical Trials (site PI)**
**AHRQ – Long Covid Care Network (PI)**

**No other financial relationships or conflicts of interest to disclose.**

# Outline:

- Long-COVID Definition and Impact
- Long-COVID Mechanisms
- Clinical Patterns of Long-COVID
- Evaluation and Treatments
- UPMC Long-COVID Initiatives

NATIONAL ACADEMIES Sciences Engineering Medicine

# A Long COVID Definition

## A Chronic, Systemic Disease State with Profound Consequences

### 2024 NASEM LONG COVID DEFINITION

**Long COVID (LC) is an infection-associated chronic condition (IACC) that occurs after SARS-CoV-2 infection and is present for at least 3 months as a continuous, relapsing and remitting, or progressive disease state that affects one or more organ systems.**

*National Academies of Sciences, Engineering, and Medicine. 2024. A Long COVID Definition: A Chronic, Systemic Disease State with Profound Consequences. Washington, DC: The National Academies Press. https://doi.org/10.17226/27768.

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# Long COVID Defined *(To Date)*

CDC defers to NASEM & adds patient-facing definition:

Long COVID is defined as a chronic condition that occurs after SARS-CoV-2 infection and is present for at least 3 months. Long COVID includes a wide range of symptoms or conditions that may improve, worsen, or be ongoing.



Long COVID Basics. Centers for Disease Control and Prevention. Accessed September 6, 2024. https://www.cdc.gov/covid/long-term-effects/index.html.

# NASEM Long COVID definition recognizes nuances:

- Type of initial infection:
  - Asymptomatic
  - Mild
  - Severe
- Previous infection:
  - Recognized
  - Unrecognized
- Clinical Presentation:
  - Very Heterogeneous
- Onset
  - Continuous
  - Delayed for weeks or months
- Severity
  - Mild to severe
- Duration
  - Months to years

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*National Academies of Sciences, Engineering, and Medicine. 2024. A Long COVID Definition: A Chronic, Systemic Disease State with Profound Consequences. Washington, DC: The National Academies Press. https://doi.org/10.17226/27768.

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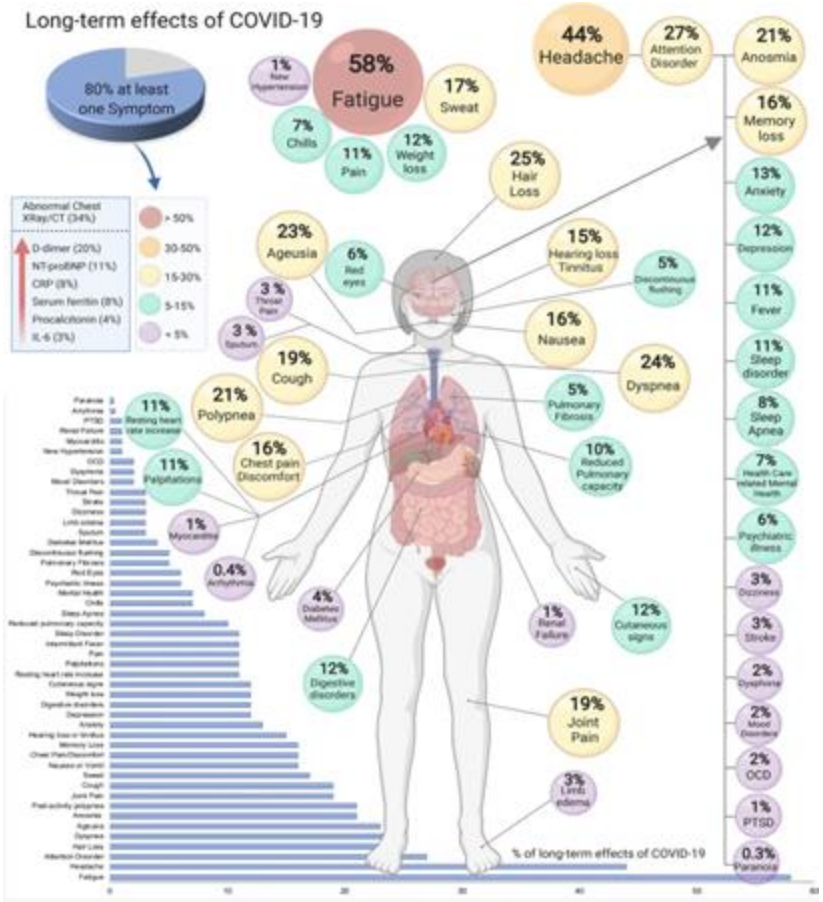
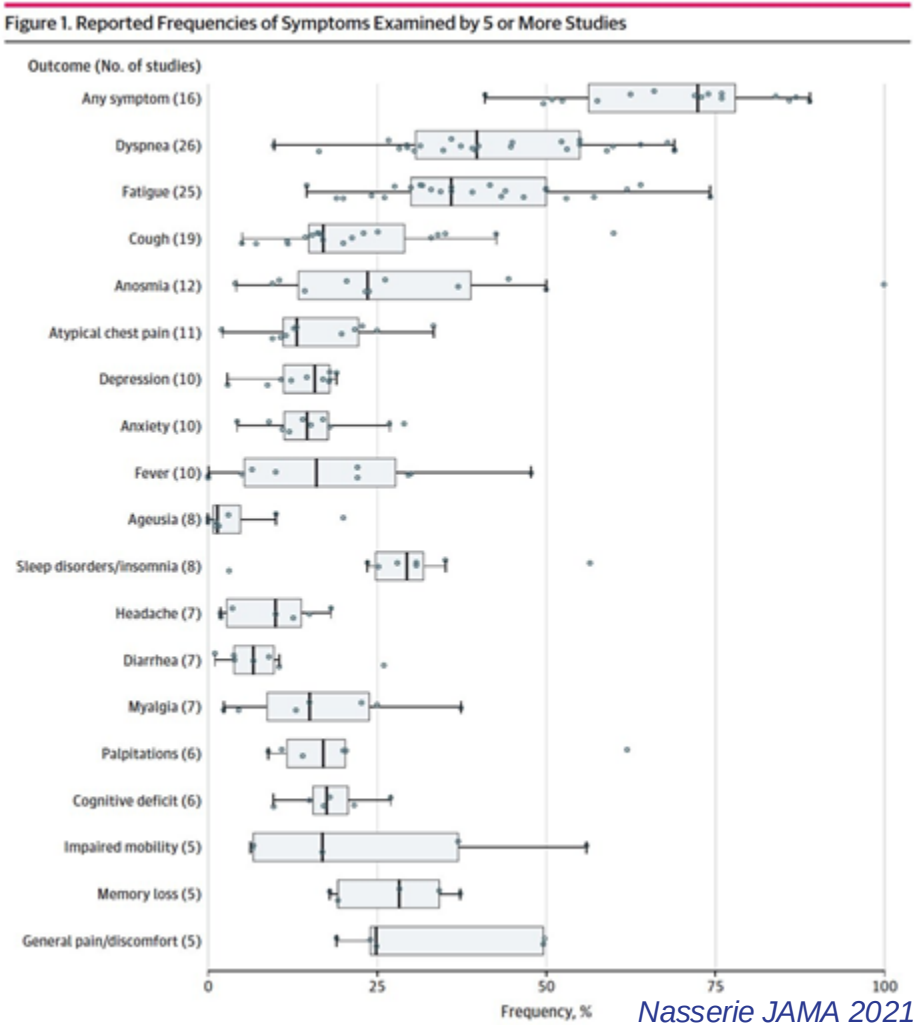
# Long COVID Defined

Thinking about Long COVID as a "Post-COVID State”:

- Combats the “unknowability” of an evolving definition
- Acknowledges that No biomarker or “tests” currently available demonstrates conclusively the presence or absence of Long COVID
- Facilitates thinking about Long COVID, especially in a clinical care setting, in a way that “demystifies” it
- Acknowledges the limited ability to definitively separate conditions associated with, but mechanistically unrelated to, the COVID-19 virus infection.




Lopez-Leon 2021




Nasserie JAMA 2021

# Public Health and Societal Implications of Long COVID

Long COVID Epidemiology:

- The World Health Organization (WHO) estimates 10-20% of persons who have been infected with COVID-19 may experience long COVID.

- The CDC estimates that approximately 16% of persons who have been infected with COVID-19 may experience symptoms persisting longer than 3 months, though the prevalence decreases over 12-month follow-up.

- The US Census Bureau Household Pulse Survey estimates that 14.3% of US adults have ever had Long COVID, with 5.3% affected currently.

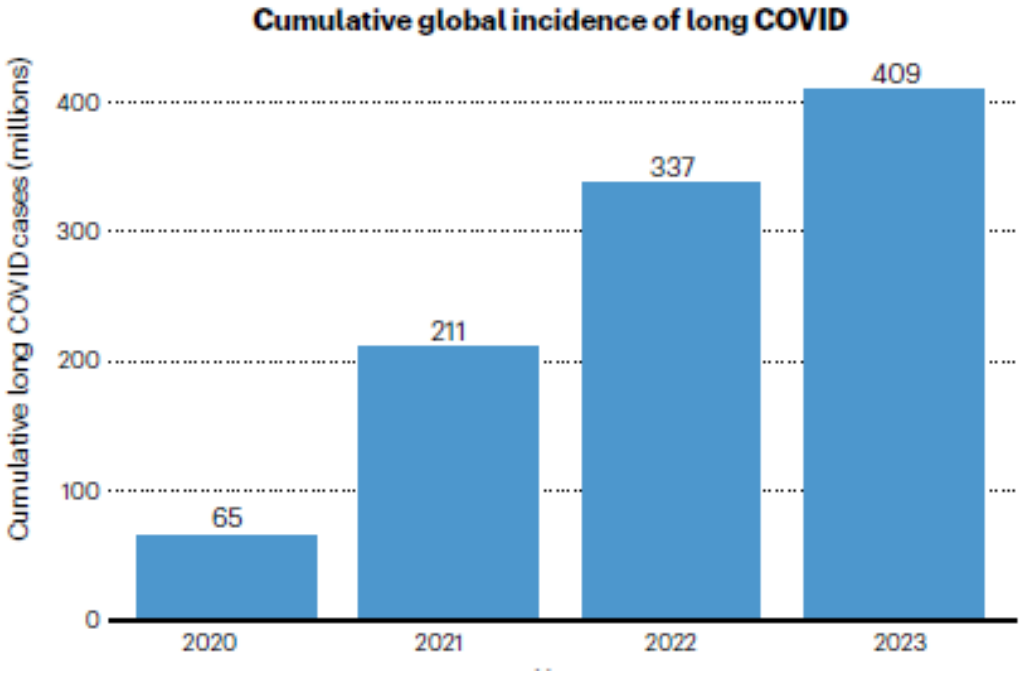
Post COVID-19 Condition (Long COVID). World Health Organization. Accessed September 10, 2024. https://www.who.int/europe/news-room/fact-sheets/item/post-covid-19-condition.

Montoy JC, Ford J, Yu H, et al. Prevalence of Symptoms ≤12 Months After Acute Illness, by COVID-19 Testing Status Among Adults — United States, December 2020–March 2023. MMWR Morb Mortal Wkly Rep 2023;72:859–865. DOI: http://dx.doi.org/10.15585/mmwr.mm7232a2

Long COVID - Household Pulse survey - COVID-19. Centers for Disease Control and Prevention. August 21, 2024. Accessed September 6, 2024. https://www.cdc.gov/nchs/covid19/pulse/long-covid.htm.

# Estimated Cumulative Global Incidence of Long COVID *

***Based on Institute for Health Metrics and Evaluation's annual estimates of SARS-CoV-2 infections and assuming the lower risk estimate of 6.2% for long COVID at 3 months**




Al-Aly et al. Nat Med 2024

# Long COVID Clinical Snapshot: Risk Factors

- Higher BMI
- Older age (>60 years)
- Prior respiratory conditions (asthma)
- Pre-morbid conditions (HTN)
- Female sex
- Smoking
- Severity of COVID infection (hospitalization or ICU admission)

Tsampasian V, Elghazaly H, Chattopadhyay R, Debski M, Naing TKP, Garg P, Clark A, Ntatsaki E, Vassiliou VS. Risk Factors Associated With Post-COVID-19 Condition: A Systematic Review and Meta-analysis. JAMA Intern Med. 2023 Jun 1;183(6):566-580. doi: 10.1001/jamainternmed.2023.0750. PMID: 36951832; PMCID: PMC10037203.

# Race / ethnicity differences in post COVID conditions (Often Not linked to COVID)



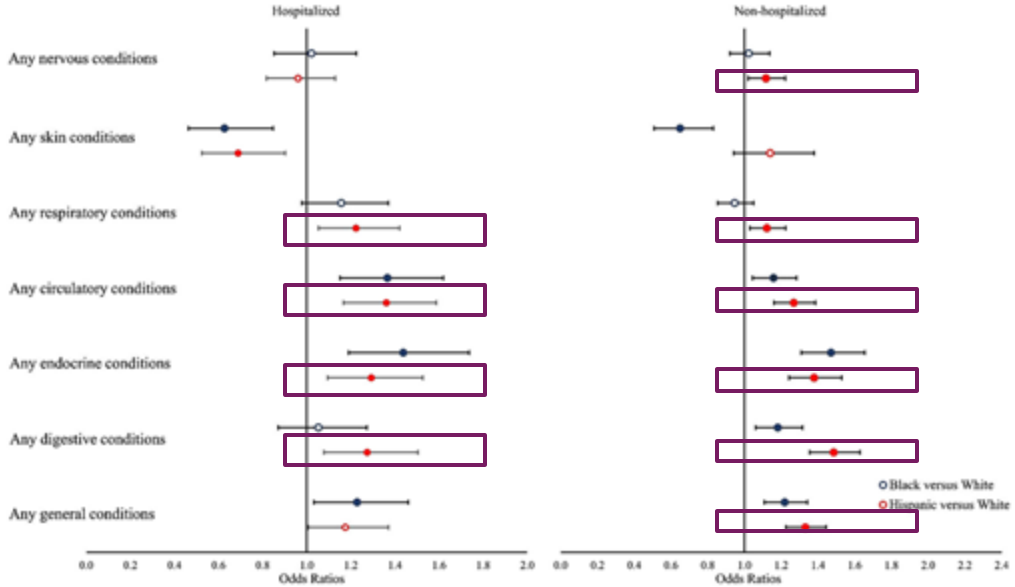



**Figure 2 Adjusted differences in incidence of groups conditions and symptoms by race/ethnicity among hospitalized and non-hospitalized COVID-19 patients. Notes: Odds ratios (ORs) were estimated from logistic regressions examining the outcome of having at least one condition or symptom in each group during the follow-up period (Reference group = White). Models were adjusted for baseline patient characteristics, including age, gender, year-month of COVID-19 positive testing, comorbidities, and indicators for the five institutions contributing data. * Filled symbols indicate significant ORs that are statistically significant after false discovery rate correction (q < 0.05).**

Study based on electronic health records of 310,220 people who receive care at five health systems in New York city.

Compared to white patients, patients who are Black and Hispanic/Latinx have **20% to 50% higher odds to be diagnosed with health problems over a 6-month period after COVID-19**.

Khullar et al. J Gen Intern Med 38(5):1127–36

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# Patterns of Long Covid

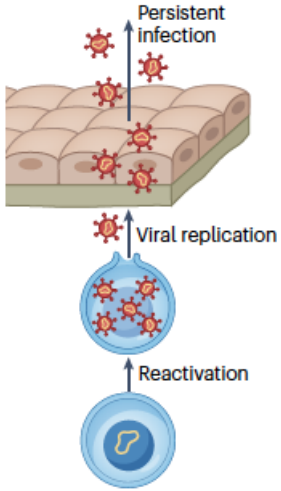
Symptoms or Conditions that:

- Persist
- Evolve
- Resolve, and reemerge following initial acute COVID-19
- Develop following asymptomatic disease
- Worsen pre-existing symptoms or conditions

# The Why?

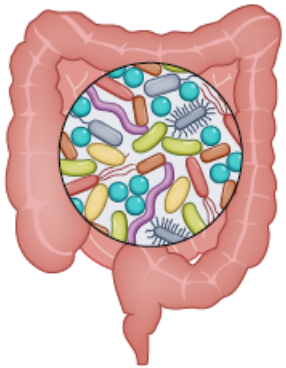
# Potential mechanisms

**Immune dysregulation**



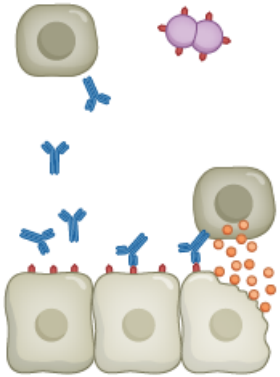

Immune dysregulation, with or without reactivation of underlying pathogens, including herpesviruses such as EBV and HHV-6

**Microbiota dysbiosis**



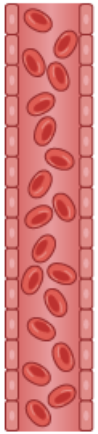
Impacts of SARS-CoV-2 on the microbiota and virome (including SARS-CoV-2 persistence)

**Autoimmunity and immune priming**



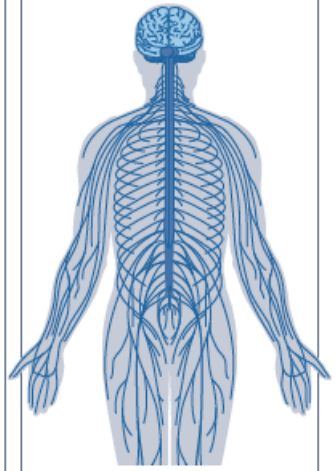
Autoimmunity and primed immune cells from molecular mimicry

**Blood clotting and endothelial abnormalities**



Microvascular blood clotting with endothelial dysfunction

**Dysfunctional neurological signalling**



Dysfunctional signalling in the brainstem and/or vagus nerve

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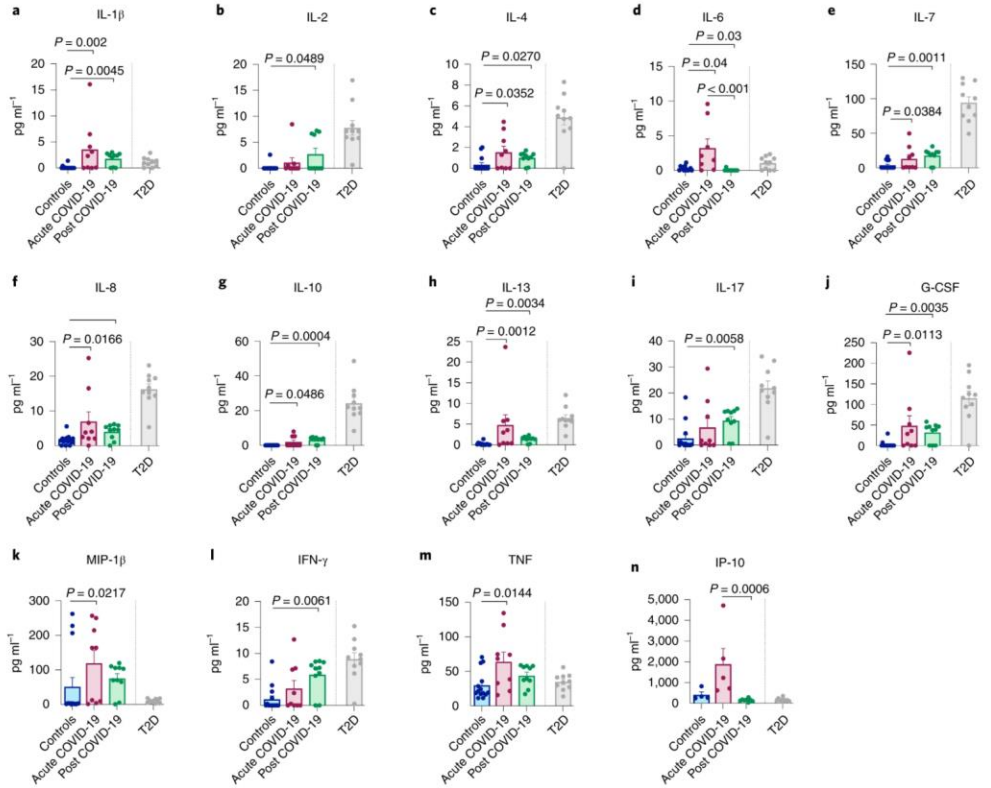
# Persistent inflammation long after recovery from COVID-19




- Persistent inflammation Associated with glucose intolerance in 46% of post-hospitalized Long-COVID patients

Montefusco et. al. Nature Medicine May 2021

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# PASC result from persistent SARS-CoV-2 positivity? UPMC Long-Covid Analysis

- Quantitation of persistent virus (RT-PCR)
  - 6/101 positive in saliva
  - 1/103 positive in stool
- Persistent Virus Not associated with clinical subtype or severity

Jacobs, Kitsios, Morris

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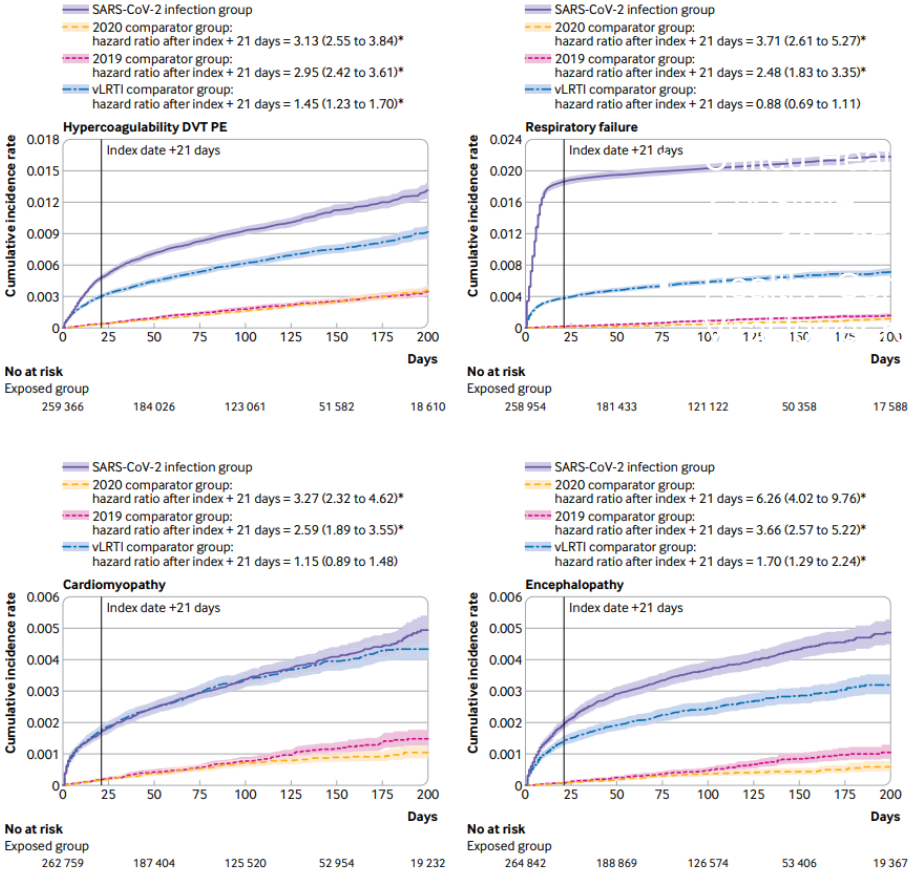
# Risk of post-acute events relative to healthy and other viral respiratory infection




Daugherty et. al. BMJ May 2021

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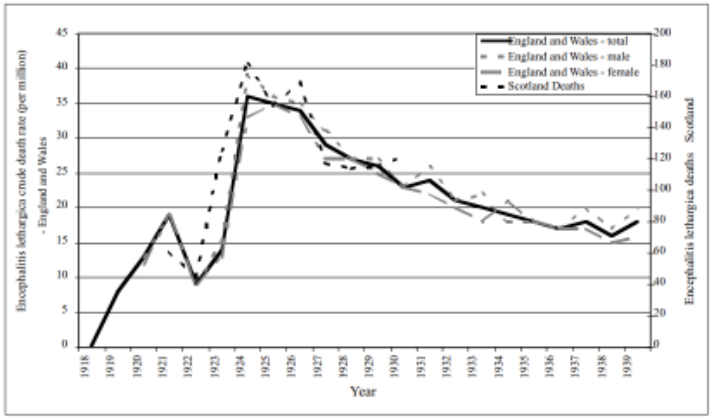
# A long history of poorly understood symptoms and syndromes occurring after infections

- Altered cognition during prior pandemics term "Encephalitis Lethargica"
  - 1889 and 1892, "Russian Flu" Pandemic
  - 1918-1919, "Spanish Flu" Pandemic
- An outbreak of "Atypical poliomyelitis" in Los Angeles in 1935.
- After epidemiological case reviews thought to be associated with diphtheria.
- Myalgic Encephalomyelitis / Chronic Fatigue Syndrome (ME/CFS)
  - First described in 1956 after outbreaks in London, Iceland, Australia, and Florida.

Fig. 9. *Encephalitis lethargica mortality in Britain 1918-1940*




Data source: *Annual Report of the Registrar-General*, 1918-1940.

Stefano, 2021
Johnson, 2003

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# Clinical Patterns?

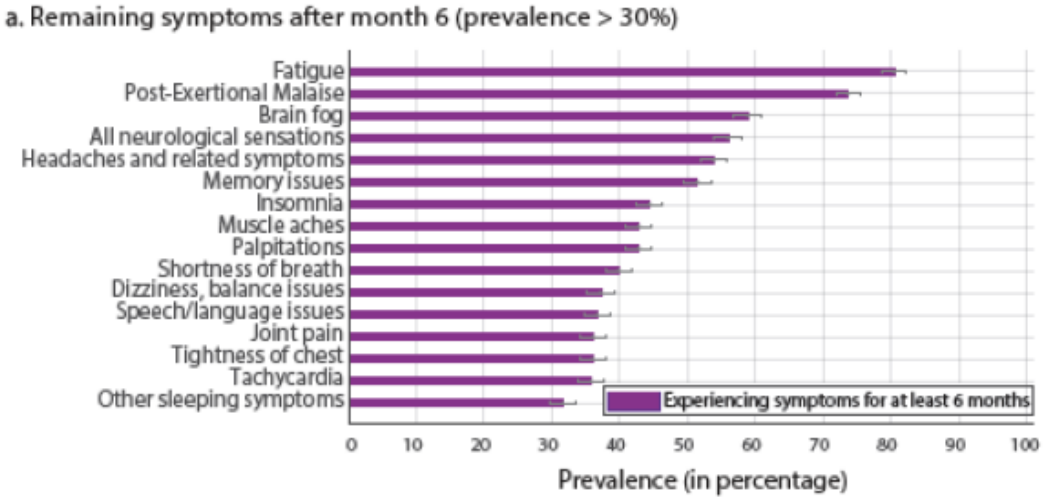
# Post-Acute Sequelae of COVID (PASC) Symptoms

•International Cohort Study, n= 3,762, >30 days from infection

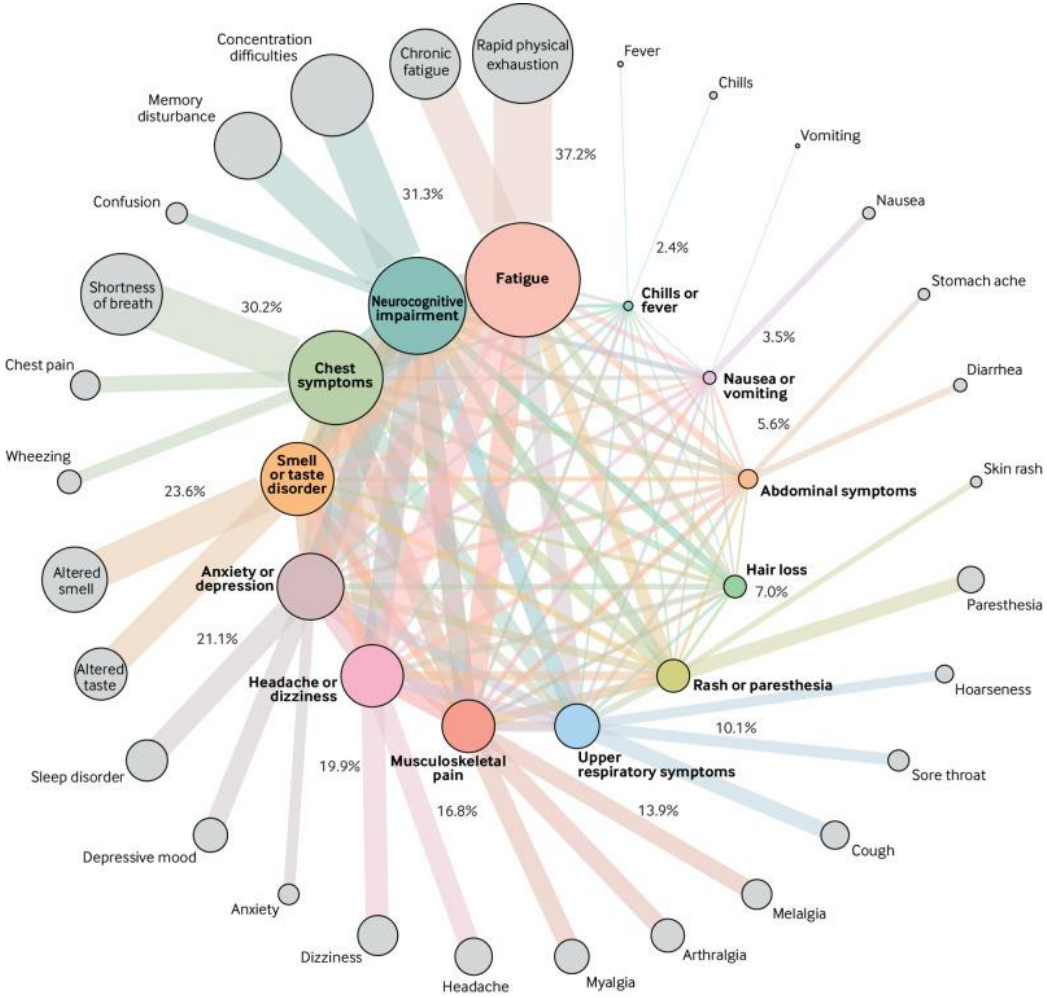
•203 symptoms in 10 organ systems prevalent

•Avg: 14.5 symptoms in 9.1 organ systems

•The most frequent symptoms reported after month 6 were:
- •fatigue (78%)
- •post-exertional malaise (72%)
- •cognitive dysfunction (55%)




Davis, et al, 2021 https://doi.org/10.1101/2020.12.24.2024880




Peter RS, Nieters A, Kräusslich HG, et al. Post-acute sequelae of covid-19 six to 12 months after infection: population based study. *BMJ*. 2022;379:e071050. Published 2022 Oct 13. doi:10.1136/bmj-2022-071050

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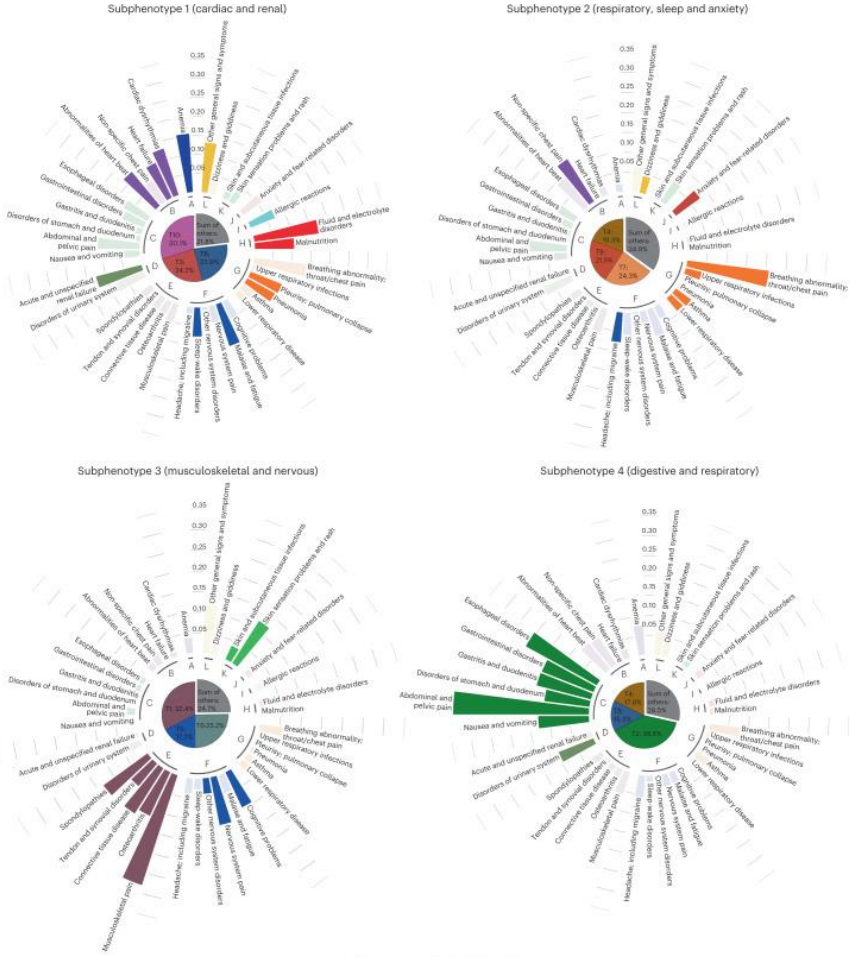


Zhang H, Zang C, Xu Z, et al. Data-driven identification of post-acute SARS-CoV-2 infection subphenotypes. *Nat Med*. 2023;29(1):226-235. doi:10.1038/s41591-022-02116-3

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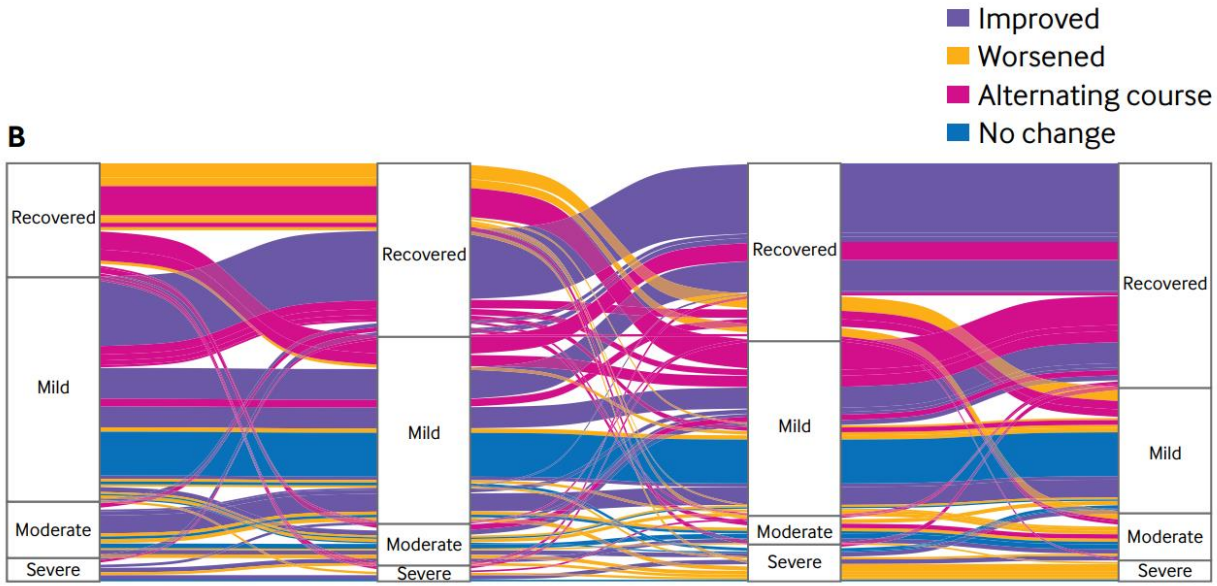
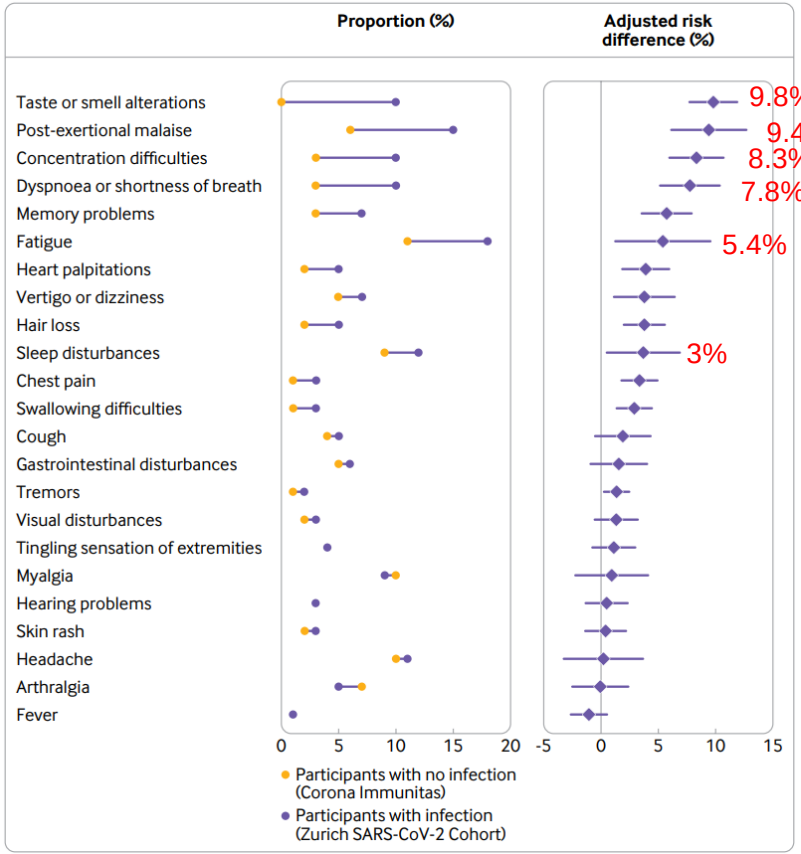
# Time Course of Long-COVID




- 1106 SARS-CoV-2 (Swiss)
- 23% symptoms at 6 mo.
- 18% symptoms at 24 mo.
  - 68% improved over time
  - 5.2% worsened
  - 4.4% alternating

Ballouz et. al. BMJ 2023

# Long-COVID Excess Symptoms Relative to Uninfected Control




Ballouz et. Al BMJ 2023

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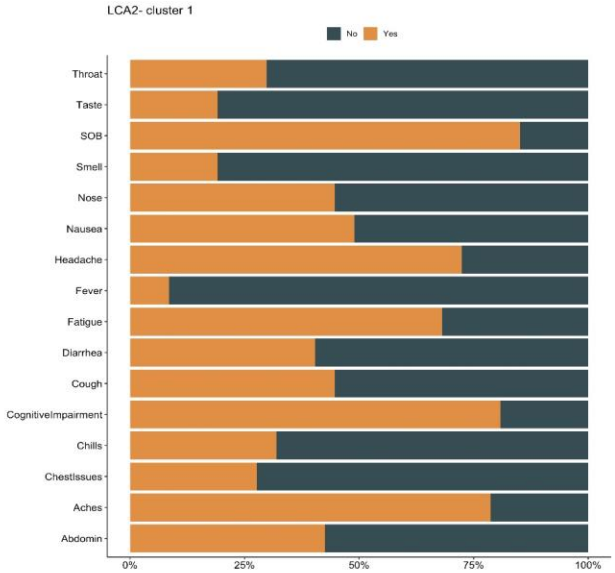
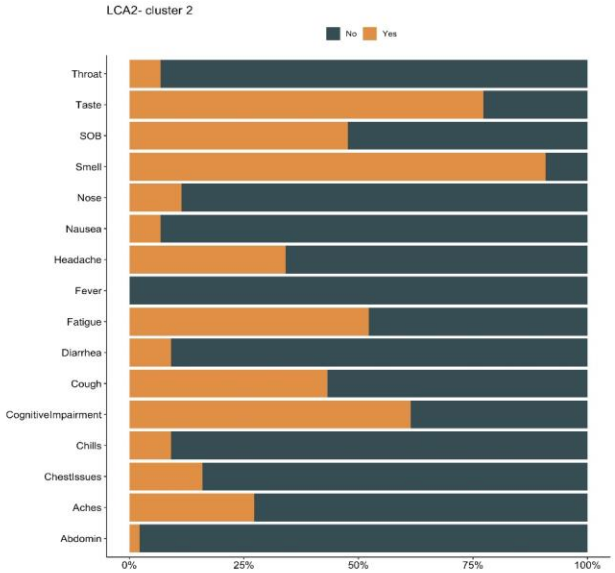
# Three distinct sub-types of PASC symptoms

Our PACCSM Long-COVID clinic, Symptom Surveys
214 patients, Females: 73.4%, Hospitalized: 33.2%, Whites: 91.6%
Age: median 50 yrs; Days post-COVID: 197 (143-323), Followed up to 1 yr

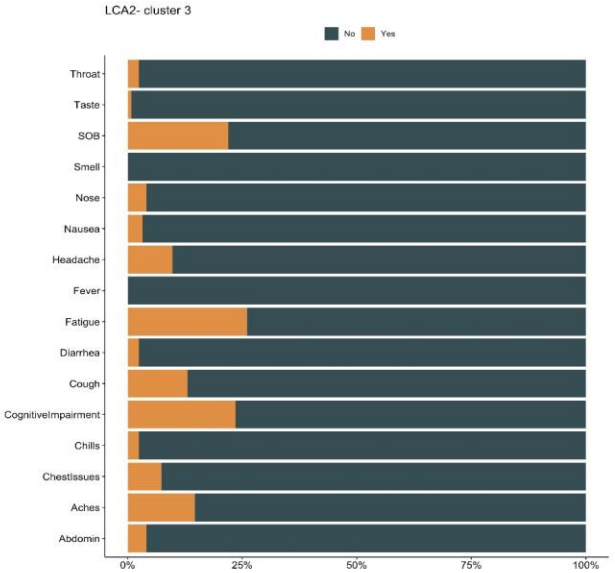
## Global




## Taste and smell




## Minimal symptoms

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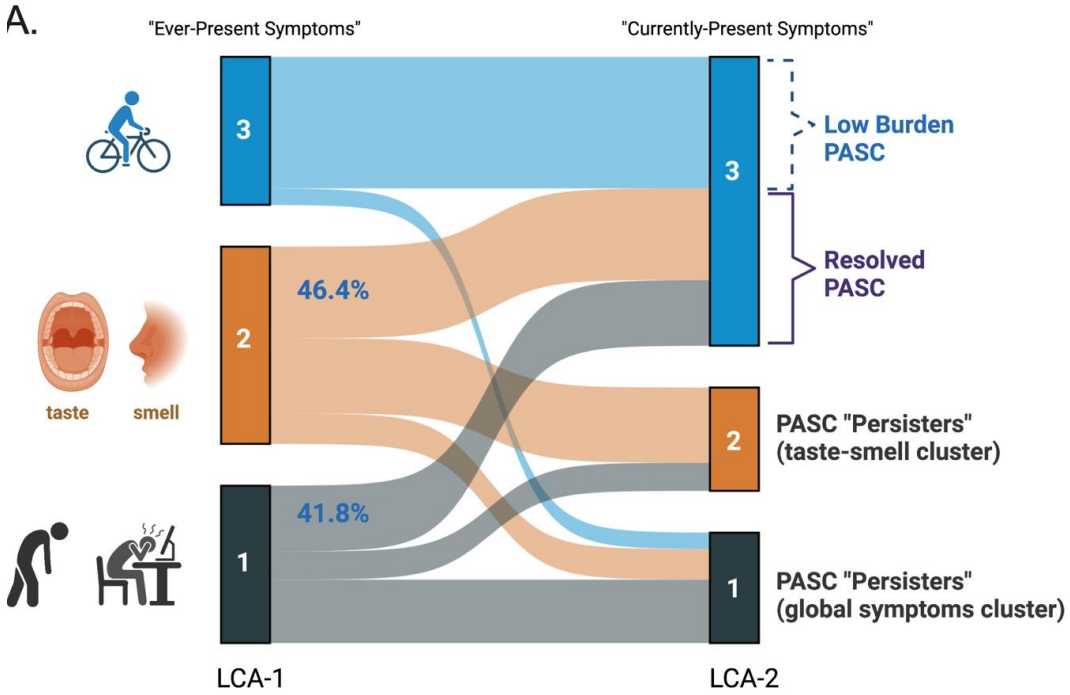
# PACCM Long-COVID Clinic Longitudinal pattern

- About half remain in their symptomatic cluster – “Persisters”



# Clinical Evaluation?

# Initial Therapy: "Language Matters"

## Validate symptoms, counsel on prognosis

**"Long COVID is a real condition and fits with your symptoms. Many people experience it – you are not alone."**

***"Every person is different. Many patients, though not all, improve or fully recover over several months or even years."***

"Although we don't have a cure right now, many patients can manage their symptoms and improve their quality of life with the treatment strategies we do have."

"Researchers are learning more about Long COVID every day, and we can work together to make sure you have access to any new treatments that are discovered and are right for you."

# Lessons learned in clinical care: Prior to Post-COVID Clinic

- **Do** demystify
  - All the symptoms and concomitant diagnosable conditions that are characteristic of Long COVID existed before the COVID-19 pandemic, and none are specific to Long COVID.
  - **Do** acknowledge gap in research findings and clinical application
- **Do** understand that many routine tests will be normal, and there is currently no diagnostic biomarker for Long COVID.
- **Do** treat an identifiable conditions based on standard, evidence-based guidelines.

# Lessons learned in Long COVID clinical care to date

- **Don't** overlook potential serious sequelae
- **Don't** misattribute to psychiatric causes alone… acknowledge vicious cycle and two things can be at play at once
- **Don't** become complacent and automatically attribute new symptoms to Long COVID alone… use shared decision making to discuss options for further work up

# Documentation Recommendation from CDC

- **U09.9: Post COVID-19 Condition, unspecified**
  - This code should be used for patients with a history of probable or confirmed SARS CoV-2 infection who are identified with a Post-COVID Condition.
  - In addition, assign codes for specific conditions and symptoms identified.

# Long COVID Clinical Snapshot: Common Presentations/Snapshots

- Brain Fog
- Fatigue
- ME/CFS
- POTS/Autonomic Dysfunction
- Taste and Smell Dysfunction

# Unique Presentations

Michael is a 56-year-old male with a history of asthma who was

**Brain Fog**

returning home, he has not been able to work as efficiently, concentrate or multi-task at work like he did before his illness.

Rose is a 27-year-old woman who is a primary

**Fatigue**
**POTS**
**Anxiety**

difficulty concentrating throughout her day and has been feeling very anxious that her symptoms will be permanent.

Tiffany is a 34-year-old woman who works full

**Post Exercise Malaise**
**ME/CFS**

has not been able to return to spinning classes due to extreme exhaustion following exercise.

Robert is a 63-year-old male chef with a history

**Taste and Smell Impairment**

difficulty at work due to loss of taste and smells.,

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# Referral for Unique Rehab Tx

Michael is a 56-year-old male with a history of

OT vs Speech Tx
Neurocognitive rehab
(TBI model)

efficiently, concentrate or multi-task at work like he did before his illness.

Rose is a 27-year-old woman who is a primary homemaker. She had a

Progressive Exercise
(Levinson Protocol)

tachycardic. She has difficulty concentrating throughout her day and has been feeling very anxious that her symptoms will be permanent.

Tiffany is a 34-year-old woman who works full time in software

OTx-
Pacing
vs.
Exercise rehab

classes due to extreme exhaustion following exercise.

Robert is a 63-year-old

OT
Taste-Smell
Retraining

loss of taste and smells.,

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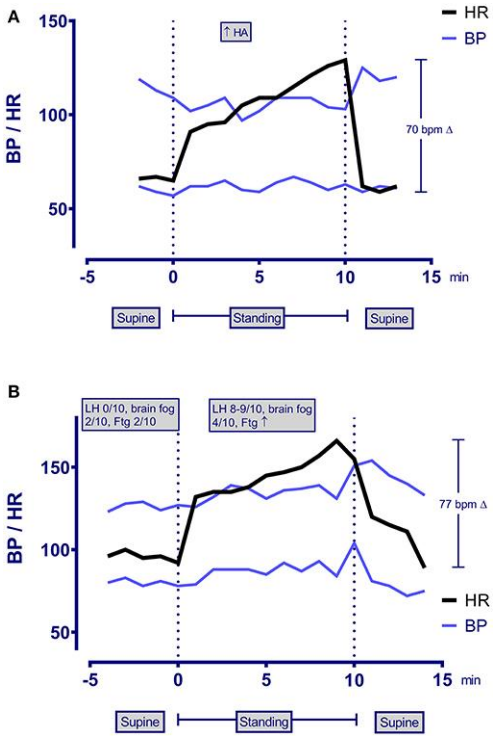
# Postural Orthostatic Tachycardia Syndrome (POTS)

# Postural Orthostatic Tachycardia Syndrome (POTS) in Long-COVID (Autonomic Dysfunction)

## Stand Test




Petrasek et. Al. Front. Med., April 2021

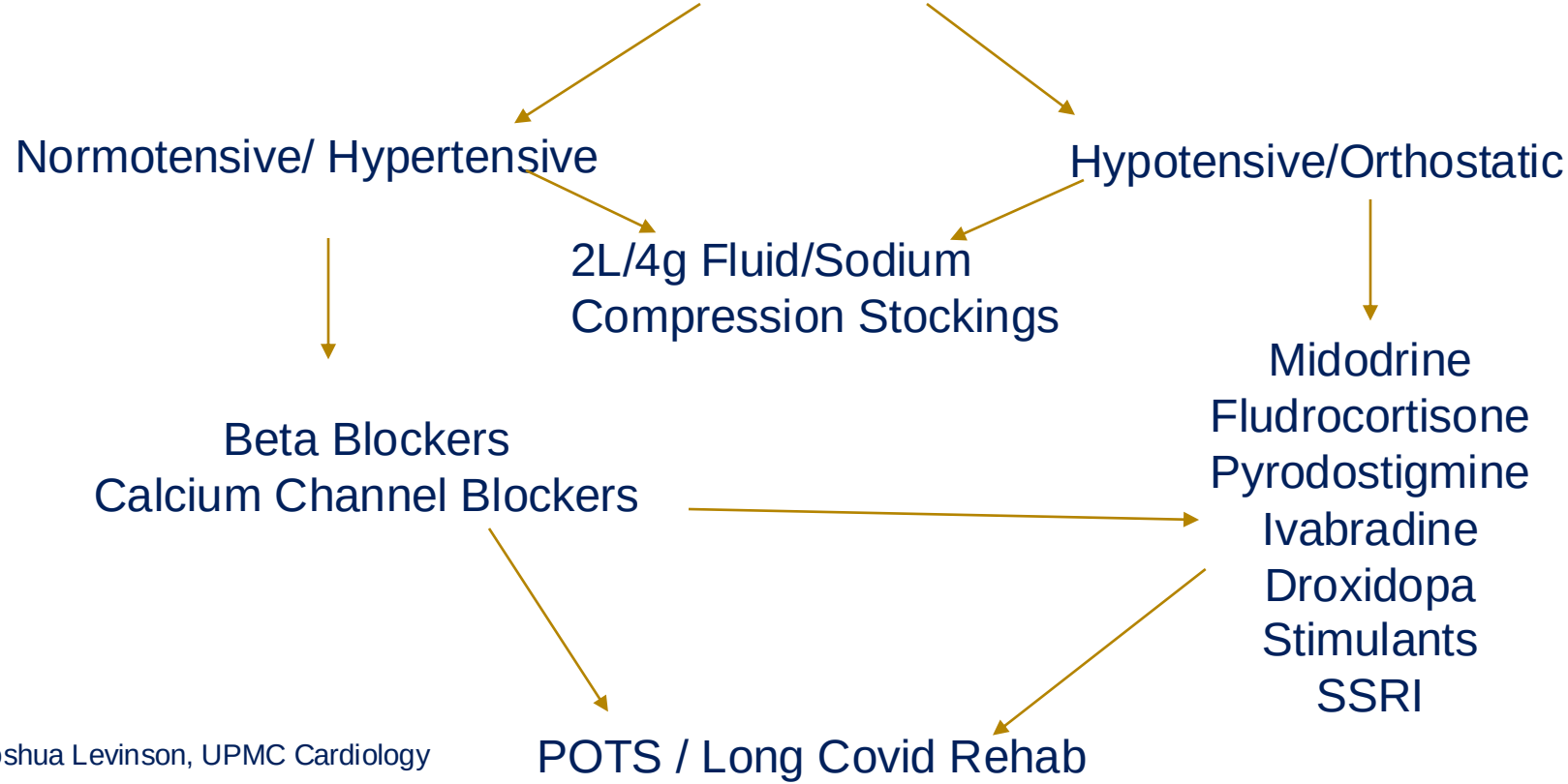
# Postural Orthostatic Tachycardia Syndrome

- Low Blood Volume / Low Salt Intake
- Physical Deconditioning
- Hyperadrenergic State
- Collagen Disorders / Hypermobile Ehlers Danlos Syndrome
- Skeletal Muscle / Mitochondria Dysregulation
- Autonomic Dysregulation

# Diagnostic Testing Options

- QSART – Quantitative Sudomotor Axon Reflex Testing + Dysautonomia Testing
  - Heads Up Tilt Table Test – Heart Rate Variability & Blood Pressure Response
  - Sympathetic Skin Response
- Measure Adrenergenic Hormones (Epi, Norepi)

# POTS Treatment Approach




Joshua Levinson, UPMC Cardiology

University of Pittsburgh

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# Beta Blockers and Calcium Channel Blockers

- Bisoprolol 2.5 mg daily or metoprolol succinate 25 mg daily
- Propranolol 10 mg TID or propranolol long acting 30 mg daily
- Diltiazem 120 mg daily

- ***START LOW, GO SLOW!***

# Midodrine

- Stimulates Peripheral alpha-adrenergic Vasoconstriction
- 2.5 mg PO q4h (QAM, Lunch, Dinner)
- Can go up to 10 mg PO QID
- Avoid lying flat for 4 hours after each dose (supine hypertension)
- Side Effect: Migraines, “Tingling”

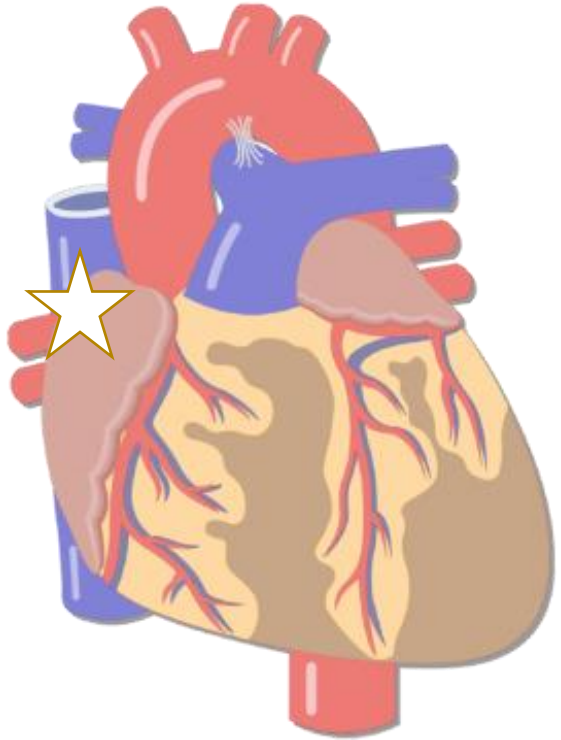
# Fludrocortisone (Florinef)

- Systemic mineralo-corticosteroid – Volume expander

- 0.1 mg PO Daily, can go up to 0.2 BID
- Need Sodium and Fluid Intake for it work
- Will Not See Effect for Weeks

- Side Effects: Tingling, Nausea, Swelling, Hypertension, Hyperkalemia

# Ivabradine



- Funny Channel Blocker
- Slows Sinus Node
- FDA-Approved for refractory angina
- 2.5mg PO daily→ BID, 5mg BID, 7.5 mg PO BID

# Myalgicencephalomyelitis/ chronic fatigue syndrome (ME/CFS)

# Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS)

A chronic, complex, debilitating, multi-system illness involving:

- regulation)
- sation and
- toimmune

**ME/** gnosis is typic been lost, or diag ness onset Imm

## Proposed Diagnostic Criteria for ME/CFS

Diagnosis requires that the patient have the following three symptoms:

1. A substantial reduction or impairment in the ability to engage in pre-illness levels of occupational, educational, social, or personal activities, that persists for more than 6 months and is accompanied by fatigue, which is often profound, is of new or definite onset (not lifelong), is not the result of ongoing excessive exertion, and is not substantially alleviated by rest, and
2. Post-exertional malaise,* and
3. Unrefreshing sleep*

At least one of the two following manifestations is also required:

1. Cognitive impairment* or
2. Orthostatic intolerance

* Frequency and severity of symptoms should be assessed. The diagnosis of ME/CFS should be questioned if patients do not have these symptoms at least half of the time with moderate, substantial, or severe intensity.

For more information, visit **www.iom.edu/MECFS**

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# Pyrodostigmine (Mestinon)

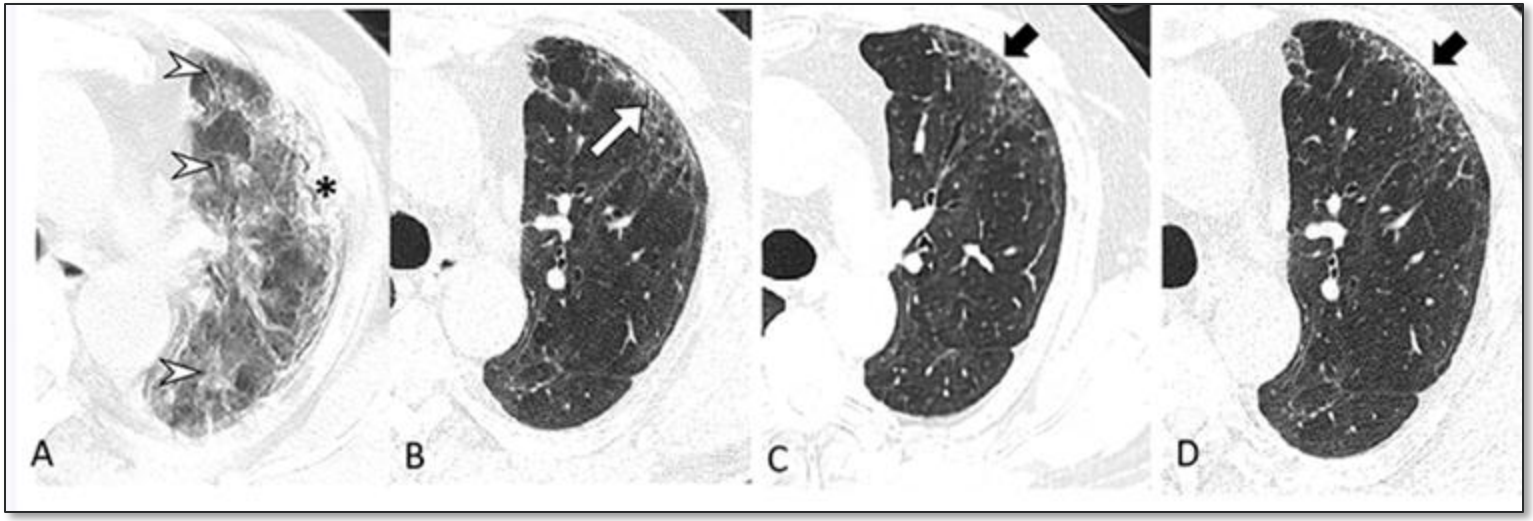
- Works at Neuro-Muscular Junction →ACh Uptake inhibitor, Enhances Peripheral Vasoconstriction
- 15 mg PO TID, go up to 60 mg PO QID
- GI Distress, Acetylcholinergic Side Effects

# Exertional Intolerance/Dyspnea

# Potential Causes of Dyspnea in Long-COVID

| | | |
|---|---|---|
| Parenchymal Lung Diseases | Pulmonary Vascular & Thromboembolic Lung Disease | Heart Failure<br>Ischemia<br>Arrhythmias |
| Anxiety<br>Depression | Inflammatory & Rheumatologic Disorders | Iron Deficiency Anemia |
| Thyroid Disorders | Myopathy/<br>Deconditioning | Autonomic Dysfunction |

# Chest CT Scan

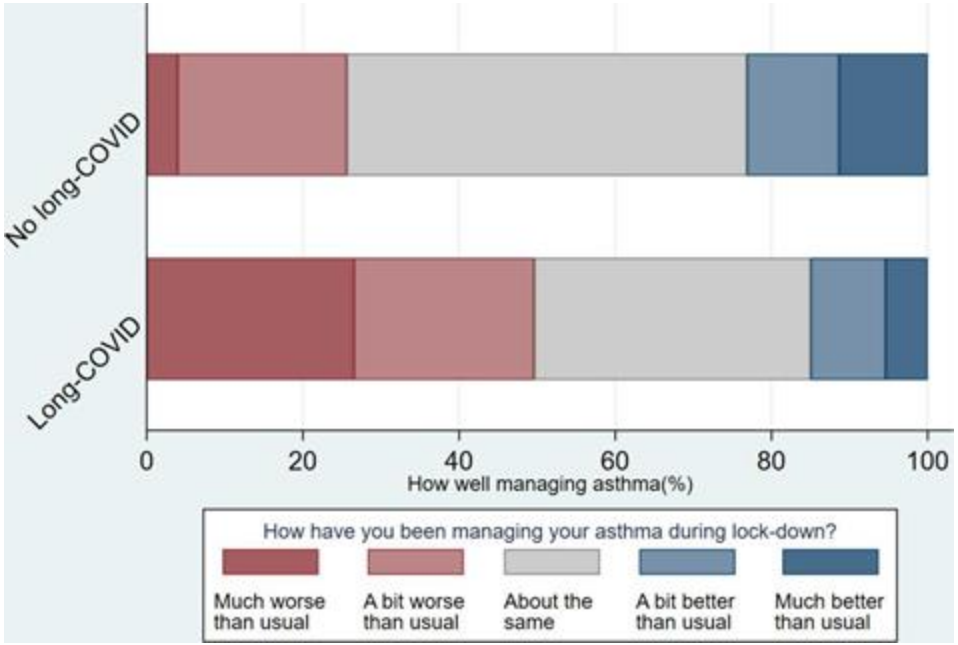


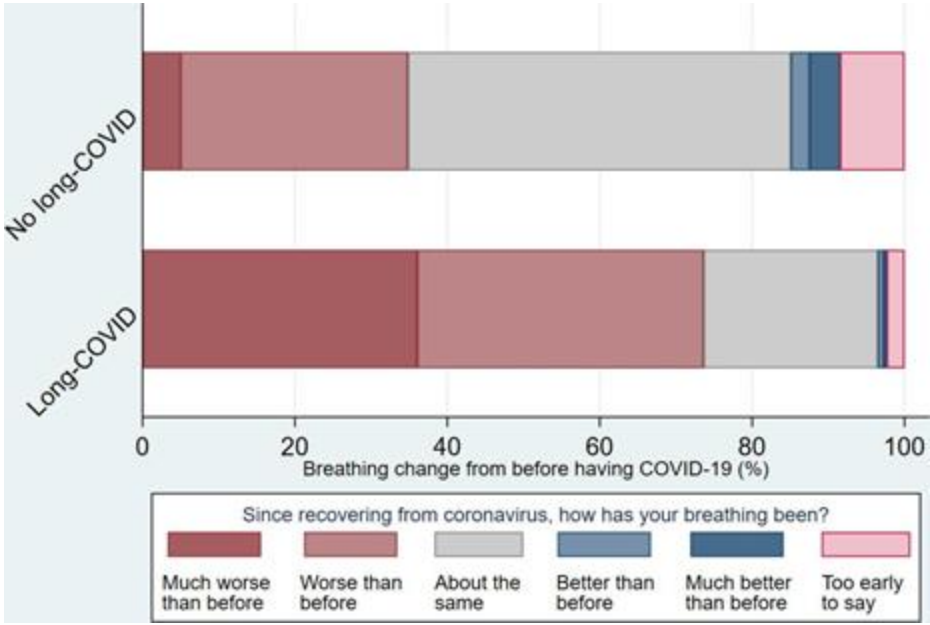

- 144 patients (79 men, median age 60)
- Chest CT scans and PFTs at 6, 12 mo and 2 years
- At discharge- fibrosis, thickening, honeycombing, cystic changes and dilation of the bronchi.
- Over two years-> gradually decreased.
- 6m - 54% of patients showed lung abnormalities.
- 2 yr - 39% lung abnormalities,
  - 23% with fibrotic lung
  - 16% with non-fibrotic lung.



*Han et al Radiology 2023*

# Asthma Control Worse After COVID

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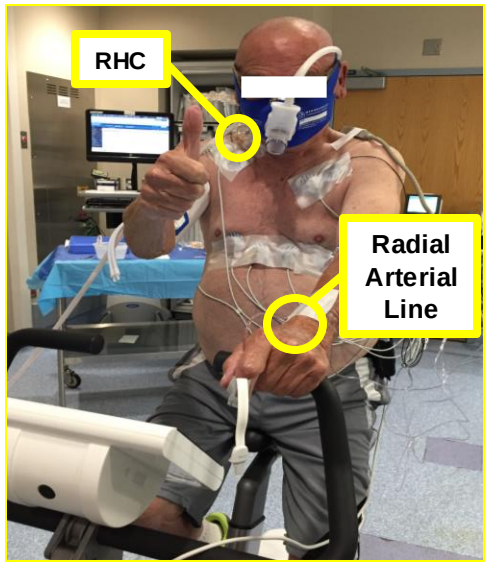
# Invasive cardiopulmonary exercise test (iCPET) and Subtypes of Exertional Intolerance




Referred to UPMC Post-Covid Clinic for persistent symptoms

**7 Excluded**
1 RER <1.05
1 Refused study
2 Referred prior to COVID-19 infection
1 Incomplete CPET data
2 Pre-existing heart failure

44 Referred to ACPET Program for exercise intolerance / dyspnea

2 Decreased $EO_2$
1 ePH

12 Normal $\dot{V}O_{2\ Peak}$

25 Reduced $\dot{V}O_{2\ Peak}$

1 without peak hemodynamics

6 Preload insufficiency

4 Preload insufficiency and decreased $EO_2$

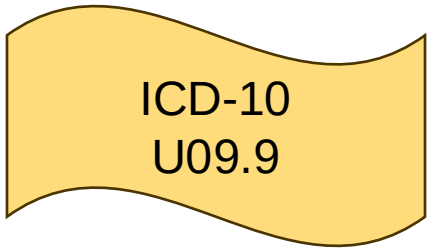
6 Decreased $EO_2$

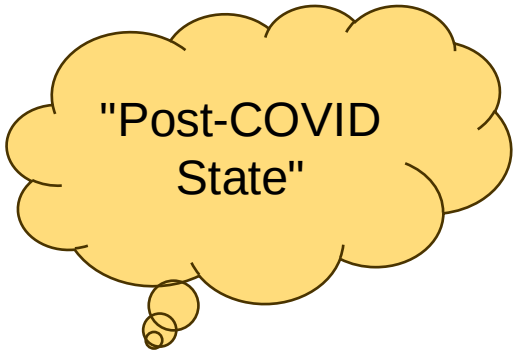
4 Deconditioning

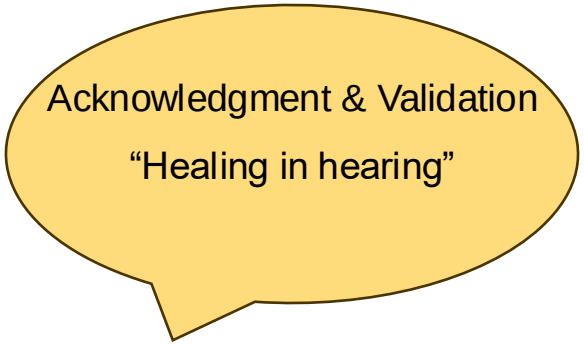
**Other**
1 CTEPD
2 ePH
1 Ventilatory limitation

Risbano MG, Kliment CR, Dunlap DG, Koch C, Campedelli L, Yoney K, Nouraie SM, Sciurba F, Morris A. Invasive cardiopulmonary exercise testing… CHEST Pulmonary. 2023;1(3):100010. https://doi:10.1016/j.chpulm.2023.100010

# Long COVID Clinical Care: Key Takeaways



# Another Case!

# Long COVID Case Study:

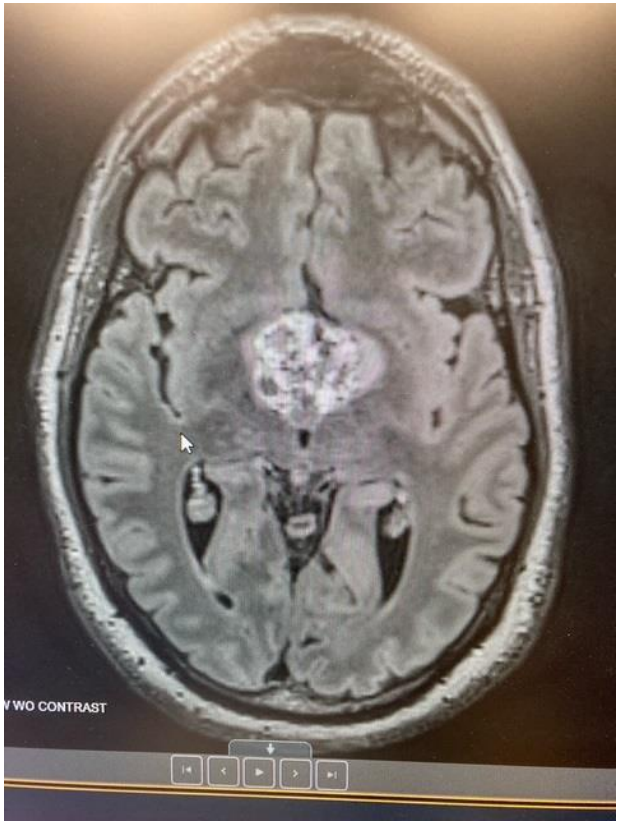
**HPI:** Anthony is 59-year-old man presenting with 2 months post acute COVID.

Patient Described:

- Exhaustion  and profound fatigue
- Dyspnea on Exertion
- Memory issues and atypical mood changes
- Hypersomnolence

6 months later following persistent symptoms a diagnostic test was performed

# #NOT_LONG_COVID (Craniopharyngioma)

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All that “Long-Hauls” is not COVID.

**Avoid anchoring** & keep ddx broad throughout.

# UPMC Long-COVID Initiatives

# UPMC Post-COVID Recovery Clinic

- Established in 2021
- Housed in PACCSM
- >1700 patients seen
- Support group
- Collaborative specialist referral group
- Referrals to (412) 864-0911

Karla Yoney, MPAS, PA-C

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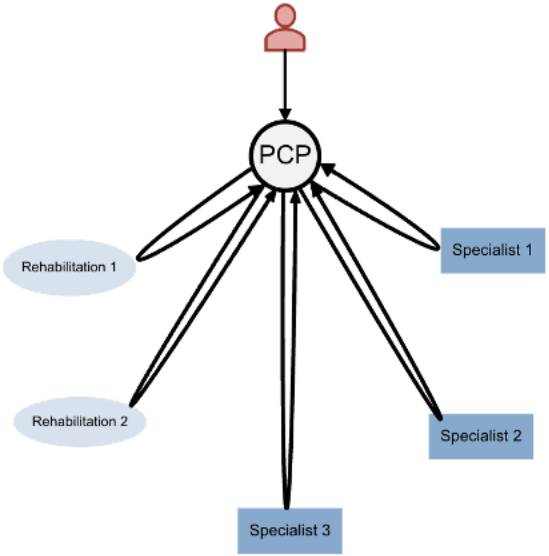
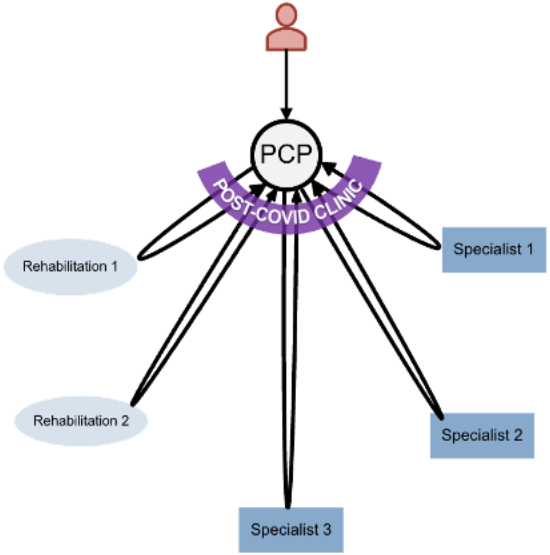
# UPMC Long COVID Clinic Care Model

**STANDARD CARE**




**STANDARD CARE**
**+ POST-COVID CLINIC**

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# IMPACCT

Pitt IMProving Access to Culturally relevant long COVID care and Treatment

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# AHRQ – (Agency for Healthcare Research and Quality) Long COVID Care Network

To expand access to comprehensive, coordinated, and person-centered care for people with Long COVID, particularly underserved, rural, vulnerable, and minority populations that are disproportionately impacted by the effects of Long COVID














# RECOVER Clinical Trial Platforms

•**Autonomic Dysfunction:** dizziness, fast heart rate, shortness of breath, upset stomach, or other changes in body functions that happen automatically
RECOVER-AUTONOMIC Severe POTS (IVIG)
RECOVER-AUTONOMIC Moderate POTS (Ivabradine)

•**Cognitive Dysfunction:** brain fog, trouble thinking clearly, memory changes, slowed attention, and other symptoms related to brain function
RECOVER-NEURO (BrainHQ, PASC-CoRE, & tDCS)

•**Exercise Intolerance and Fatigue:** exhaustion or low energy that interferes with daily activities
•RECOVER-ENERGIZE-Exercise Intolerance (Personalized Exercise Rehab )
•RECOVER-ENERGIZE-Post-Exertional Malaise (Structured Pacing)

•**Sleep Disturbances:** changes in sleep patterns or ability to sleep
•RECOVER SLEEP (Hypersomnia) (Modafinil/Solriamfetol)
•RECOVER SLEEP (Complex Sleep Disturbance) (Melatonin + Light Therapy)

•**Viral Persistence:** when the virus that causes COVID-19 stays in the body and causes damage to organs or the immune system to not function properly
•RECOVER VITAL (PAXLOVID)

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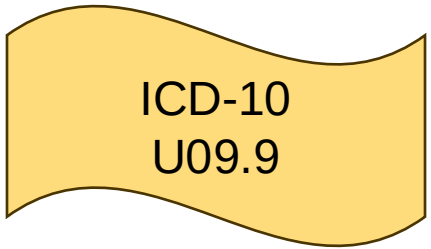
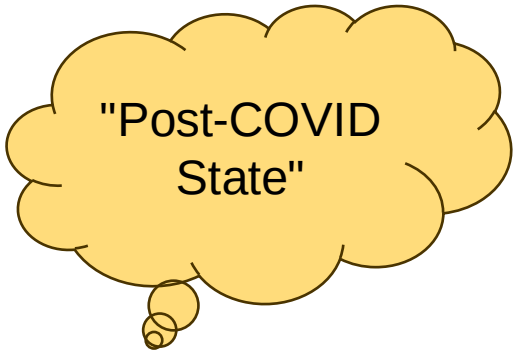
# Long COVID Clinical Care: Key Takeaways




# Acknowledgments


- Alison Morris, MD, MS
  - Co-Director, UPMC Post-COVID Recovery Clinic
  - Division Chief, PACCSM
- Michael Risbano, MD, MA
  - Co-Director, UPMC Post-COVID Recovery Clinic
  - Pulmonary, Allergy, and Critical Care Medicine and Vascular Medicine Institute
- Karla Yoney MPAS, PA-C
  - Senior Advanced Practice Provider, UPMC Post-COVID Recovery Clinic

- Joshua Levenson, MD, FACC
  - Co-Director Noninvasive Cardiology, UPMC Shadyside

**External Contributors**

**ECHO Colorado Long COVID and Fatiguing Illness Recovery Program** University of Colorado School of Medicine
- Dr. Sarah Jolley, MD, MSc
- W. Niehaus, M.D.
- Thida Thant, MD

**AOCPM&R Long COVID: An overview for clinicians**
American Osteopathic College of Physical Medicine and Rehabilitation (AOCPM&R)
- Abby Cheng, MD, MPHS
  - Wash U Medicine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3.7.2025

# GLP-1s

## There’s a ton with GLP-1

**Nicole Likar, PharmD, BCPS**

**Sarah Winter, PharmD, BCACP**

AHN

# Disclosure

No Disclosures

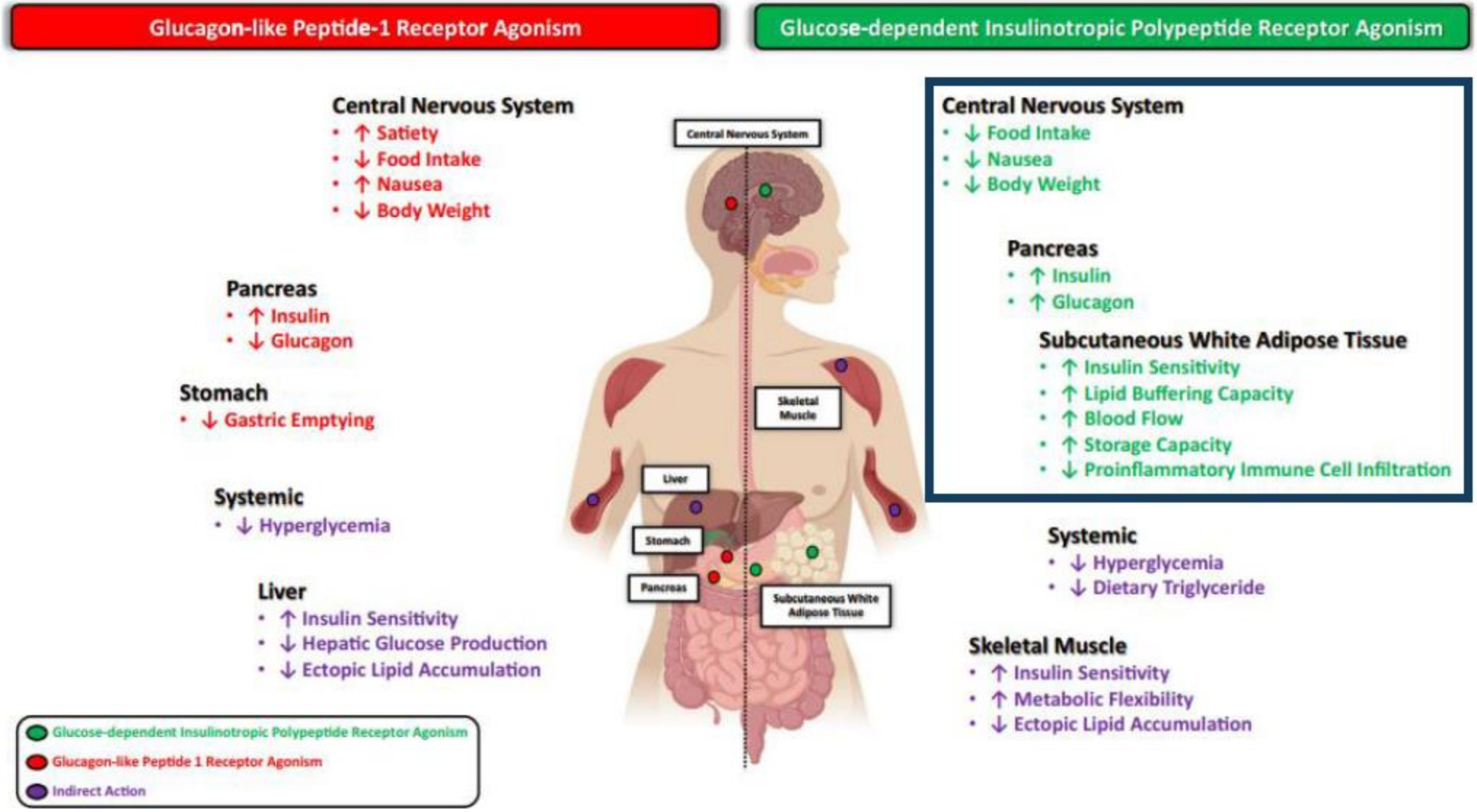
# Objectives

- Outline the indications for GLP-1/GIP agents
- Review dosing, side effects, contraindications
- Discuss the data and outcomes for obesity and diabetes
- Apply information to patient case



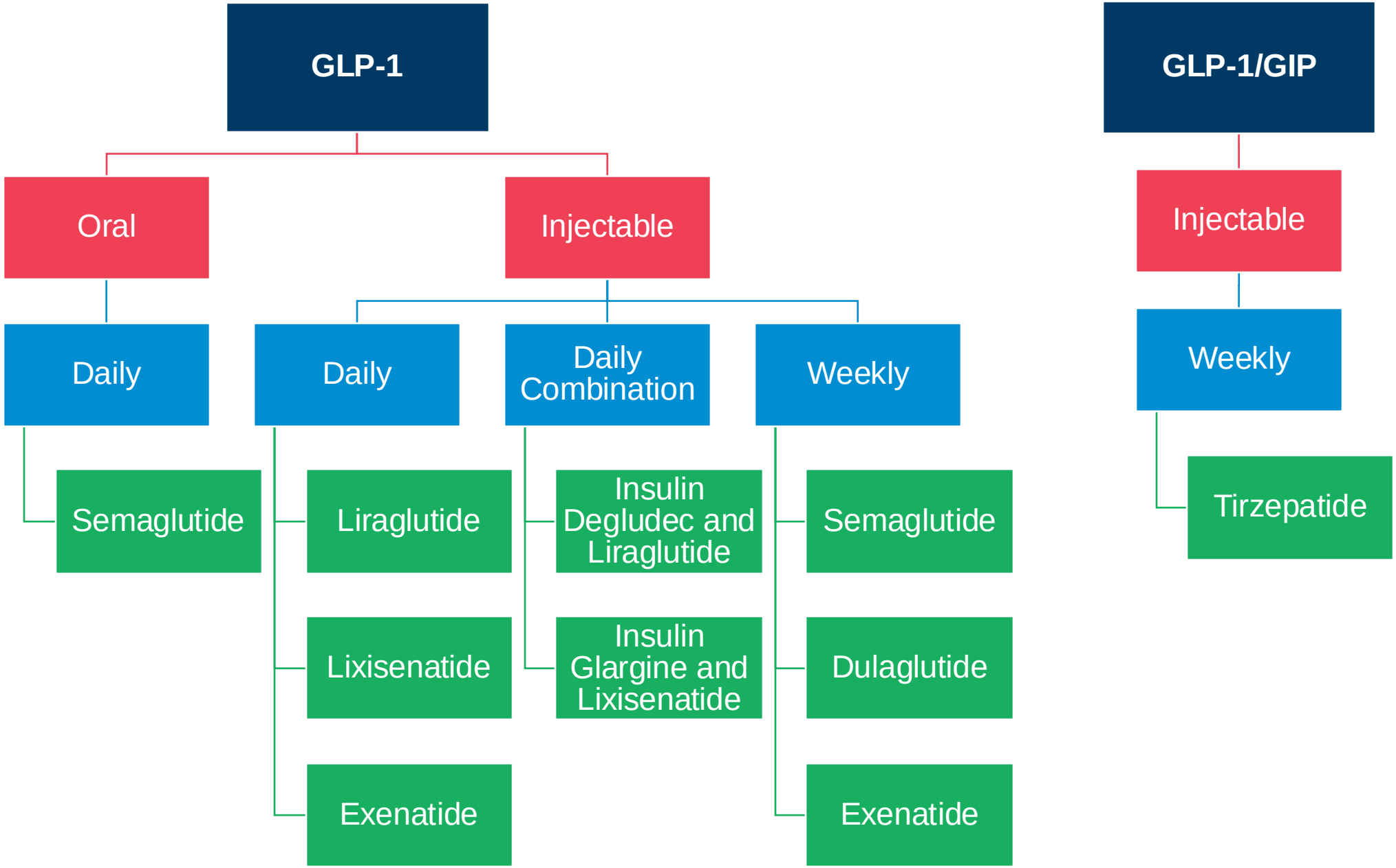
*GLP-1: Glucagon-Like Peptide-1 Receptor Agonist, GIP: Glucose-dependent Insulinotropic Polypeptide Agonist*

# GLP-1 Mechanism




*Trends Endocrinol Metab.* 2020;31(6):410-421.

# GLP-1/GIP Agents



# GLP-1/GIP Medications and Indications

| Medication | Diabetes | Obesity | Cardiovascular Risk Reduction | OSA |
|---|---|---|---|---|
| Liraglutide | Victoza | Saxenda | -- | -- |
| Semaglutide | Ozempic (SC) | Wegovy | Wegovy | -- |
| | Rybelsus (oral) | -- | -- | -- |
| Dulaglutide | Trulicity | -- | -- | -- |
| Tirzepatide | Mounjaro | Zepbound | -- | Zepbound |



*Lexicomp Accessed 25 Feb 2025.*

# GLP-1/GIP Dosing Per Indication

| Medication | Diabetes | Obesity | Cardiovascular Risk Reduction |
|---|---|---|---|
| Liraglutide | **Victoza**<br>Initial dose 0.6mg daily, titrate weekly by 0.6mg*, max dose 1.8mg daily | **Saxenda**<br>Initial dose 0.6mg daily, titrate weekly by 0.6mg*, max dose 3mg daily | -- |
| Semaglutide | **Ozempic** (SC)<br>Initial dose 0.25mg daily, titrate monthly<br>0.25mg*, 0.5mg, 1mg, 2mg (max)<br><br>**Rybelsus** (oral)<br>Initial 3mg daily, titrate monthly – 3mg*, 7mg, 14mg (max) | **Wegovy**<br>Initial dose 0.25mg daily, titrate monthly<br>0.25mg*, 0.5mg, 1mg, 1.7mg 2.4mg (max) | |
| * Doses not intended to be maintenance doses | | | |

*Lexicomp Accessed 25 Feb 2025.*

# GLP-1/GIP Dosing Per Indication

| Medication | Diabetes | Obesity | OSA |
|---|---|---|---|
| Dulaglutide | **Trulicity**<br>Initial 0.75mg weekly, titrate monthly, 0.75mg, 1.5mg, 3mg, 4.5mg | -- | -- |
| Tirzepatide | **Mounjaro and Zepbound**<br>Initial 2.5mg weekly, titrate monthly, 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, 15mg<br>• 2.5mg dose not intended to be maintenance for diabetes and obesity<br>• Doses <10mg not intended to be maintenance for OSA | | |

*Lexicomp Accessed 25 Feb 2025.*

# GLP-1/GIP Agent Considerations

**Contraindications:**
- Personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2
- Serious hypersensitivity reaction to the medication or any excipients

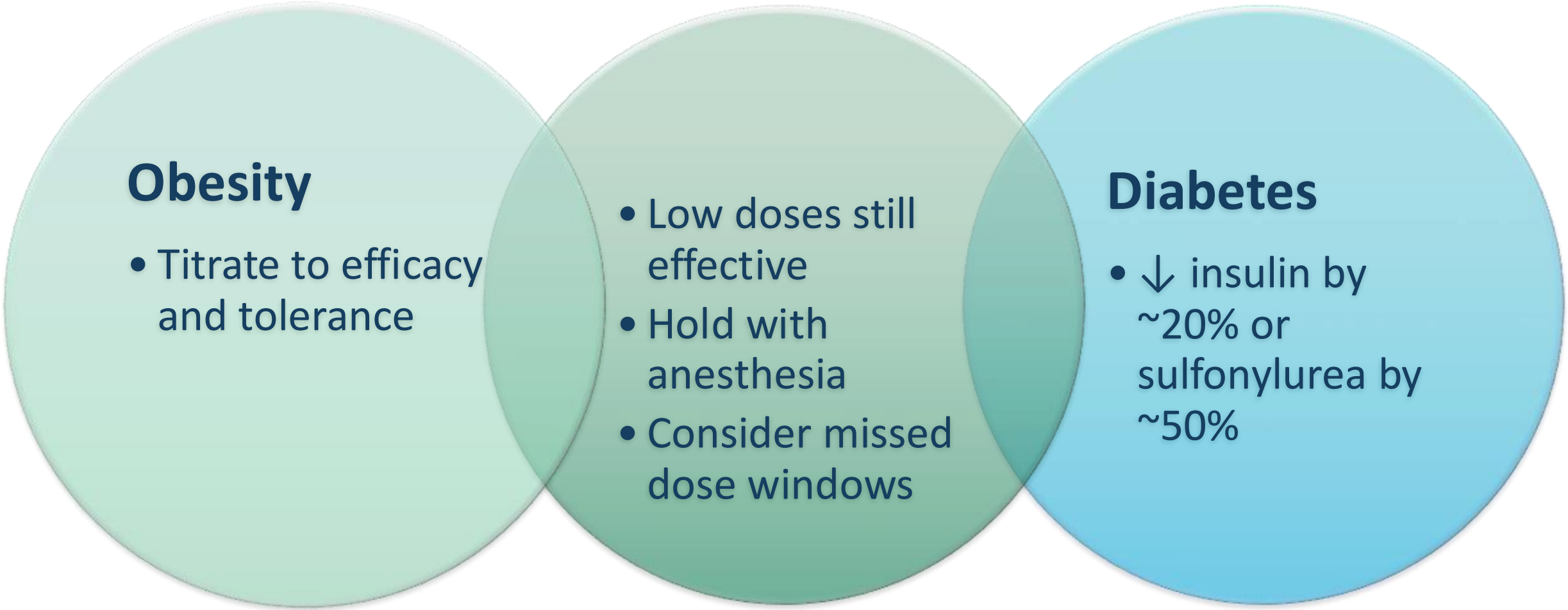
**Warnings:**
- Pancreatitis
- Diabetic Retinopathy complications
- Concomitant use with an insulin secretagogue or insulin may increase the risk of hypoglycemia
- Acute Kidney Injury
- Acute Gallbladder disease
- Drug Absorption– oral contraception (tirzepatide)

**Side Effects:**
- Nausea, vomiting, diarrhea, abdominal pain and constipation



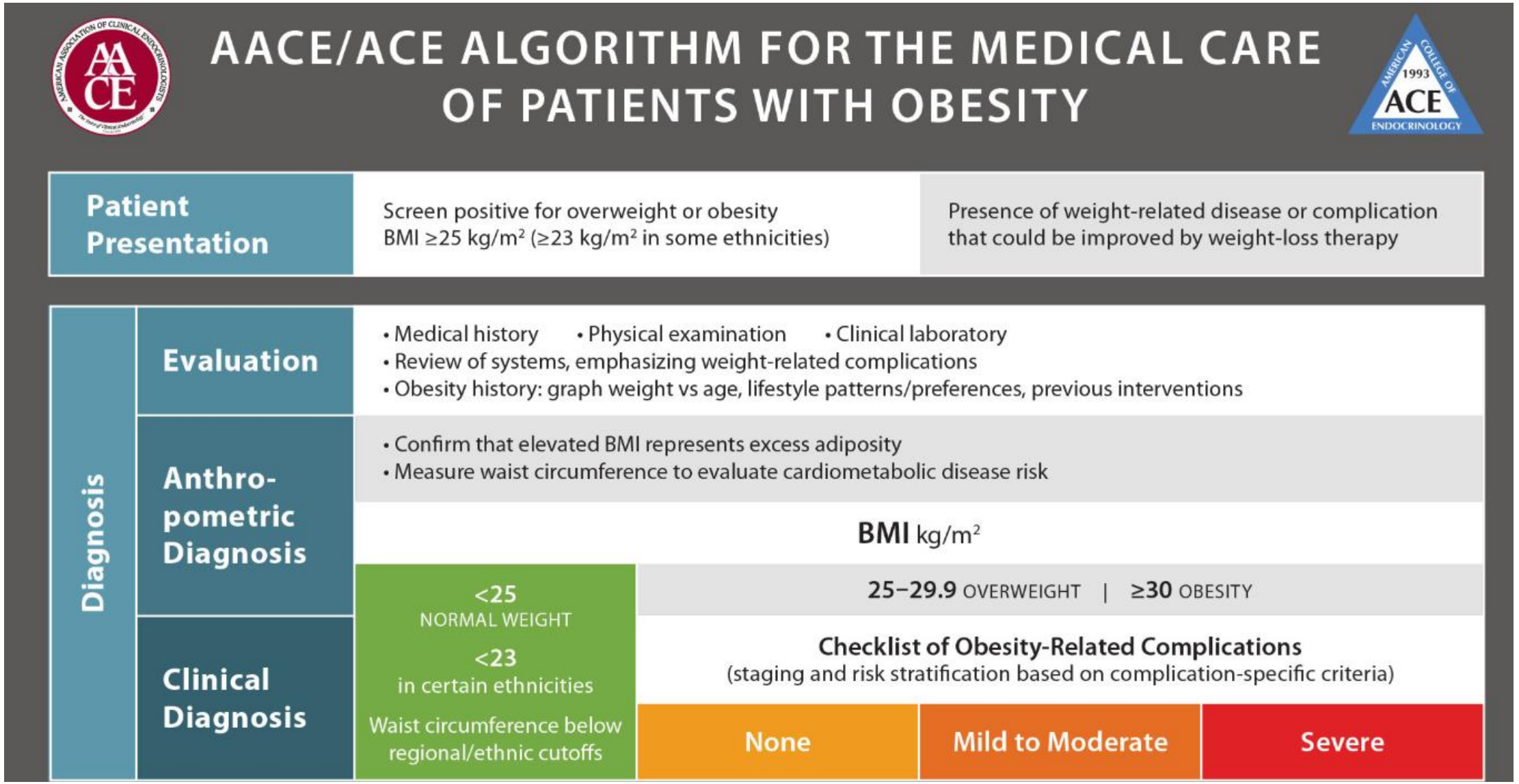
*Diabetes Care. December 2024, Vol.48, S181-S206*

# GLP-1/GIP Agents – Clinical Pearls



# Obesity Data

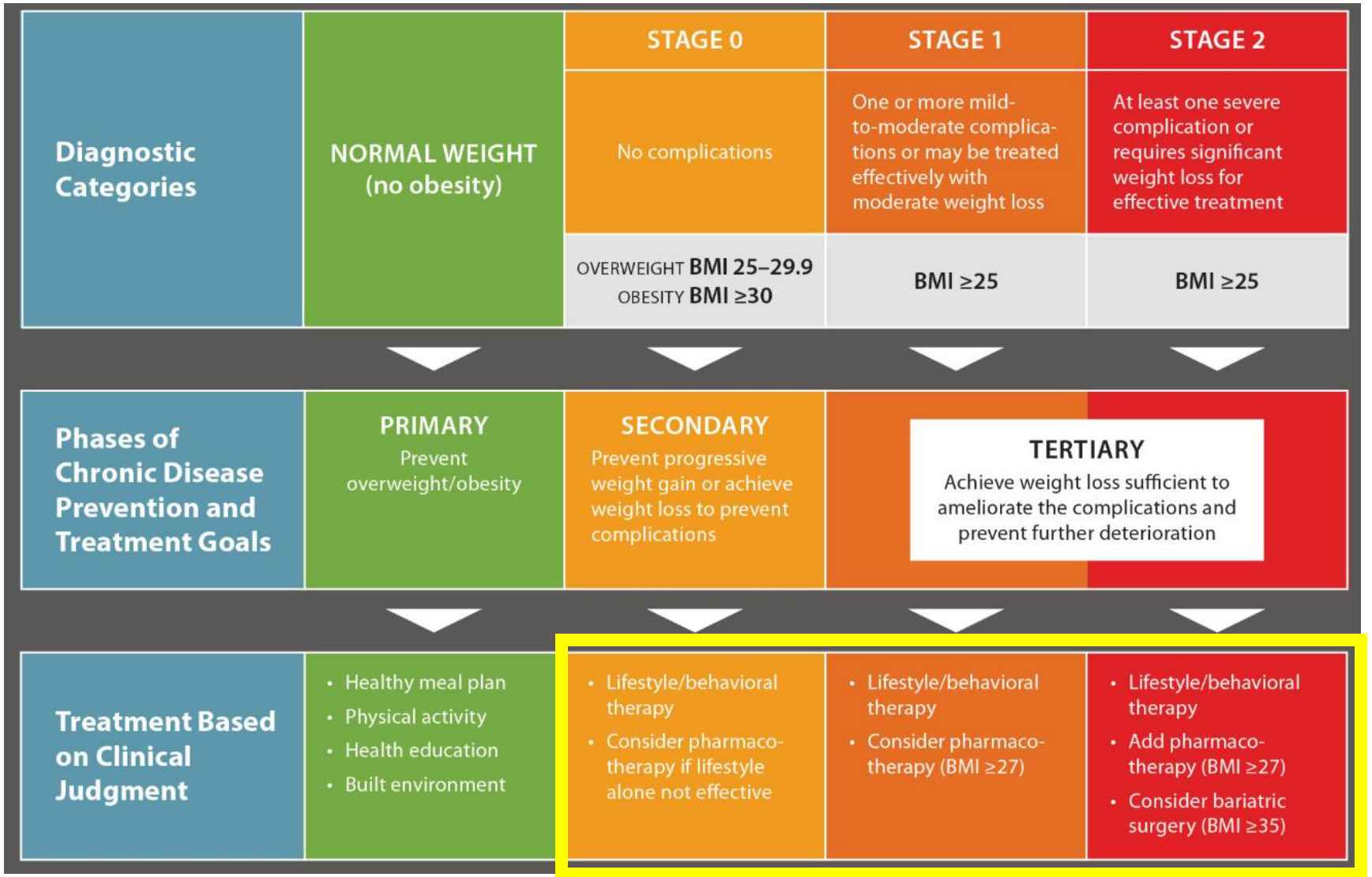
# Guidelines – American Association of Clinical Endocrinology 2016






*AACE/ACE Obesity CPG, Endocr Pract.2016;22(Suppl 3)*

# Guidelines – AACE 2016






*AACE/ACE Obesity CPG, Endocr Pract.2016;22(Suppl 3)*

# Guidelines – AACE 2016


In need of updated guidelines

No longer on the market

Only GLP-1 included



*AACE/ACE Obesity CPG, Endocr Pract.2016;22(Suppl 3)*

# Guidelines – AACE 2016

## GLP-1 preferred

- Diabetes
- Prediabetes
- Metabolic Syndrome
- Hypertension
- Chronic Kidney Disease
- Nephrolithiasis
- Depression
- Anxiety
- Seizure
- Opioid use
- Women of Reproductive Potential
- Age >/=65
- Alcoholism
- Post-bariatric surgery

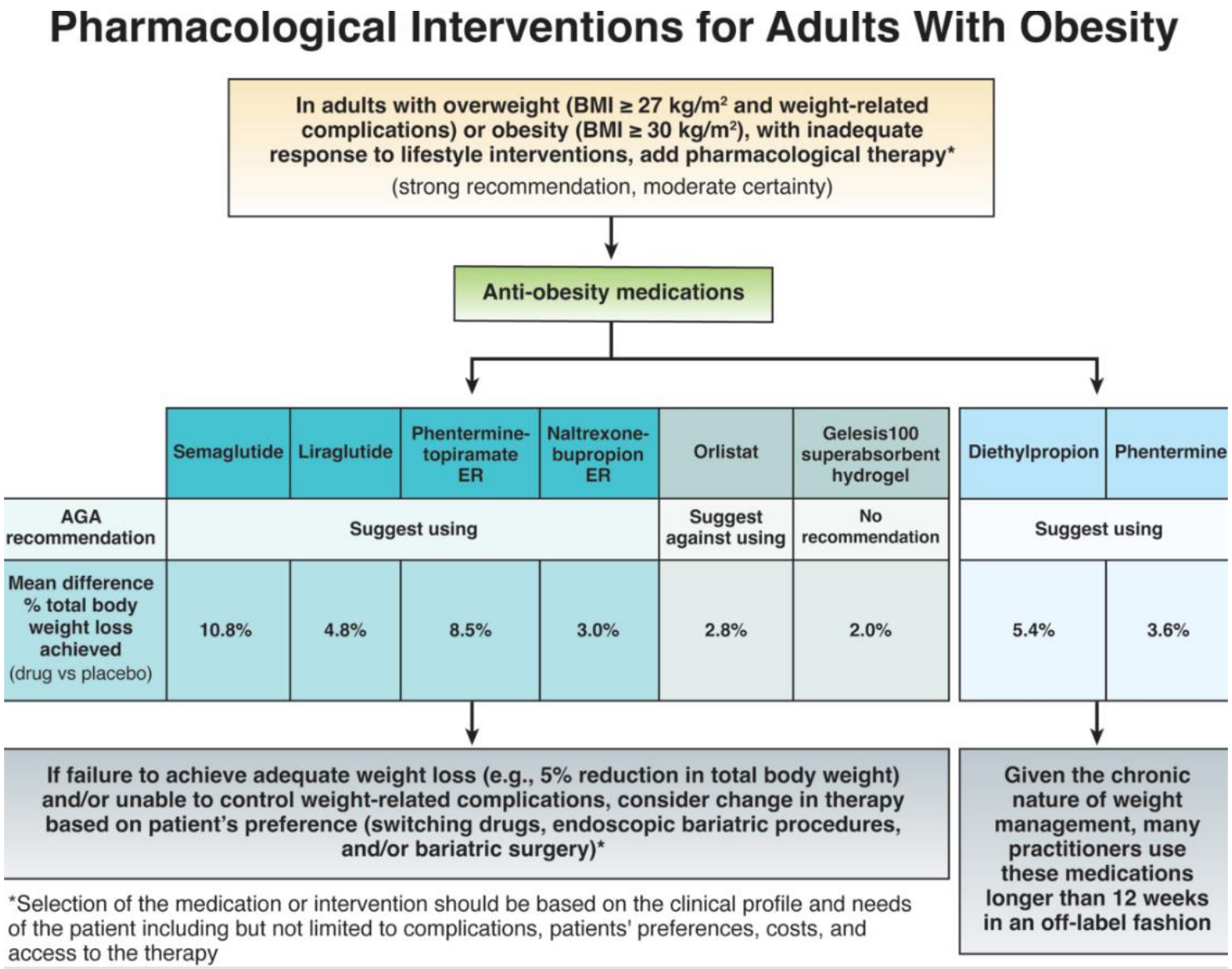
## GLP-1 not preferred

- Pancreatitis
- CHF *
- Severe Hepatic impairment *
- Breastfeeding *

* No preferred agent for the treatment of obesity

*AACE/ACE Obesity CPG, Endocr Pract.2016;22(Suppl 3)*

# Guidelines – American Gastroenterological Association 2022




"Given the magnitude of net benefit, semaglutide 2.4mg may be prioritized over other approved anti-obesity medications"



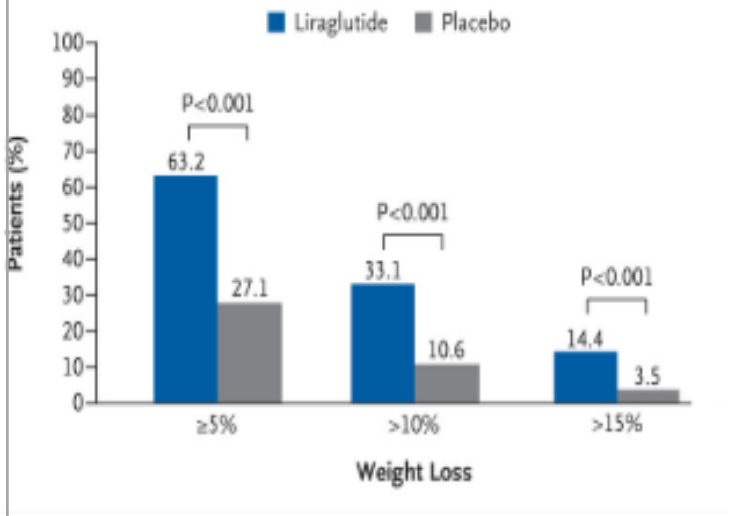
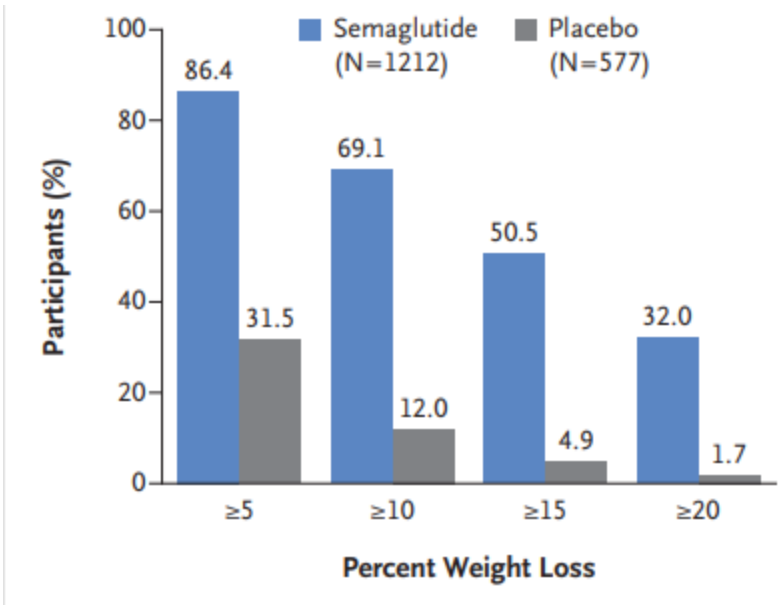
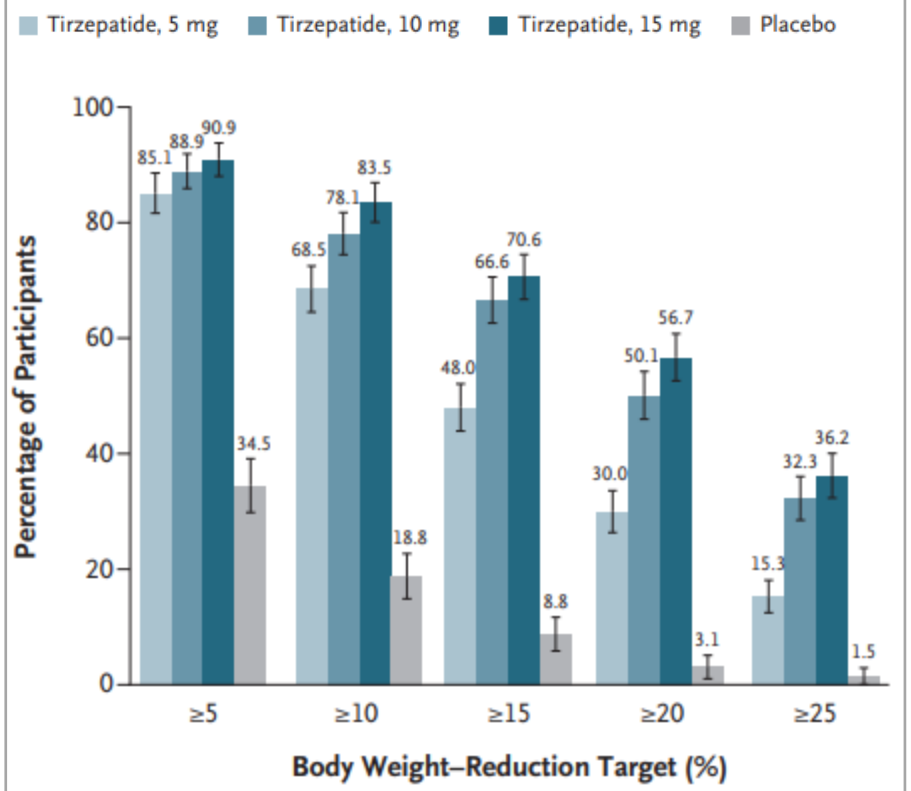
*AGA 2022 November Volume 163, Issue 5, P1198-1225*

# Weight Loss Summary

| Drug | Pertinent Trials | Evidence |
|---|---|---|
| Liraglutide (Saxenda®) | SCALE Trials | • **8%** difference in mean weight loss of 3mg compared to placebo<br>• ≥ 5% of baseline body weight lost was 44 to 62% at 56 weeks. |
| Semaglutide (Wegovy ®) | STEP Trials | • **14.85%** difference in mean weight of 2.4mg compared to placebo<br>• ≥ 5% of baseline body weight lost was 67 to 85% at 52 weeks. |
| Tirzepatide (Zepbound®) | SURMOUNT Trials | • **20.9%** difference in mean weight of 15mg compared to placebo<br>• ≥ 5% of baseline body weight lost was 85 to 91% at 72 weeks. |

*N Engl J Med 2015;373:11-22*
*N Engl J Med 2021;384:989-1002.*
*N Engl J Med 2022;387:205-16.*

# Weight Loss Summary

| Liraglutide | Semaglutide | Tirzepatide |
|---|---|---|
|  |  |  |



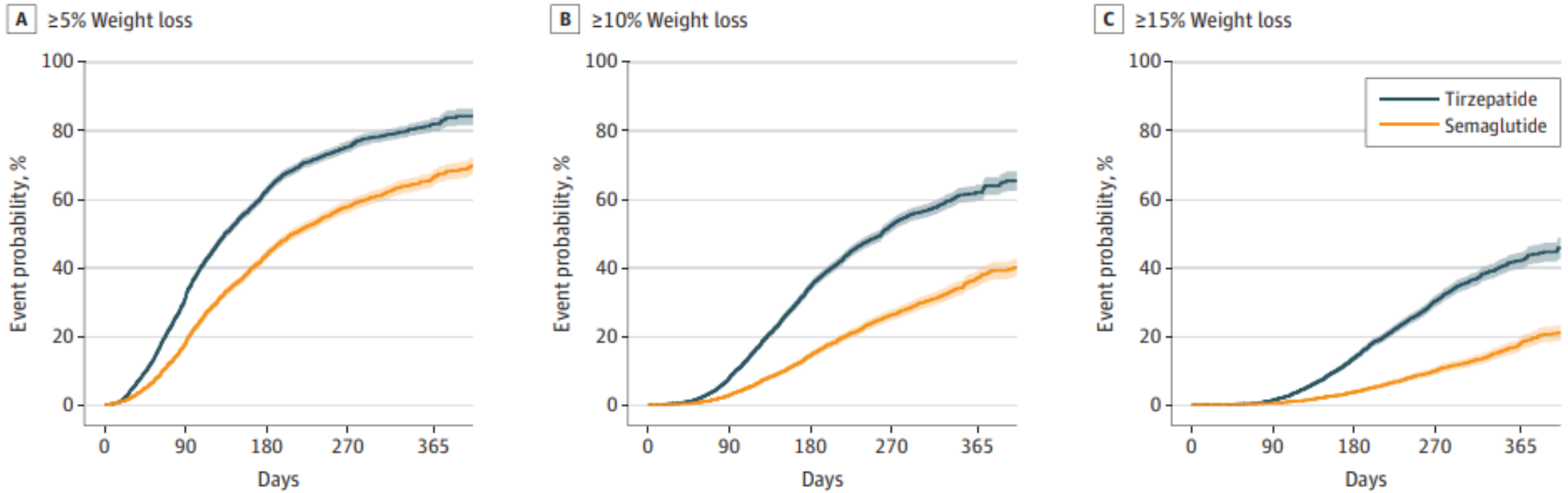




*N Engl J Med 2015;373:11-22*
*N Engl J Med 2021;384:989-1002.*
*N Engl J Med 2022;387:205-16.*

# Head to Head - Semaglutide vs Tirzepatide

**Figure 2. Event Probabilities for 5% or Greater, 10% or Greater, and 15% or Greater Weight Reduction Among Propensity-Score Matched Patients on Treatment**






*JAMA Intern Med. 2024;184(9):1056-1064.*

# Weight Changes with Discontinuation

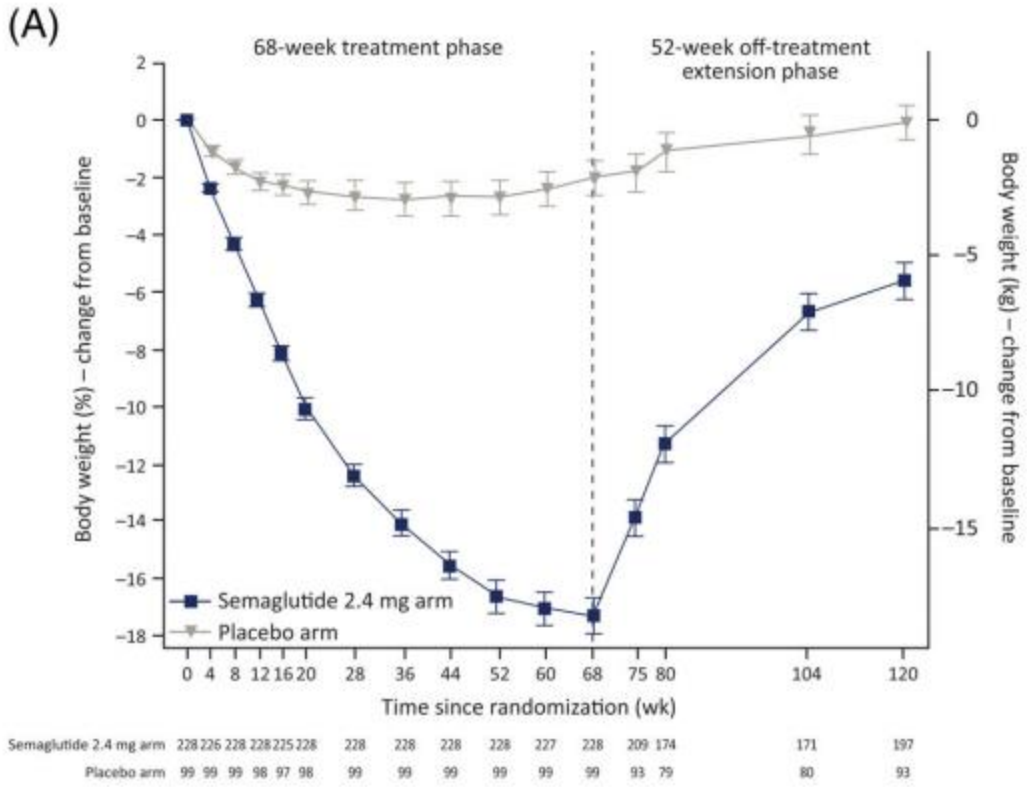
| Drug | Pertinent Trials | Evidence |
|---|---|---|
| Semaglutide (Wegovy ®) | STEP-1 Extension N=327 | • Semaglutide and placebo participants regained 11.6% of lost weight, respectively, by week 120<br>• Net losses of 5.6% from week 0 to week 120<br>• Cardiometabolic improvements seen from week 0 to week 68 with semaglutide reverted towards baseline at week 120 for most variables |

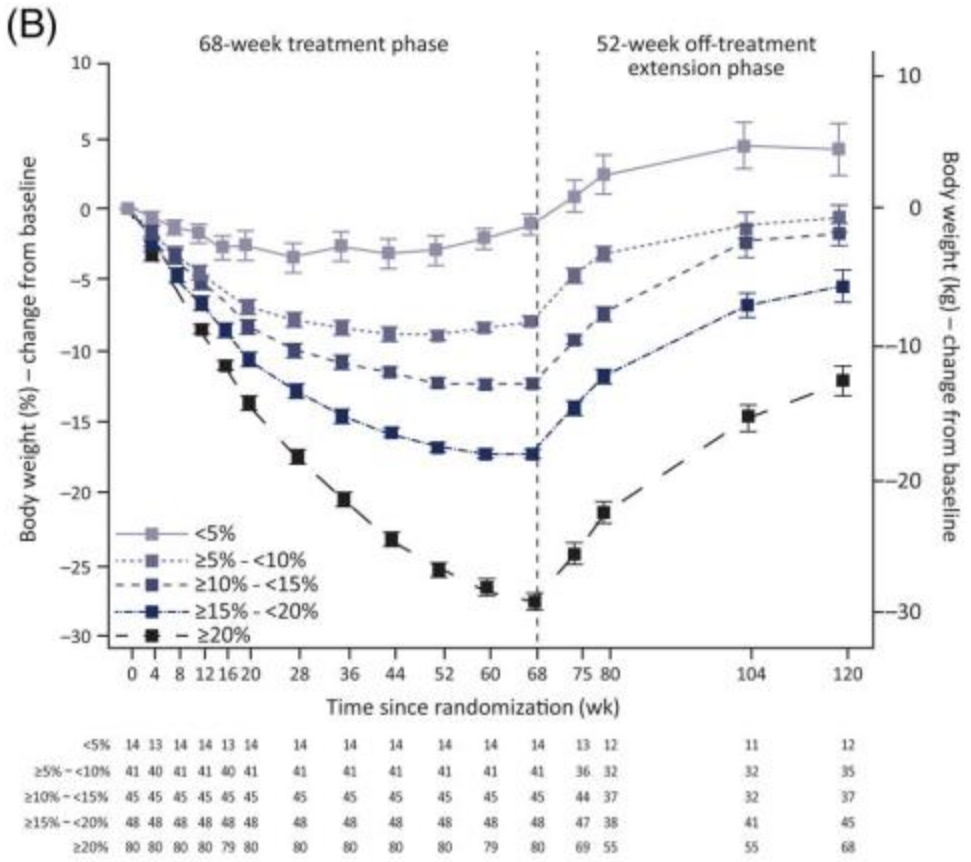


*Diabetes Obes Metab. 2022;24:1553–1564*

# Weight Changes with Discontinuation

Step 1 Trial Extension with Semaglutide




Findings suggest ongoing treatment is required to maintain improvements in weight and health



*Diabetes Obes Metab. 2022;24:1553–1564*

# Weight Changes with Discontinuation

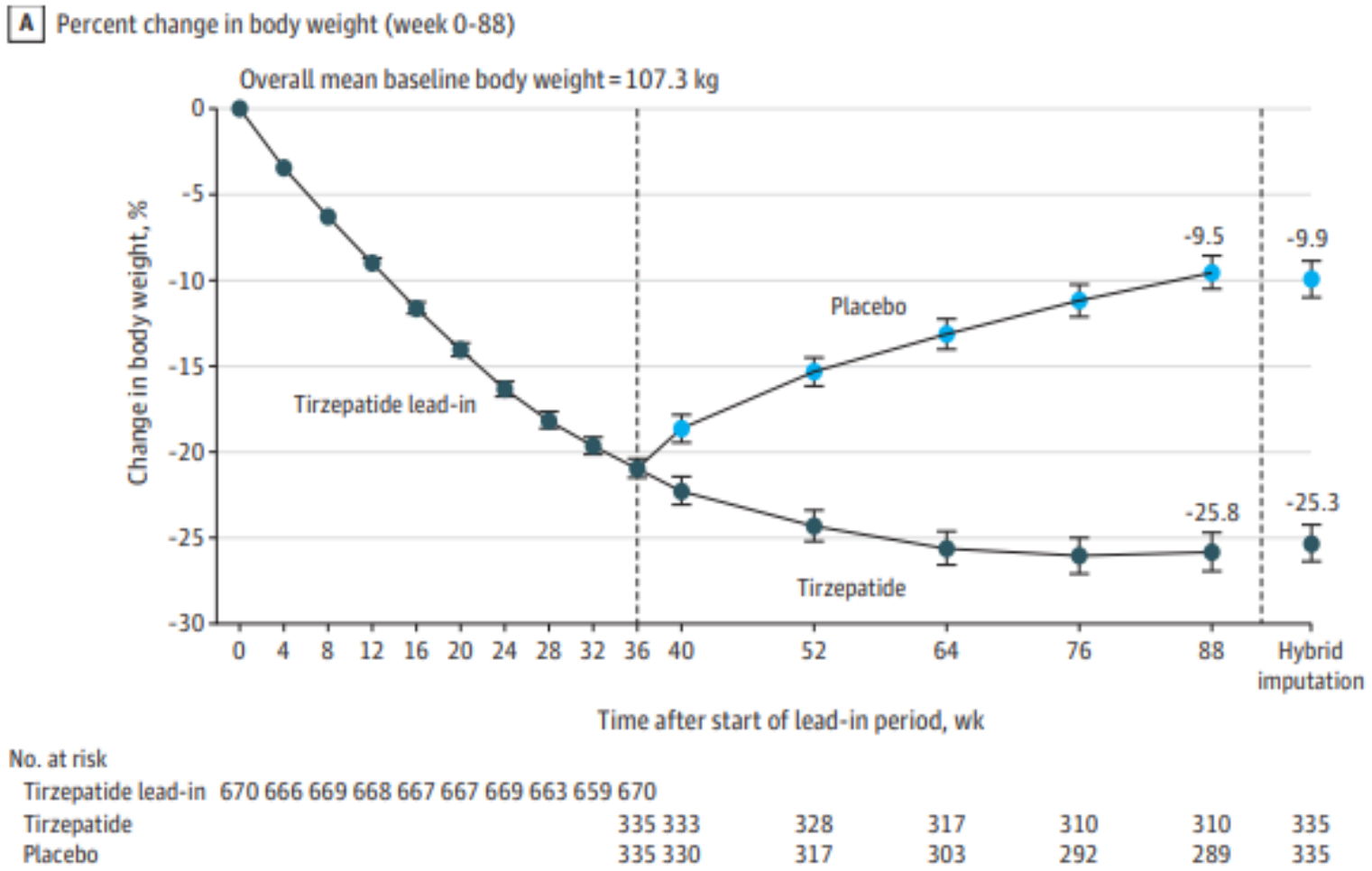
| Drug | Trial N=670 | Evidence |
|---|---|---|
| Tirzepatide (Zepbound ®) | • Open-label lead-in period received tirzepatide for 36 weeks<br>• Participants were randomized (1:1) to continue tirzepatide or switch to placebo for 52 weeks. | • The mean percent weight change from week 36 to week 88 was −5.5% with tirzepatide vs 14.0% with placebo<br>• The overall mean weight reduction from week 0 to 88 was 25.3% for tirzepatide and 9.9% for placebo |



*JAMA. 2024;331(1):38-48.*

# Weight Changes with Discontinuation

**Figure 2. Effect of Tirzepatide vs Placebo on Body Weight and Waist Circumference**






*JAMA. 2024;331(1):38-48.*

# Back to the Guidelines – Duration of Therapy

**AACE**

- Available data support the need for **long-term** use of weight-loss medications in appropriate patients
- High quality clinical trials from 1-4 years
- Optimal duration of therapy is unknown

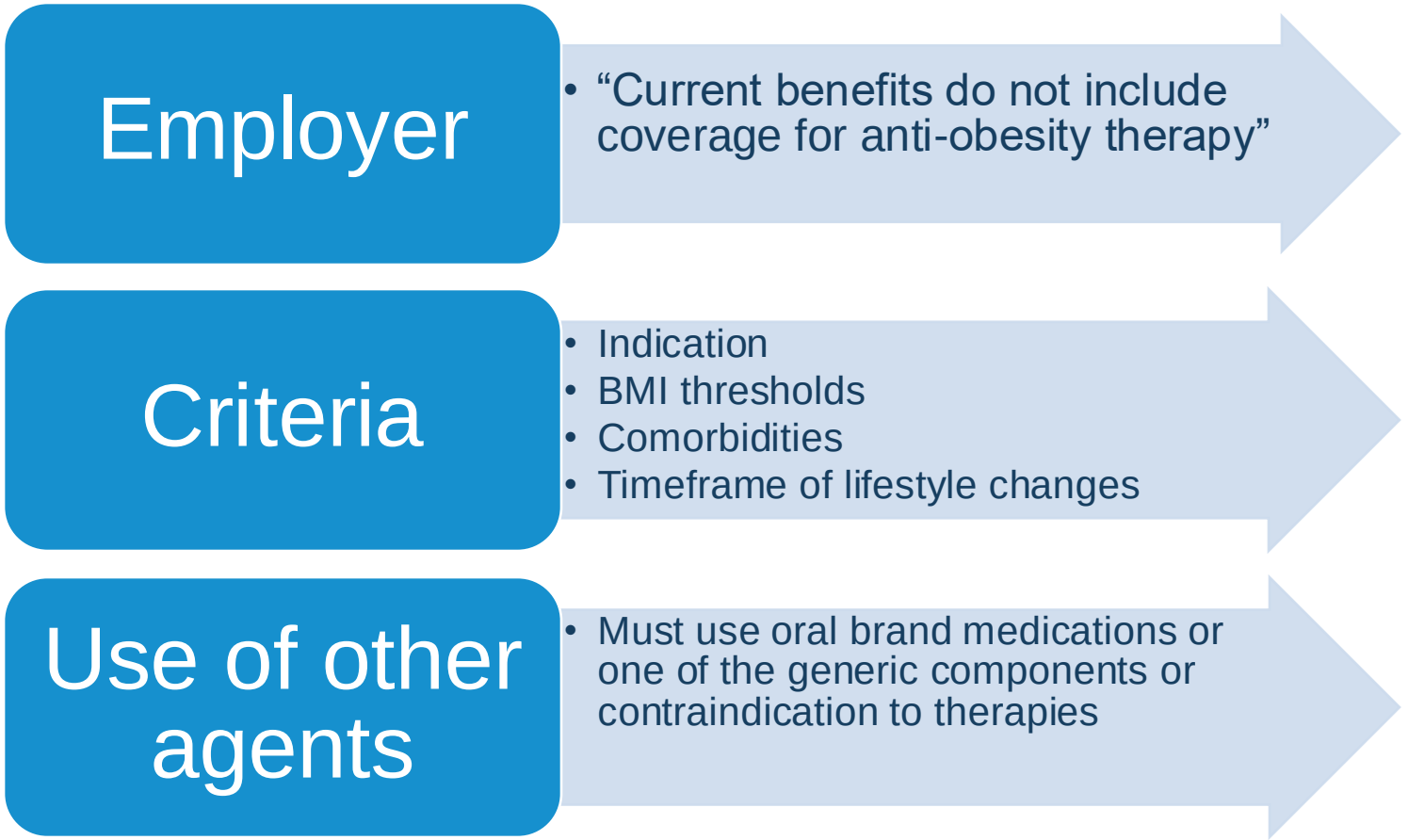
**AGA**

- In adults with overweight and obesity who have an inadequate response to lifestyle interventions along, **long-term** pharmacological therapy is recommended, with multiple effective and safe treatment options

*AACE/ACE Obesity CPG, Endocr Pract.2016;22(Suppl 3)*
*AGA 2022 November Volume 163, Issue 5, P1198-1225*

# Coverage Confusion

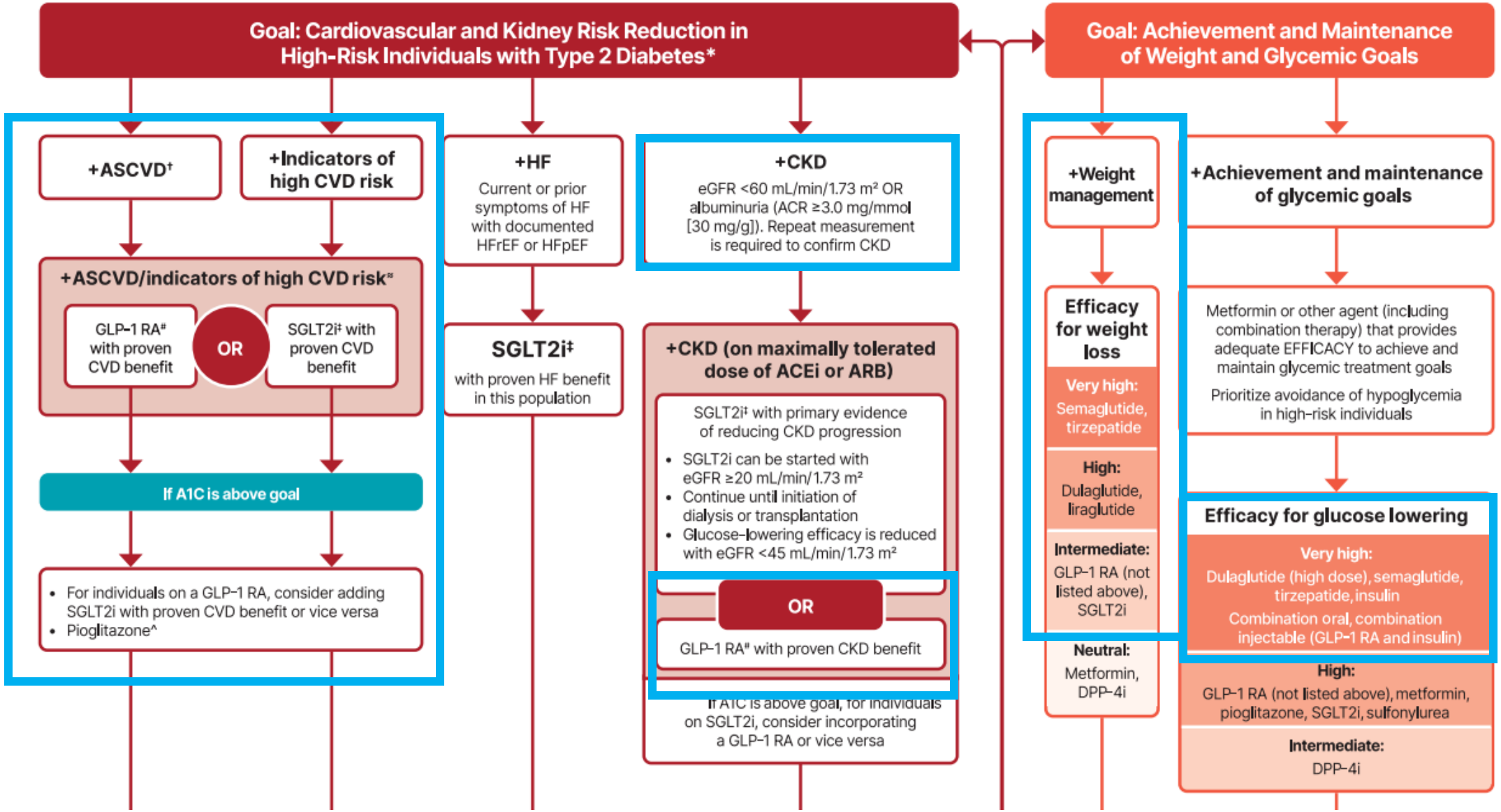
Reasons for denials can differ between patients and insurance companies




Key to Success –Documentation!

# Diabetes Data

# Guidelines – American Diabetes Association (ADA) Standards of Care in Diabetes 2025






*Diabetes Care.* December 2024, Vol.48, S181-S206.

# GLP-1/GIP Agents Role In Therapy

**Established or High Risk of ASCVD, HF and/ or CKD**

- Should include agent(s) that **reduce cardiovascular and kidney disease risk** (e.g. SGLT2 and/or GLP-1) for glycemic management and comprehensive cardiovascular risk reduction
- **Independent of A1c and in consideration of patient-specific factors**. A

**CKD**

- CKD (with confirmed eGFR of 20–60 mL/min/1.73 $m^2$ and/or albuminuria)
- To reduce cardiovascular risk and kidney disease progression, a **GLP-1 with demonstrated benefit in this population** is recommended. A

**Advanced CKD**

- eGFR < 30 mL/min/1.73 $m^2$
- **GLP-1 is preferred** for glycemic management due to lower risk of hypoglycemia and for cardiovascular event reduction. B

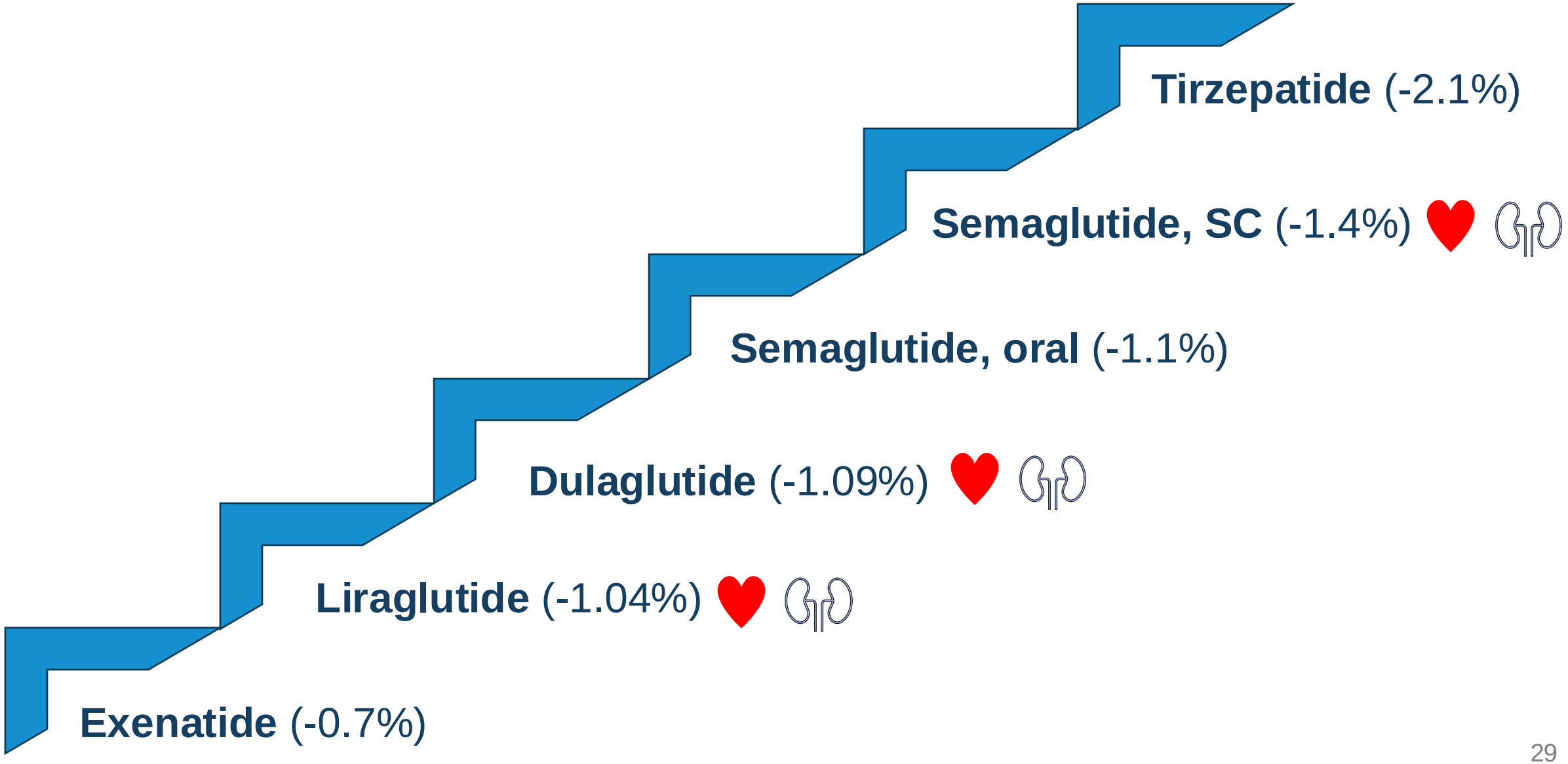
**Weight and/or A1c ≥ 1.5% above goal**

- **GLP-1/GIP agent preferred to insulin, when possible**. A
- If used with insulin, combination with GLP-1/GIP agent is recommended for greater glycemic effectiveness as well as **beneficial effects on weight and hypoglycemia risk**. A



*Diabetes Care. December 2024, Vol.48, S181-S206.*

# GLP-1/GIP Agents A1c Reduction and Benefits






*Clinical Resource. Comparison of GLP-1 Agonists. Pharmacist's Letter/Pharmacy Technician's Letter/Prescriber Insights. August 2024.*

# GLP-1/GIP Agent Dose Comparison

**TABLE 4** GLP-1 Receptor Agonist Drug Shortages and Suggested Comparative Doses for Treating Type 2 Diabetes

| Agent | Dosing Route and Interval | Comparative Doses | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Exenatide | SC twice daily | 5 μg* | 10 μg | | | | | | | |
| Lixisenatide | SC once daily | 10 μg* | 20 μg | | | | | | | |
| Liraglutide | SC once daily | 0.6 mg* | 1.2 mg | 1.8 mg | | | | | | |
| Exenatide XR | SC once weekly | | | 2 mg | | | | | | |
| Dulaglutide | SC once weekly | | 0.75 mg[a]* | 1.5 mg[a] | 3 mg[b]† | 4.5 mg[b]† | | | | |
| Semaglutide | SC once weekly | | 0.25 mg[b]* | 0.5 mg[b] | | 1 mg[a] | 2 mg[a]‡ | | | |
| Semaglutide | PO once daily | 3 mg* | 7 mg | 14 mg | | | | | | |
| Tirzepatide | SC once weekly | | | 2.5 mg[a]* | | | 5 mg[a]‡ | 7.5 mg[a] | 10 mg[a] | 12.5 mg[a] | 15 mg[a] |

According to the FDA's drug shortage database as of 10 March 2023 (2), patients may have limited or intermittent access in community pharmacies to three agents in varying doses: dulaglutide, injectable semaglutide, and tirzepatide. [a]Drug doses that are currently in short supply but still available. [b]Drug doses with only limited or intermittent availability. *Comparative efficacy of starting doses is not known and based on the clinical judgement of authors. †Based on information from ref. 33. ‡Based on information from ref. 35. PO, by mouth; SC, subcutaneous.



*Clin Diabetes* 2023;41(3):467–473

# Cardiovascular Benefits Summary

- FDA Approved Indication for Major Cardiovascular Events (MACE):
    - Liraglutide, Dulaglutide, Semaglutide (SC)
- 3-point MACE: stroke, nonfatal MI, CV death

| Drug | Trial | Population | Primary composite CV Outcome HR (95% CI) | P-value | NNT |
|---|---|---|---|---|---|
| Liraglutide (Victoza®) | LEADER | CVD or CV risk | 0.87 (0.78 to 0.97) | 0.01 | 53 |
| Dulaglutide (Trulicity®) | REWIND | CVD or CV risk | 0.88 (0.79 to 0.99) | 0.026 | 71 |
| Semaglutide (Ozempic®) | SUSTAIN-6 | CVD, CV risk, or CKD | 0.74 (0.58 to 0.95) | 0.02 | 44 |

*N Engl J Med.* 2016;375:311–322.
*Lancet.* 2019;394:121–130.
*N Engl J Med.* 2016;375:1834–1844.

# Kidney Benefits Summary

| Drug | Trial | Secondary End Points | Secondary Outcome HR (95% CI) | P-value | NNT |
|---|---|---|---|---|---|
| Liraglutide (Victoza®) | LEADER | New macroalbuminuria or doubling of Scr + eGFR ≤ 45 mL/min, dialysis/transplant or death from kidney causes | 0.78 (0.67–0.92) | 0.003 | 83 |
| Dulaglutide (Trulicity®) | REWIND | New macroalbuminuria, 30% decrease in eGFR, or dialysis/transplant | 0.85 (0.77-0.93) | 0.0004 | 40 |
| Semaglutide (Ozempic®) | SUSTAIN-6 | New macroalbuminuria or doubling of Scr + eGFR ≤ 45 mL/min, dialysis/transplant or death from kidney causes | 0.64 (0.46–0.88) | 0.005 | 44 |

*N Engl J Med.* 2016;375:311–322.
*Lancet.* 2019;394:121–130.
*N Engl J Med.* 2016;375:1834–1844.

# FLOW Trial

***Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes*** *(Evaluate Renal Function with Semaglutide Once Weekly)*

**Inclusion Criteria:**

- A1c ≤10%
- High risk CKD (eGFR 50-75 mL/min/1.73m$^2$ and ACR >300 and <5000 mg/g, OR eGFR 25 - <50 mL/min/1.73m$^2$ and ACR >100 and <5000 mg/g)
- Maximal tolerated dose of ACE/ARB

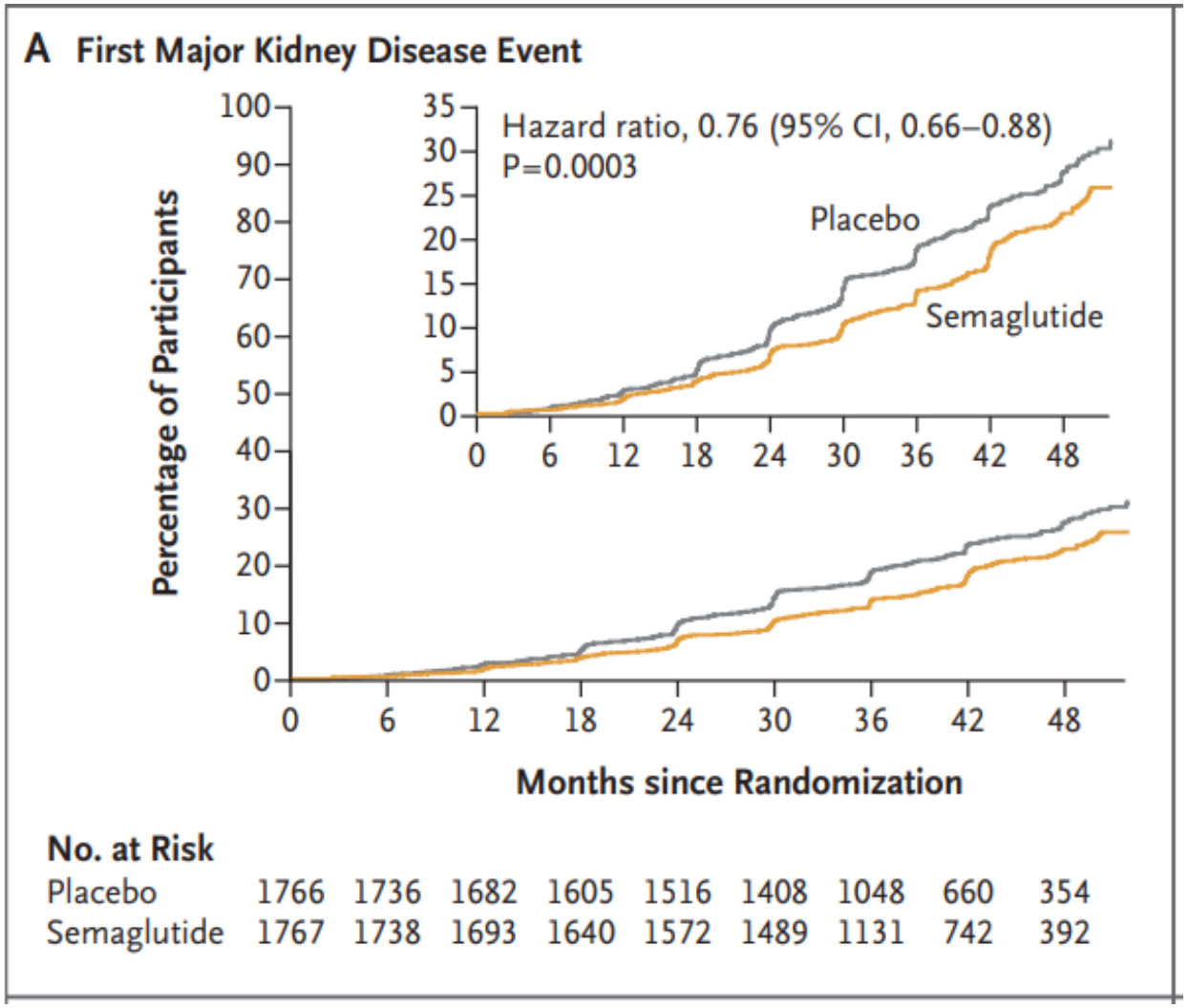
**Intervention:** semaglutide 1 mg weekly vs placebo

**Primary Outcome:** composite of kidney failure, ≥ 50% reduction in eGFR, kidney or CV death

ACR: urinary albumin-to-creatinine ratio

*N Engl J Med* 2024;391:109-121.

# FLOW Trial




N= 3,533 and median follow-up of 3.4 years

**Major Kidney Disease Events: HR 0.76 (95% CI, 0.66 to 0.88)**

Composite of Kidney-Specific Outcomes: HR 0.79 (95% CI, 0.66 to 0.94)

≥50% Reduction in eGFR: HR 0.73 (95% CI, 0.59 to 0.89)

Death from Kidney-Related Causes: 0.97 (95% CI, 0.27 to 3.49)

Death from CV Causes: 0.71 (95% CI, 0.56 to 0.89)



*N Engl J Med* 2024;391:109-121.

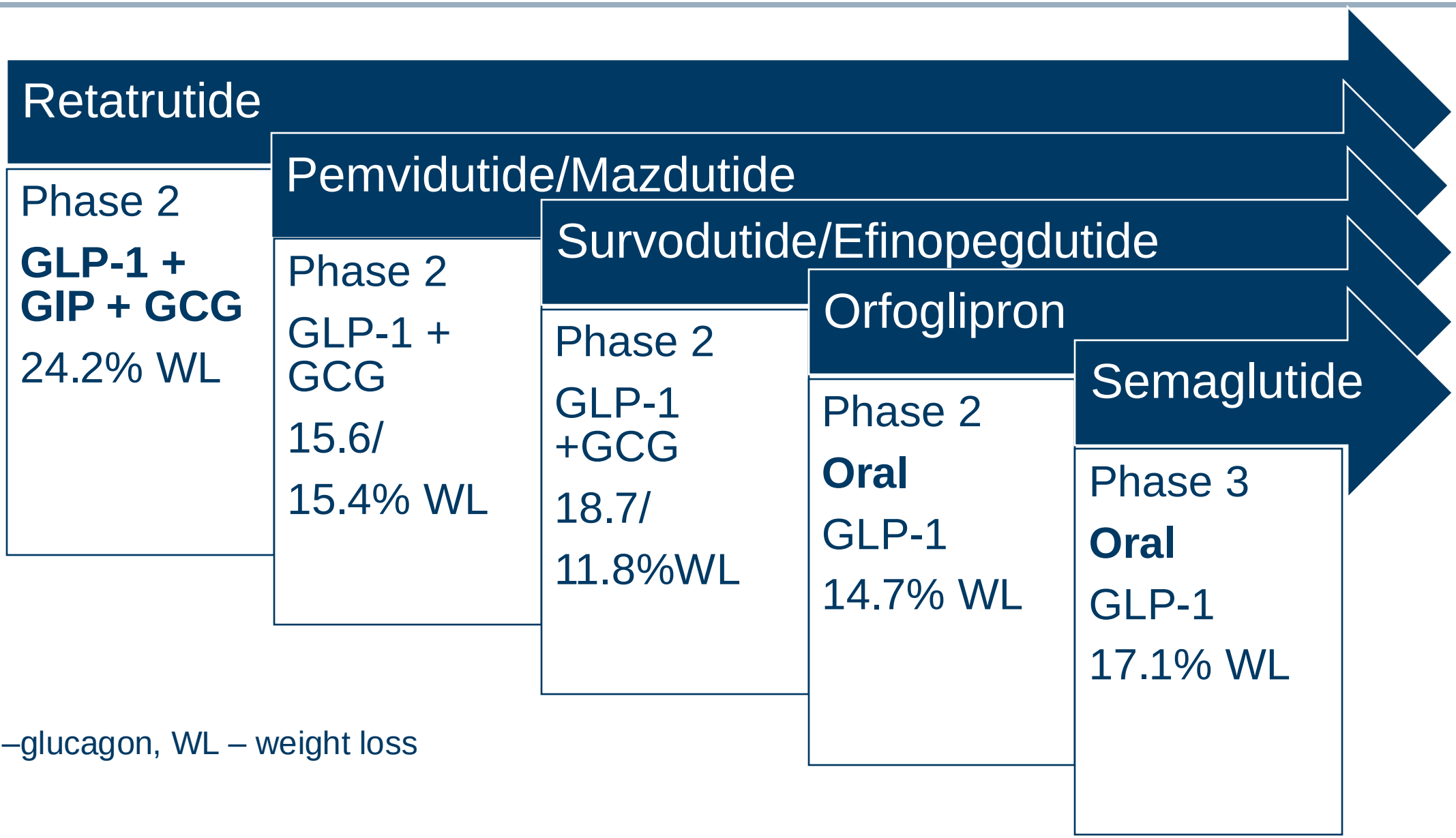
# Additional Indications and Medications in the Pipeline

# Additional Populations being Studied

| Tirzepatide | Semaglutide |
|---|---|
| • Approved for Sleep Apnea*<br>• SURPASS-CVOT: Tirzepatide vs. dulaglutide on MACE with established CVD and T2DM<br>• Heart failure with preserved ejection fraction (HFpEF)<br>• Non-alcoholic steatohepatitis (NASH)<br>• Chronic kidney disease (CKD)<br>• Morbidity/mortality in obesity (MMO) | • Approved for Cardiovascular Risk Reduction*<br>• Alzheimer's Disease<br>• Metabolic dysfunction-associated steatohepatitis (MASH)<br>  <br>• * See supplemental slides for review of data |

Clinical Development Pipeline | Science | Eli Lilly and Company Accessed 28 February 2025
*https://www.novonordisk.com/science-and-technology/r-d-pipeline.html Accessed 28 February 2025*

# Future weight loss medications




GCG –glucagon, WL – weight loss



*International Journal of Obesity; https://doi.org/10.1038/s41366-024-01473-y. Published online 1 Feb 2024. Accessed 25 Feb 2025*

# Patient Case

# Patient Case

A 59 year old female presents to office for an annual physical.
**Type 2 diabetes mellitus without complication, with long-term current use of insulin (HCC)**
A1c: 8.9%, 11/2022, will repeat today
- Current meds: Metformin 1000mg BID, Jardiance 25mg, Insulin (lantus) 38 units at night
- Interested in CGM Monitor, will follow up with pharmacist

Repeat A1c: 9.9%  Weight: 292lbs  BMI: 52.1
History of CAD, HTN, HLD, hx TIA, OA

Amlodipine 5mg daily
Atorvastatin 40mg daily
Carvedilol 25mg BID
Vitamin D3 1000 units daily
Furosemide 40mg daily PRN

Medication tried in past:
Victoza – stopped due to diarrhea

# Patient Case

Metformin 1000mg BID, Jardiance 25mg, **Lantus 10 units at night, Mounjaro 2.5mg weekly**
**(74% reduction of insulin)**

**Plan:**
**Increase** Mounjaro to 5mg weekly
Continue Jardiance 25mg daily
Continue Metformin 1000mg twice daily
**Hold** Lantus 10 when increasing dose

## AGP Report

November 24, 2023 - December 7, 2023 (14 Days)

LibreView

### GLUCOSE STATISTICS AND TARGETS

| | |
|---|---|
| November 24, 2023 - December 7, 2023 | 14 Days |
| Time CGM Active: | 29% |

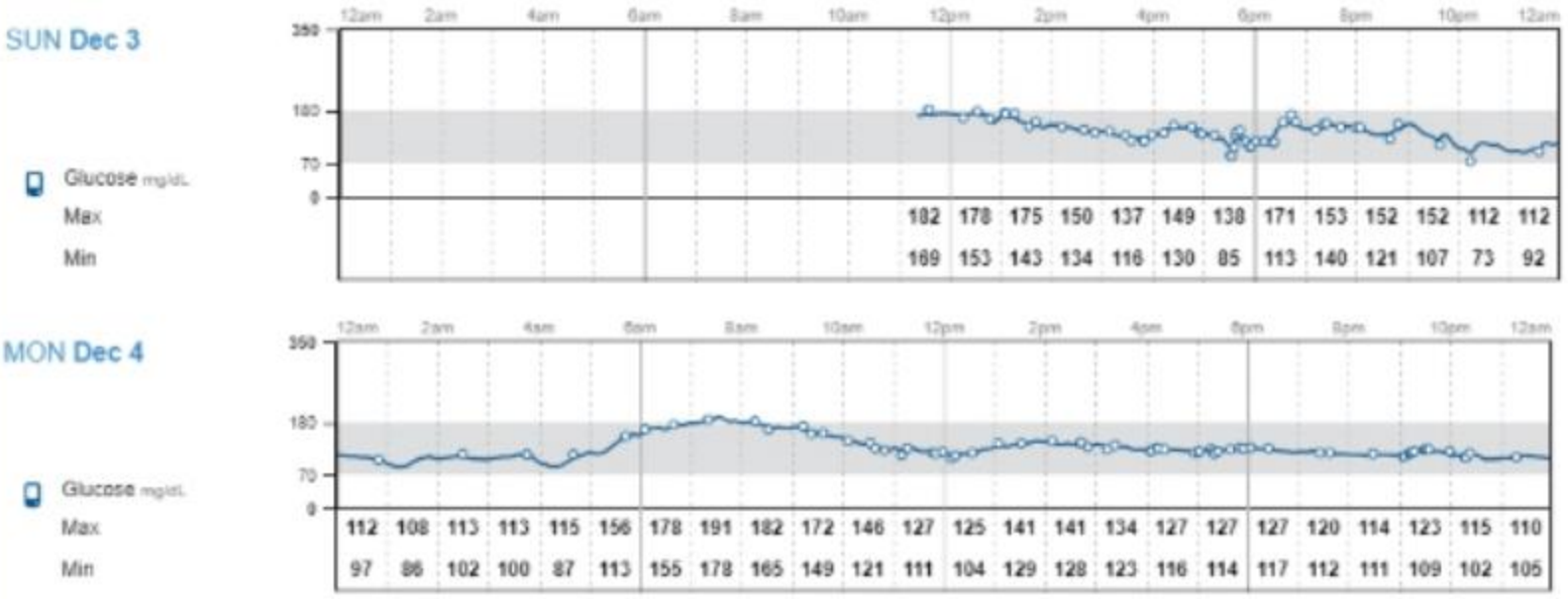
| Ranges And Targets For | Type 1 or Type 2 Diabetes |
|---|---|
| Glucose Ranges<br>Target Range 70-180 mg/dL | Targets % of Readings (Time/Day)<br>Greater than 70% (16h 48min) |
| Below 70 mg/dL | Less than 4% (58min) |
| Below 54 mg/dL | Less than 1% (14min) |
| Above 180 mg/dL | Less than 25% (6h) |
| Above 250 mg/dL | Less than 5% (1h 12min) |
| Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial | |

| | |
|---|---|
| Average Glucose | 123 mg/dL |
| Glucose Management Indicator (GMI) | - |
| Glucose Variability | 20.7% |

Defined as percent coefficient of variation (%CV); target ≤36%

### TIME IN RANGES


| | | |
|---|---|---|
| Very High | >250 mg/dL | 0% (0min) |
| High | 181 - 250 mg/dL | 3% (43min) |
| Target Range | 70 - 180 mg/dL | 97% (23h 17min) |
| Low | 54 - 69 mg/dL | 0% (0min) |
| Very Low | <54 mg/dL | 0% (0min) |



# Patient Case

Metformin 1000mg BID, Jardiance 25mg, **Mounjaro 12.5mg weekly**

**No insulin**

**3/24 A1c: 6.4%**

**Weight: 243 lbs**
**49 lbs loss**
**16.8% reduction**

## AGP Report

August 1, 2024 - August 14, 2024 (14 Days)

LibreView

### GLUCOSE STATISTICS AND TARGETS

| | |
|---|---|
| August 1, 2024 - August 14, 2024 | 14 Days |
| Time CGM Active: | 96% |

| Ranges And Targets For | Type 1 or Type 2 Diabetes |
|---|---|
| Glucose Ranges<br>Target Range 70-180 mg/dL | Targets % of Readings (Time/Day)<br>Greater than 70% (16h 48min) |
| Below 70 mg/dL | Less than 4% (58min) |
| Below 54 mg/dL | Less than 1% (14min) |
| Above 180 mg/dL | Less than 25% (6h) |
| Above 250 mg/dL | Less than 5% (1h 12min) |

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

| | |
|---|---|
| Average Glucose | 113 mg/dL |
| Glucose Management Indicator (GMI) | 6.0% |
| Glucose Variability | 15.4% |

Defined as percent coefficient of variation (%CV); target ≤36%

### TIME IN RANGES


| | | |
|---|---|---|
| Very High | >250 mg/dL | 0% (0min) |
| High | 181 - 250 mg/dL | 0% (0min) |
| Target Range | 70 - 180 mg/dL | 100% (24h) |
| Low | 54 - 69 mg/dL | 0% (0min) |
| Very Low | <54 mg/dL | 0% (0min) |

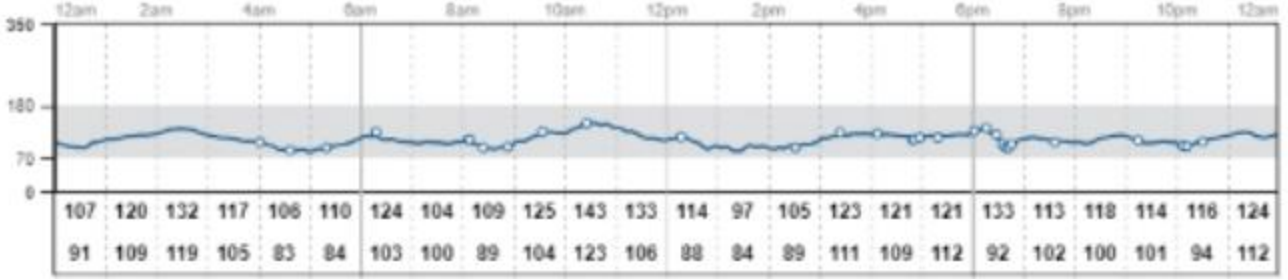
| | Latest Ref Rng & Units | 4/14/2021 | 11/21/2023 | 3/6/2024 |
|---|---|---|---|---|
| Creatinine, Urine | mg/dL | 99.4 | 70.5 | 44.4 |
| Micoralbumin, Random, Urine | mg/dL | 4.3 | <1.2 | <1.2 |
| Microalbumin/Creatinine Ratio | | 43.26 ^ | — | — |

**Vitals from encounters over the past 365 days**

| | 3/6/24 | 11/21/23 |
|---|---|---|
| BP | 122/78 | 152/89 ! |

FRI **Aug 9**


SAT **Aug 10**




Glucose mg/dL
Max
Min

3.7.2025

# GLP-1s

## There’s a ton with GLP-1

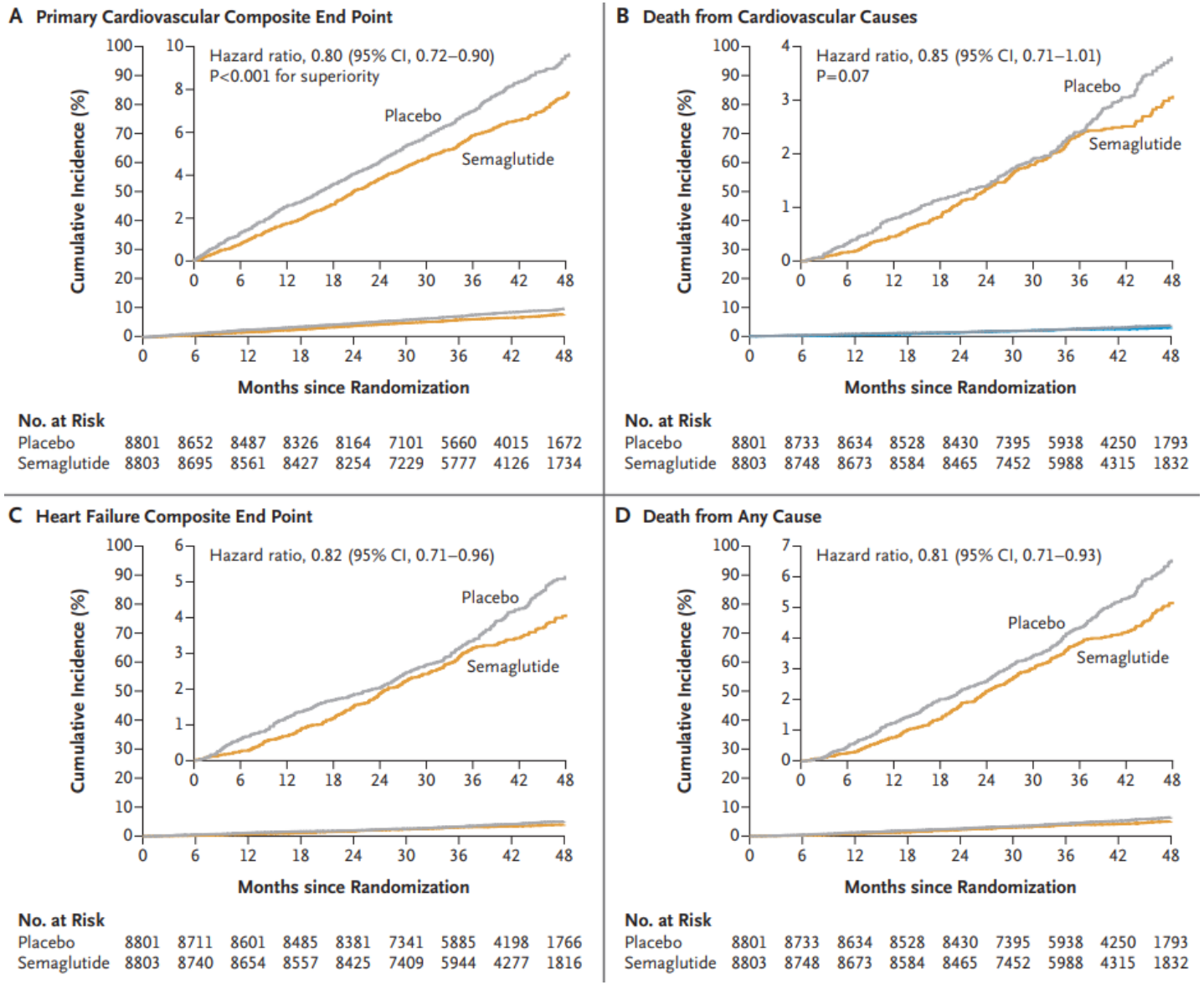
**Nicole Likar, PharmD, BCPS**

**Sarah Winter, PharmD, BCACP**

AHN

# Obesity – Cardiovascular Risk Reduction - Semaglutide

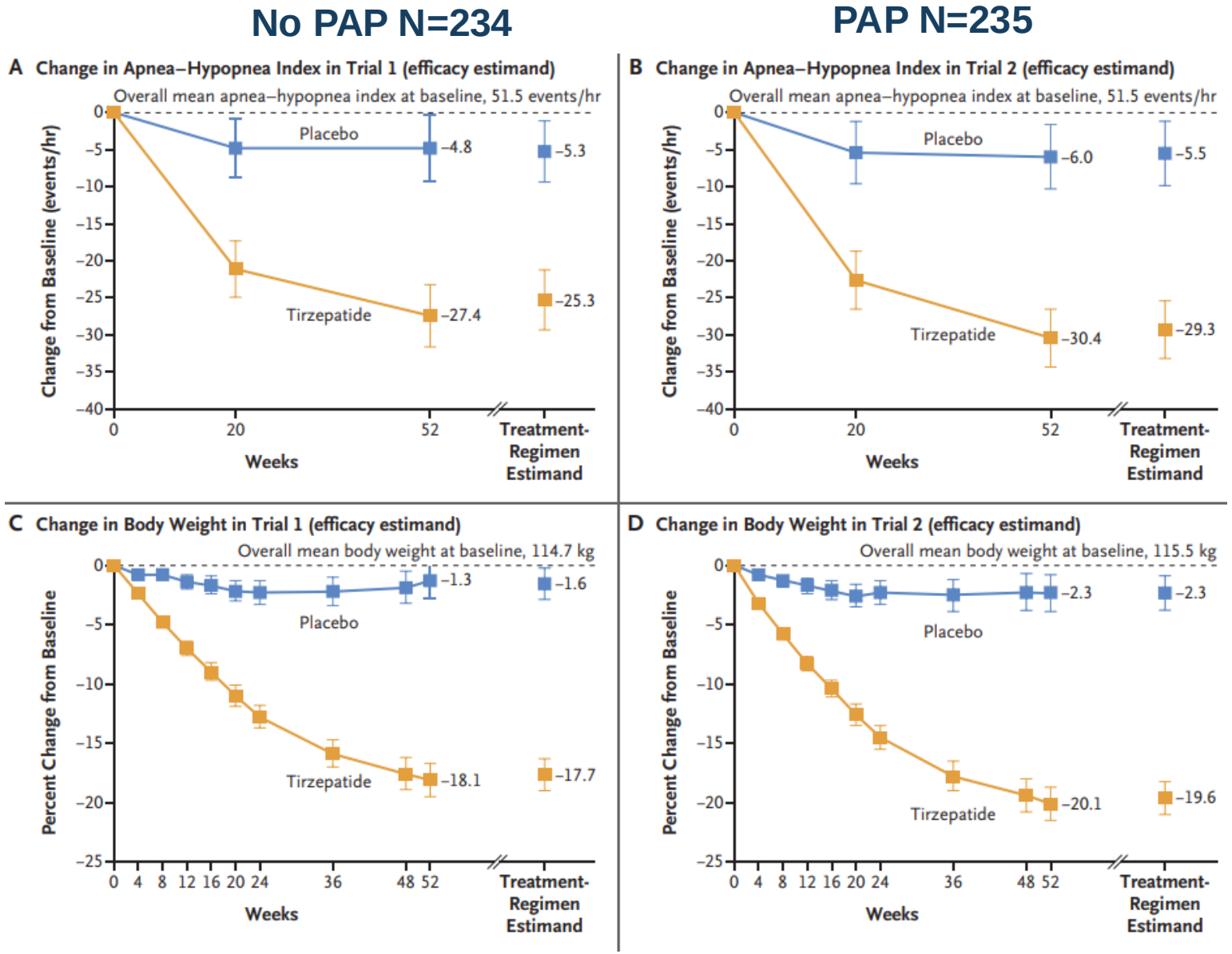
- SELECT Trial  N=17,606 patients
- 39 month trial of semaglutide 2.4mg vs placebo
- 45 years of age or older who had preexisting cardiovascular disease and a BMI ≥ 27
- A primary cardiovascular end-point event occurred in 569 patients (6.5%) in the semaglutide group and in 701 (8.0%) in the placebo group (hazard ratio, 0.80; 95% confidence interval, 0.72 to 0.90; P<0.001)




*N Engl J Med 2023;389:2221-2232.*

# Obesity – Sleep Apnea - Tirzepetide

- SURMOUNT-OSA
- Two 52 week trials with highest tolerated dose of tirzepetide vs placebo
- Moderate to Severe Sleep Apnea with Obesity
- AHI decreased significantly by up to 29.3 events per hour (a 58.7% change from baseline)




*N Engl J Med 2024;391:1193-1205.*

UPMC
LIFE CHANGING MEDICINE

# Updates in Menopause

Martin Johns, MD

Program Director: UPMC Horizon Family Medicine Residency Program

Chair of Medicine: UPMC Horizon and UPMC Jameson Hospitals

# Objectives

- Improve knowledge and management of symptoms and conditions associated with menopause
- Understand the mechanism of action and new therapies for vasomotor symptoms of menopause
- Increase baseline understanding of options for hormone replacement therapy

# Definitions

- Menopause
  - Cessation of menses due to physiologic decrease in ovarian function
  - Diagnosed after 12 months of amenorrhea
- Perimenopause
  - The period immediately before menopause and the first year after the last menstrual period
  - Normal cycles + anovulatory cycles
  - Beginning of vasomotor symptoms
  - 3-5 years prior to menopause

# Onset

- Median age of menopause is 51 years
  - Earlier in smokers
- Considered premature if <40 years
  - Normal time can be between 40 and 60 years of age
- Perimenopause starts at 47 years on average
- Artificial menopause occurs due to surgery, chemotherapy, pelvic radiation
  - Risks for osteoporosis, heart disease, abnormal libido can start shortly thereafter

# Hormonal changes

- Decreased number of ovarian follicles leads to decreased estrogen production in the ovary
- Decreased negative feedback to the pituitary leads to increased FSH and LH levels
- FSH rises more than LH
  - 20-fold increase in FSH level, 3-fold increase in LH levels
  - Peak levels 1-3 years after menopause

# Hormonal Changes

- Androgen production continues in the ovarian stroma and adrenal glands
  - Androstenedione→estrone in fat cells
    - Obesity increases estrone levels
    - Higher risks of endometrial hyperplasia and breast cancer in obese women
- Progesterone levels also decline significantly contributing to irregular bleeding and endometrial hyperplasia

# Diagnosis

- Usually a clinical diagnosis
  - Associated symptoms + 1 year of amenorrhea
- Can test FSH (high) and Estradiol (low) levels to prove
  - Not necessary age >45
  - Helpful if <45 years
- FSH levels are measured
  - Anytime if no menses
  - Day 3 of cycle if still menstruating but having perimenopausal symptoms
  - Day 6 of placebo pills if taking OCPs and trying to determine discontinuation plans

# Clinical Signs and Symptoms

- Irregular volume, duration, and timing of menses
- Vasomotor symptoms (hot flashes, night sweats)
  - Insomnia
- Vaginal Dryness and dyspareunia
- Urinary incontinence / UTIs
- Memory loss (brain fog), fatigue, depression, mood swings, joint pain, decreased libido

# Opportunities for intervention

- Majority of women will go through many of these symptoms
  - Many won’t bring them up
- A lot of misconceptions and fear over the last 20 years related to hormone replacement therapy
- Essential to introduce your willingness to address and treat your patient’s symptoms

# Vasomotor Symptoms

- Up to 80% of women, lasting up to 10 years
- Sudden, transitory rushes of intense heat “like a furnace in my chest”
  - Hot flashes and Night Sweats
- Disruptive to sleep, productivity and wages, contribute to mood changes

- FDA study inclusion recommendations
  - 7-8 episodes of moderate to severe intensity daily
  - Over a several week period

# Vasomotor Pathophysiology

- Neurons in the central thermoregulatory zone of the hypothalamus
  - Express kisspeptin, neurokinin b, and dynorphin receptors (KNDy neurons)
- Estrogen inhibits these neurons and downregulates neurokinin receptors
- Decreasing estrogen increases neurokinin receptors which activate these neurons and promotes thermoregulatory dysfunction
- Several Neurokinin receptor antagonists are in development, one is FDA approved

# Fezolinetant (Veozah)

- Neurokinin-3 receptor antagonist
  - Blocks neurokinin-b from binding to thermoregulatory neurons
- 3 clinical trials—total 1,100 people
  - At least 7 vasomotor symptoms/day (moderate to severe)
  - Average age 53-55, max 65 years
  - Max trial length 52 weeks
  - Not studied in women who could not otherwise take hormones

# Fezolinetant Effectiveness

- 81-94% of patients on fezolinetant had a >50% reduction in the number of VMS/day
  - compared to 58% of placebo (placebo does well in most studies)
  - Reduction in severity of episodes as well
- Average improvement was 74-87% at 4, 12 weeks
  - 55% for placebo
- Estrogen: 80-90% of patients have a 90% reduction in VMS/day at 4 weeks

# Fezolinetant: Safety, Cost

- Contraindicated:
  - Cirrhosis, ESRD, Severe renal impairment
- Transient LFT elevations (2-3x ULN) in 2% of patients.
  - Resolved with stopping medication
- Requires LFTs at baseline, 3, 6, 9 months
  - Contraindicated with CYP1A2 inhibitors (fluvoxamine)

- Cost: $540/month

# Estrogen Therapy

- Estrogen replacement therapy (90% effective)
  - Lowest effective dose
  - Must have some progestin if patient has a uterus (continuous or pulsed-dose)
- Oral, transdermal, vaginal forms
  - Vaginal dosing is generally not recommended for VMS symptoms
  - Alone or in combination with progesterone (oral and patches)
- Each formulation has multiple dosing options
- Limited comparable data across formulations
- Recommended to re-evaluate risks/benefits, symptoms and effectiveness regularly.

# Contraindications to Hormone Therapy

- Unexplained vaginal bleeding
- History of stroke
- Active estrogen-sensitive cancer
  - History of estrogen-sensitive cancer
- History of VTE
  - Personal History or Strong Family History of thromboembolism
- History of Coronary Artery Disease
- Active Liver Disease

# Additional Counseling

- Follow up and re-evaluate plan
- Heart Disease: no increased risk of death
- Osteoporosis: Decreased risk of fracture (but not first line treatment)
- Follow up and re-evaluate plan
- Breast Cancer: estrogen alone decreases risk of breast cancer, estrogen + progesterone increases risk by a very small amount, but no effect on mortality
- Diabetes: Decreased risk
- Follow up and re-evaluate plan

# Hormone Replacement Options

| Medication | Delivery options | FDA approved indications |
|---|---|---|
| Estradiol (bioidentical) | Oral, transdermal patch, transdermal gel, transdermal spray, vaginal cream, vaginal ring, vaginal insert | Vasomotor symptoms, vulvovaginal atrophy, osteoporosis prevention (oral only), vaginal ring can be used for vasomotor symptoms |
| Conjugated equine estrogen | Oral, vaginal cream | Vasomotor symptoms, vulvovaginal atrophy, osteoporosis prevention (oral only) |
| Conjugated equine estrogen / bazedoxifene (duavee) | Oral<br>estrogen + SERM (no progesterone needed) | Vasomotor Symptoms, osteoporosis prevention |
| Conjugated equine estrogen/medroxyprogesterone | Oral | Vasomotor Symptoms, vulvovaginal atrophy |
| Estradiol/norethindrone | Oral, transdermal patch | Vasomotor symptoms, vulvovaginal atrophy |
| Estradiol/levonorgestrel | Oral, transdermal patch | Vasomotor symptoms, vulvovaginal atrophy |
| Estradiol/drosperinone | Oral | Vasomotor symptoms, vulvovaginal atrophy |
| Estradiol/ progesterone (Bioidentical) | oral | Vasomotor symptoms, vulvovaginal atrophy |
| Ethinyl Estradiol/norethindrone | Oral | Vasomotor symptoms, vulvovaginal atrophy |

# Compounded Bio-identical Hormones

- Not FDA approved
- No studies of efficacy, No warning labels
- Possibly increased endometrial cancer risk

- Commonly used but should be avoided

# Other non-hormonal therapies

- SSRIs and SNRIs
  - Paroxetine mesylate 7.5mg (Only FDA approved SSRI/SNRI for VMS)
  - Citalopram, Escitalopram, Paroxetine
  - Venlafaxine and Desvenlafaxine
- Clonidine
- Oxybutynin
- Non-pharmacologic options
  - CBT: may decrease severity without decreasing frequency
- Not Recommended
  - Black cohosh—meta-analysis of six studies found a positive benefit but oversight of supplements is very limited
  - Acupuncture
  - Isoflavones
  - Compounded Estrogen / Estrogen-progesterone formulations

# Urogenital Symptoms

- Stress incontinence
- Dyspareunia
- Recurrent Urinary Infections
- Itching
- Vulvovaginal dryness

# Treatment of Symptoms

- Vaginal Moisturizers

- Vaginal Estrogen cream, insert, or ring
  - Estradiol or Conjugated Estrogen
- Oral ospemifene (SERM)

- Subjectively improves incontinence symptoms but does not improve objective incontinence testing parameters
  - Increased risk of urge incontinence

# Joint Aches and Pain

- As many as 50-60% of women report joint pain in the perimenopausal and postmenopausal period
- Important to ask about symptoms—this is an area for research and likely underdiagnosed
- Perform an appropriate workup for diffuse symptoms
- Observational studies have shown an improvement in symptoms with hormonal therapy

# Depression

- New-onset depression is more common in women in menopause transition than premenopausal
  - In one study 2.5 times more likely in a within-woman 8-year longitudinal study
- More common in a prior history of depression
- Treat with anti-depressants and/or CBT
- Studies are ongoing to use transdermal estrogen to prevent depression in the menopause transition

# Insomnia

- Mostly from hot flashes / night sweats
- More common even in the absence of VMS
- 30-50% of women during menopause transition will report sleep disturbances

- Sleep apnea, restless legs, anxiety and depression can all contribute and co-exist

# Testosterone Deficiency / Hypoactive Sexual Desire Disorder

- Decreased libido/arousal
- More common with surgical menopause as the ovaries continue to make androgens
- Treat with DHEA or testosterone replacement
  - Vaginal DHEA preparations are available

# Other symptoms

- Brain Fog /Cognitive function
- Menstrual migraines
- Breast pain
- Skin Changes
- Balance

# Summary

- Vasomotor Symptoms are extremely common and can be very debilitating
- Decreasing estrogen levels trigger upregulation of neurokinin receptors in the KNDy neurons of the hypothalamus
- Neurokinin receptor antagonists offer an effective, non-hormonal treatment –expect more medications on the market soon
- Women with moderate to severe symptoms should be offered treatment. Hormone replacement is the most effective option
  - Get comfortable with a couple of dosing /treatment options
- Follow up frequently and re-evaluate your treatment plan
  - Adjust doses, re-visit risk factors, avoid inertia

# References and additional resources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# Osteopathic Approach to Low Back Pain

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# Objectives

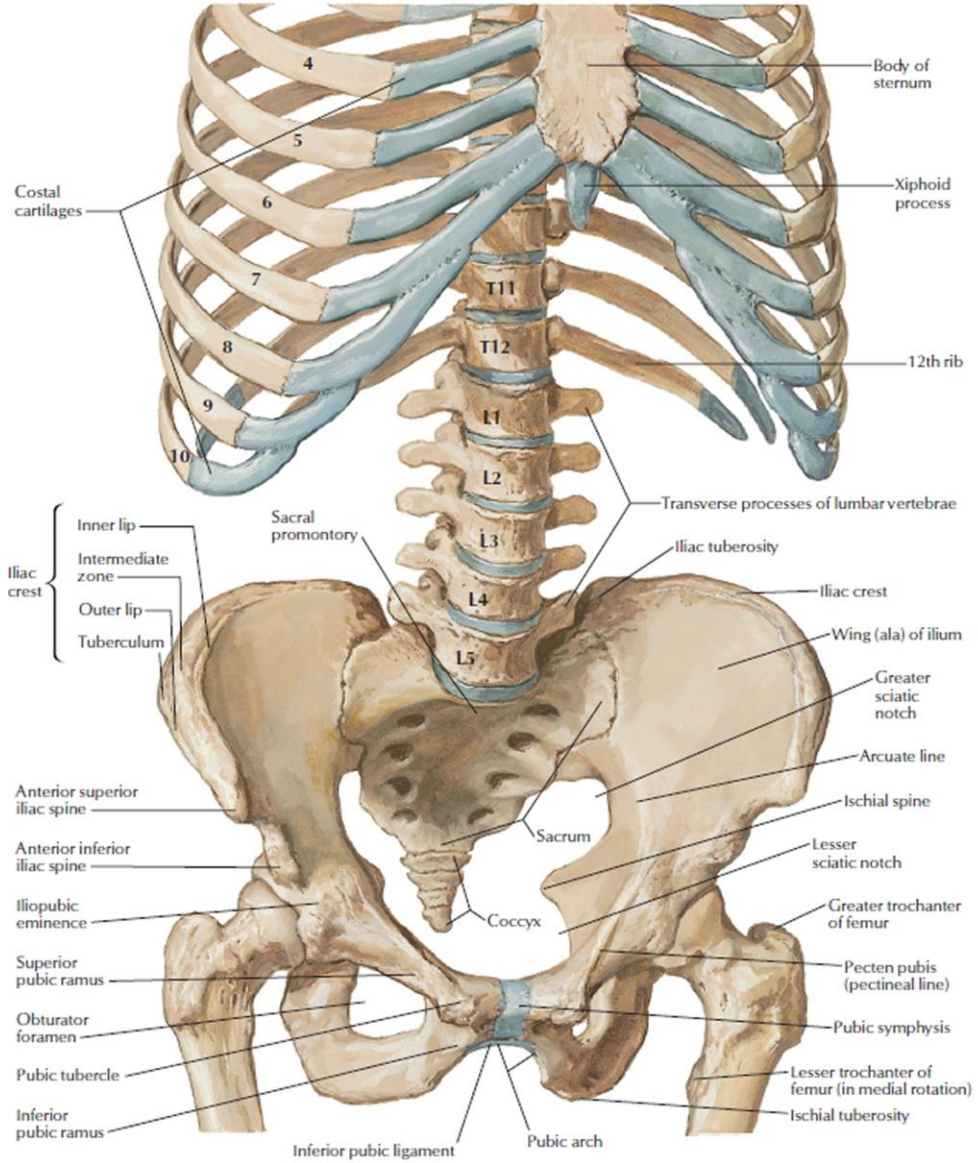
- Review pertinent anatomy of the lumbar spine and how it can be associated with low back pain
- Review common causes of low back pain
- Review Fryette’s Laws as they pertain to the lumbar spine
- Apply OMT to various causes of low back pain

# Facts about Low Back Pain

- 31 million Americans suffer from low back pain
- Affects 619 million people worldwide
- LBP is the number one cause of disability worldwide
- $50 billion US dollars a year spent on medical costs for LBP
- Can be experienced at any age, but prevalence increases with age.  Highest number of cases occur between ages 50-55 years.
- 80% of all people will experience low back pain at some point in their lives.
- Non-specific LBP is the most common presentation (about 90% of cases).
    - Common risk factors include low physical activity levels, poor posture, smoking, obesity, and high physical stress at work, and improper lifting

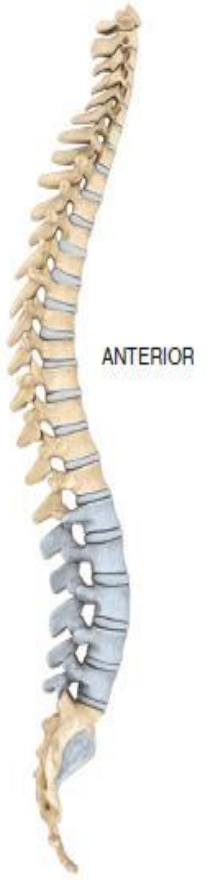
# Lumbar Spine Anatomy

- Lumbar spine consists of 5 vertebrae
- Forms a smooth lordotic curve just above the pelvis
  - Typically extends from L2 to L5 with an average of about 43 degrees
- Are the most massive segments of the vertebral column
- Carries the weight of the upper half of the body
- Occupies ½ to 2/3 of the posterior skeletal and myofascial wall of the true abdomen.
- It is directly linked to the thoracic and pelvic regions.
  - Because of these anatomic connections, it can influence the head/neck, upper extremities, lower extremities, and the viscera.
  - The location of symptoms does not necessarily indicate the region of their etiology. Problems in the pelvis, abdomen, leg, arm, head, and thoracic regions as well as the lumbar regions.

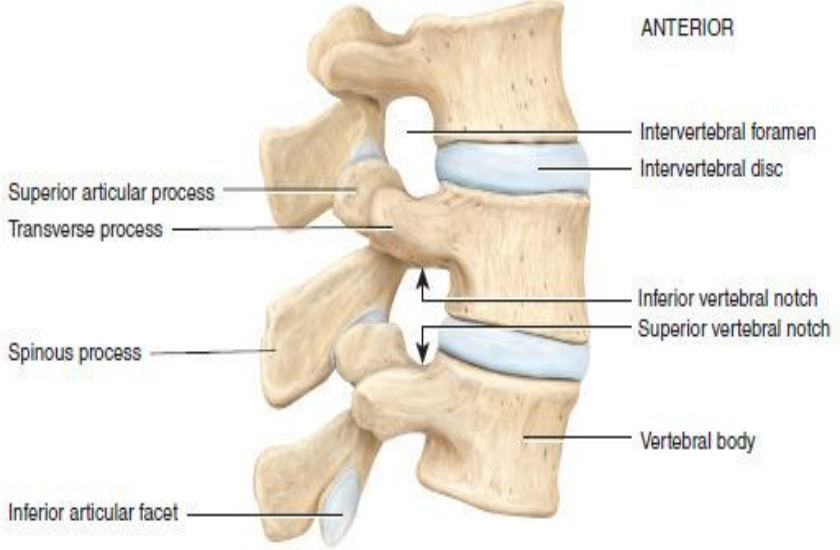

4
5
6
7
8
9
10
Costal cartilages
Body of sternum
Xiphoid process
T11
T12
12th rib
L1
L2
L3
L4
L5
Transverse processes of lumbar vertebrae
Iliac crest
Inner lip
Intermediate zone
Outer lip
Tuberculum
Sacral promontory
Iliac tuberosity
Iliac crest
Wing (ala) of ilium
Greater sciatic notch
Arcuate line
Ischial spine
Lesser sciatic notch
Greater trochanter of femur
Pecten pubis (pectineal line)
Pubic symphysis
Lesser trochanter of femur (in medial rotation)
Ischial tuberosity
Anterior superior iliac spine
Anterior inferior iliac spine
Iliopubic eminence
Superior pubic ramus
Obturator foramen
Pubic tubercle
Inferior pubic ramus
Sacrum
Coccyx
Inferior pubic ligament
Pubic arch

# Anatomy

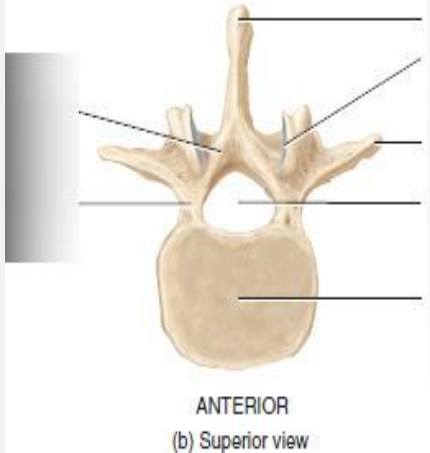
- **Vertebral Bodies**
  - Largest vertebral bodies in the vertebral column
  - Distinguished by the absence of costal facets
  - Is wider transversely and deeper anterioposteriorly than other vertebral body
  - The large cross-sectional area and its longitudinal and vertical trabecular arrangement increases strength and stability.
  - Also act as accessory organs for hematopoiesis




Location of lumbar vertebrae

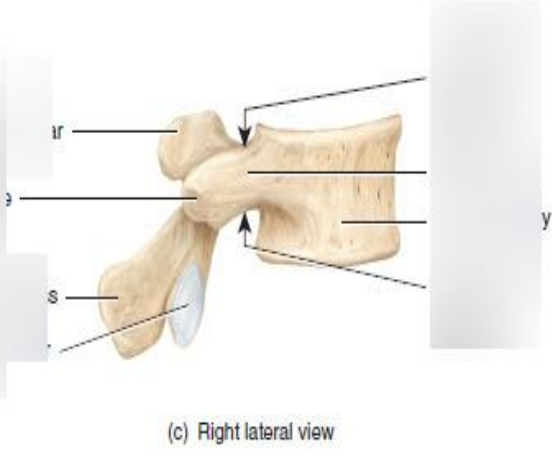



(a) Right lateral view of articulated lumbar vertebrae



ANTERIOR

(b) Superior view



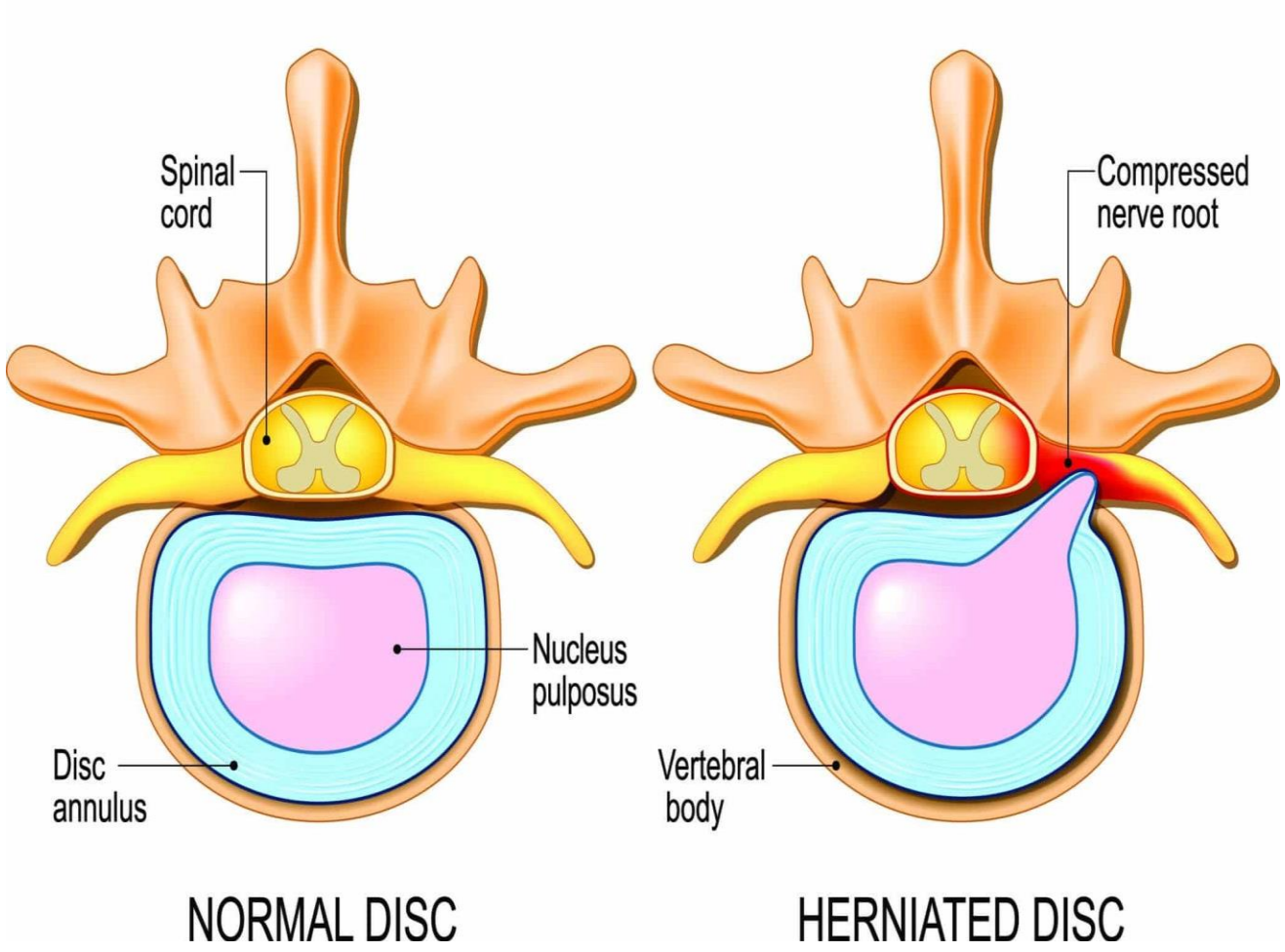
(c) Right lateral view

# Anatomy

- **Intervertebral Disk**
  - Located between each lumbar vertebrae
  - Are large and built to tolerate and dissipate heavy loads
  - Composed of:
    - Glycosaminoglycans
    - Mucopolysaccharides
    - Proteoglycans
    - Collagen
  - Each disk is jointed to the inferior plate of the vertebra above it and the superior plate of the vertebra below it.
  - Separates each vertebrae from each other and provides the surface for shock absorbing
  - The disks are innervated by fibers from an elaborate plexus supplied by the sinuvertebral nerve on the posterior longitudinal ligament and the somatosympathetic nerve on the anterior longitudinal ligament. In the early stages of compression, the SV nerve on the PLL is irritated giving rise to low back pain.
  - Is composed of the nucleus pulposus and the annulus

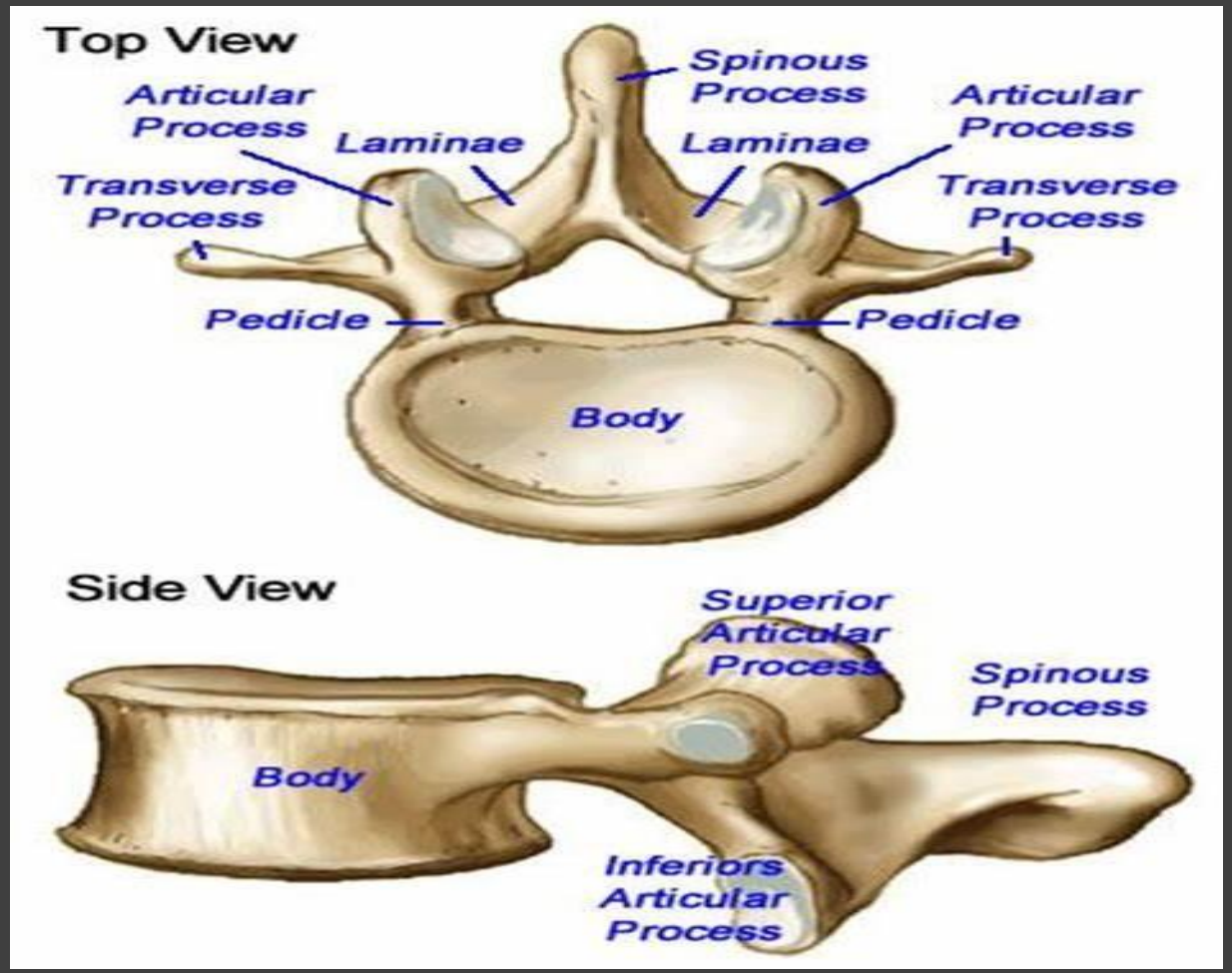
# Anatomy

- **IV Disk cont**:
  - Nucleus pulposus – is the gel-like center that is compressible and located at the center of the disk. It is surround by layers of the annulus.
    - composed of 70-90% water; is semifluid and hydrophilic
    - With postural weight bearing it expands laterally against the annulus working together mechanically to act as a shock absorber between each vertebral body.
  - Annulus – outer fibrous ring
    - Composed of several lays of fibrocartilage of both type 1 and type 2 collagen; type 1 collagen is concentrated towards the outer edge of the ring where it provides the greatest strength.



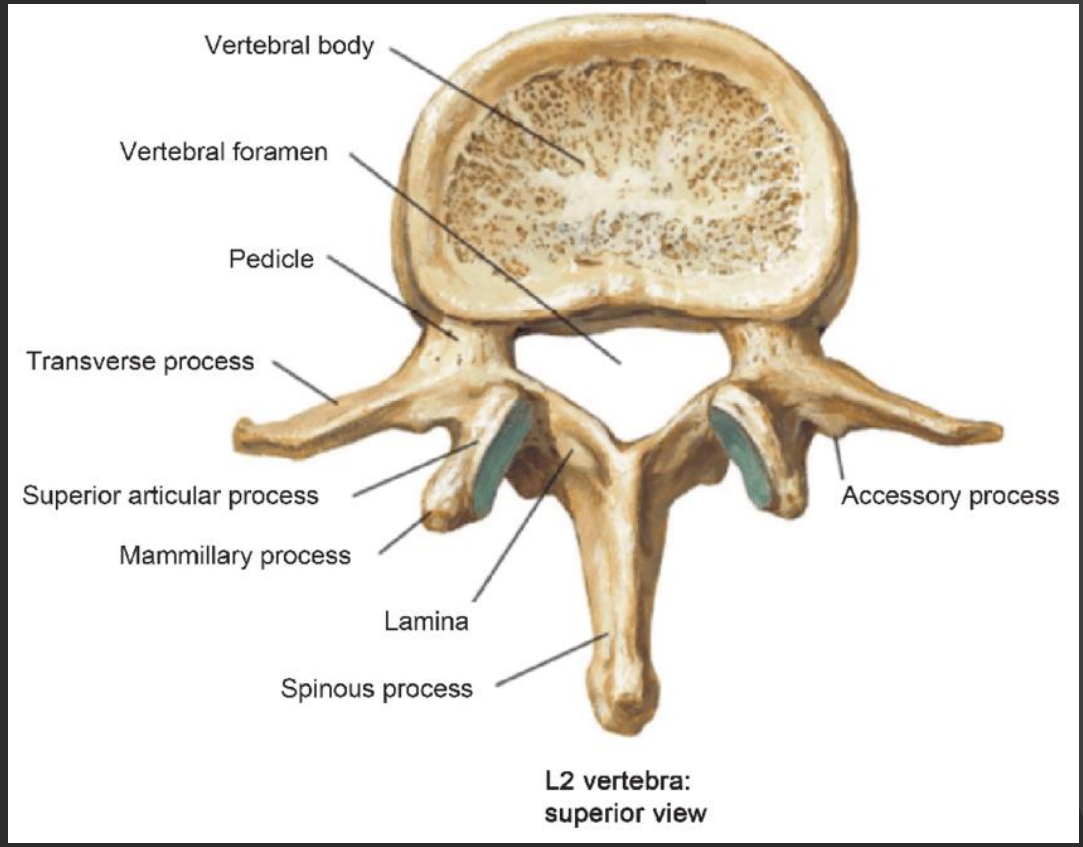
# Anatomy

- **Pedicles**
  - Connects the posterior elements to the vertebral body and marks the site where the posterior vertebral elements begin.
  - Protects the nerve root of a vertebral unit from being injured by a significantly herniated IV disk of that same unit.



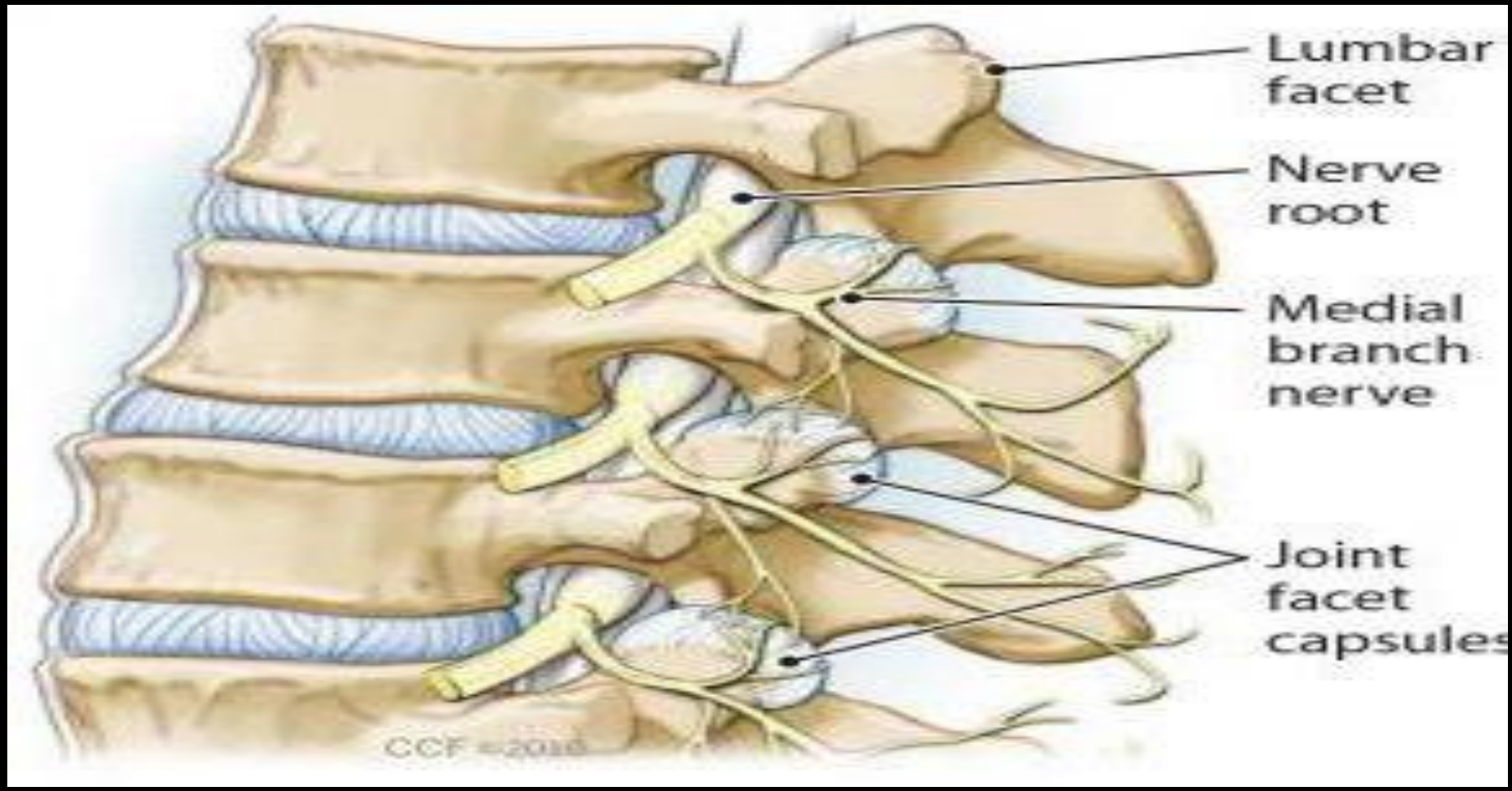
# Anatomy

- **Transverse Process**
  - Projects laterally from the region of each pedicle
  - In the lumbar region these processes are anatomically located directly lateral to the spinous process of the vertebra of their origin.
  - Attachment sites of many of the trunk muscles (e.g. quadratus lumborum).



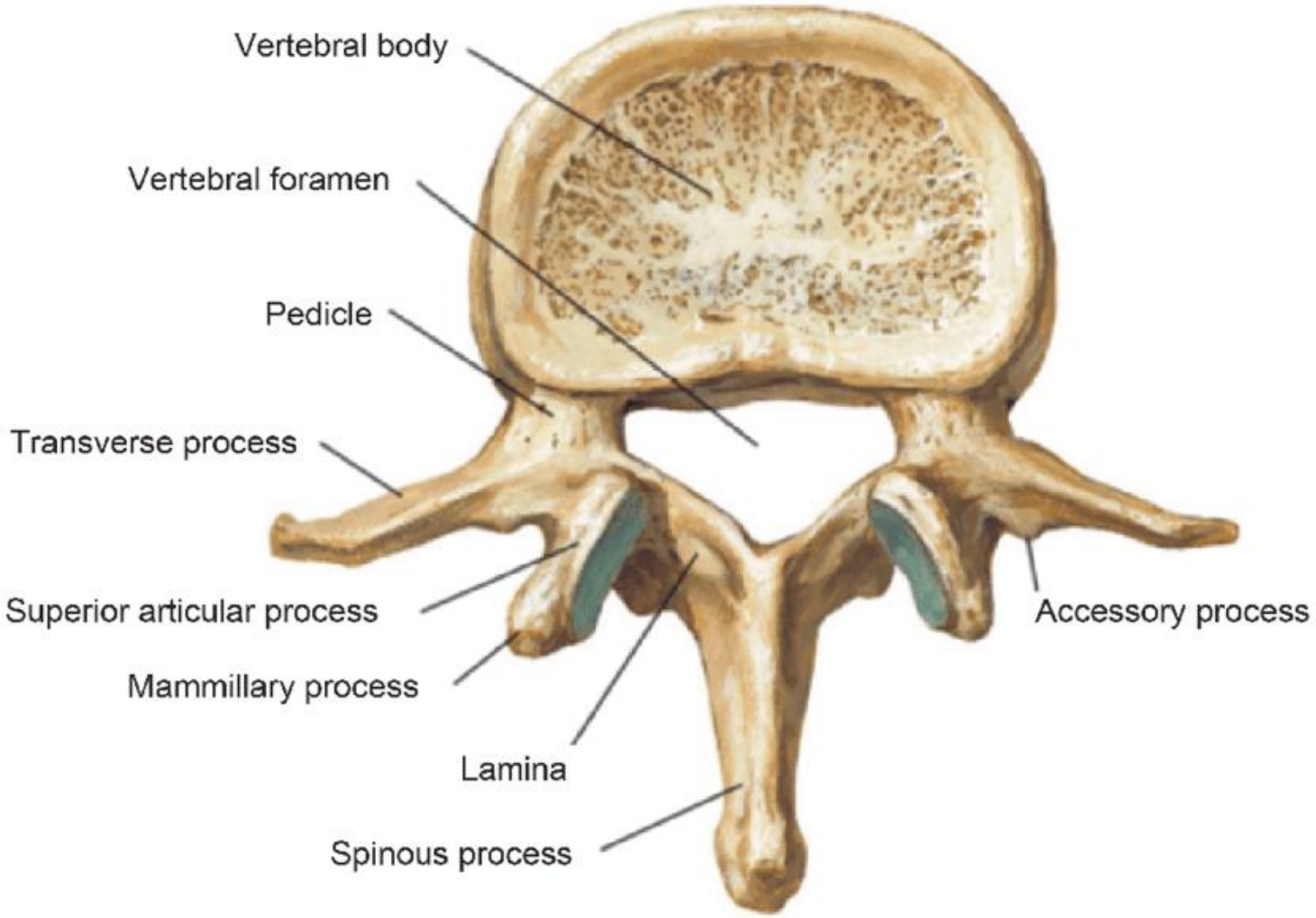
# Anatomy

- **Articular Processes**
  - **Inferior articular process** projects in an inferior direction from the region of the pedicle, and its articular surface faces laterally
  - **Superior articular process** projects superiorly from the same pedicle and its facet faces medially.
  - The joint space of an intervertebral synovial joint is formed by the facet of an inferior articular process of one vertebra and the face of a superior articular process of the next.
  - Each facet joint is innervated by 2 small nerves – paired **medial branches** of the posterior ramus of the spinal nerves.
    - Receives a medial branch from the spinal nerve above the facet and the nerve below.
    - Degeneration or inflammation within a facet joint creates a pain signal via the medial branch nerves. Is a cause of low back pain in adults.
    - These nerves do not control any muscles or sensations to the limbs


Lumbar facet
Nerve root
Medial branch nerve
Joint facet capsules
CCF ©2018

# Anatomy

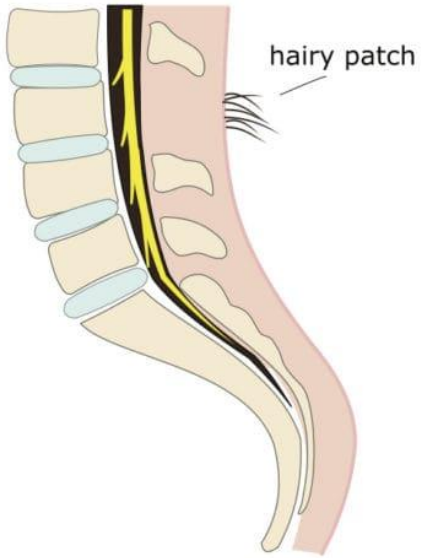
- **Lamina**
  - Projects medially and inferiorly from each pedicle and tends to meet its partner in the posterior midline to form a typical rectangular lumbar spinous process
  - In some instances, the lamina will not completely meet in the mid-line causing a spina bifida.
  - Most common anomaly is the "hidden" SB = spina bifida occulta. Frequently found at L5-S1 – the only physical clue to its presence may be a midline patch of coarse hair on a patient's skin over its site. The skin is intact and no meningeal components. It may modify muscle attachments
    - SBO – no herniation through the defect – can treat with OMT – can be ligamentous asymmetry and abnormal loading stress; some reports of sacral base unleveling (may need heel lift). OMT – soft tissue, MFR, counter strain, balanced ligamentous tension.
    - SB with Meningocele – a herniation of the meninges/spinal fluid through the defect – no nerves affected but patients can have some minor trouble with bowel/bladder function.
    - SB with Myelomeningocele – a herniation of the meninges and the nerve roots through the defect. Is associated with neurological deficits – bowel and bladder incontinence, sensory/motor loss in the lower extremities or nerve root only involvement. Usually there is flaccid paralysis but if the spinal cord is involved then there is spastic paralysis.
      - Is the most severe form and infections are common with death during infancy due to sepsis




**L2 vertebra: superior view**

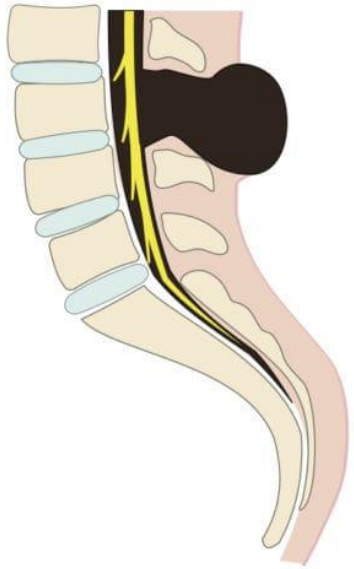
**Spina bifida occulta**

(opened posterior vertebral body)



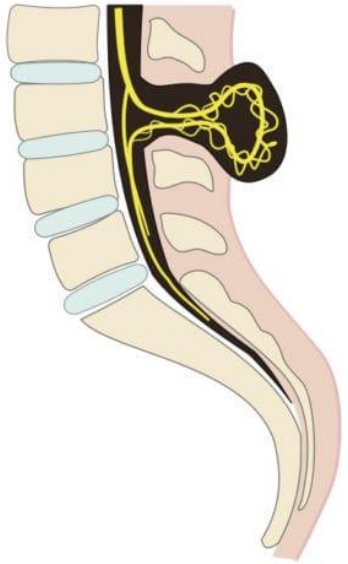

**Meningocele**

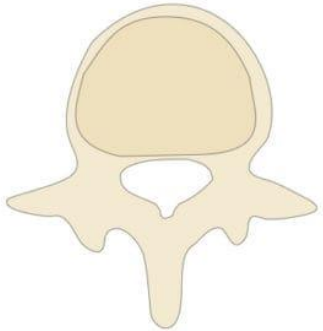
(protrusion of the meningis)



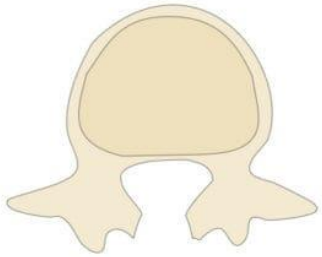
**Myelomeningocele**

(protrusion and opened spinal cord)





normal vertebra



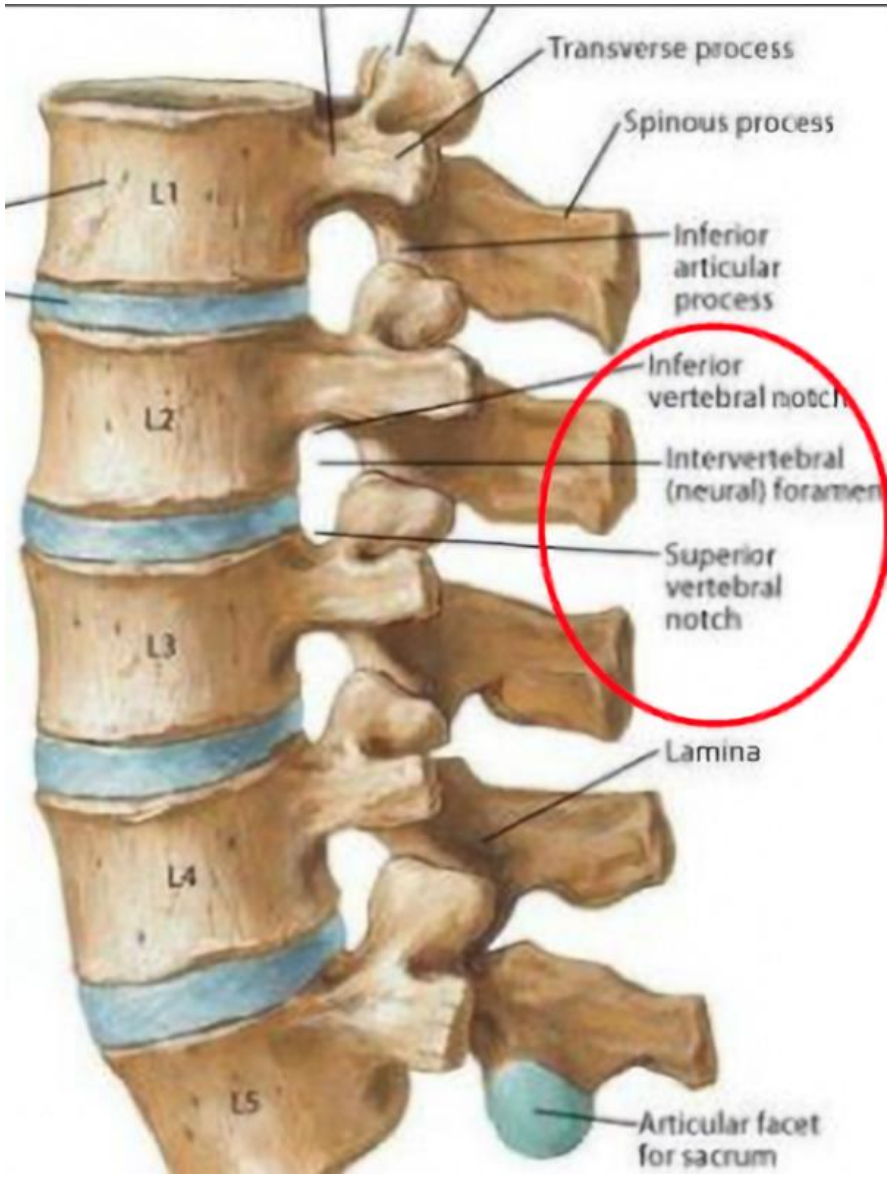
not completely closed vertebra

# Anatomy

- **Spinus Process**
  - Lumbar SP's are distinguished by their palpable, thick, quadrangular, and "spade-like" distal ends.
  - The only exception is the SP of L5 which is smaller, lies in a hollow just above the sacral base, and its distal end is about 1/3 smaller than the rest of the lumbar spine. If feels more like a thoracic SP rather than a lumbar SP.
  - Project posteriorly and often inferiorly from the laminae.
  - Shape provides palpatory evidence of where the lumbar region begins and where the thoracic spine ends.
  - Functions as a series of levers for both muscles of posture and muscles of active movement.  Most muscles that attach to the SP act to extend the spine.
  - Also serve as attachment sites for ligaments

# Anatomy

- **Intervertebral Foramina**
  - One on either side (left and right).
  - Formed by two adjacent vertebrae of a vertebral unit
    - 2 adjacent vertebral bodies and the IV disk between them
    - 2 adjacent pedicles
    - The inferior articular process of one vertebra and the superior articular process of the next, including the synovial joint between them
  - A spinal nerve and a recurrent meningeal nerve pass through the lumbar foramen. The nerve will exit below its corresponding vertebrae.
  - A lumbar foramen is normally 2-3x large than the area taken up by the lumbar nerves, so it seems that compression of the nerve would be difficult.
  - With flexion, the facets and pedicles glide away from the one another, and the size of the IV foramen increases.
  - With extension, the pedicles glide toward one another, and the foramen is reduced in size.
  - Reduction of the foramen size also results from: arthritis/spurs, hypertrophy of the posterior longitudinal ligament, extrusion of the nucleus pulposus, tissue congestion or edema, inflammation, perineural edema.
    - Removal or reduction of the effect produced by any of these factors may be enough to allow a symptomatic patient to be asx, pain free and able to work.


Transverse process
Spinous process
L1
Inferior articular process
Inferior vertebral notch
L2
Intervertebral (neural) foramen
Superior vertebral notch
L3
Lamina
L4
L5
Articular facet for sacrum

# Muscles

## Anterior Muscles

**Psoas Major**

Abdominal muscles

- rectus abdominis
- external and internal obliques
- transverse abdominis

## Posterior muscles

**Superficial** – Latissimus dorsi and Serratus posterior inferior

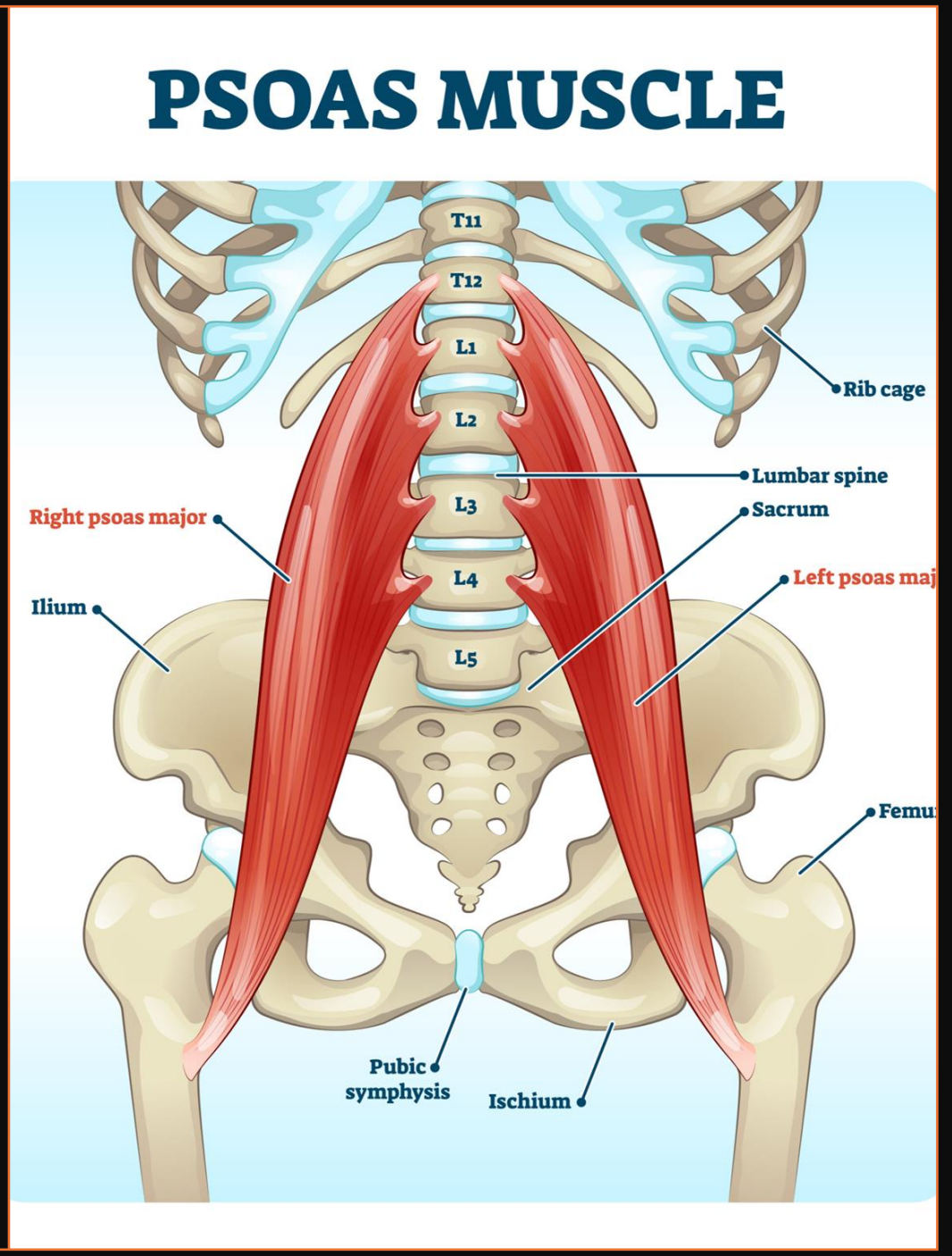
**Intermediate Muscles – Erector spinae**

- **Spinalsis, Longissimus, and Iliocostalis**

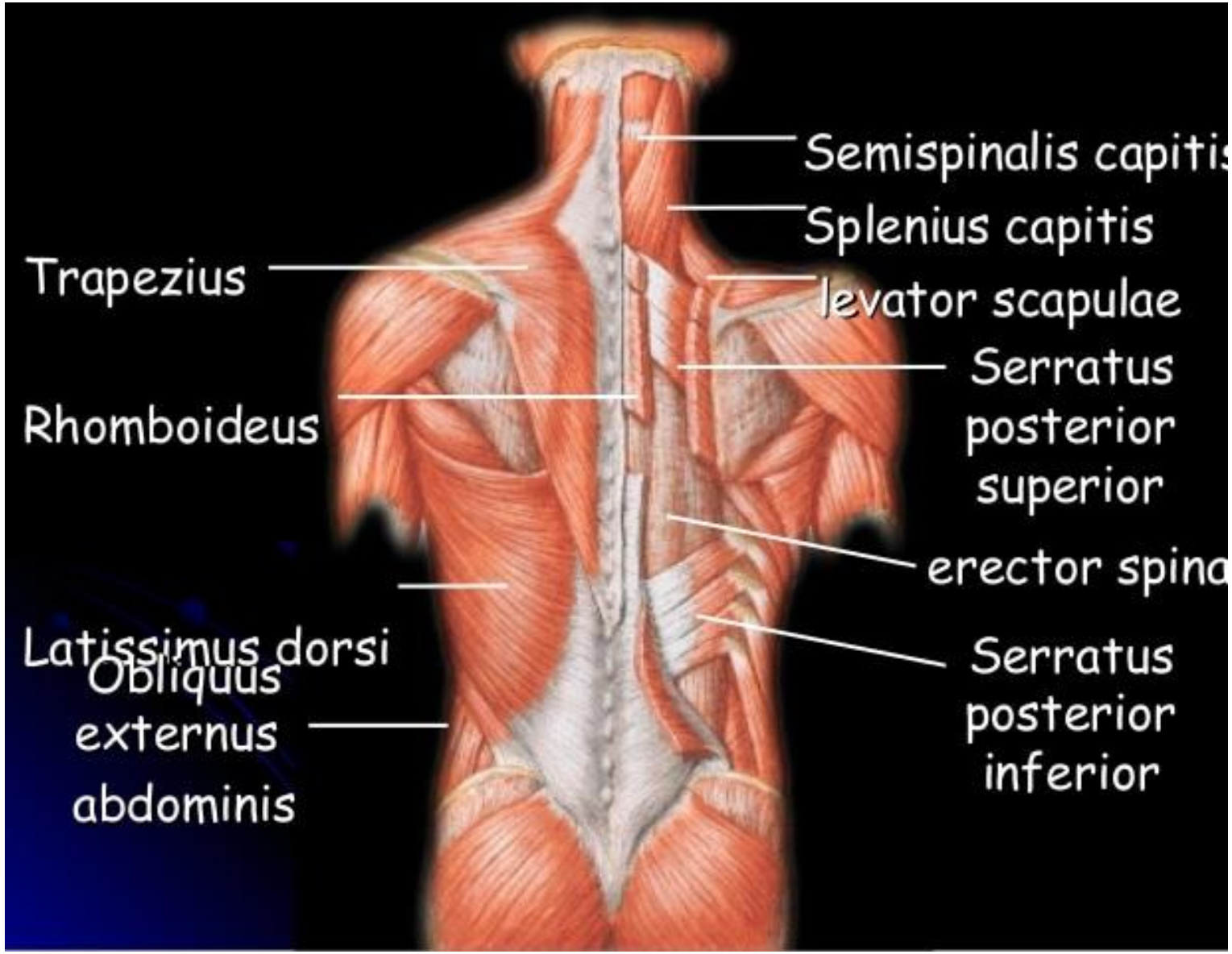
**Deep Muscles** –

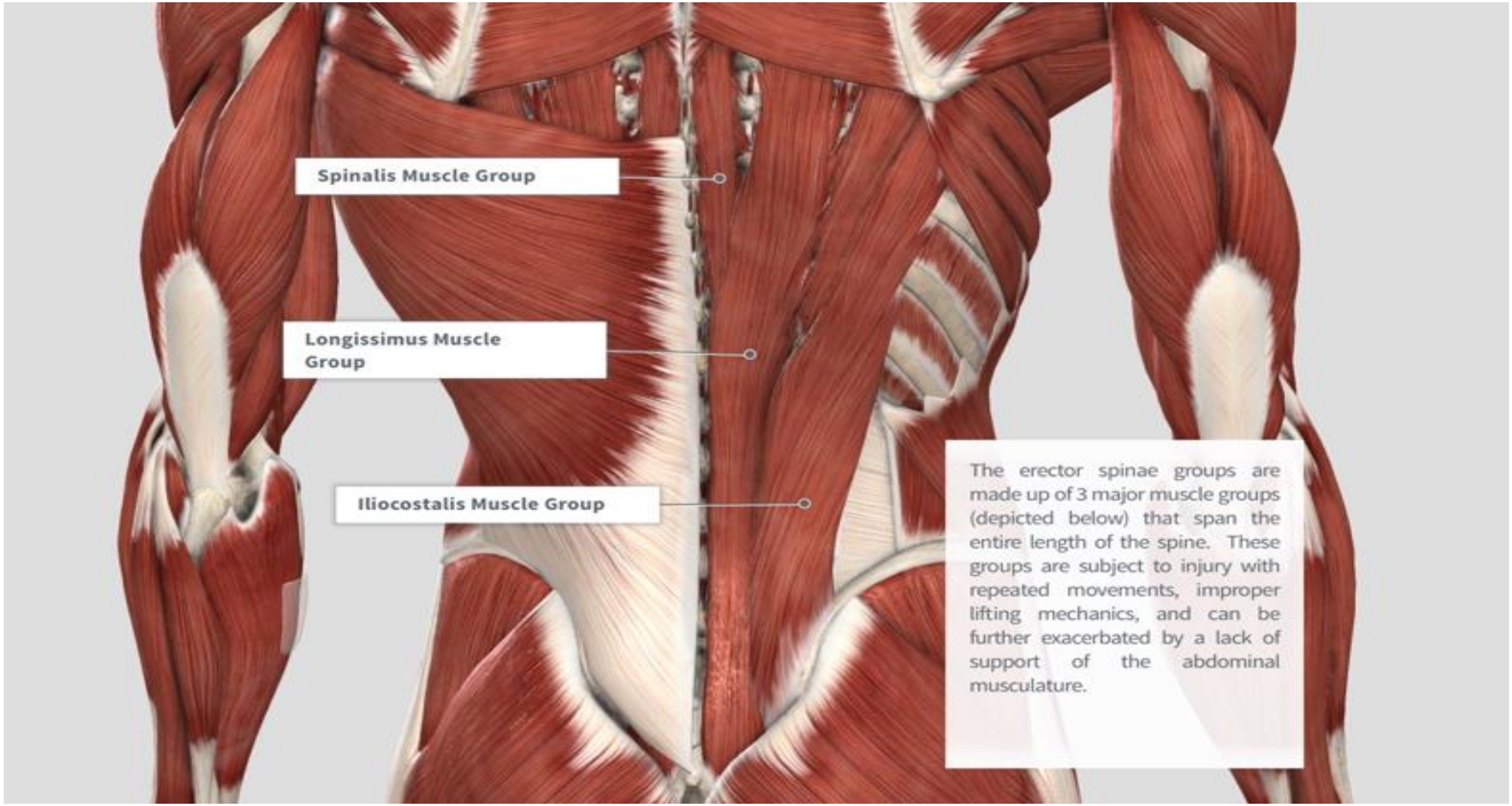
- Transversospinalis
  - rotatores, multifidus, semispinalis
- **Quadratus lumborum**

# Anterior Muscle Group



Superficial Posterior Muscle Group



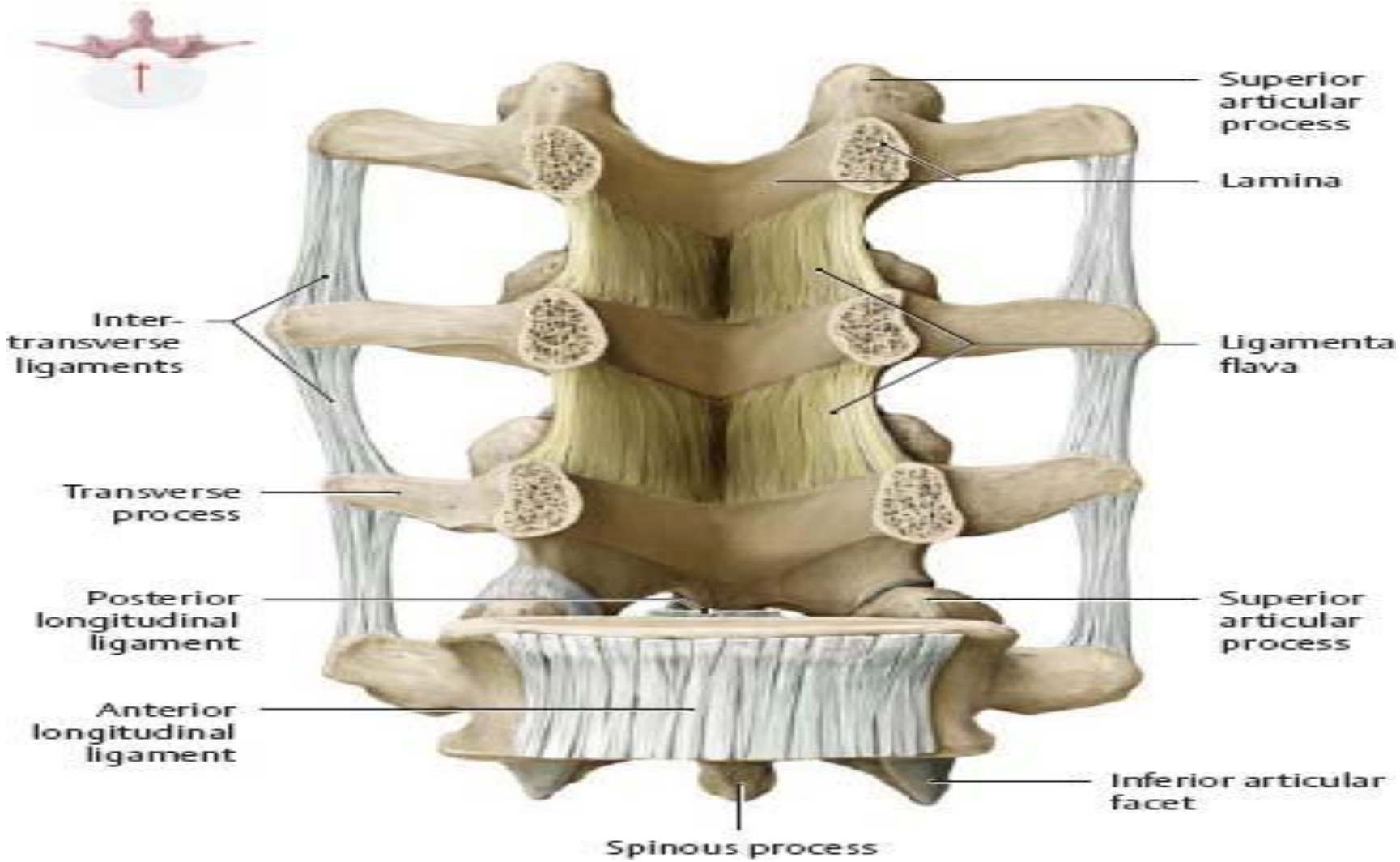

Spinalis Muscle Group
Longissimus Muscle Group
Iliocostalis Muscle Group
The erector spinae groups are made up of 3 major muscle groups (depicted below) that span the entire length of the spine. These groups are subject to injury with repeated movements, improper lifting mechanics, and can be further exacerbated by a lack of support of the abdominal musculature.

# Ligaments

- Form a continuous, dense connective tissue stocking that houses the lumbar vertebrae and sacrum
- Provide attachment sites for associated muscles
- Provides a self-bracing mechanism of the pelvis, a mechanism that functions to maintain the integrity of the low back and pelvis during the transfer of energy from the spine to the lower extremities.

# Ligaments

- Ligamentum Flavum
  - “Yellow Ligament”
  - Attaches the posterior elements of each vertebra together.
  - Runs from each pedicle and lamina to the next and makes up the posterolateral boundary of the neural foramen.  It makes up the covering of the spinal canal
  - Thickening and calcification can cause foraminal narrowing, spinal stenosis, and nerve root compression
  - Is the main opposition to flexion loading of the lumbar spine and can be injured with excessive spinal flexion.
  - Little to no regenerative ability thus a damaged ligament is replaced by dense connective tissue.


Superior articular process
Lamina
Inter-transverse ligaments
Ligamenta flava
Transverse process
Posterior longitudinal ligament
Superior articular process
Anterior longitudinal ligament
Inferior articular facet
Spinous process

# Ligaments

## Interspinous Ligament

- Anchors the thoracolumbar fascia and multifidus sheath to the facet joint capsules
- Central support system for the lumbar spine

## Anterior Longitudinal Ligament

- Courses along the anterior vertebral bodies from the 2$^{nd}$ cervical down to the sacral base, where it blends into the ligamentous encapsulation of the sacrum.
- Lateral borders of the ALL are attachment sites for the psoas muscle
- Thicker in the lumbar spine than the PLL.
- Can be a pain generator

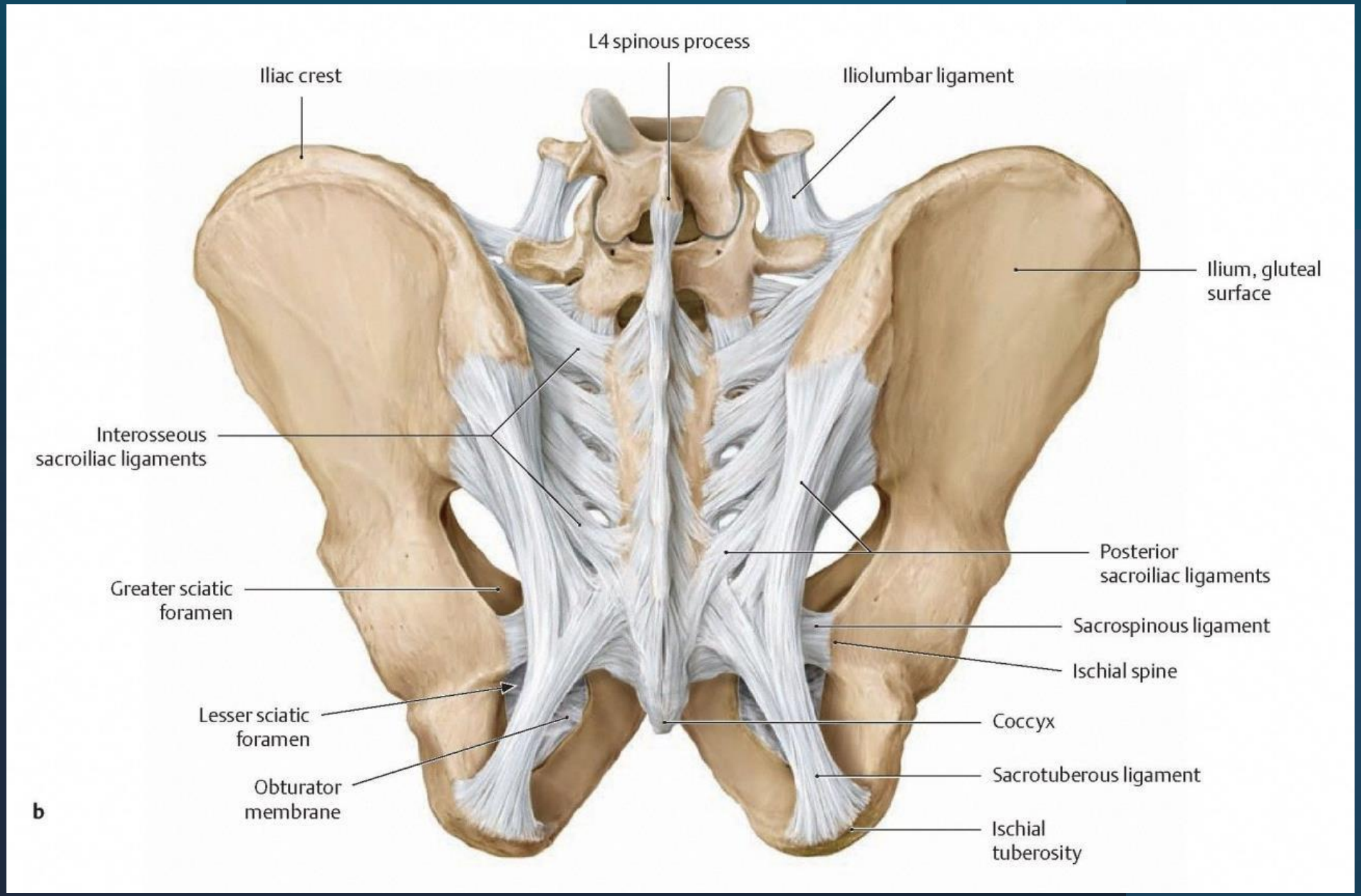
# Ligaments

## Posterior Longitudinal Ligament

- Extends from the basiocciput to the sacrum.
- Attachments are strongest to the outer layer of the annulus of the IV disk and weakest to the vertebral body where the ligament arches over the opening of the foramen for the central vein.
- Is broad in the neck, narrows when it reaches L1.  It takes on a scalloped appearance and is only ½ its original width at L5.
- The scalloped configuration produces a deficiency in the PLL that is located over the posterolateral portion of each lumbar IV disk, to which the posterior portion of the IV disk is also the thinnest portion of the annulus, therefore, is the region of a lumbar disk that is most likely to rupture.

## Iliolumbar Ligament

- Located in the lumbosacral region.
- Attached to the transverse process of L4 and L5 and extends to the iliac crest and anterior and posterior regions of the SI joint.
- Restricts motion at the lumbosacral junction, particularly side bending.
- Clinically it is the first ligament to become tender to palpation when there is LS postural stress.
- A tender point on the iliac crest, located 1 in superior and lateral from the inferior margin of the PSIS
- Its tenderness is a physical clue that should prompt questions about posture and to carefully examine the spine, lower lumbar region and SI joints for somatic dysfunction or acquired short leg.
- The first compliant with irritation to this ligament may be groin pain, causing the patient to think they may have a hernia.


L4 spinous process
Iliac crest
Iliolumbar ligament
Ilium, gluteal surface
Interosseous sacroiliac ligaments
Posterior sacroiliac ligaments
Greater sciatic foramen
Sacrospinous ligament
Ischial spine
Lesser sciatic foramen
Coccyx
Sacrotuberous ligament
Obturator membrane
Ischial tuberosity
b

# Nerve Structures

- **Spinal Cord**
  - Spinal cord terminates at L2 as the conus medullaris (terminal range T12-L2 and some say L3).
  - The dural sac terminates by attaching to the spinal canal at S2 level.
  - Lumbar spinal canal has a triangular shape configuration and normally decreases in AP dimension as it progresses from L1 to L5.
    - As a person ages, the diameter of the lumbar spinal canal may further be compromised by:
      - Hypertrophy of the PLL; thickening of the ligamnetum flava anteriorly, OA, exostoses, osteophytes, tumors, ruptured IV disk.
    - With enough pressure on the canal or the nerves in the cauda equina, there will be loss of reflexes, weakness of muscles, paralysis of the lower extremities, and sphincters of the bladder and rectum (cauda equina syndrome).

# Nerves

- Spinal nerve roots and spinal nerves
  - LS spine gives rise to numerous nerve rootlets from dorsolateral and ventrolateral sulci.
  - These nerve roots descend into the vertebral canal, exiting at each IV foramen.
  - The roots enter a funnel-shaped lateral recess of the spinal canal that narrows to form the lumbar nerve root canal. The distal end of the root canal is the IV foramen.
    - The walls of the nerve foot are pedicle, ligamentium flavum, and lateral aspect of the IV disk.
  - As the nerve root enters the canal it is enveloped by a sheath of spinal dura.
  - As the spinal nerves leave the canal, they are attached to the foramen by several fibrous expansions of the canal wall. As the root traverses the canal and foramen it is at risk from several structures
    - Pedicles
    - IV disk
    - Ligamentum flavum
    - Capsule of the facet joint
    - Foraminal ligaments

# Lumbar Plexus

- Composed of T12-L4 nerves and is located next to the lumbar spine behind the psoas major muscle, supply motor and sensory innervation to the lower limb and pelvic girdle.
  - Iliohypogastric nerve: T12-L1 – supplies motor innervation to the caudal portions of the transverse abdominis and internal oblique muscles of the abdomen. Further divided into the anterior cutaneous branch and the lateral cutaneous branch for sensory of the skin above and to the side of the inguinal ligament
  - Ilioinguinal nerve: T12-L1 – provides motor innervation to caudal transverse abdominis and internal obliques and sensory branches (femoral branch) to the upper and inner thigh, and the anterior scrotal nerve supplying anterior part of the scrotum or labia majora.
  - Genitofemoral nerve: L1-2 – femoral branch supplies the skin below the inguinal ligament; genital branch accompanied by the spermatic cord or round ligament of the uterus giving sensory innervation to these areas and for the medial thigh. Motor innervation to the cremaster muscle
  - Lateral cutaneous nerve of the thigh: L2-L4 – purely sensory supplies the lateral skin of the thigh.
  - Femoral nerve: L1-L4 – **longest nerve of the lumbar plexus.** Just below the inguinal ligament the nerve divides into the sensory anterior femoral cutaneous nerves to the supply the skin of the anterior thigh and into the motor branches that supply the iliopsoas, pectineus, sartorius, and quadriceps femoris muscles. The Saphenous nerve is the sensory terminal branch of the femoral nerve that courses along the femoral artery and vein and moves into the adductor canal. Finally, it follows the great saphenous vein to the medial side of the lower leg, thus innervates the skin between the knee and the foot on the medial side
  - Obturator nerve: :L2-4 – from a motor standpoint it innervates the adductor muscles (adductor longus, brevis, gracilis, pectineus, and adductor magnus muscles), as well as the obturator externus muscle. The anterior branch ends in the sensory cutaneous branch which innervates a palm-sized area at the distal end of the inner thigh.

# Causes of Low Back Pain

# Causes of Low back pain

- May be acute or chronic
- Acute causes of low back pain may be due to fracture, recent strain, disk herniation, infection (osteomyelitis, meningitis, discitis), referred pain.
- Chronic causes are much more common
  - Congenital
  - Metabolic
  - Neoplastic
  - Degenerative

# Sprains/Strains

- Microscopic or macroscopic injury to the soft tissue
- Maybe acute or chronic
- Strain – soft tissue injury to the muscles/tendons
- Sprain – ligamentous injury
- Most lumbar strains are first degree strains. They refer pain into the low back, buttock, and posterior lateral thigh. The patient complains of achiness and muscle spasms. Pain is increased with activity or prolonged sitting/standing
  - May cause somatic dysfunction of lumbar spine with rotation. Any form of OMT is acceptable.
  - In the acute phase soft tissue techniques and indirect techniques seem to be more beneficial. Direct techniques carry a likelihood of exacerbating problems by increasing sympathetic drive.
  - Use of hot and cold packs, NSAIDS, low dose opioids, muscle relaxers maybe be beneficial on a case to case basis - <2 weeks time duration.

# Somatic Dysfunctions of the LS spine (Non-Specific Low Back Pain)

- Location of back pain: low back, buttocks, posterior lateral thigh → localized type of pain
- Quality: ache, muscle spasm
- Signs and symptoms: increased pain with activity or prolonged standing/sitting/increased muscle tension
- TX: OMT – counterstain, muscle energy, HVLA. Should be directed at decreasing restrictions in other areas that may alter the structure-function relationship of the lumbosacral spine.  Look for pelvic/sacral dysfunction; thoracic dysfunction as well.

# Psoas Syndrome

- Flexion contracture of the iliopsoas
- Pathogenesis- often precipitated from prolonged positions that shorten the psoas (sports injuries, overuse injury, repetitive jumping). However, organic causes may also cause psoas spasm through viscero-somatic or somato-somatic reflexes. Organic causes must be ruled out before initiating treatment for mechanical causes
- Organic causes: appendicitis, sigmoid colon dysfunction, ureteral calculi, endometriosis, ureter dysfunction, metastatic cancer of prostate, salpingitis
- Location of Pain – low back sometimes radiating to groin
- Quality- ache/muscle spasm
- S/S – restricted hip extension, increased pain when standing or walking, positive Thomas Test, tenderpoint 1 cm medial to ASIS, non-neutral dysfunction of L1 or L2, positive pelvic shift test to the contralateral side, lumbar hyper lordosis, and contralateral piriformis spasm
- Treatment - an acute spasm may benefit from ice to decrease pain and edema. Do not initially use heat. Counterstrain to the anterior iliopsoas tender point or prone psoas muscle energy is very effective followed by muscle energy or HVLA to the lumbar dysfunction. Some believe that symptoms will not resolve until the L1-L2 dysfunction is treated.

# Iliolumbar Ligament Syndrome/Iliac Crest Syndrome

- Pathogenesis – iliolumbar ligament becomes stressed, irritated/inflamed, or torn. Occurs with acute L5 disc protrusion/herniation, spinal instability, or spondylolisthesis, direct trauma, lifting injury, a direct fall in which the ligament is pulled at the iliac crest insertion site.
- S/S – tissue texture changes at the ilial insertion of the ligament. Pelvic side shift towards the iliolumbar ligaments. Ipsilateral adductor muscle tight
- TX –rest, ice, analgesics, massage, injections; OMT- counterstrain to iliolumbar ligament has significant clinical value

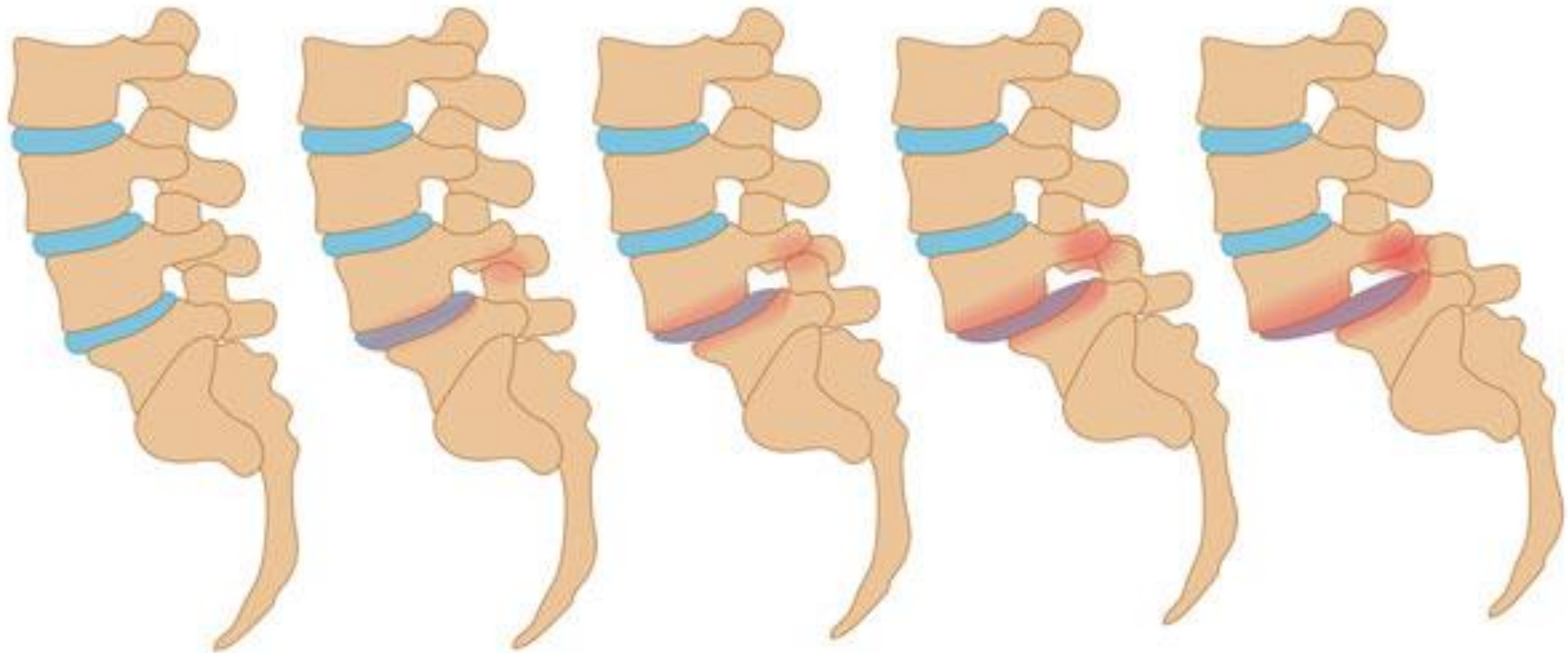
# Spinal Stenosis

- Narrowing of the spinal canal or IV foramina usually due to degenerative changes, causing pressure on the nerve roots (or rarely the cord).
- Pathogenesis – degenerative changes in the lumbar spine include:
  - Hypertrophy of the facet joints or ligamentum flavum
  - Broad based disc bulge, protrusion or herniation
  - Loss of IV disc height
- Location of pain – lower back to legs
- Quality of Pain – ache, shooting pain or parathesias
- S/S – worsened by lumbar extension (standing, walking or lying supine).
- Radiology – osteophytes and decreased IV disc space are usually present. MRI demonstrating central or foraminal stenosis
- TX – OMT should be directed at decreasing any restrictions, improving ROM and releasing any lumbar extensor spasm. Conservative tx – PT, NSAID's, low dose tapering steroids. An epidural steroid injection may be useful if conservative tx is not effective. Surgical laminectomy with decompression indicated if all above fails.

# Degenerative Changes

- Spondylosis – radiographic term for degenerative changes within the IV disc and ankylosing of adjacent vertebral bodies.
- Spondylolysis – a defect usually of the pars interarticularis without anterior displacement of the vertebral body. Symptoms and treatment similar to spondylolisthesis. Since lateral lumbar x-rays will not reveal slippage, oblique views will identify the fracture of the pars interarticularis. If is often seen a "collar" on the neck of the scotty dog.
- Spondylolisthesis – anterior displacement of one vertebra in relation to the one below. Often occurs at L4 or L5. Can be due to bilateral fractures in the pars (usually L5/S1) or can be related to degeneration of the facet joints from longstanding instability (usually L4/5).
  - 5% of the population – half are asx. Patients who become sx do usually after the age of 20
  - Location – low back pain, buttocks and/or posterior thigh
  - Quality – ache
  - S/S – increase pain with extension based activities. Tight hamstrings bilaterally. Stiff-legged, short stride, waddling type of gait. Typically, no neurological deficits. Positive vertebral step off sign (palpating the spinous process there is an obvious anterior displacement at the area of the lithesis.
  - Radiology – anterior displacement of one vertebrae on another on lateral films. Can be classified by grades 1-4 based on the degree of slippage.
  - TX- most patients (85-90%) can be managed conservative management. The goals of manipulation is to reduce lumbar lordosis and somatic dysfunction. Can treat a Grade 1 and 2 with omt. HVLA is relatively contraindicated. Can use lateral recumbent soft tissue techniques, MFR, lumbar/sacral release and/or traction techniques. Additional conservative management includes weight loss, avoiding high heels and avoiding flexion based exercises. Heel lifts have been advocated to control postural mechanics. Lumbo-sacral orthotics can be considering for short term stability. Patient with a high grade lithesis with neurologic sx or findings will need neurosurgical evaluation for spinal fusion, and either postural or instrumented reduction of the amount of slip.

# Spondylolisthesis



Normal spine | Grade 1 <25% | Grade 2: 25-50% | Grade 3: 50-75% | Grade 4 >75%

# Cauda Equina Syndrome

- Pressure on the nerve roots of the cauda equina usually due to a massive central disc herniation, spondylolisthesis, fracture, or tumor
- Location of pain – low back and legs
- Quality – sharp
- Radiology – MRI is the gold standard
- S/S – saddle anesthesia, decreased deep tendon reflexes, decreased rectal sphincter tone, and loss of bowel and bladder control
- TX – **emergent surgical decompression** of the cauda equina is imperative within 48 hours. If surgery is delayed too long, permanent neurologic damage can ensue. **NO OMT!!!!!!**

# Osteopathic Discussion

# Tenets of Osteopathic Medicine

- The body is a unit; the person is a unit of body, mind, and spirit
- The body is capable of self-regulation, self-healing, and health maintenance
- Structure and function are reciprocally interrelated
- Rational treatment is based upon an understanding of the basic principles of body unity, self-regulation, and the interrelationship of structure and function

# Lumbar Mechanics and Somatic Dysfunction

Due to the alignment of the facets (backward and medial to the superior facets), the major motion of the lumbar spine is flexion and extension.

There is a small degree of side bending and very limited amount of rotation

Motion follows Fryette's Laws

Somatic dysfunction may occur in any of the three planes of motion

It is not uncommon to find that a single segment dysfunction does not follow Fryette's Principle, especially L5. In sacral torsions, motion of L5 will influence the motion of the sacrum in 2 ways:

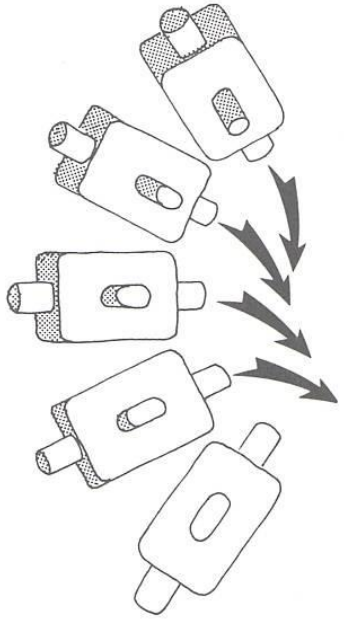
- Side bending of L5 will cause a sacral oblique axis to be engaged on the same side
- Rotation of L5 will cause the sacrum to rotate towards the opposite side

# Somatic Dysfunction

- “Impaired or altered function of related components of the somatic system: skeletal, arthrodial, and myofascial structures, and related vascular, lymphatic, and neural elements.”
- **TART changes**
  - Tenderness → Where does it hurt?
  - Asymmetry → Where is there a change in structure on one side?
  - Range of Motion is altered → Where is there less motion?
  - Tissue texture abnormality → where do the tissue feel tight? Knot-like or swollen?

# Fryette Law's – Law 1

- **Law I** = when the spine is in neutral (easy normal), sidebending and rotation are in opposite directions. (Type I Mechanics)

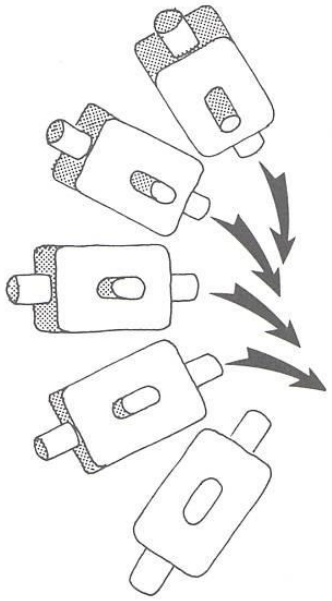


- Occurs in neutral (facets not engaged)
- Found in thoracic and lumbar spines
- Forms long curves, multiple segments
- Compensatory

# Type I Mechanics

- Posterior transverse process and paravertebral fullness visible when spine is in neutral
- Asymmetry not significantly altered by flexion/extension
- Side bending and rotation opposite directions

- Side bending right
- Rotation left



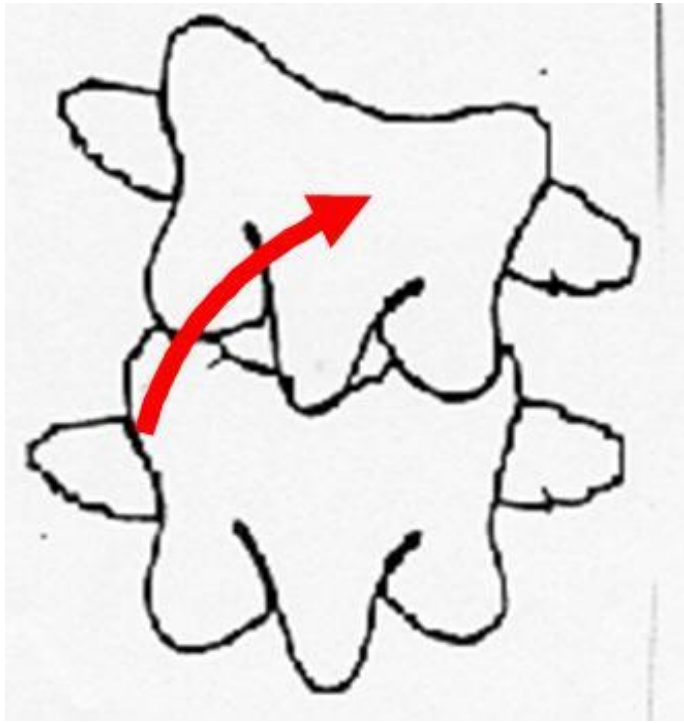
# Fryette's Law II

- When the spine is flexed or extended (non-neutral), side bending and rotation are in the same directions (Type 2 mechanics)
- Occurs in flexion and extension
  - Facets engaged
- Occurs in thoracic and lumbar spines
- Usually single segment
- Found at apices and crossovers and/or site of viscerosomatic reflexes
- Primary somatic dysfunction
  - Due to strain or viscerosomatic reflex

# Type 2 Mechanics

Extension Somatic Dysfunction

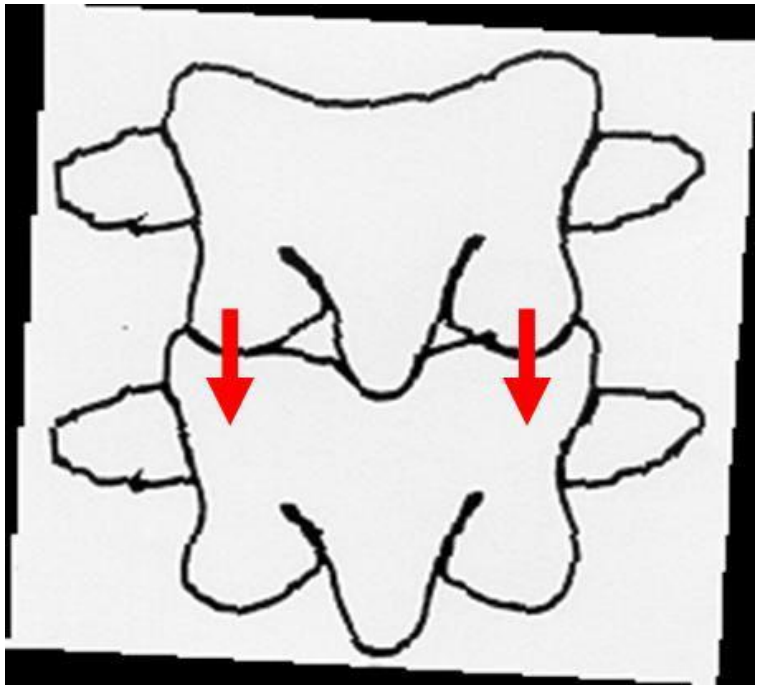
- In flexion – exaggeration of asymmetry
  - Left facet can open freely
  - Right facet locked closed – cannot open
  - Pivots around right facet
  - Rotates and side bents right
- Restriction = $FR_LS_L$
- Somatic Dysfunction = $ER_RS_R$



# Type II Mechanics

## Extension Somatic Dysfunction

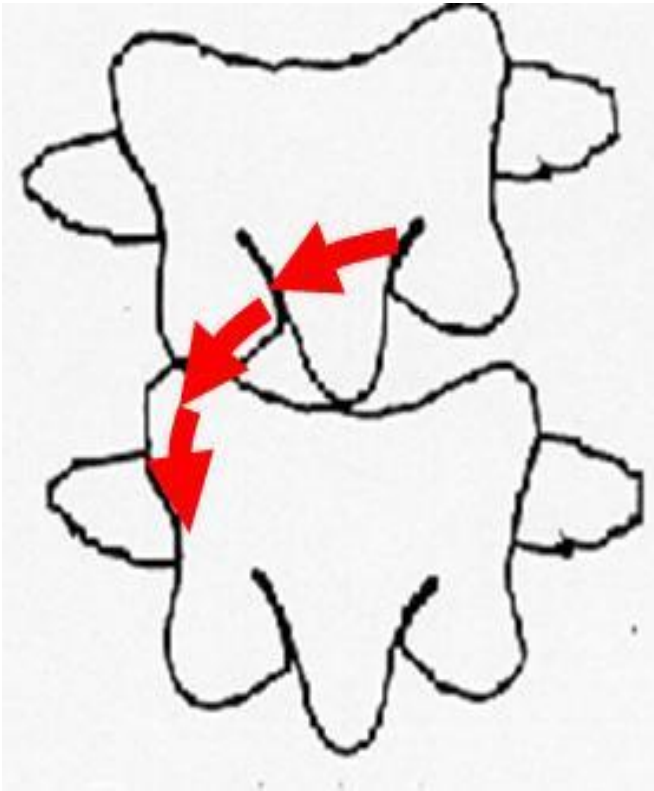
- **In extension** – no asymmetry as both facets close easily
  - No apparent rotation/side bending asymmetry
  - Most comfortable position for patient
- Restriction = $FR_LS_L$
- Somatic Dysfunction = $ER_RS_R$



# Type II Mechanics

## Flexion Somatic Dysfunction

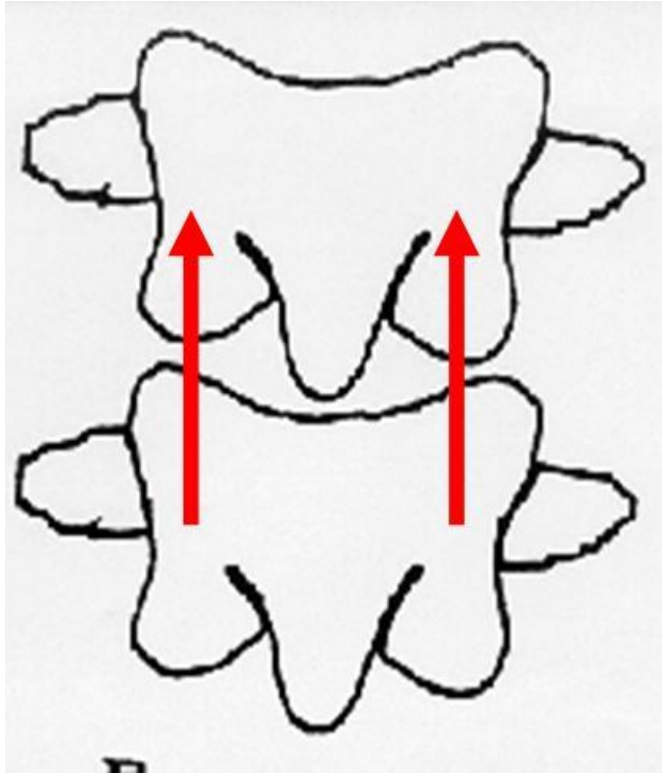
- In extension – exaggeration of asymmetry
  - Left facet closes normally
  - Right facet locked open – cannot close
  - Causes sidebending and rotation left
- Restriction = $ER_RS_R$
- Somatic Dysfunction = $FR_LS_L$



# Type II Mechanics

## Flexion Somatic Dysfunction

- In Flexion – no asymmetry as both facets can open easily
  - No apparent rotation/side bending asymmetry
  - Most comfortable position of the patient
  - Restriction = $ER_RS_R$
  - Somatic Dysfunction - $FR_LS_L$

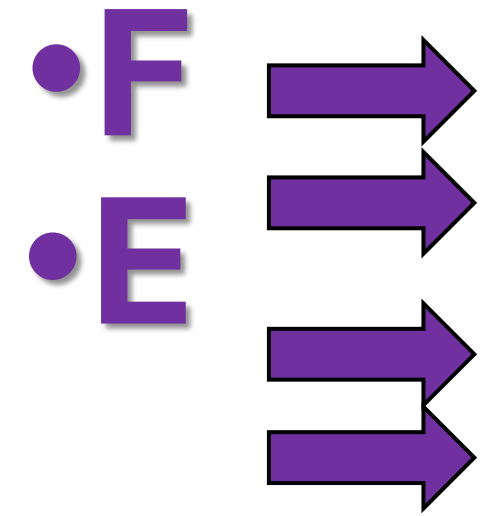


# Memory Aid

- Type 1:


- Sidebending and Rotation <u>opposite</u> directions

- **Type 2:**




- **Sidebending and Rotation <u>same</u> directions**

| Type I S/D | Type II S/D |
| --- | --- |
| Neutral; sidebending and rotation opposite sides | Flexion or extension; sidebending and rotation to same side. |
| NS(R)R(L) or NS(L)R(R) | FR(R)S(R), ER(R)S(R),<br>FR(L)S(L), or ER(L)S(L) |
| Facets not engaged | Facets engaged |
| Multiple segments, long curves | Single segments |
| Compensatory, adaptive | Traumatic / primary / viscerosomatic |
| Rotation toward convexity, out from under the load | Rotation towards the concavity,<br>into the load |
| Smooth curves | Apices and crossovers,<br>viscerosomatic reflexes |
| Treat last after Type II, if necessary | Treat first |

# OMT Diagnosis and Treatment

# Goals of OMT

- Restore maximum pain-free movement of the musculoskeletal system
- To do this:
  - Assess what movement is present
  - Perform a technique to improve motion if there is a dysfunction
  - Reassess to see if there is better movement
- Know your indications and contraindications

# Assessment

- The key in history is ruling out “Red Flag”
- Red Flags = **R I F T**
  - Radiculoapthy – saddle anesthesia, GU symptoms, severe or progressive neurological deficits of lower extremity, loss of anal tone, weak quads (knee extension weakness), ankle plantar flexors, evertors, dorsiflexors (foot drop).
  - Infection – fever, chills, risk factors (immunosuppression, IV drug use)
  - Fracture – trauma, fall, lifting
  - Tumor – patient <20 or >50 years old; history of cancer, constitutional symptoms, pain worse in supine/night.

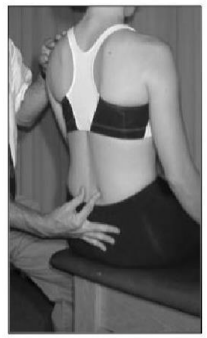
- Prior to OMT:
  - Neurological Screen → motor, sensory, deep tendon reflexes for both upper and lower extremities.
- Osteopathic Structural Exam
  - TART

# Choice of Treatment Modality

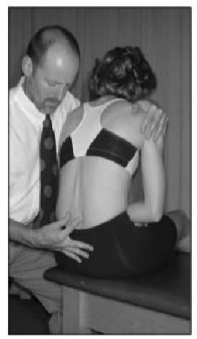
- Direct vs Indirect Techniques
  - Direct - “engages” the restrictive barrier (we move the tissue we treat into the restrictive barrier).
    - HVLA, muscle energy, direct MFR, soft tissue (can be direct or indirect), lymphatic pumps, BLT (can be both)
  - Indirect – treatment moves the tissue away from the restrictive barrier
    - Counterstain, FPR, indirect MFR, certain soft tissue, BLT
- The more acute the injury, we should use an indirect technique or very gentle direct techniques. As more time passes from injury, we can use more direct techniques
- The older the patient, the more likely we should use indirect techniques
- Avoid HVLA when fracture could be suspected, or when we could cause a fracture (osteoporotic patients).
- Lumbar strains/sprains – treat the lumbar spine first, then treat the psoas, since the psoas is the most often the problem, and is often the most acute part of the problem.
  - Treat the L1-L2 as noted prior first.

### Lumbar Rotation Testing—Seated

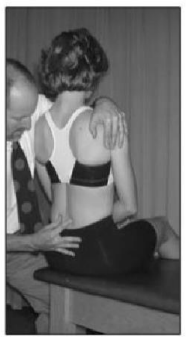
1. With the patient seated or prone, palpate the lumbar paraspinal area, comparing right and left sides for increased fullness;
2. Fullness may be due to muscle tension, edema, or vertebral rotation to that side;
3. Vertebral rotation multiple segments = neutral or type 1 somatic dysfunction with sidebending to opposite side;
4. Vertebral rotation single segment = nonneutral or type 2 somatic dysfunction with sidebending to same side—test flexion and extension;
5. Rotation worse in flexion = extension somatic dysfunction; rotation worse in extension = flexion somatic dysfunction.



**Palpation for L3 rotation**



**Flexion testing**



**Extension testing**



### Lumbar Rotation Testing—Prone

1. With the patient prone or seated, place your thumbs on a lumbar vertebra's transverse processes located an inch lateral to the spinous process;
2. Push anteriorly on the right transverse process to induce rotation left; Push anteriorly on the left transverse process to induce rotation right;
3. Restricted rotation left = rotated right; Restricted rotation right = rotation left.

**Testing L4 rotation left**

**Neutral, sidebending left, rotation right (Drawing by William A. Kuchera, DO, FAAO)**

# Soft Tissue

## Treatment

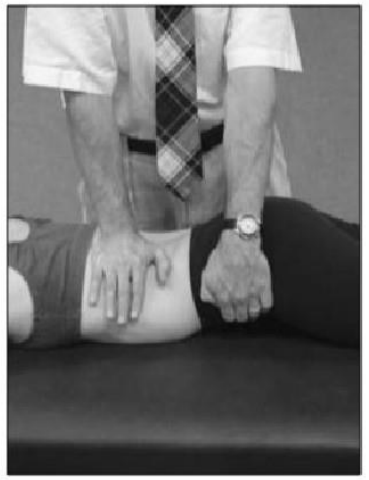
### THORACOLUMBAR KNEADING/STRETCHING

**INDICATIONS:** Thoracic or lumbar paraspinal muscle tension associated with back pain, chest wall pain, and other problems.

**RELATIVE CONTRAINDICATIONS:** Acute lumbar strain and sprain, acute vertebral or rib fracture.

**TECHNIQUE** (prone):

1. Stand on the opposite side and place your cephalad palm on the tense muscle lateral to the spinous processes;
2. Grasp the ASIS on the side of tension with your caudad hand;
3. Slowly knead the tension by leaning into your cephalad hand with the arm straightened to push the muscle anteriorly and laterally, avoiding sliding over the skin;
4. Simultaneously stretch the tense muscle by slowly pulling your caudad hand posteriorly to lift the ASIS until resistance is felt;
5. Repeat simultaneous kneading and stretching until tension is reduced.



**Thoracolumbar kneading/stretching**

# Counterstrain – Anterior and Posterior points



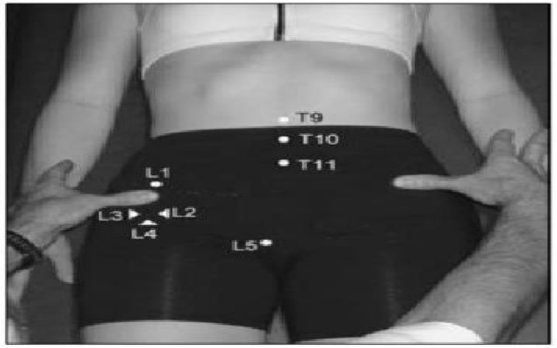
## PALPATION

### Lumbar Tender Points

1. Palpate for posterior lumbar tender points at the following locations:
   a) **Posterior T10–L5**—spinous processes or 1/2–1" lateral;
   b) **Posterior L3**—gluteal musculature halfway between posterior L4 and L5;
   c) **Posterior L4**—iliac crest in posterior axillary line;
   d) **Posterior L5** (upper pole L5)—superior surface of posterior superior iliac spine (PSIS) at insertion of iliolumbar ligament;
   e) **Lower pole L5**—inferior surface of the PSIS.

**Posterior lumbar palpation (LPL5 shown)**

2. Palpate for anterior lumbar tender points at the following locations:
   a) **Anterior T9**—1/2–1" superior to umbilicus;
   b) **Anterior T10**—1" below umbilicus;
   c) **Anterior T11**—2" below umbilicus;
   d) **Anterior T12**—inner aspect of iliac crest in mid-axillary line (not visible in photo);
   e) **Anterior L1**—1/2" medial to anterior superior iliac spine (ASIS);
   f) **Anterior L2**—medial surface of anterior inferior iliac spine (AIIS);
   g) **Anterior L3**—lateral surface of AIIS;
   h) **Anterior L4**—inferior surface of AIIS;
   i) **Anterior L5**—pubic ramus 1/2" lateral to pubic symphysis.



**Anterior lumbar tender points (ASIS palpation shown, AT12 not shown)**

# Counter Strain Techniques – Posterior



## LOWER POLE L5 COUNTERSTRAIN

**INDICATIONS:** Lower pole L5 tender point associated with back pain, pelvic pain, hip pain, and other problems.

**RELATIVE CONTRAINDICATIONS:** Acute fracture, hip dislocation, and severe hip osteoarthritis.

**TECHNIQUE** (prone):

1. Locate the tender point on the inferior aspect of the posterior superior iliac spine, labeling it 10/10;
2. Flex the hip and knee 90° and retest for tenderness;
3. Fine tune this position with slight hip adduction until tenderness is minimized to 0/10 if possible but at most 3/10;
4. Hold the position of maximum relief for 90 seconds, maintaining finger contact to monitor for tissue texture changes but reducing pressure;
5. Slowly and passively return the leg to the table and retest for tenderness with the same pressure as initial labeling.

**Lower pole L5 tender point and treatment position**



## T10–L5 POSTERIOR COUNTERSTRAIN

**INDICATIONS:** Posterior T10–L5 tender point associated with back pain, pelvis pain, chest pain, and other problems.

**RELATIVE CONTRAINDICATIONS:** Acute fracture, hip dislocation, severe hip osteoarthritis.

**TECHNIQUE** (prone):

1. Locate the tender point, labeling it 10/10;
2. Stand on the opposite side and lift the thigh on the side of the tender point to extend the hip;
3. Retest for tenderness;
4. Fine tune this position with slightly more hip extension, abduction, or adduction until tenderness is minimized to 0/10 if possible but at most 3/10;
5. Hold the position of maximum relief for 90 seconds, maintaining finger contact to monitor for tissue texture changes but reducing pressure;
6. Slowly and passively return the hip to neutral and retest for tenderness with the same pressure as initial labeling. If successful, consider prescribing LUMBAR POSITION OF EASE.

**L3 posterior tender point and treatment position**

# Counterstrain – Anterior



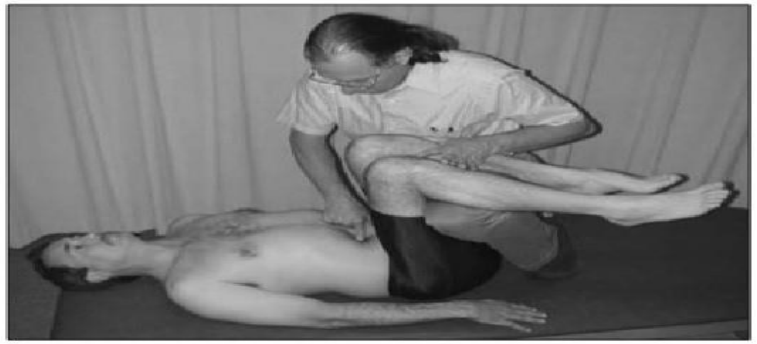
## T9–L5 ANTERIOR COUNTERSTRAIN

**INDICATIONS:** Anterior T9–L5 tender point associated with back pain, pelvic pain, chest wall pain, abdominal pain, and other problems.

**RELATIVE CONTRAINDICATIONS:** Acute lumbar fracture, acute lumbar strain and sprain.

**TECHNIQUE** (supine):

1. Stand beside the patient and locate the tender point, labeling it 10/10;
2. Passively flex the knees and hips 90° and retest for tenderness;
3. Fine tune this position with increased hip flexion and slight rotation or sidebending of the knees until tenderness is minimized to 0/10 if possible but at most 3/10;
4. Hold the position of maximum relief for 90 seconds, maintaining finger contact to monitor for tissue texture changes but reducing pressure;
5. Slowly and passively return the legs to the table and retest for tenderness with the same pressure as initial labeling.



**Anterior T10 tender point and treatment position**

# Psoas OMT and Stretching



## ILIOPSOAS COUNTERSTRAIN

**INDICATIONS:** Iliacus or psoas tender point associated with abdominal pain, pelvic pain, back pain, and other problems (see ILIOPSOAS MUSCLE, p. 72).

**RELATIVE CONTRAINDICATIONS:** Acute lumbar or hip fracture, or hip dislocation.

**TECHNIQUE** (supine):

**Psoas tender point and counterstrain position**

1. Stand beside the patient and locate the tender point 1" medial and slightly inferior to the ASIS, labeling it 10/10;
2. Cross the ankles and passively flex the knees and hips 90°, allowing the hips to externally rotate;
3. Retest for tenderness and fine-tune this position with increased hip flexion until tenderness is 0/10 if possible, but at most to 3/10;
4. Hold the position of maximum relief for 90 seconds, maintaining finger contact to monitor for tissue texture changes but reducing pressure;
5. Slowly and passively return the legs to the table and retest for tenderness with the same pressure as initial labeling; if successful, consider prescribing ILIOPSOAS POSITION OF EASE and/or ILIOPSOAS STRETCH.



## ILIOPSOAS POSITION OF EASE

1. Lie on your back with legs propped up on a chair or stool;
2. Cross your ankles with the foot on the side of the back or pelvic pain on top;
3. Let your knees fall apart;
4. If comfortable, take a few deep breaths and rest in this position for 2–5 minutes;
5. Slowly uncross your legs, bring them down, and roll to one side before getting up;

   Use this position 2–4 times a day, or as needed for pain relief.

**Iliopsoas position of ease**

## ILIOPSOAS STRETCH[1]

1. Kneel with one foot on the floor a few feet in front of the other knee;
2. Slowly lean forward onto the leg in front while using your hand to push the other hip forward;
3. Take a few deep breaths and stretch for 10–20 seconds;
4. Repeat to the opposite side;
5. Do this stretch 1–4 times a day.

**Left iliopsoas stretch**

# Lumbar Spine Muscle Energy



## LUMBAR MUSCLE ENERGY—LATERAL

**INDICATIONS:** Restricted multisegment lumbar rotation associated with back pain, scoliosis, and other problems.

**RELATIVE CONTRAINDICATIONS:** Acute lumbar sprain, undiagnosed radiculopathy, acute vertebral fracture, and vertebral cancer or infection.

**TECHNIQUE:**

1. Stand in front of the patient who is lying with the vertebral rotation side up;
2. Flex the hips until you feel motion in the middle of the restricted segments;
3. Lift both ankles until you feel sidebending in the middle of the restricted segments;
4. Ask the patient to push the ankles down toward the table for 3–5 seconds against your equal resistance;
5. Allow full relaxation and then slowly lift the ankles to a new lumbar sidebending restrictive barrier;
6. Repeat this isometric contraction and stretch 3–5 times or until lumbar mobility returns;
7. Retest lumbar rotation. If successful, consider prescribing LUMBAR EXTENSOR STRETCH.

**Muscle energy for L1–5 N R left S right**



## LUMBAR MUSCLE ENERGY—LATERAL RECUMBENT

**INDICATIONS:** Restricted lumbar rotation associated with back pain, scoliosis, and other problems.

**RELATIVE CONTRAINDICATIONS:** Acute lumbar sprain, undiagnosed radiculopathy, acute vertebral fracture, and vertebral cancer or infection.

**TECHNIQUE:**

1. Stand in front of the patient who is lying with the side of lumbar rotation toward the table;
2. Flex the upward hip until you feel motion at the restricted segment and tuck the foot behind the other knee;
3. Rotate the back toward the table by pushing the upward shoulder posteriorly and lifting the table-side arm and shoulder until you feel rotation at the restricted segment;
4. Place your forearm across the buttock, lean over top of that arm, and use your other arm to stabilize the patient's shoulder, taking care not to push into the ribs or breast;
5. Ask the patient to push the pelvis backward for 3–5 seconds against your equal resistance;
6. Allow full relaxation and then slowly move the pelvis anteromedially to a new lumbar rotation restrictive barrier;
7. Repeat 3–5 times or until lumbar mobility returns;
8. Retest lumbar rotation. If successful, consider prescribing LUMBAR EXTENSOR STRETCH.

**Muscle energy for L3 rotated right**

# Lumbar Spine HLVA



## LUMBAR THRUST—LATERAL RECUMBENT (LUMBAR ROLL)

**INDICATIONS:** Restricted lumbar rotation associated with back pain, scoliosis, and other problems.

**RELATIVE CONTRAINDICATIONS:** Acute lumbar sprain, lumbar joint hypermobility, undiagnosed radiculopathy, acute vertebral fracture, acute herniated or ruptured disc, and vertebral cancer or infection.

**TECHNIQUE:**

1. Stand in front of the patient who is lying on the side of lumbar rotation;
2. Flex the upward hip until you feel motion at the restricted segment and then tuck the patient's foot behind the other knee;
3. Rotate the back toward the table by lifting the table-side arm until you feel rotation at the restricted segment;
4. Use your cephalad arm to stabilize the shoulder, place your other forearm across the buttock, and lean over top of that arm;
5. Ask the patient to take a deep breath and during exhalation slowly push the pelvis anteromedially to take up the rotational slack;
6. At the end of exhalation apply a short quick thrust with your arm and body onto the pelvis in an anteromedial direction;
7. Retest lumbar rotation. If successful, consider prescribing LUMBAR SELF-MOBILIZATION or THORACOLUMBAR STRETCH/SELF-MOBILIZATION.

**Lateral recumbent thrust for L3 rotated right**



## THORACOLUMBAR MUSCLE ENERGY/THRUST—SEATED

**INDICATIONS:** Restricted lumbar or thoracic rotation associated with back pain, scoliosis, and other problems.

**RELATIVE CONTRAINDICATIONS:** Acute lumbar sprain, joint hypermobility, undiagnosed radiculopathy, acute vertebral fracture, and vertebral cancer or infection.

**TECHNIQUE:**

**ME for L1–5 N R right S left**

1. Standing behind the seated patient, place your thenar eminence on the posterior transverse process(es);
2. Reach across the upper chest with your other hand and arm to control the patient's shoulders and trunk;
3. Move the trunk into the rotation, sidebending, and flexion–extension restrictive barriers until you feel movement at the restricted segment(s);
4. Ask the patient to straighten the trunk and/or shoulders for 3–5 seconds against your equal resistance;
5. Allow full relaxation and then slowly move the trunk to new restrictive barriers as you push anterior into the posterior transverse process(es);
6. Repeat this isometric contraction and stretch 3–5 times or until lumbar mobility returns;
7. Add a thrust if needed by a short and quick anterior push into the posterior transverse process(es) as you simultaneously move the trunk into its restrictive barriers;
8. Retest lumbar rotation. If successful, consider prescribing LUMBAR SELF-MOBILIZATION or THORACOLUMBAR STRETCH/SELF-MOBILIZATION.

# OMT Billing

- Make sure on your note on the physical exam you document your somatic dysfunction/restriction diagnosis under your osteopathic structural exam
  - L2-L5 N Rr Sl
  - L2 Posterior Tenderpoint
- On assessment – you need a pain diagnosis and the somatic dysfunction together (need both for proper billing) for each region (if there are other areas of treatment than you need to do the same for all areas that you treated).
  - Lumbar strain/chronic lumbar back pain
  - Lumbar Somatic Dysfunction
- On your plan – document what technique(s) that you did, along with resolution/improvement/non-improvement of symptoms and improvement/resolution/non-improvement of somatic dysfunction (proves that you rechecked your work after the treatment). It is ok that you document if a particular technique isn't effective and that you choose another technique.
- Billing – along with a .25 modifier
  - 98925 – 1-2 Regions
  - 98926 – 3-4 Regions
  - 98927 - 5-6 Regions
  - 98928 - 7-8 Regions
  - 98929 - 9-10 Regions

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# Intro to POCUS with Basic Lung Ultrasound

FM Refresher Course

James Liszewski, MD
Erin Meier, DO
Diana Davidek, MD
Sarah Sinno, MD

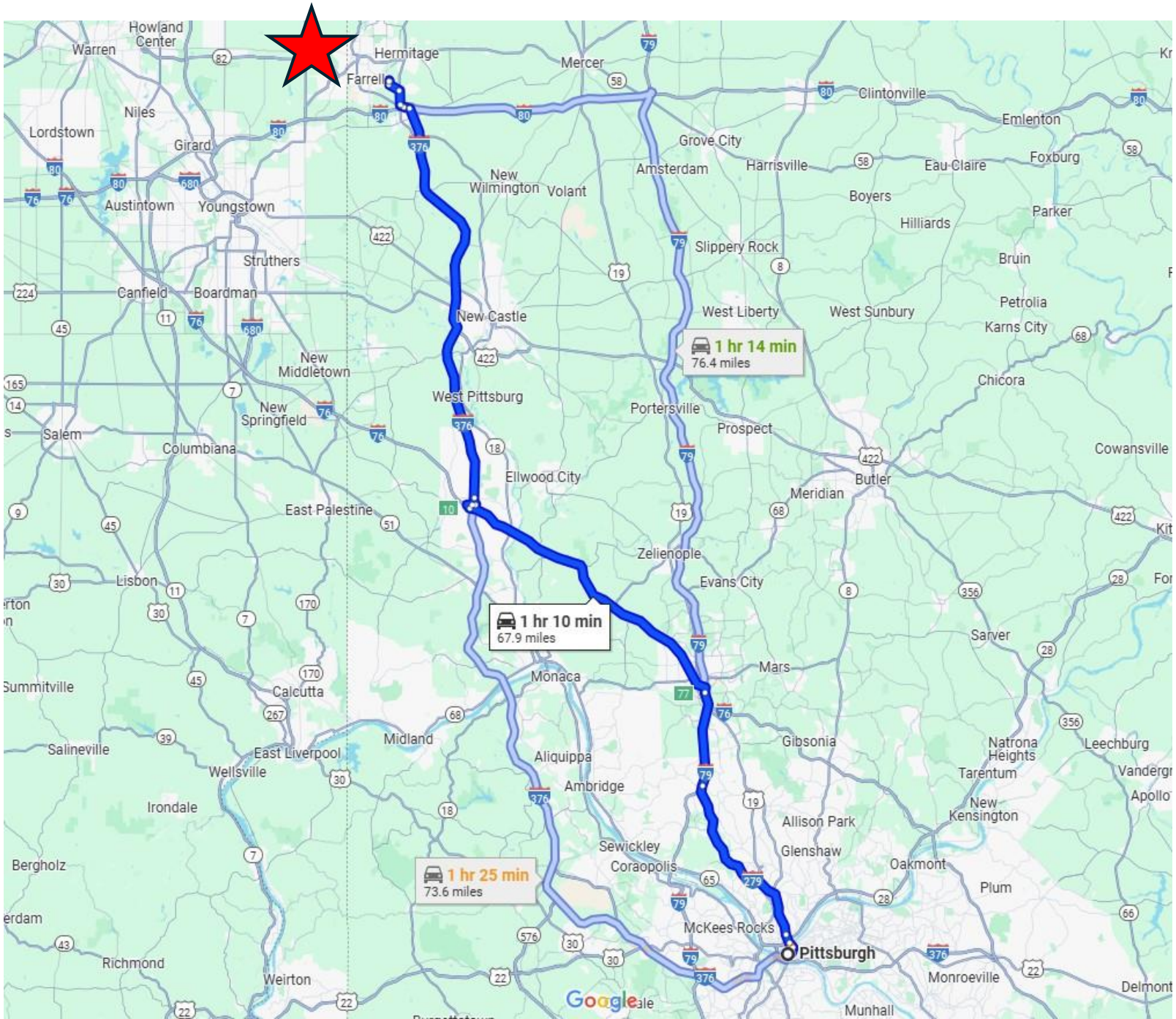
just a bunch of

# HOCUS POCUS

# Introduction

- UPMC Horizon Family Medicine Residency faculty and residents
- Jim Liszewski MD - faculty
- Erin Meier DO - faculty
- Sara Sinno MD – 3rd year FM resident
- Diana Davidek MD – 3rd year FM resident
- Ultrasound models: Caitlin, Isabella, Lydia, Noah

(no financial disclosures)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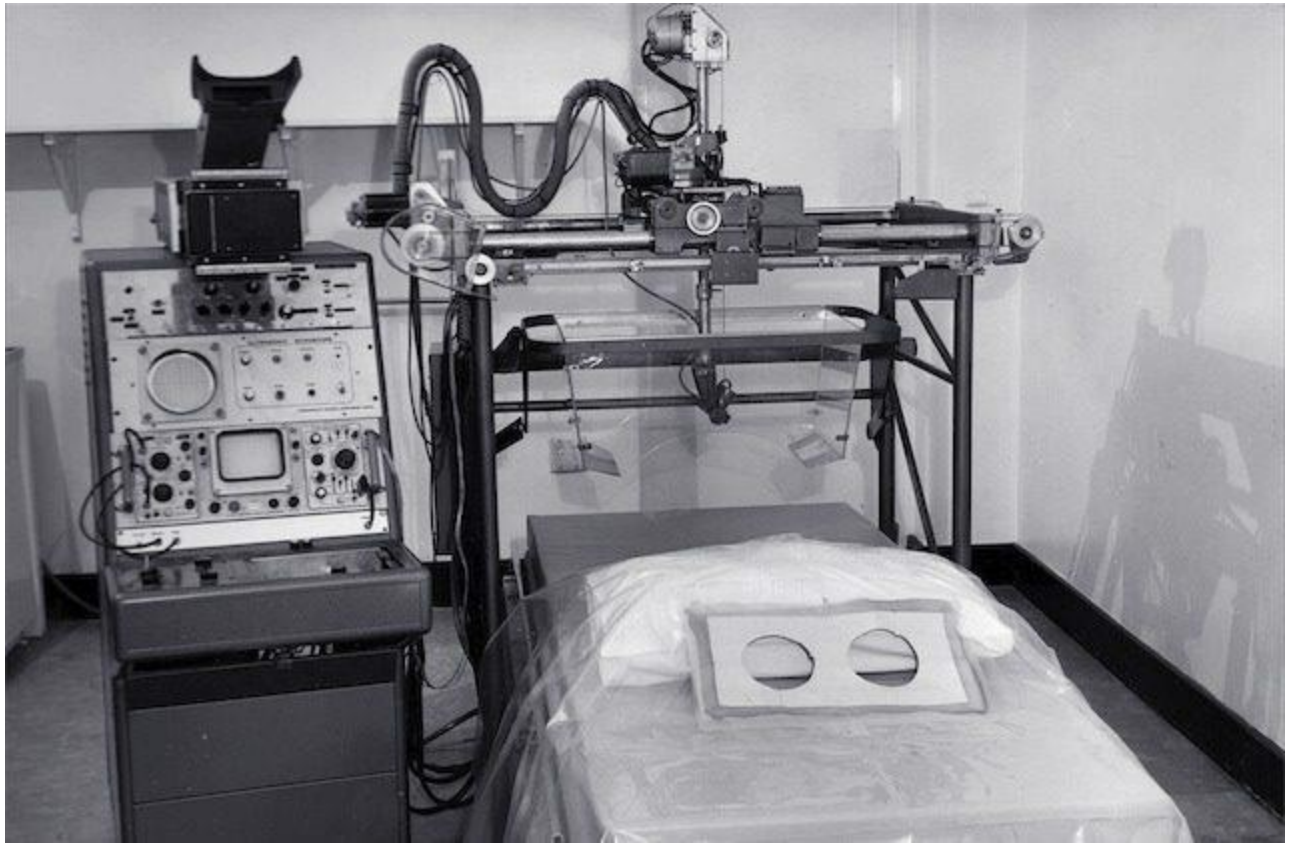
Girard
Grove City
Amsterdam
Harrisville
Eau Claire
Foxburg
New Wilmington
Volant
Boyers
Austintown
Youngstown
Hilliards
Parker
Slippery Rock
Struthers
Bruin
Canfield
Boardman
West Liberty
West Sunbury
Petrolia
New Castle
Karns City
New Middletown
Chicora
West Pittsburg
Portersville
New Springfield
Prospect
Salem
Columbiana
Cowansville
Ellwood City
Butler
Meridian
East Palestine
Zelienople
Lisbon
Evans City
Sarver
Mars
Monaca
Summitville
Calcutta
Gibsonia
Midland
Natrona Heights
Leechburg
Salineville
East Liverpool
Aliquippa
Tarentum
Wellsville
Ambridge
New Kensington
Irondale
Allison Park
Sewickley
Glenshaw
Bergholz
Coraopolis
Oakmont
Plum
McKees Rocks
Richmond
Weirton
Monroeville
Munhall
Google

# Objectives

- Understand basic operation of a portable ultrasound device
- Understand the benefits of performing lung ultrasound
- Learn how to perform ultrasound exams of normal lung and pleura

# What is POCUS?

- Ultrasound technology developed initially for military purposes; submarines used to locate other vessels
- First medical ultrasound devices developed in 1940's were large and immobile
- As technology improved, allowed bedside exams (laptop size)
- Initial use was in obstetrics and emergency medicine
- Smaller and more affordable handheld devices since 2000s have led further growth and use



# What is POCUS?

**DIAGNOSTIC ULTRASOUND**

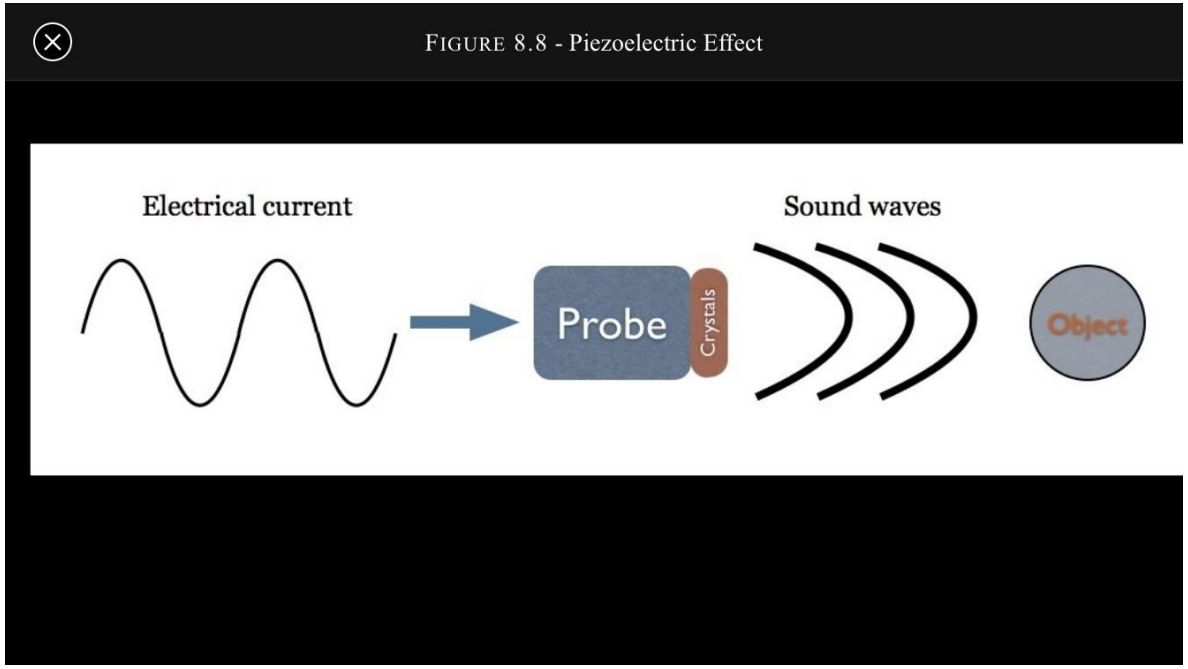
- High-end device
- Formal complete exam
- Performed by a trained sonographer
- Read by board certified radiologist
- Takes days/weeks to schedule and to obtain results

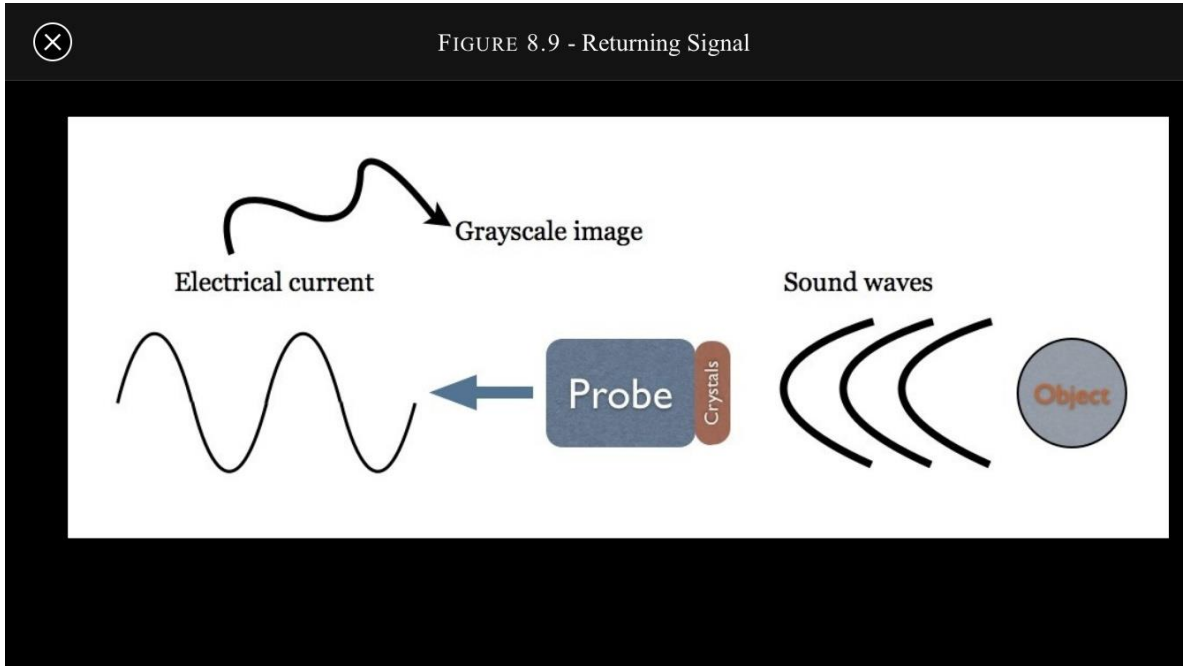
**POCUS**

- Less costly device
- Bedside or handheld
- Performed and interpreted by the treating and examining physician
- Immediate results at bedside
- Intended to answer a specific clinical question

# POCUS - Physics

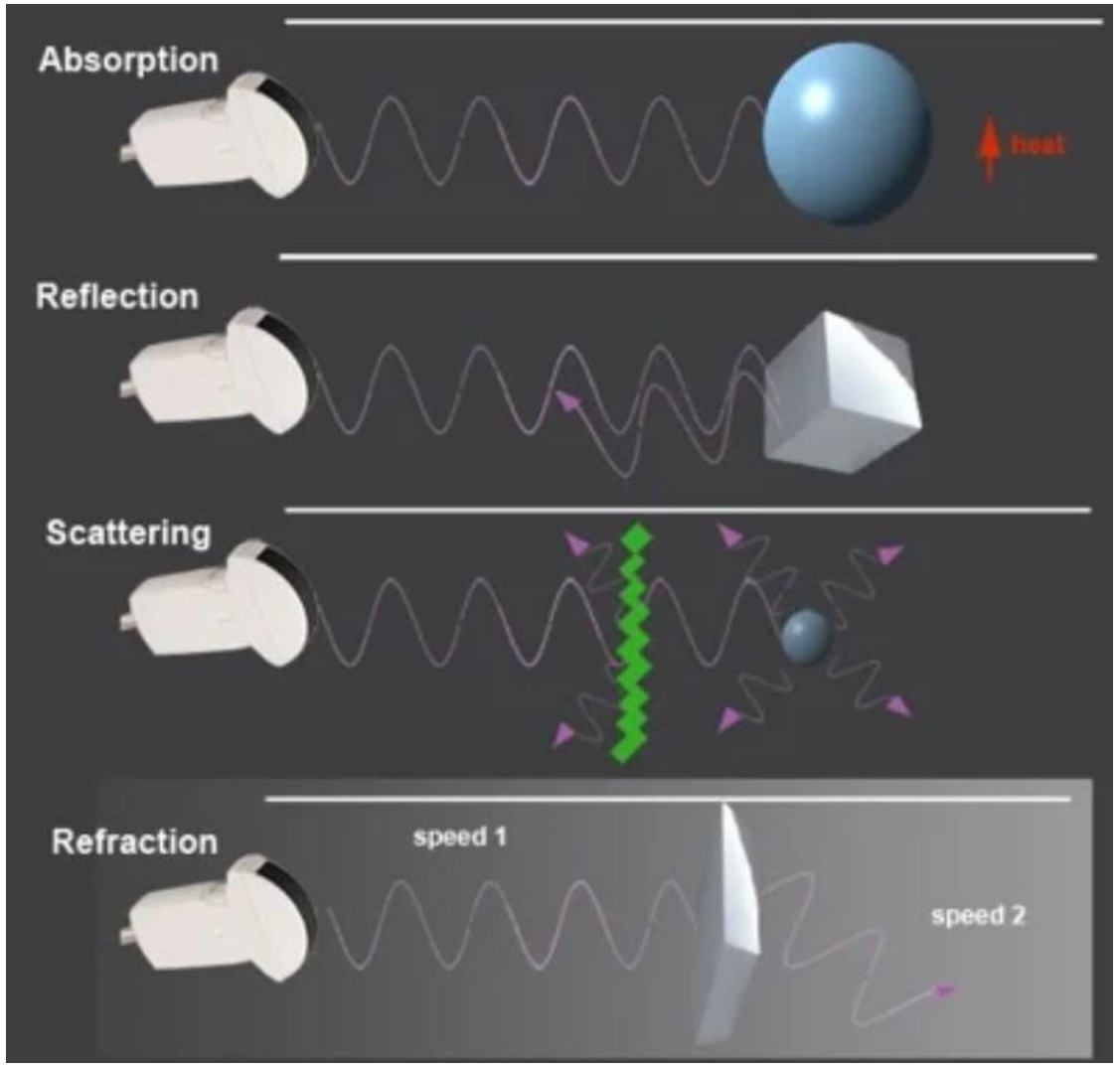
- US is high frequency sound wave
- Electricity powers transducer (crystal)
- Sound wave from crystal travels until hits object
- US waves reflected back to transducer
- Crystal detects US signal
- CPU/processor produces image



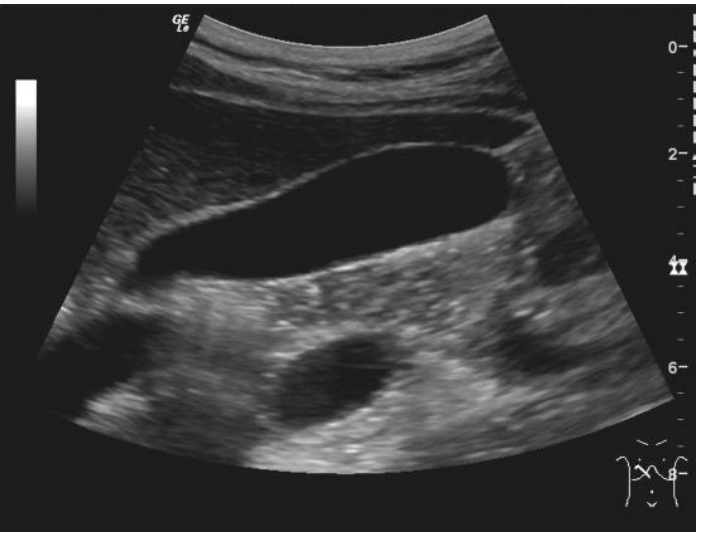
# POCUS - Physics

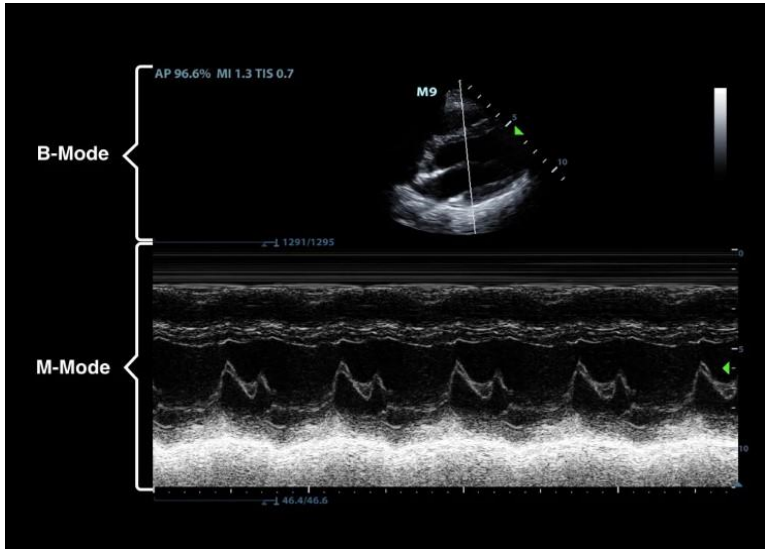
- How US wave interacts with objects, determines what we see
- Several things can happen:
  - Absorbed
  - Reflected
  - Scattered
  - Refracted

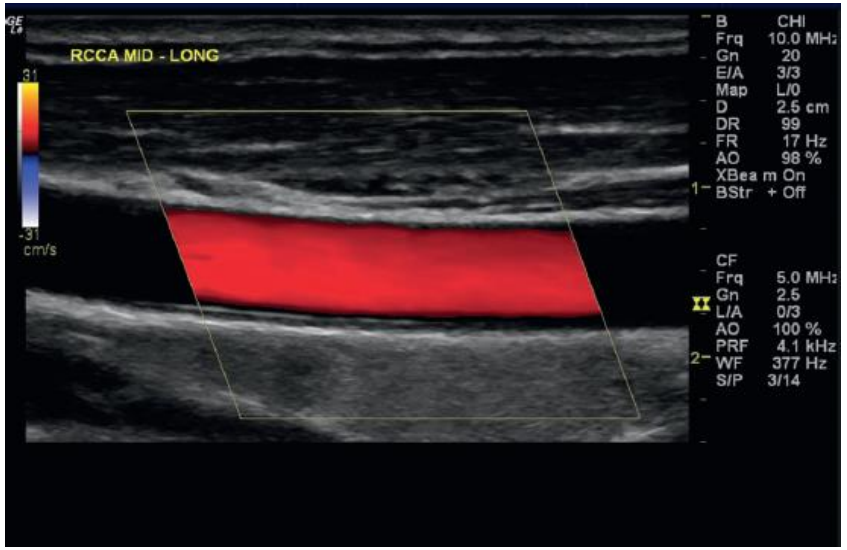


# POCUS - Modes

- B-mode scan: grayscale
- M-mode: tracing of tissue movement over time (cardiac)
- Color Doppler: measures direction of flow

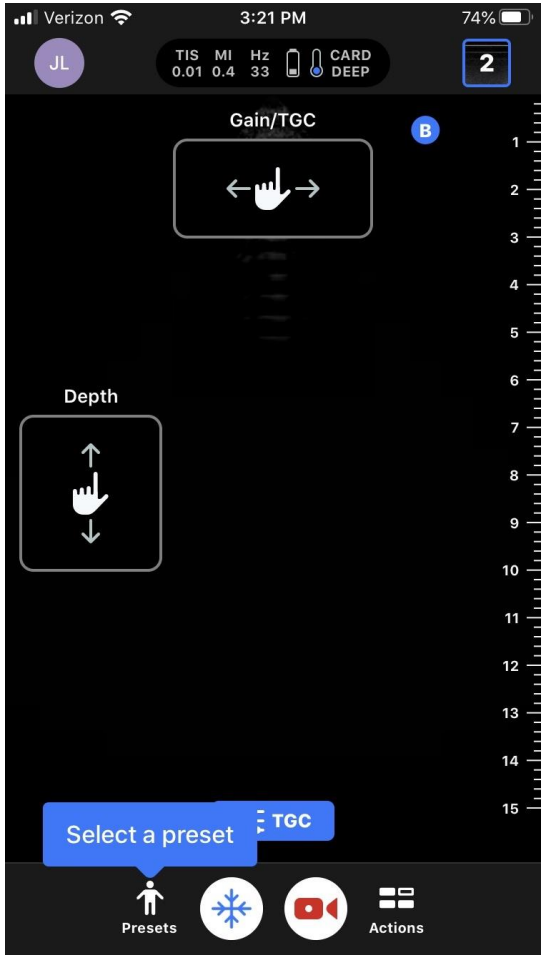




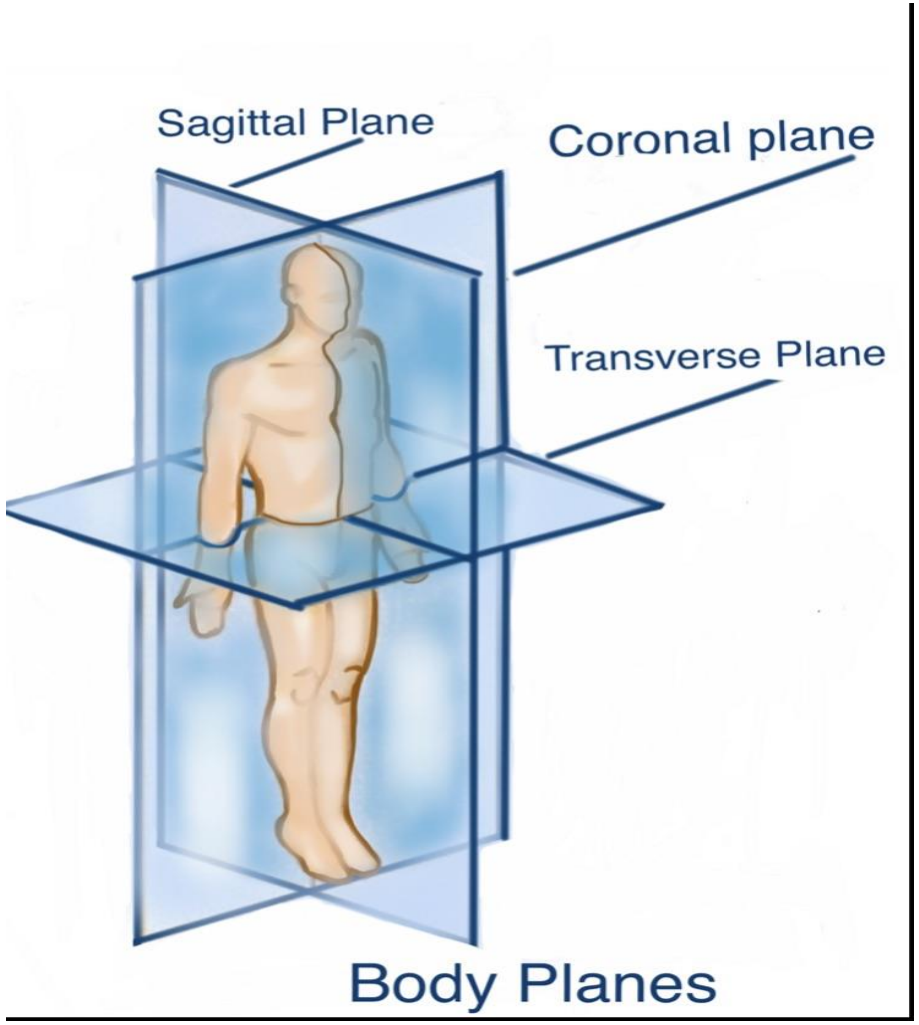



# POCUS – US terms

- Power: energy delivered (fixed)
- Frequency:
  - Number of waves per sec
  - Higher freq = superficial structures
  - Lower freq = deeper structures
- Gain: degree of amplification of return signal
- Depth: adjust to structure

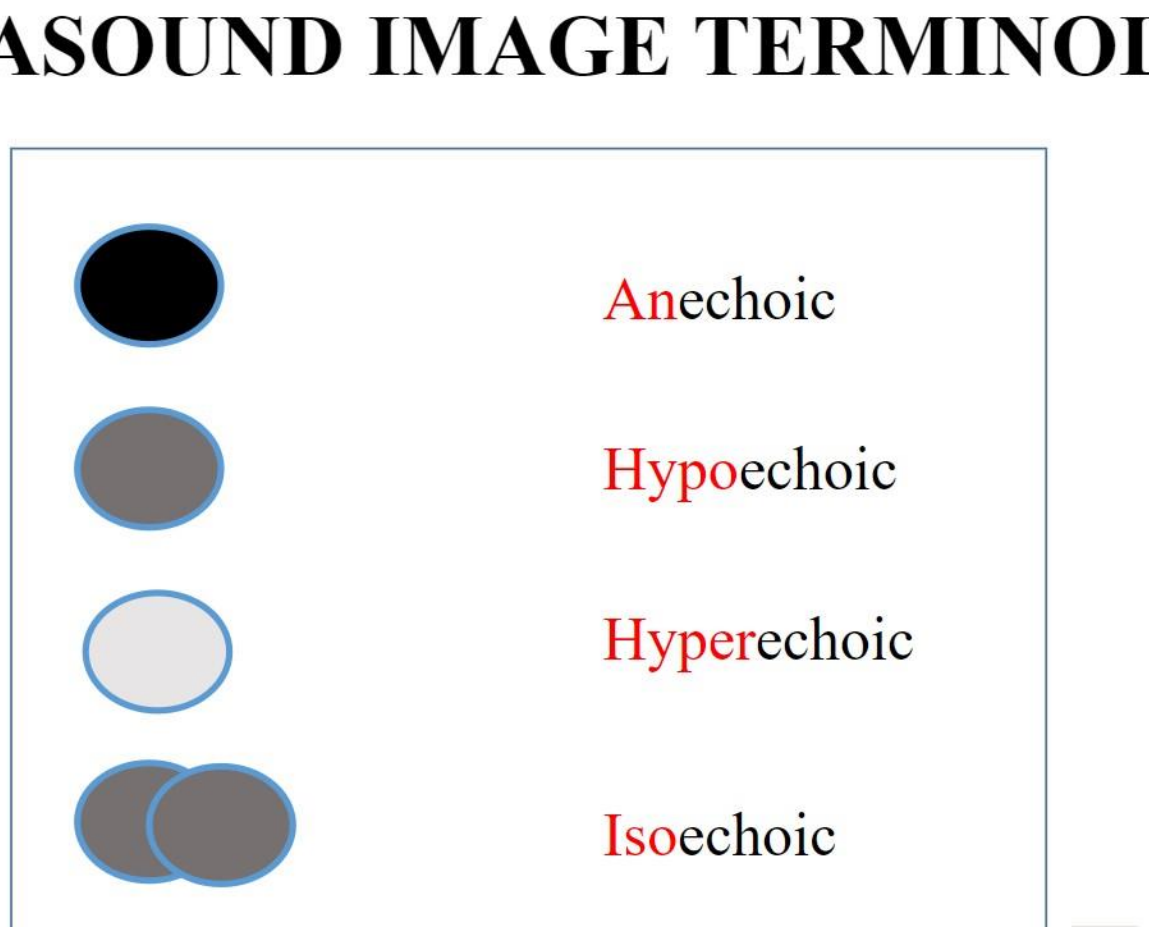


# POCUS – US terms

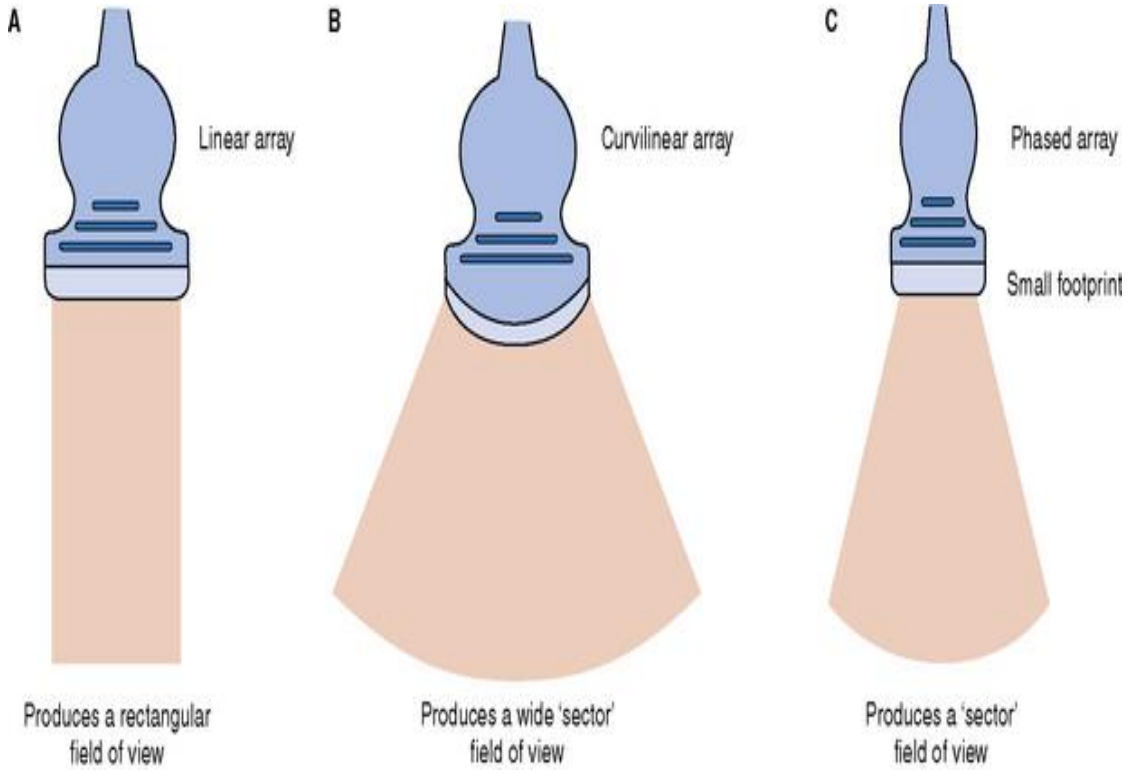



- Sagittal: cephalad to caudal view, or "**long axis**" in frontal plane
- Coronal: **long axis** view in lateral plane
- Transverse/axial: cross section, or "**short axis**"

# POCUS – US terms



# POCUS – Transducers

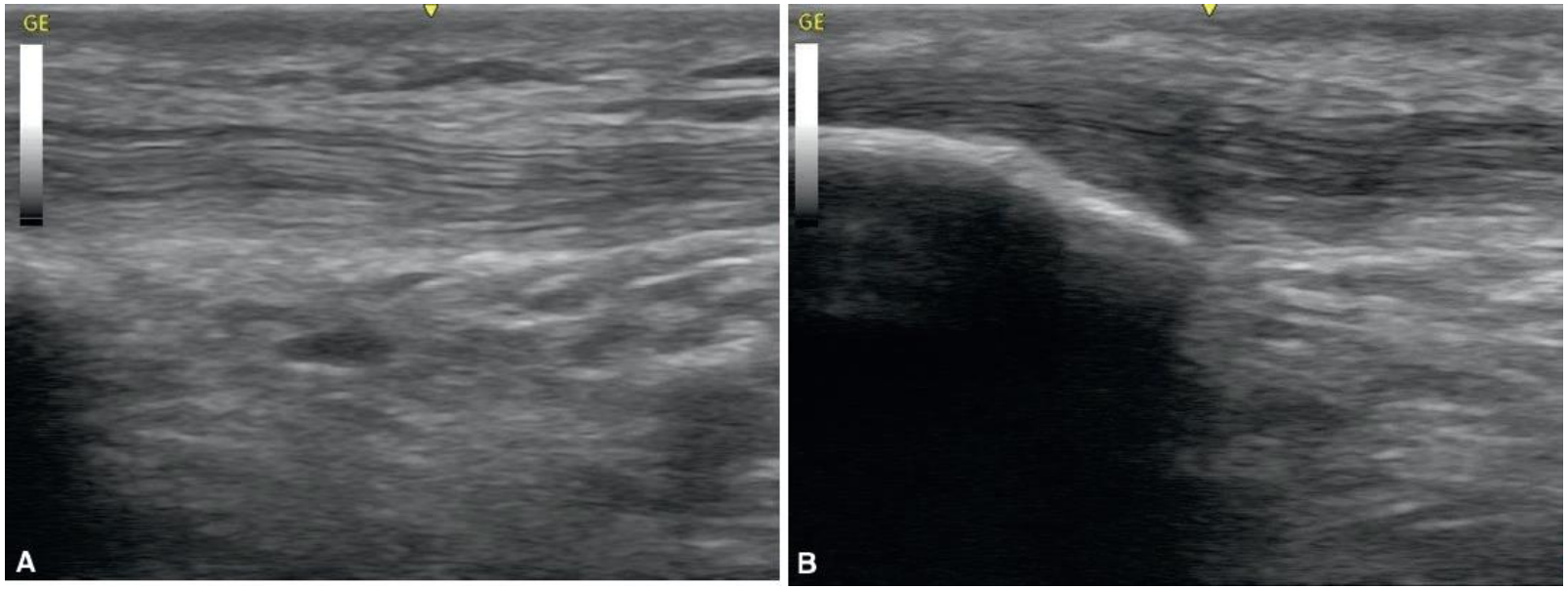



- Linear array:
  - high frequency, better resolution but less penetration
  - Superficial structures
- Curved array:
  - low frequency, deeper penetration but lower resolution
  - Deep structures
- Phased array:
  - Low frequency, small footprint
  - Cardiac and lung.

# POCUS – tissue appearance

Bone/calcium

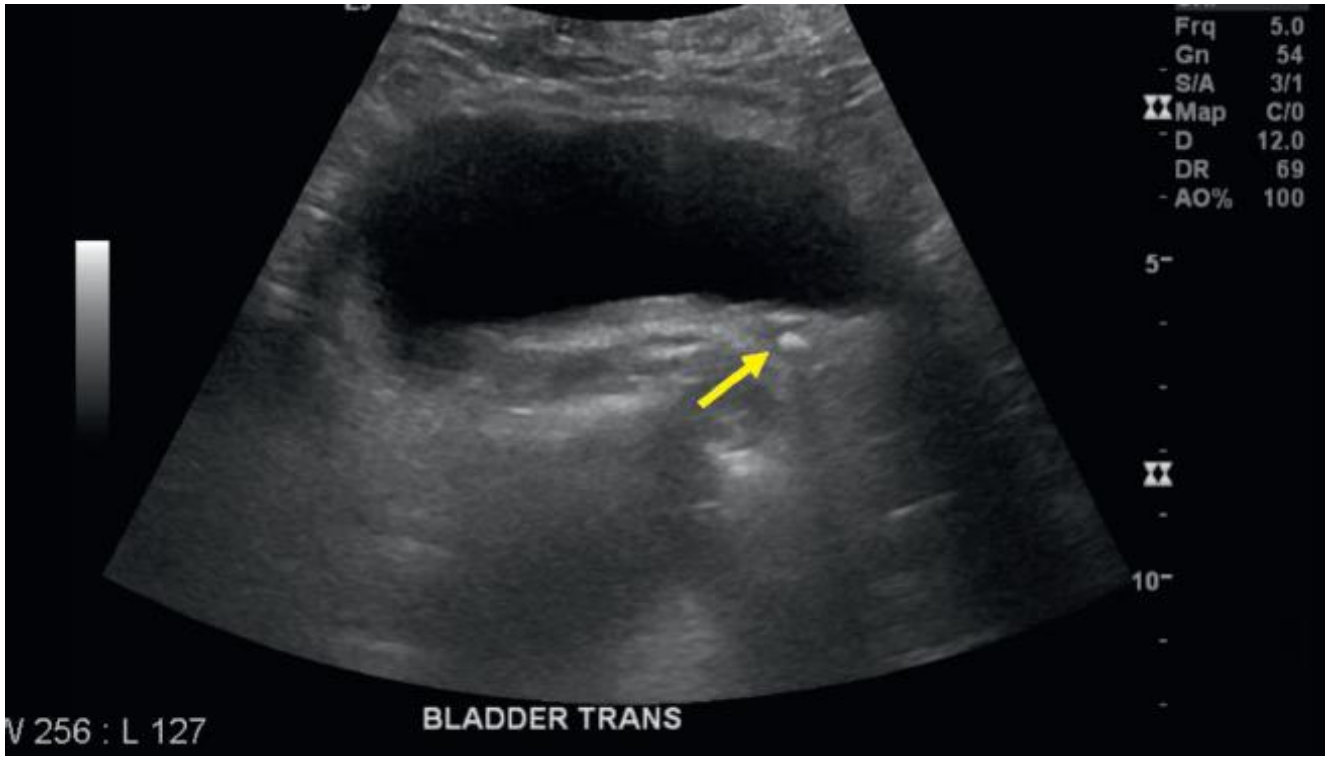
- Does not transmit US wave
- Hyperechoic
- Shadowing



# POCUS – Tissue appearance

Fluid

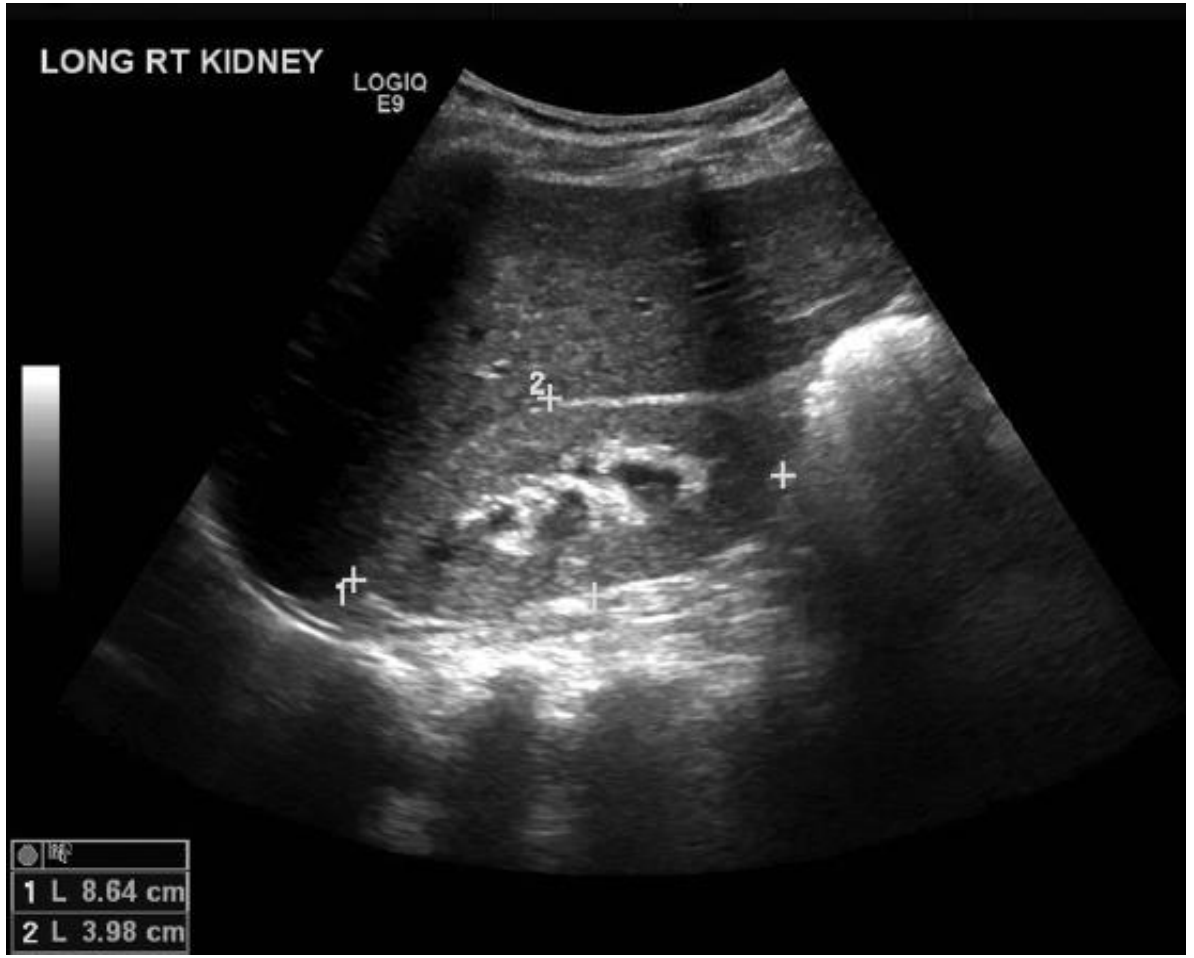
- Transmits but does not reflect
- Hypoechoic
- Appears dark



# POCUS – Tissue appearance

Acoustic window

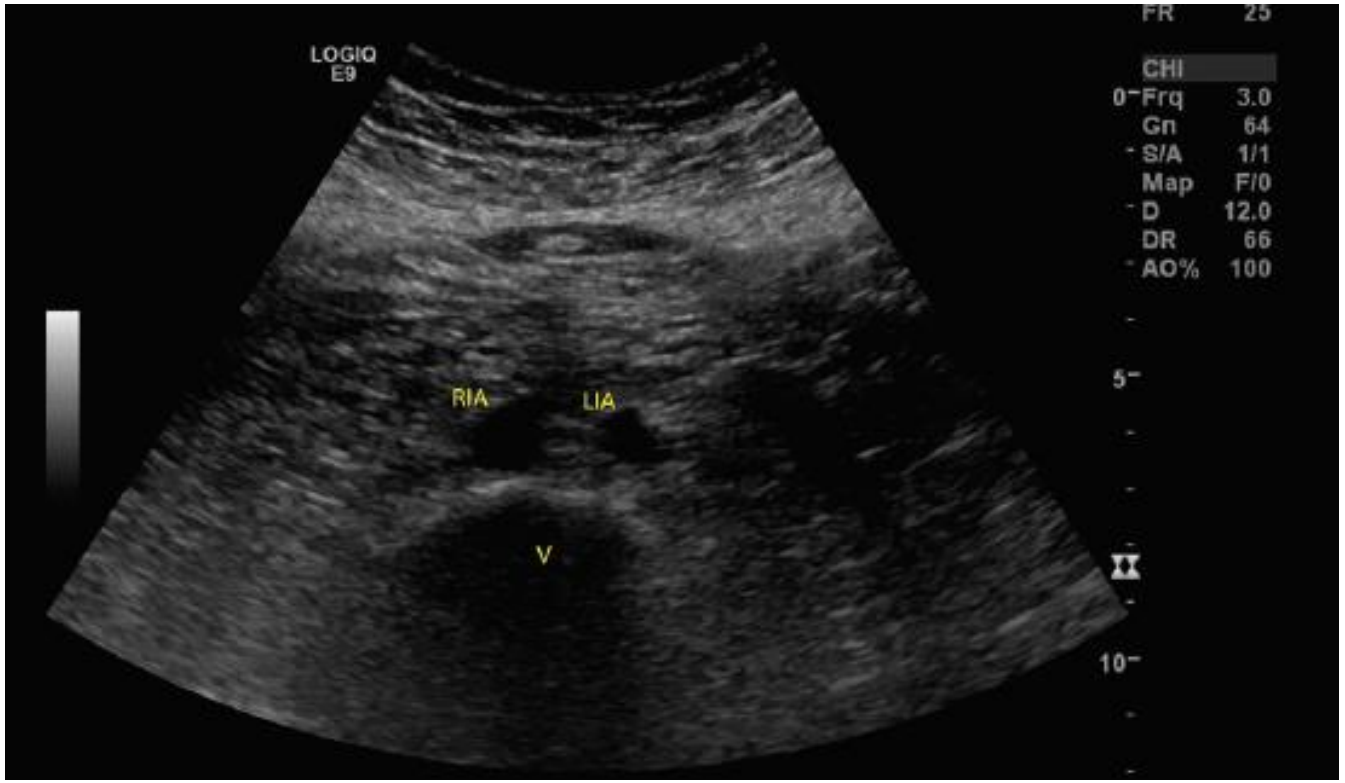
- Used to see deeper structures
- Example: liver, bladder



# POCUS – Tissue appearance

Gas

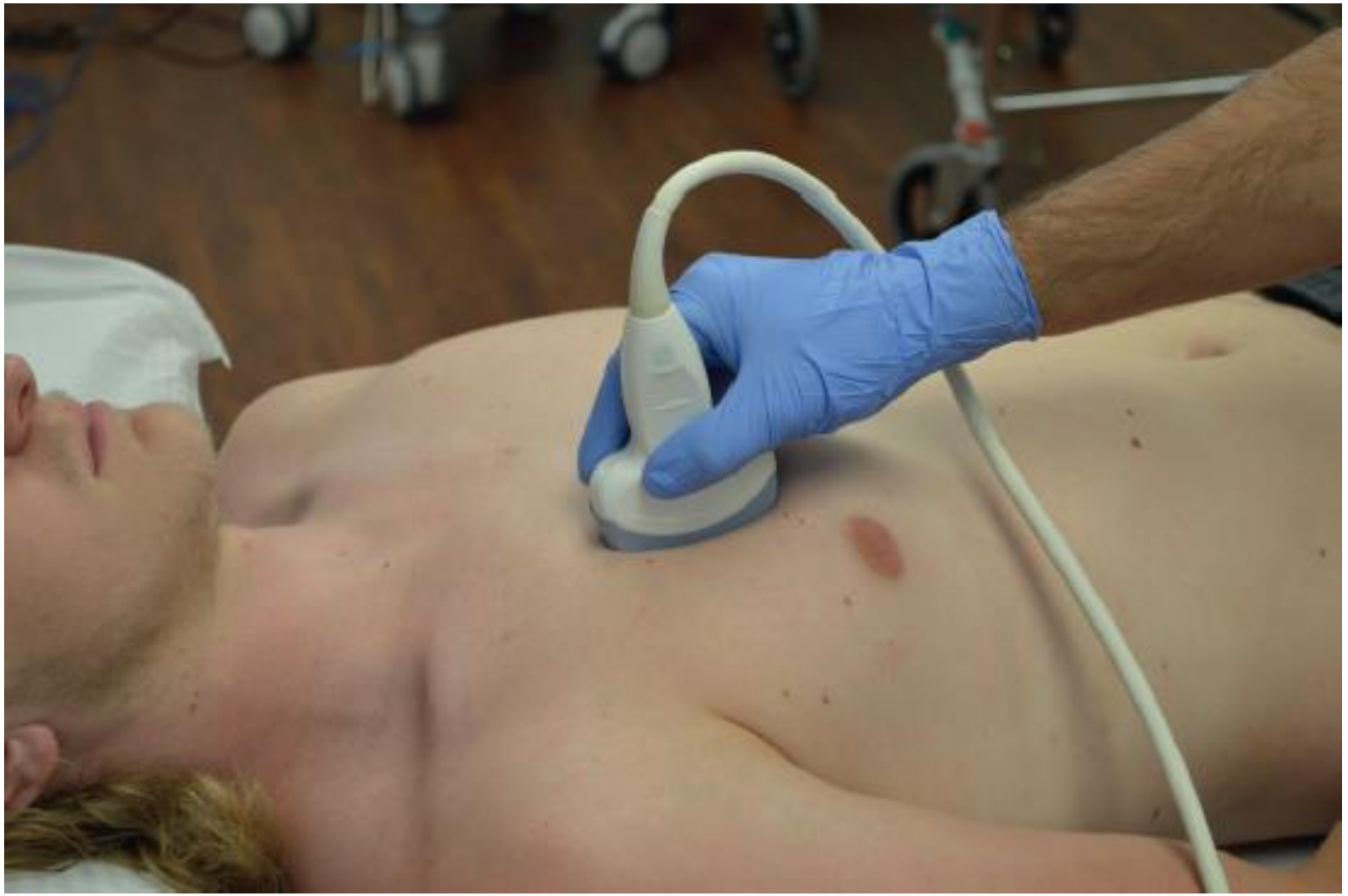
- Does not transmit or reflect
- Obscures/scatters signal image
- Try to avoid



# Handheld Ultrasound

- "Handheld" ultrasound  come in many shapes/sizes
- Most utilize cellular phone or tablet to display images
- Butterfly IQ: upfront cost $2700-$3900, plus annual cloud fee ($300-$400)
- Other devices: GE Vscan, Clarius, EXO iris

# Lung Ultrasound



# Lung Ultrasound

**What is lung ultrasound?**

- Uniquely used in point-of-care ultrasound
- Method of detecting interstitial edema
- Used for pleural effusion exam
- Added to standard diagnostic evaluation

**Why learn lung ultrasound?**

- Immediate accessibility
- Ability to follow clinical response
- Superior than lung auscultation and chest xray
- Increases the probability and timing of making correct diagnosis

# Lung Ultrasound

- The only ultrasound exam which is purely a POCUS exam
- Initially developed and utilized in critical care settings
- Applies to both inpatient, outpatient, and pediatrics settings
- IDEAL primary care POCUS exam
- Straightforward, easy to learn
- Sensitivity/specificity 88%-100% in detecting fluid overload, pneumonia, pneumothorax, and asthma/COPD

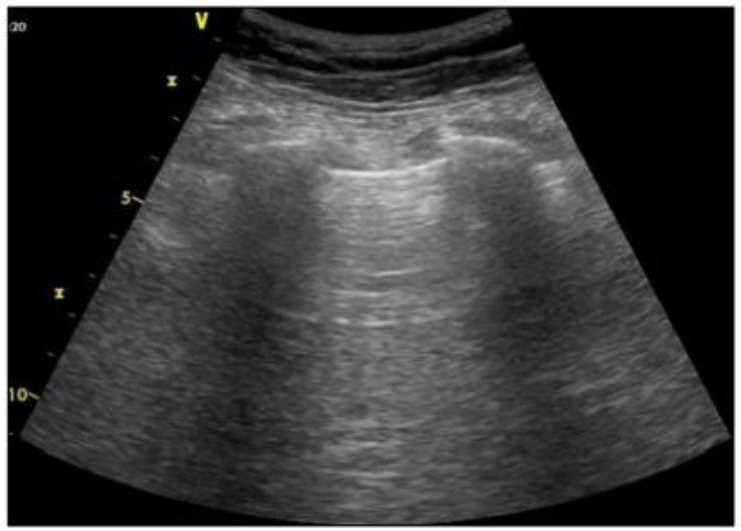
# Lung Ultrasound vs Auscultation

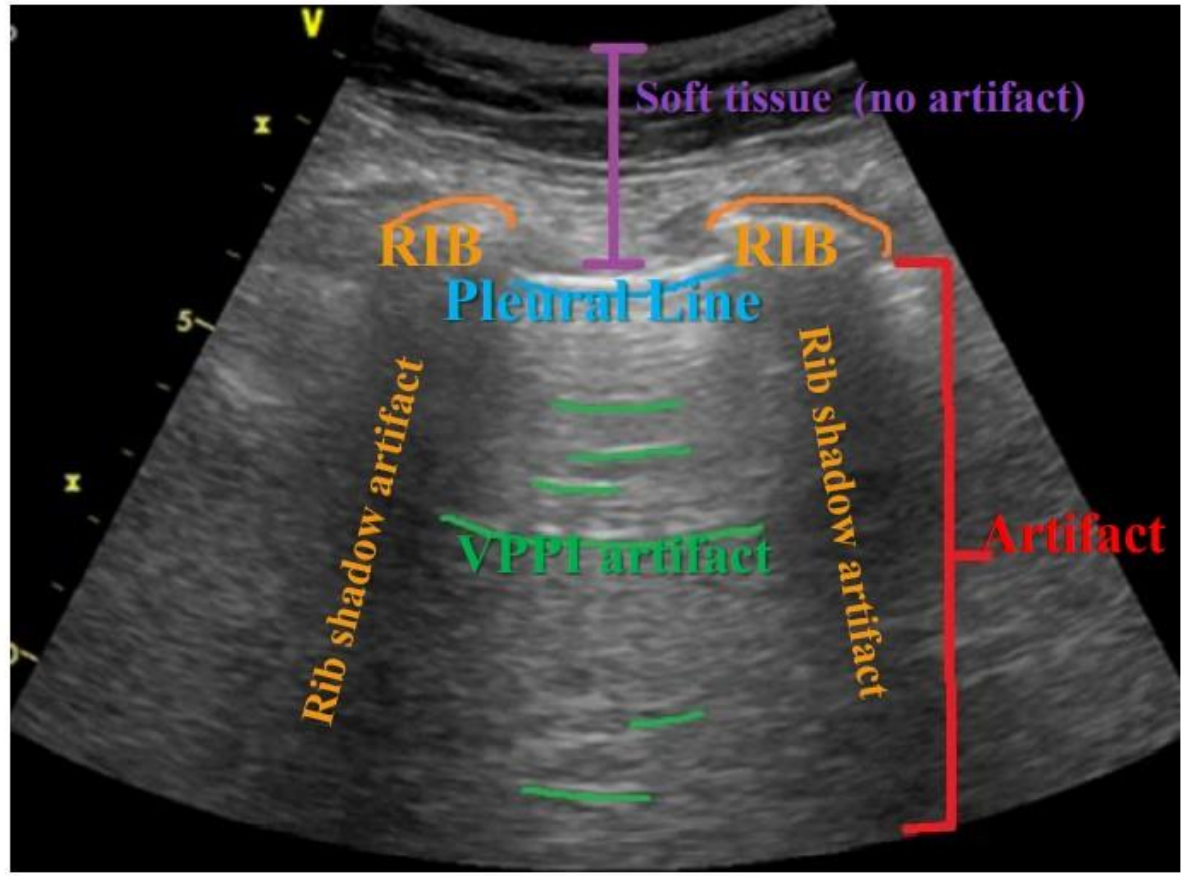
**Table 3**

Interobserver variability.

| | |
|---|---|
| **Lung Ultrasound** | |
| A-pattern | κ = 0.71 (95% CI: 0.70–0.74) |
| Pathological B-lines | κ = 0.73 (95% CI: 0.73–0.75) |
| Focal B-lines | κ = 0.73 (95% CI: 0.72–0.75) |
| Diffuse B-lines | κ = 0.81 (95% CI: 0.81–0.83) |
| Consolidation | κ = 0.94 (95% CI: 0.93–0.95) |
| Pleural effusion | κ = 0.89 (95% CI: 0.88–0.90) |
| **Lung Auscultation** | |
| Wheezes | κ = 0.63 (95% CI: 0.61–0.65) |
| Fine crackles | κ = 0.68 (95% CI: 0.66–0.70) |
| Coarse crackles | κ = 0.18 (95% CI: 0.16–0.20) |
| Rhonchi | κ = 0.38 (95% CI: 0.36–0.40) |
| Normal | κ = 0.29 (95% CI: 0.27–0.31) |

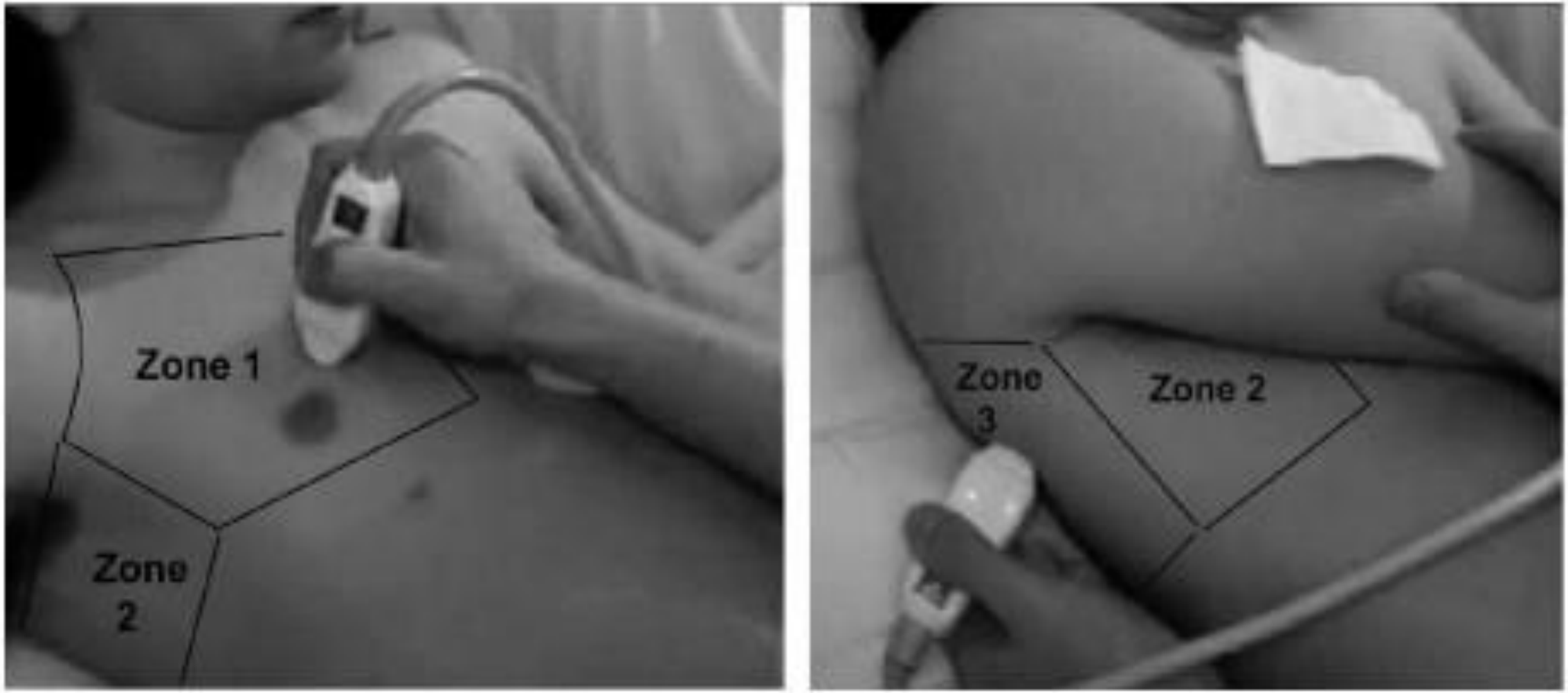
# MAKING SENSE OF ARTIFACTS



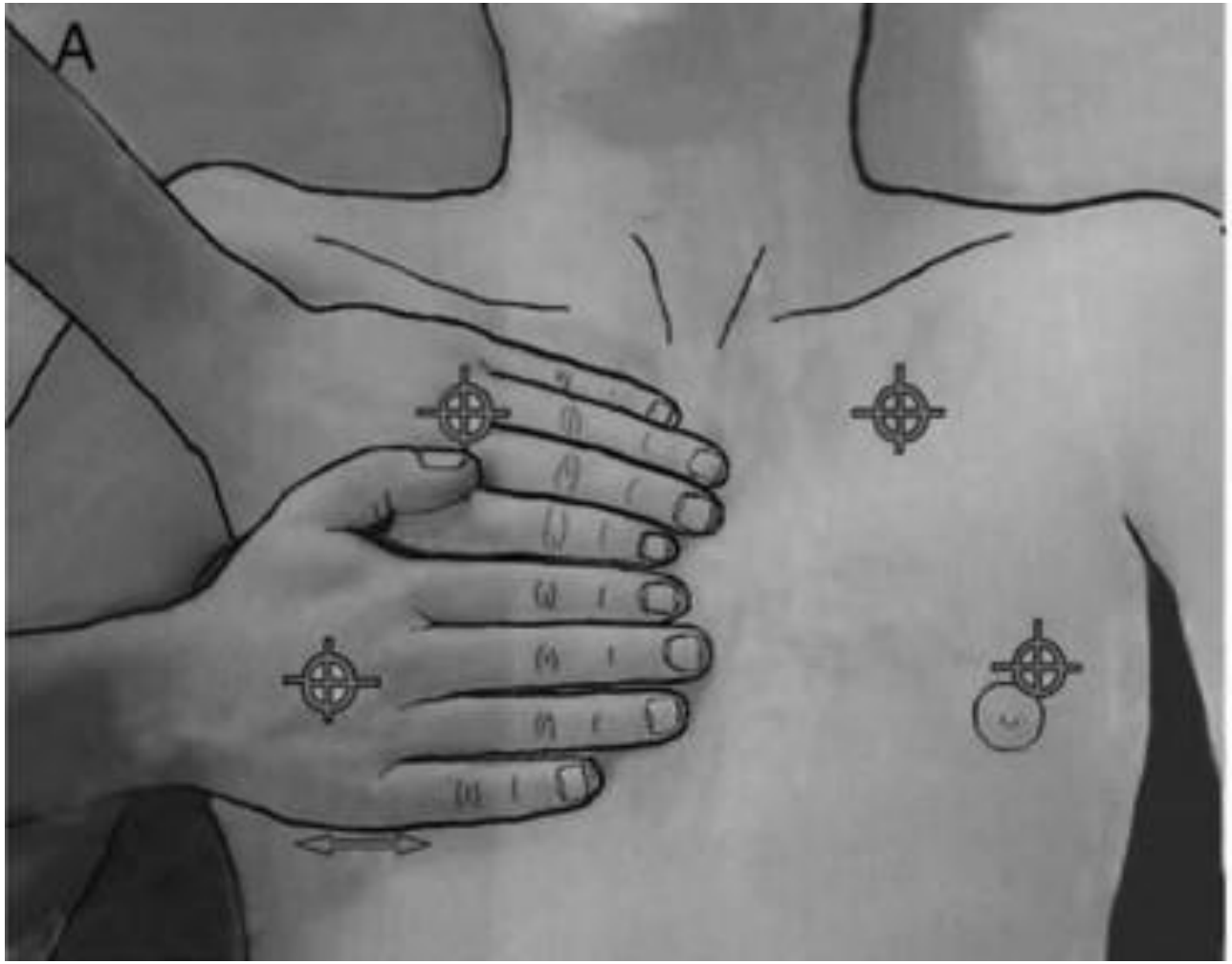


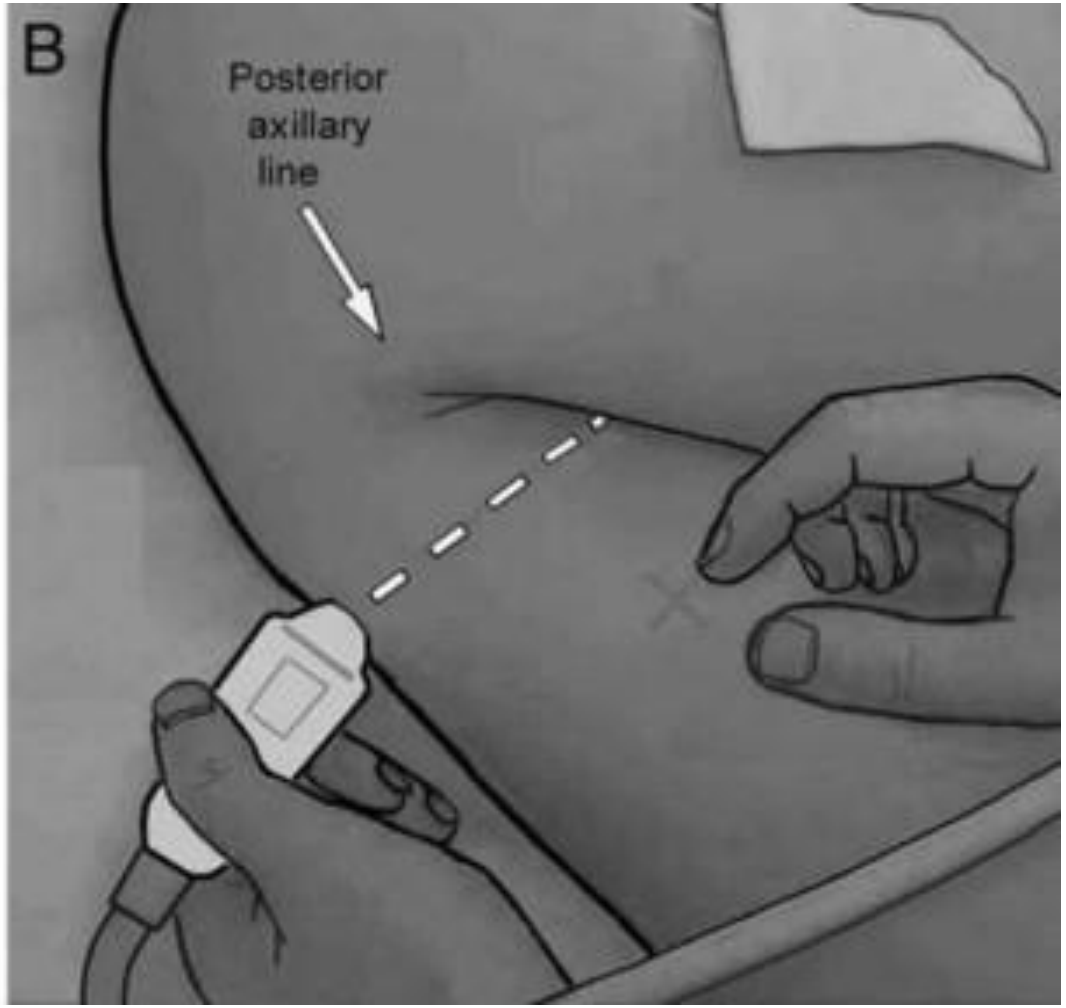

Goal is to distinguish *Abnormal* artifacts from the normal ones…

# Lung Ultrasound - location



# Lung Ultrasound - Location



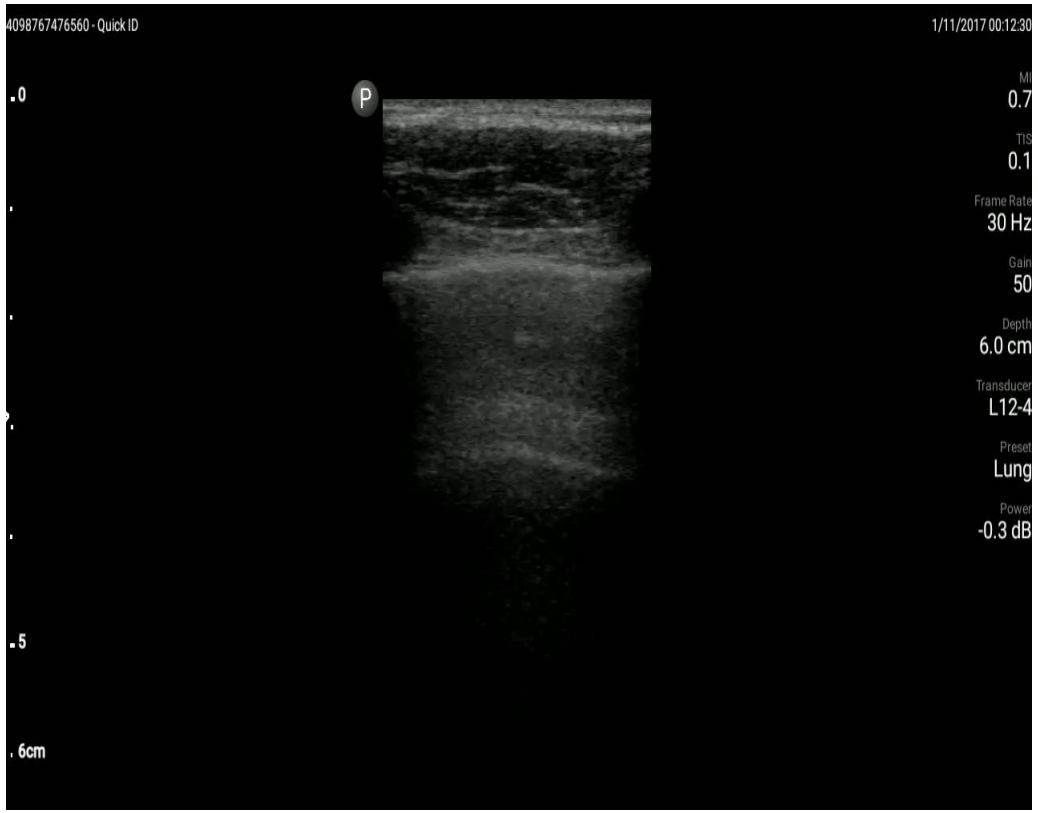



# Lung Ultrasound – Key components

1. Lung sliding: visceral and parietal pleura motion
2. Interpret lung artifacts:
   - A lines: normal finding
   - B lines: lung pathology
   - Sometimes, consolidation is seen
3. Pleural space evaluation

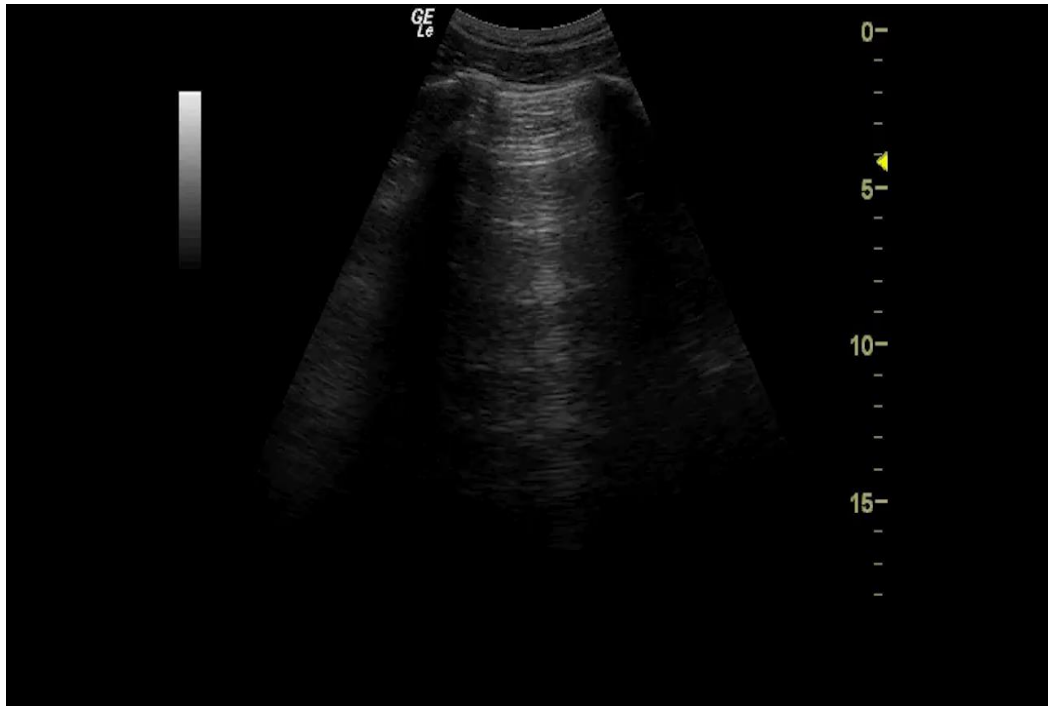
# Lung Ultrasound – Step 1:Lung sliding

- Transducer on chest wall, straddling ribs
- Focus on pleural line deep to ribs (visceral and parietal pleura)
- "Sliding" indicated by shimmering or "ants marching" appearance
- Normal lung sliding rules out PTX
- Absence denotes
  - Pneumothorax
  - Consolidation
  - Pleural disease/mass/pleurodesis
  - Emphysema



# Lung Ultrasound – Step 2: A lines artifact

- A lines are horizontal lines on the screen at regular interval
- A lines represent reverberation of the ultrasound signal from the pleura
- Presence of A lines signifies presence of air (normal)

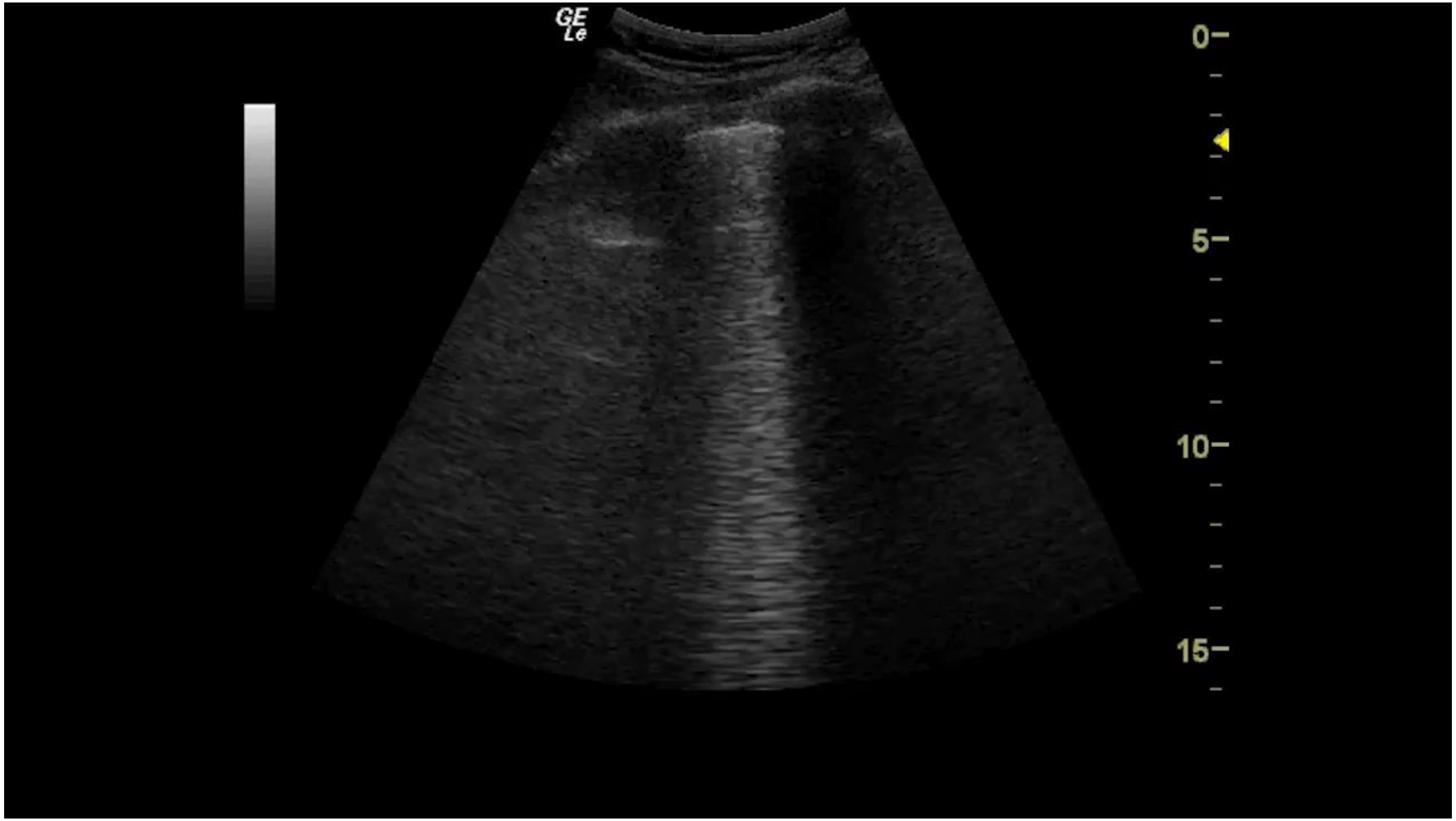


# Lung Ultrasound – Step 2: B lines artifact

- Vertical lines from pleura
- 4 or more is abnormal
- Obliterate A lines
- Move with lung
- Extend to edge of screen (18cm)

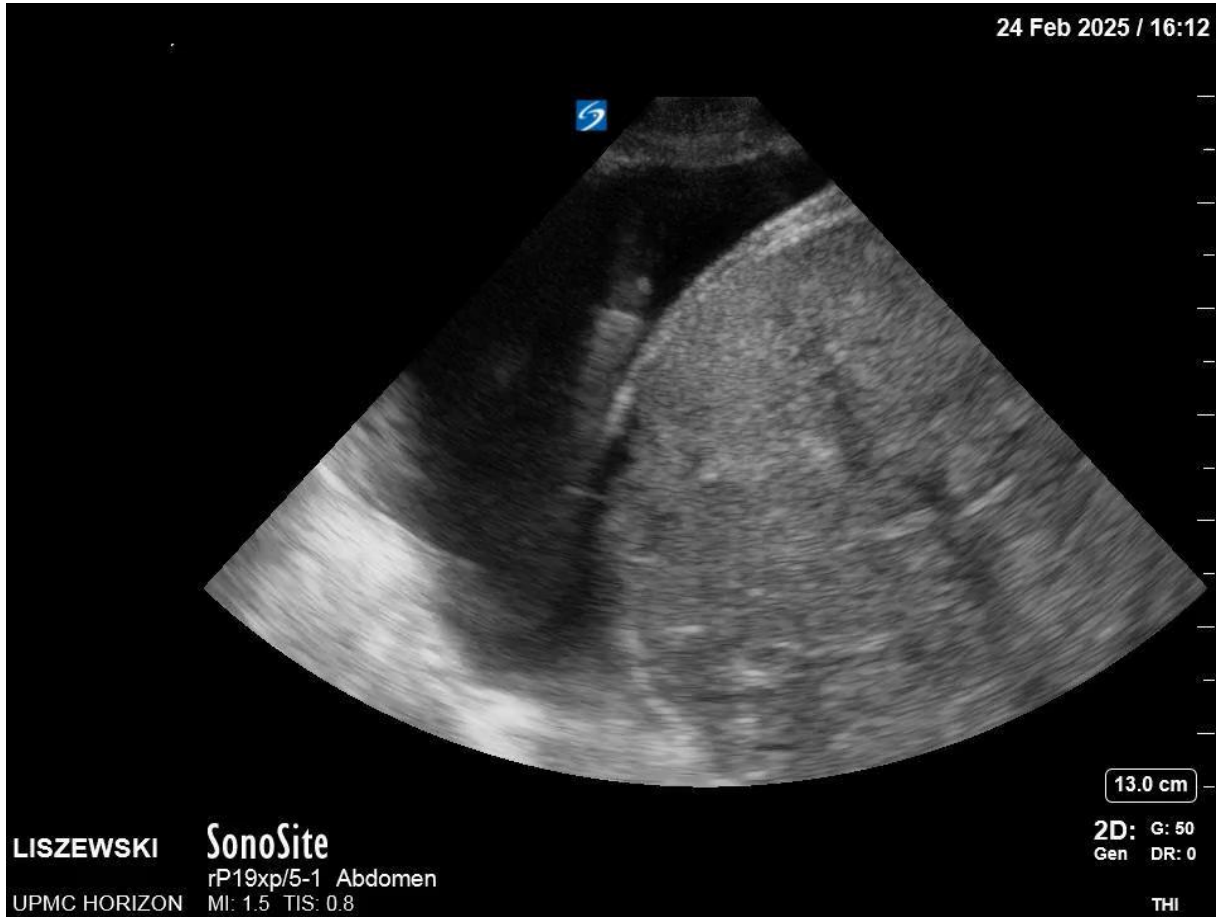
- B-lines indicate abnormality in interstitial or alveolar compartment
- Can represent alveolar fluid, or interstitial thickening (fluid or fibrosis)
- Pulmonary edema: **minimum 2 positive zones and bilateral**

# Lung Ultrasound – B lines



# Lung Ultrasound – Step 2: Pleural effusion

- Costophrenic view (Zone 3)
- Place probe posterior or inferior to Zone 2
- Identify liver (right side) or spleen (left side) and diaphragm
- Pleural fluid appears dark (anechoic) just above diaphragm



# Lung Ultrasound - Interpretation

| **Ultrasound findings** | **Clinical interpretation** |
| --- | --- |
| • Bilateral B-lines +/- effusion → | • Pulmonary edema/HF |
| • Focal B-lines +/- effusion → | • Pneumonia |
| • No lung sliding → | • Pneumothorax |
| • A-lines and lung sliding → | • COPD/asthma or PE |

# Lung Ultrasound – Exam/breakout

1. Is there lung sliding?
2. Is there artifact?:
   - Are there A lines?
   - Are there B lines?
3. Is there a pleural effusion?

# Lung POCUS - Summary

- Reviewed **basics of operating** a POCUS device
- Discussed **benefit** of performing lung POCUS
- Practiced performing **lung ultrasound**
- Interest in POCUS?
- See links attached

# POCUS articles and interest links

- Ultrasound for Primary Care. Bornemann PH. 2021
- Point of Care Ultrasonography. Arnold MJ, Jonas CE, Carter RE. Am Fam Physician. 2020;101(5):275-285. https://www.aafp.org/pubs/afp/issues/2020/0301/p275.html
- Relevance of Lung Ultrasound in the Diagnosis of Acute Respiratory Failure: The BLUE Protocol. Lichtenstein DA, Meziere GA. CHEST 2008; 134:117–125
- Validity of Lung Ultrasound: Is an Image Worth More Than a Thousand Sounds? Ramoz-Hernandez C et al. J. Clin. Med. 2021, 10, 2292

# POCUS articles and interest links

- Butterfly IQ: https://www.butterflynetwork.com/
- GUSI: Global Ultrasound Institute: https://globalultrasoundinstitute.com/
- University of South Carolina: Ultrasound Education - School of Medicine Columbia | University of South Carolina. https://sc.edu/study/colleges_schools/medicine/centers_and_institutes_new/ultrasound_institute/education.php

# Cracking the Code on Continuous Glucose Monitors (CGMs): A Practical Guide for Providers

UPMC St Margaret Pharmacy Residency Program

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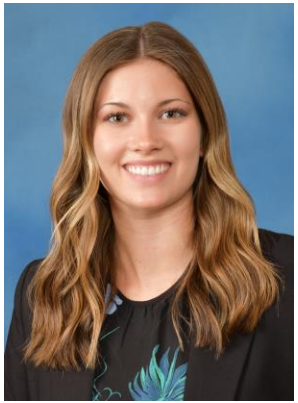
Scan this code to download Dexcom G7 mobile application



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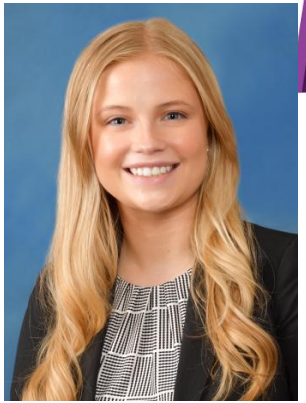

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# Objectives

**Recall** the purpose and at least 2 components of CGMs

**Discuss** how to:

- Order CGMs
- Initial set up of CGM
- Reviewing & interpreting CGM data

**Apply** new knowledge to patient case example

# Disclosure

None of the presenters have any conflicts of interest to disclose.

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# Introduction

# Road Map

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- Background
- Ordering a CGM
- Initial set up of CGM
- Reviewing & interpreting CGM data

# Introduction

- Continuous glucose monitors (CGM) allow for real time glucose information to guide treatment
- Can connect to many smart phones
- Provide peace of mind for patients: alarms to alert patients about lows
- Improved patient satisfaction without the use of multiple daily finger sticks
- Data for providers to adjust treatment regimens
- Information regarding glycemic control between A1c’s

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# Ordering a CGM

# CGM Options

| | Freestyle Libre 3 Plus | Dexcom G7 | Dexcom G6 | Stelo |
|---|---|---|---|---|
| **Sensor Life** | Up to 15 days | Up to 10 days | Up to 10 days | Up to 15 days |
| **Time Between Readings** | 1 minute | 5 minutes | 5 minutes | 15 minutes |
| **Length of Warm-up Period** | 1 hour | 30 minutes | 2 hours | -- |
| **Body sites with FDA approval** | Upper arm | Upper arm, buttocks | Abdomen, buttocks | -- |
| **FDA pregnancy approval** | Yes | Yes | No | -- |
| **FDA approved age** | ≥ 4 yr | ≥ 2 yr | ≥ 2 yr | -- |
| **Pearls** | Replacing Freestyle Libre 2 and 3 | Sensor only, transmitter no longer needed | Separate sensor/transmitter | OTC Product |

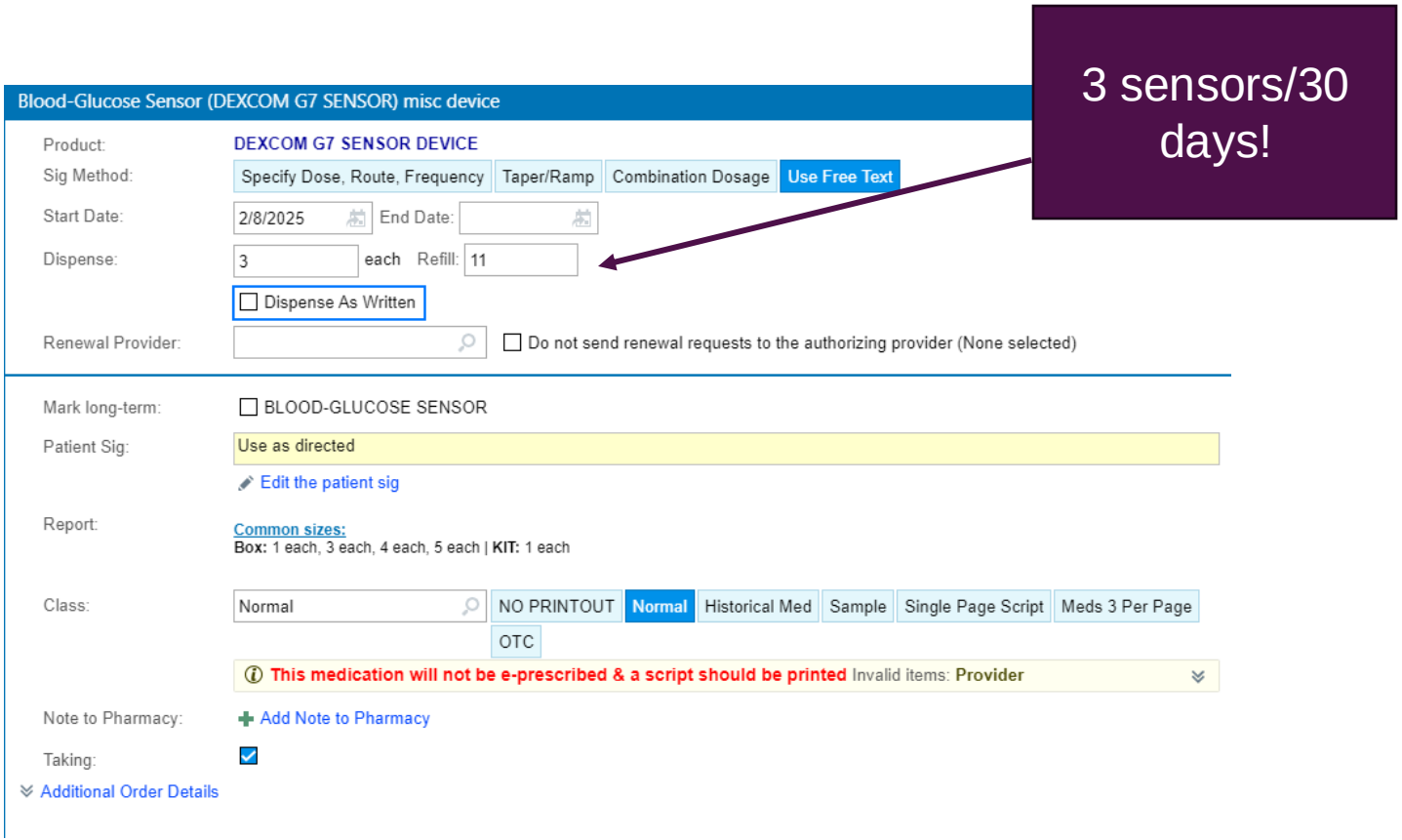

dexcom
dexcom


dexcom

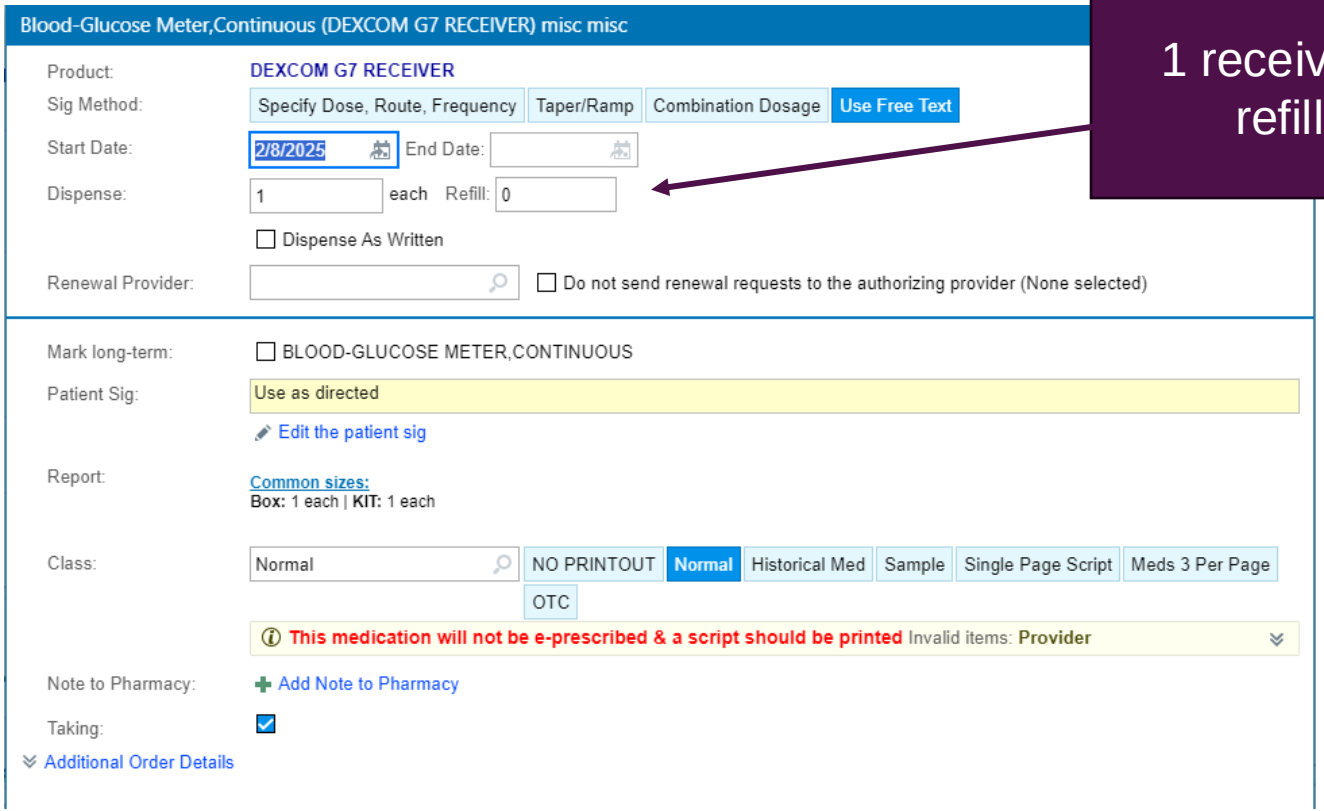

Abbott
FreeStyle
Libre 3
PLUS
Sensor


DEXCOM

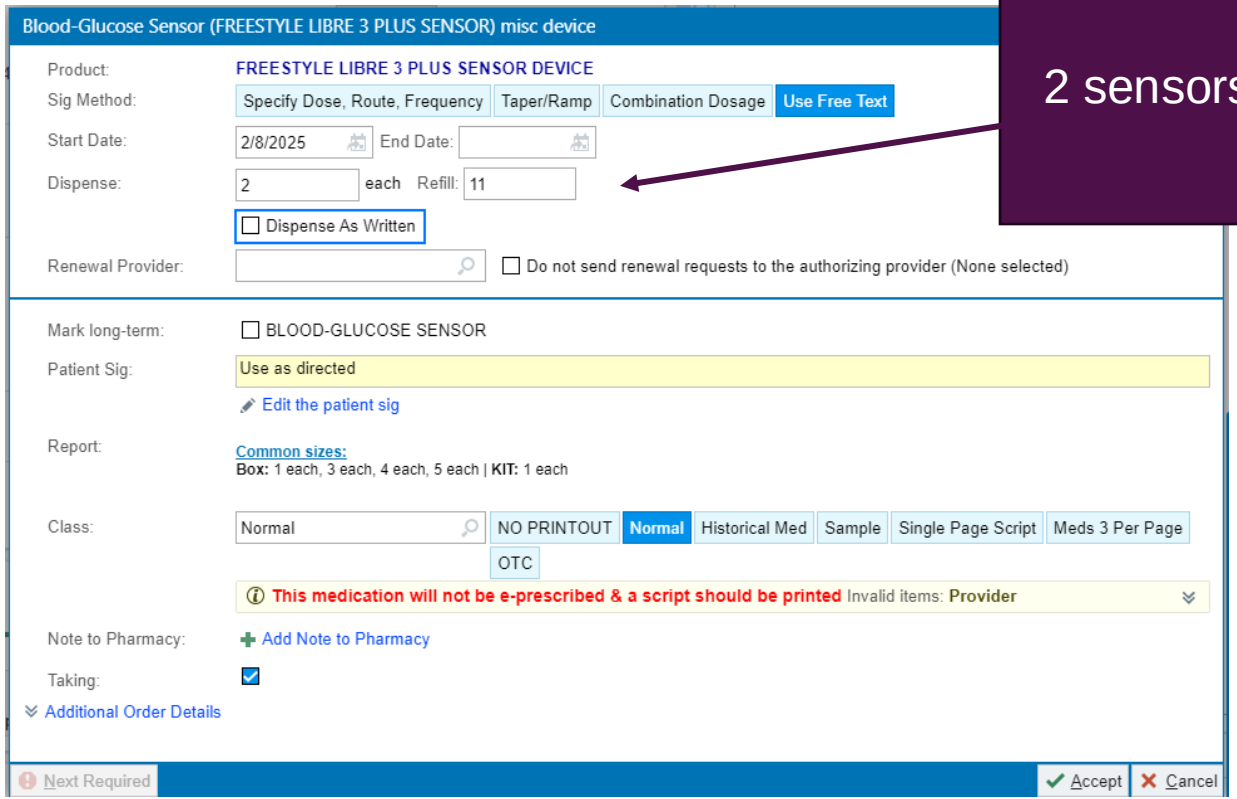
# Ordering CGM Supplies – Dexcom G7



# Ordering CGM Supplies – Dexcom G7

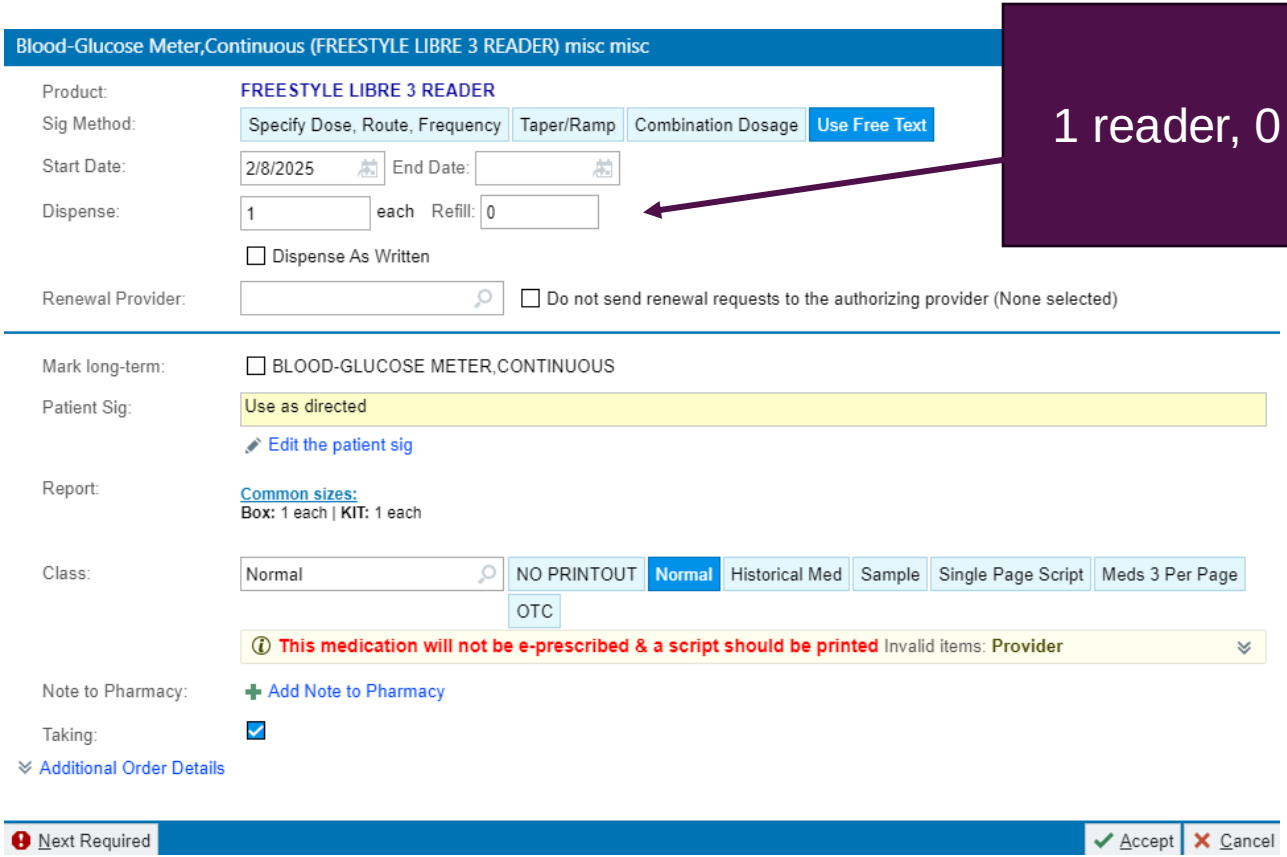


# Ordering CGM Supplies – Freestyle Libre 3




2 sensors/30 days!

# Ordering CGM Supplies – Freestyle Libre 3



# CGM Supplies & Medicare

- Order through Parachute Health
  - Common suppliers: Byram Health, CCS Medical, etc.
- Billed through Medicare Part B
- Can get shipped to office or patient's home

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# Insurance Coverage

| | Freestyle |
|---|---|
| **Medicare** | |
| Requirements | 1 or more insulin injection **OR** problematic hypoglycemia |
| Where to send | Durable medical supply company (i.e. CCS Medical)* |
| **Medicaid** | |
| Requirements | None |
| Where to send | Pharmacy |
| **UPMC Commercial **** | |
| Requirements | Problematic hypoglycemia **AND** 1 or more insulin injections |
| Where to send | Pharmacy |
| **Highmark & Aetna Commercial **** | |
| Requirements | Multiple daily injections |
| Where to send | Durable medical supply company |

*For United Health care, Humana, & UPMC Medicare insurances: send to pharmacy (same requirements)
**Patients can always get 2 sensors at the pharmacy for $74.99/month if not on insulin

# Dexcom – Cost & Coverage

[Dexcom Cost & Coverage Estimator]

## Dexcom Coverage Evaluator

This tool evaluates Dexcom pharmacy coverage for clinicians and determines the most affordable option for each patient.

Simply input the patient information along with NPI in the form below to receive coverage results, recommended action, and consideration.

Verifying patient information is accurate is crucial for determining coverage.

Patient First Name *

Patient Last Name *

Patient Date of Birth *

mm/dd/yyyy

Patient Gender *

- Select -

Patient Zip Code *

A valid 5 digit zip code.

Provider NPI Number *

Provider's 10 digit NPI number.

# Dexcom Coverage

| Plan | Plan Name | Status | Requirements |
|---|---|---|---|
| **Medicare** | UPMC Health Plan For Life | No Manual PA | At least once daily insulin or problematic hypoglycemia |
| | Aetna – MA | No Manual PA | |
| **Managed Medicaid** | UPMC Health Plan For You (PA) | Preferred (PA/ST) | Diabetes diagnosis and on any diabetes medication |
| | Highmark Wholecare (PA) | Preferred (PA/ST) | |
| **Commercial** | UPMC Health Plan | No Manual PA | At least 1 daily injection of insulin |
| | Omni Hotels (OptumRx) | No Manual PA | |
| | Highmark Blue Cross Blue Shield | Preferred | |
| PA/ST = Prior Auth/Step Therapy | | | |

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# Initial CGM Set-Up Visit

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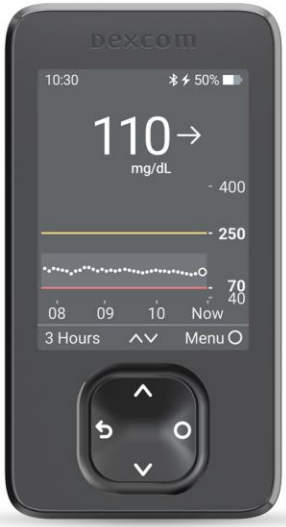
Disclaimer: The graphics and information come directly from Dexcom / Freestyle Libre

# Initial Visit

- Introduce CGM and Components





# Initial Visit


App/ Device pairing

- Phone
  - Download Dexcom G7 app → create account
  - Download Dexcom clarity → login with same credentials
    - No longer required for data sharing
- Reader
  - Set date and time

# Apps

### Dexcom G7 app

- **Who uses it?** The person wearing the Dexcom G7.
- **What does it do?** Shows user's glucose information.

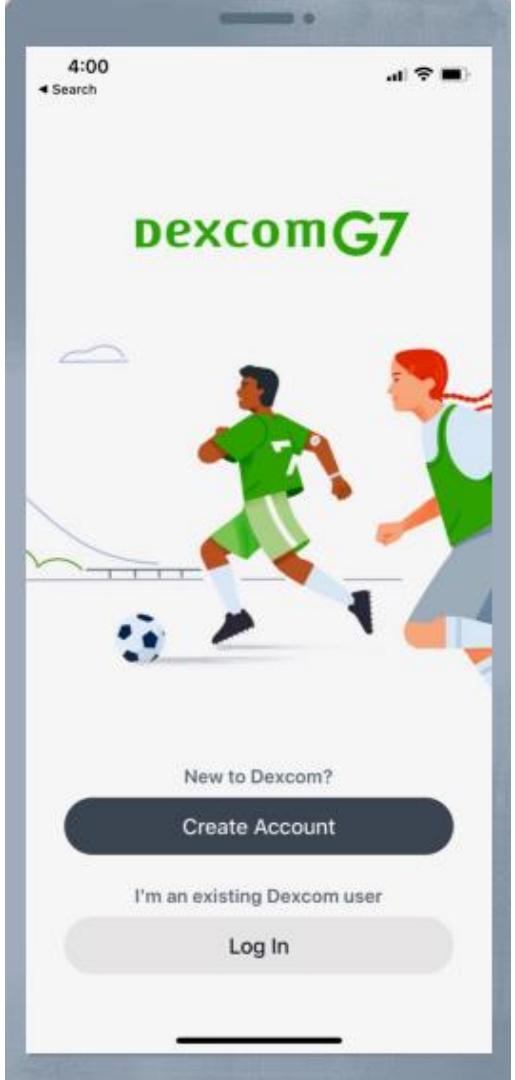
### Dexcom Clarity app

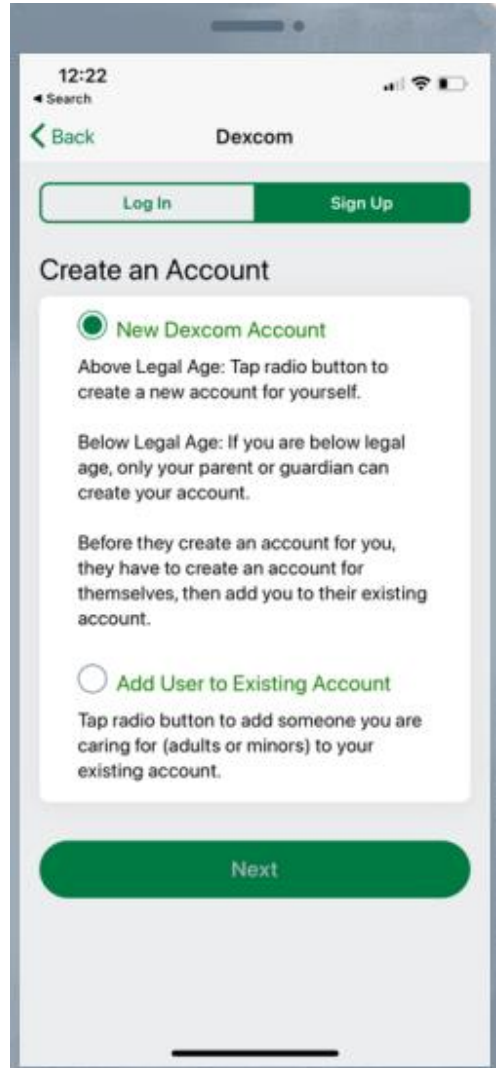
- **Who uses it?** Dexcom G7 user wearing the sensor.
- **What does it do?** Review key metrics, create reports, or authorize data sharing with your clinic.

### Dexcom Follow app*

- **Who uses it?** Someone who wants to view Dexcom G7 user's data. Examples: Parents, spouse, or caregivers.
- **What does it do?** Allows a person to view and follow the glucose levels and trends of a loved one.

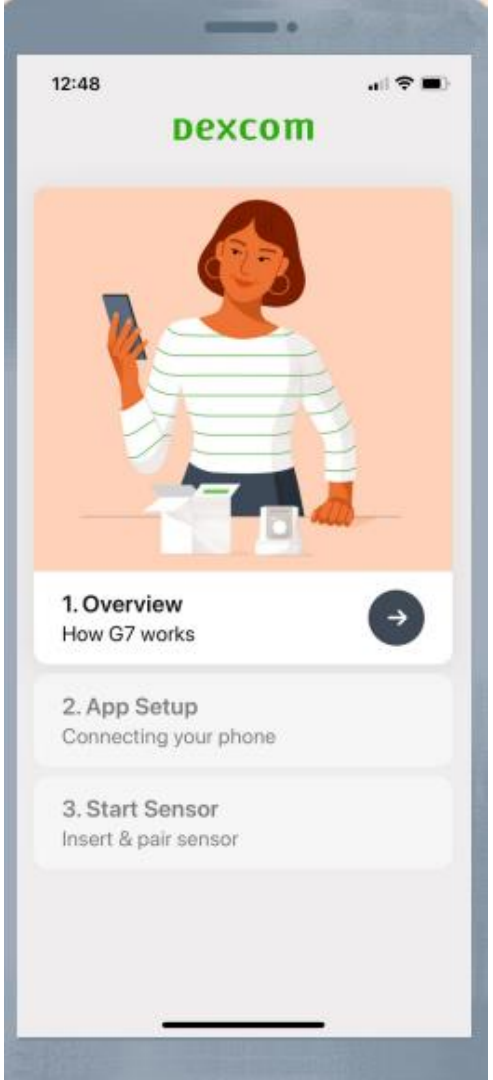
*Internet connectivity required for data sharing. Following requires the use of the Follow app. Followers should always confirm readings on the Dexcom G7 app or receiver before making treatment decisions.



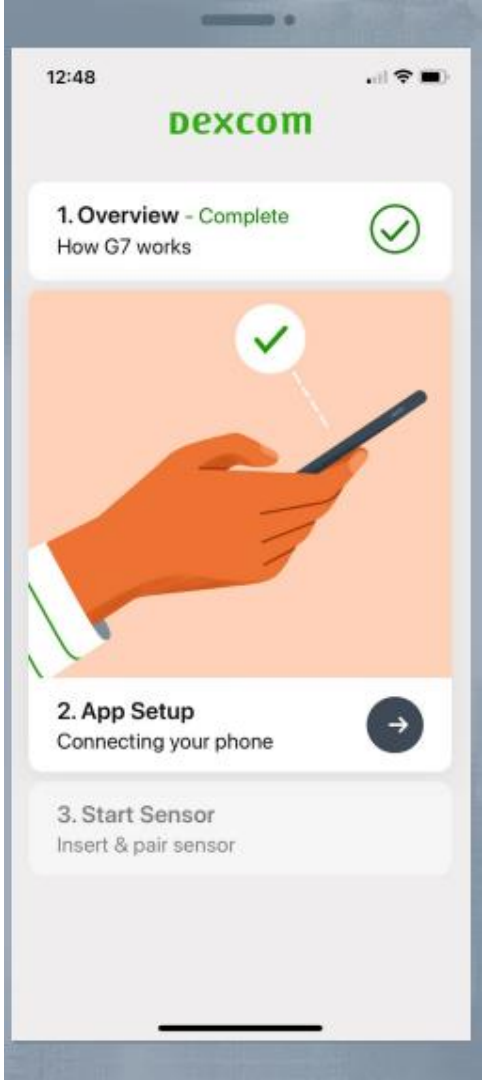
# Overview Walkthrough

- The app walks you through the entire setup process step-by-step.
  - G7 Basics
  - Sensor readings (video and text versions available)
  - Alerts (video and text versions available)
  - When to use your blood glucose meter
    (video and text versions available)
  - Safety



# App Setup

- Enabling Bluetooth (must be on for the system to work)
- Setting other required phone settings (Android and iOS are different)



# Start Sensor

Avoid areas:

- With loose skin or without enough fat to avoid muscles and bones
- That get bumped, pushed, or you lie on while sleeping
- Within 8 centimeters of infusion or injection site
- Near waistband or with irritations, scarring, tattoos, or lots of hair


Wash hands with soap and water. Dry.

Rub site with an alcohol wipe. Wait until dry.

Unscrew cap. Don't touch inside applicator.


Press and hold applicator firmly against skin and then push button.

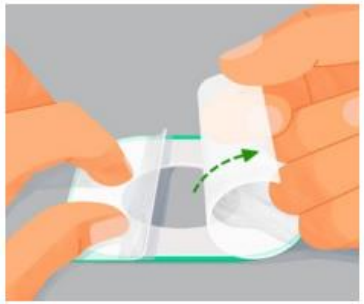
Remove applicator.


Rub firmly around patch 3 times.


Gently press on top of sensor for 10 seconds.

# Apply Over-Patch

- Bundled in the patient instructions in the sensor box



Carefully pull off both clear liners, one at a time. Don't touch white adhesive area.

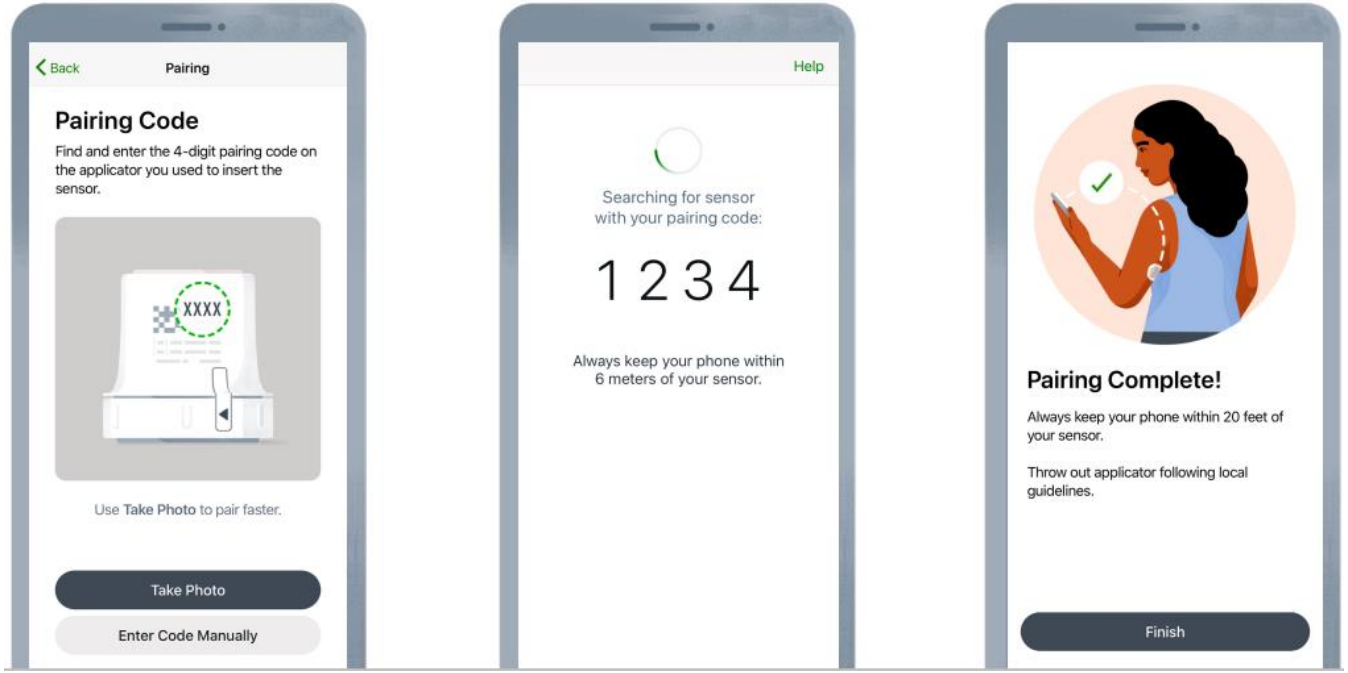
Use colored tab to place overpatch around sensor.

Rub around overpatch.

Use tab to peel off colored liner.

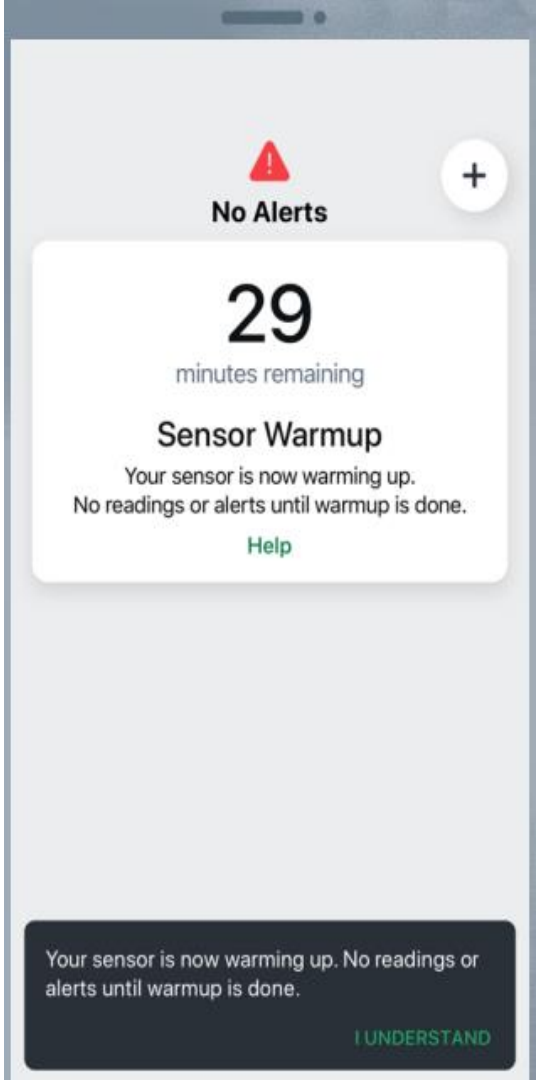
Rub around overpatch.

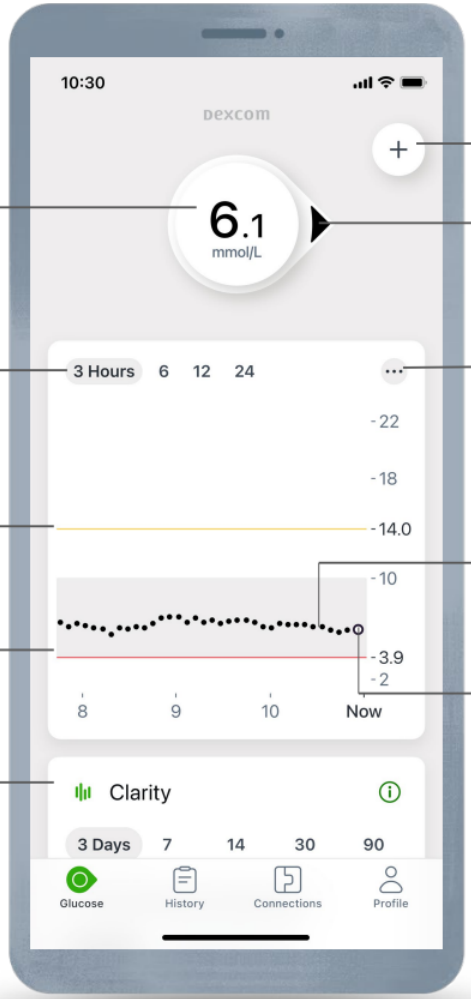
# Pair Sensor with Device



# Warmup

- This will happen each time it is paired
- Once communication is confirmed, the warmup starts
- The sensor warmup timer tells you when readings and alerts will start
- The warmup starts at sensor insertion, so you may see fewer than 30 minutes
- Keep smart device within 6 meters during this time






Current Sensor Reading

Hours Shown

High Alert Level

Low Alert Level

Clarity Card

Add Event

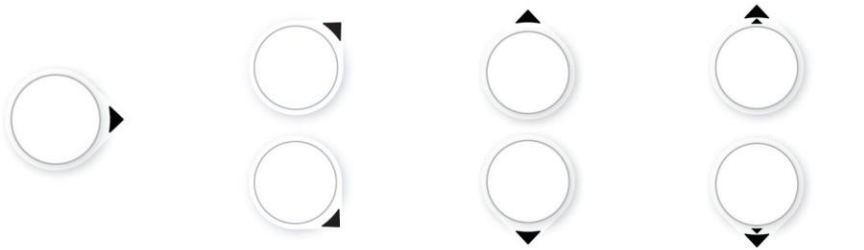
Trend Arrow

Edit Alerts

Trend Graph
(scrub along to view past glucose values)

Current Sensor Reading

# Review the Basics

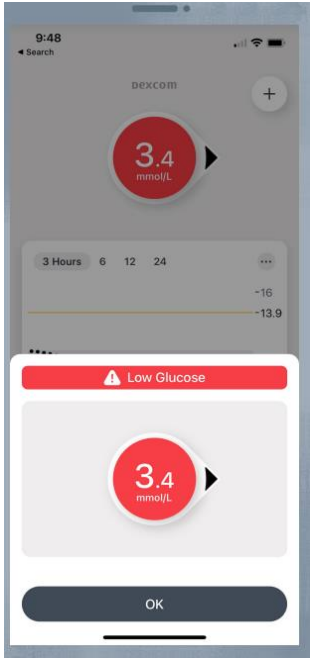


**Steady**
Changing less than 0.8 mmol/L in 15 minutes

**Slowly rising or falling**
Changing 0.8-1.7 mmol/L in 15 minutes

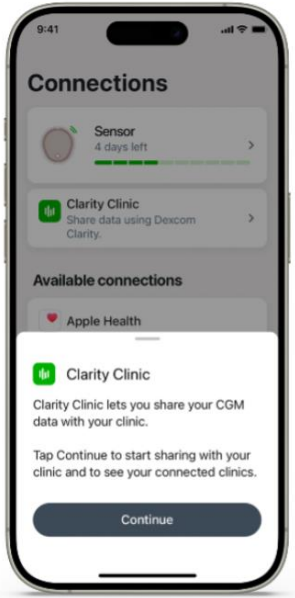
**Rising or falling**
Changing 1.7-2.5 mmol/L in 15 minutes

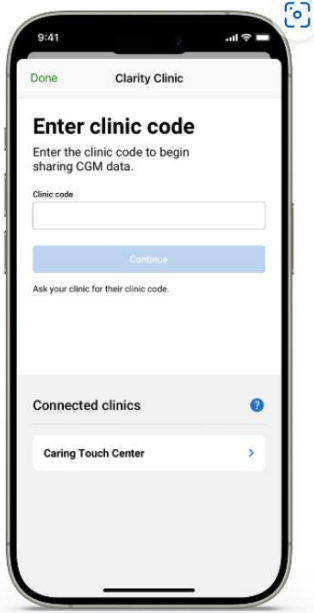
**Rapidly rising or falling**
Changing more than 2.5 mmol/L in 15 minutes

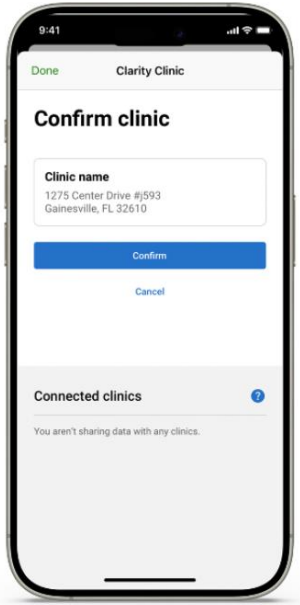


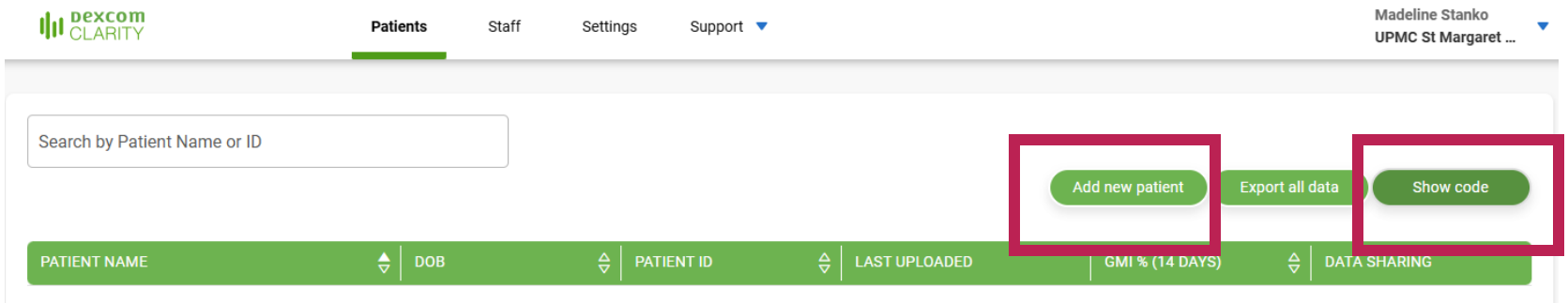

Setup data sharing (Dexcom Clarity)

Add patient to list (provider professional account)



# Freestyle Libre

## Invite Patient

First Name | MI | Last Name

Date of Birth

Month
Select Month | DD | YYYY

Link Patient

Link patient to a LibreView Practice or as a Private Patient.

Practice
Select Practice

Members of this Practice's Care Team will have access to this patient.

LibreView Account

Invite patient to upload and share their glucose data remotely.

Email Address

Cancel

Save

# Information for the Patient

- It may take 24 hours for sugars to normalize
- Keep phone/reader within 20 feet of sensor
- If CGM does not match symptoms, check with glucometer

# End of Sensor/ Removing

- Sensor lasts for 10 days (12-hour grace period)
- To make it easier and avoid irritating skin:
  - Loosen edge and soak patch in body oil, like baby oil or an adhesive remover for skin (alcohol wipe)
  - Use adhesive removal wipes to rub the skin that gets exposed as you peel back the patch

# Keep Sensor On When...

- **Showering & Bathing** – Waterproof up to 24 hours (G7)
- **Swimming** – Waterproof up to 8 feet deep for 24 hours
- **Exercise & Sweating** – Adhesive may loosen but reinforcement (tape/overlay patches) can help
- **Sleep** – No need to remove it overnight
- **Airport Security** – Safe through metal detectors and body scanners; avoid x-ray machines
- **Mild Skin Irritation** – If not severe, try barrier wipes, different site placement, or medical tape

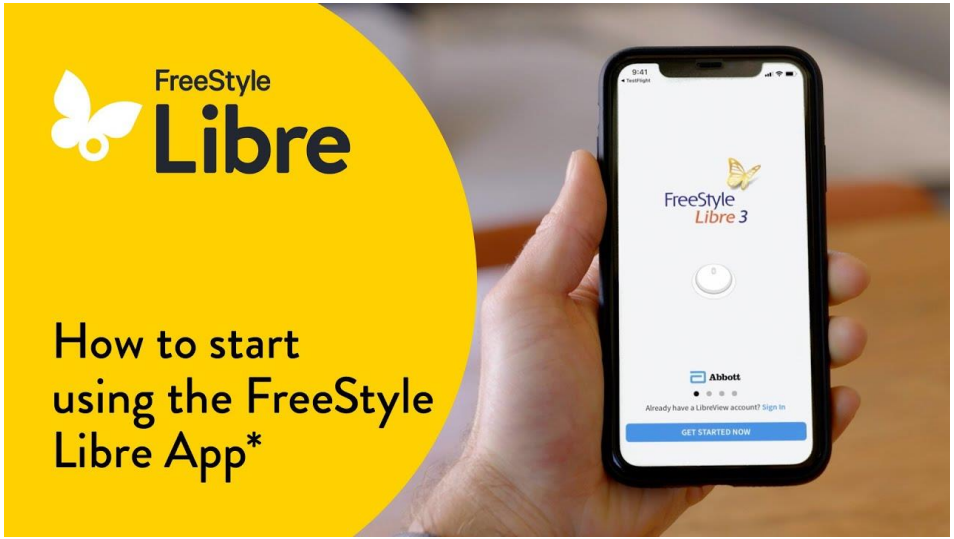
# Remove Sensor When...

- **Imaging** – MRI, CT Scan, X-rays, or Radiation Therapy
- **Severe Skin Reaction** or Infection
- **Sensor Expiration** – G7: Remove after 10 days (auto shut-off).
- **Prolonged Water Exposure** (>24 hours) – Dexcom is water-resistant but not designed for extended soaking.
- **Surgery** – Remove before procedures where medical staff require it

# Troubleshooting

- Always keep sensor box/applicator until end of 10 days
- If problems with sensor (not working/ falls off) remove sensor and place new one
- Call manufacturer – explain error and request replacement
- Manufacturer phone #s:
  - Dexcom: 888-738-3646
  - Freestyle: 1-855-632-8658

# Freestyle Libre




# UPMC Billing

- **Billing**
  - 95249 – first time you see the patient to review CGM set up **AND** interpret at least 72 hours' worth of CGM data
  - 95251 – code you can bill once every 30 days for CGM interpretation
- **Revenue**
- **Improving STAR ratings**

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# Data Interpretation

# DISCLAIMER

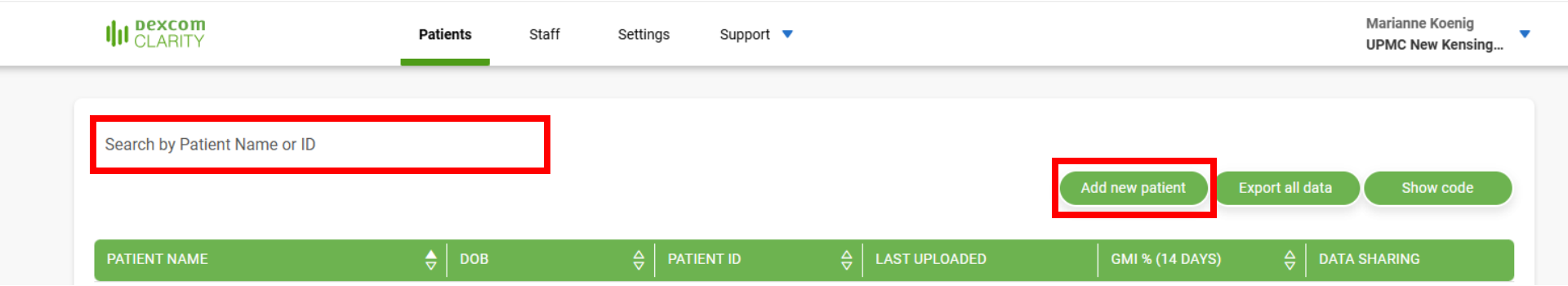
- Additional software is needed on the *physical* computer that is connected to a reader device
- At UPMC, information technology can download the driver needed to upload data
- This is not needed for viewing and interpreting data from patients that share remotely

# Dexcom

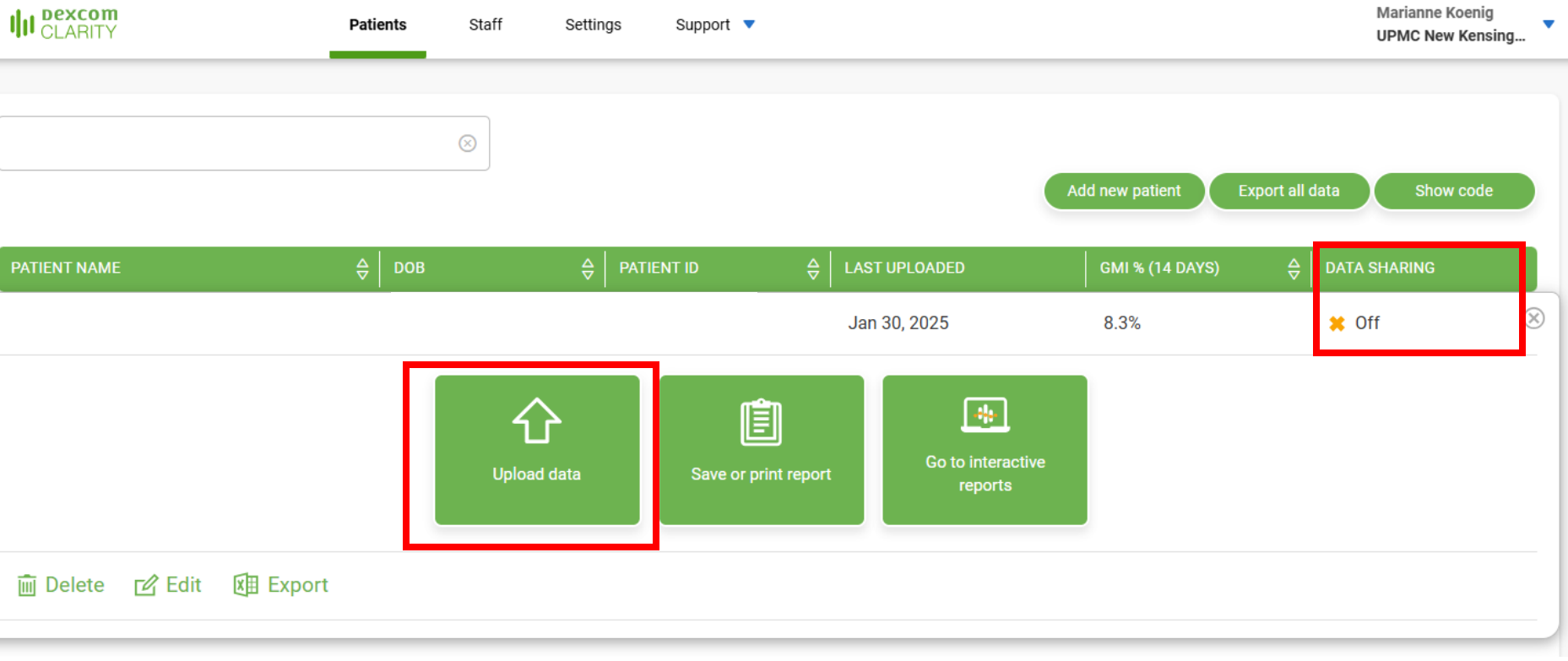
**Steps to download:**

1. Log into Dexcom Clarity website
2. Search for patient / add new patient
3. If remote sharing, can print / save report
4. If patient has a reader, plug in reader device and select patient
5. Upload the data
6. Print / save report

# Dexcom


dexcom CLARITY
Patients
Staff
Settings
Support
Marianne Koenig
UPMC New Kensing...
Search by Patient Name or ID
Add new patient
Export all data
Show code
PATIENT NAME
DOB
PATIENT ID
LAST UPLOADED
GMI % (14 DAYS)
DATA SHARING

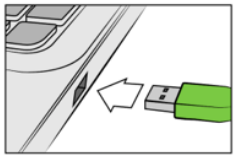
# Dexcom


dexcom CLARITY
Patients
Staff
Settings
Support
Marianne Koenig
UPMC New Kensing...
Add new patient
Export all data
Show code
PATIENT NAME
DOB
PATIENT ID
LAST UPLOADED
GMI % (14 DAYS)
DATA SHARING
Jan 30, 2025
8.3%
Off
Upload data
Save or print report
Go to interactive reports
Delete
Edit
Export

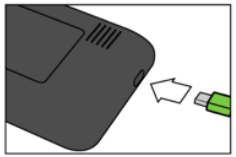
# Upload Data

| PATIENT NAME | DOB | PATIENT ID | LAST UPLOADED | DATA SHARING |
|---|---|---|---|---|
| | | | Jan 30, 2025 4:06 PM | ✖ Off |

Verify — 2 Connect Device — 3 Collect Data — 4 Success



1. Connect the USB cable to your computer.



2. Connect the cable to your receiver.

3. Press and hold the power button on the receiver until it turns on.

Cancel Upload

# Upload Data

| PATIENT NAME | DOB | PATIENT ID | LAST UPLOADED | DATA SHARING |
|---|---|---|---|---|
| | | | Jan 30, 2025 4:06 PM | Off |

1. Verify
2. Connect Device
3. **Collect Data**
4. Success

## Collecting Data

Please wait while data is collected.

Reading...

# Upload Data

| PATIENT NAME | DOB | PATIENT ID | LAST UPLOADED | DATA SHARING |
|---|---|---|---|---|
| | | | Feb 13, 2025 3:34 PM | Off |

## Upload complete!

Upload data

Save or print report

Go to interactive reports

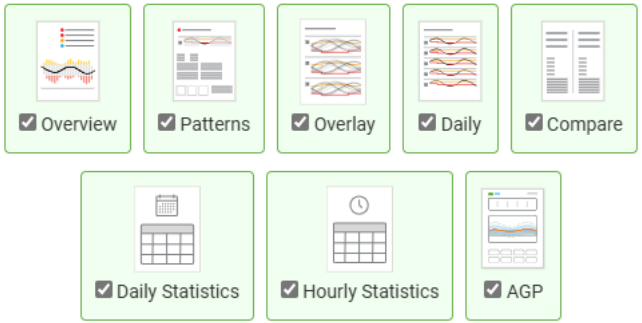
← Return to Patient List

# Save or print report

Primary date range to display:

14 Days Fri Jan 31, 2025 - Thu Feb 13, 2025

Report sections to display:




Color Mode:

Color  Black and White

NOTE: The Compare report will compare the date range selection shown above with the previous 14 days

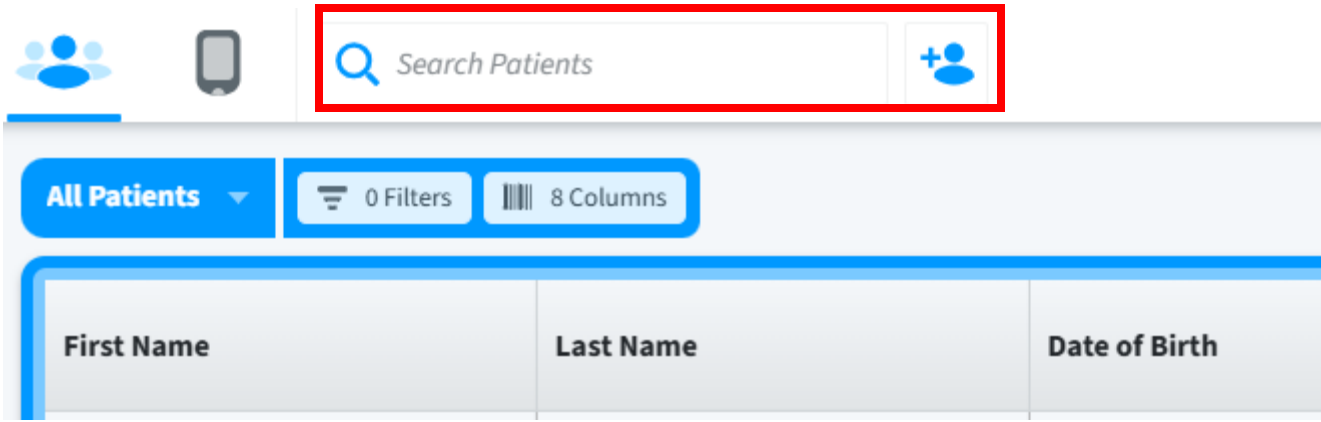
Save as PDF  Print report  Cancel

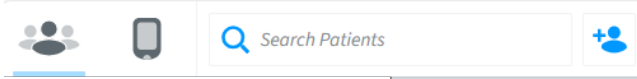
- Can change date range for report
- 7 days up to 90 days
- Can upload full PDF to patient chart
- Provide printed reports to patients upon request

# Freestyle Libre

Steps to download:

1. Log into Freestyle LibreView website
2. Search for patient / add new patient
3. If remote sharing, can print / save report
4. If patient has a reader, plug in reader device and select patient
5. Upload the data
6. Print / save report






# Profile

- Profile
- Glucose History
- New Kensington FHC

## Identity

Age Date of Birth Email

**Connected to LibreView Patient**

New glucose data will appear in LibreView when the patient uploads into their personal LibreView account.

## My Practices

Below are the LibreView Practices that have access to view this patient.

- ✔ New Kensington FHC

Download all of the patient's glucose data in LibreView. Download Glucose Data

Search Patients

# Glucose History

2 weeks | Compare

- Profile
- Glucose History
- New Kensington FHC

All Data | FreeStyle Libre | FreeStyle Libre Pro

## New Glucose Data

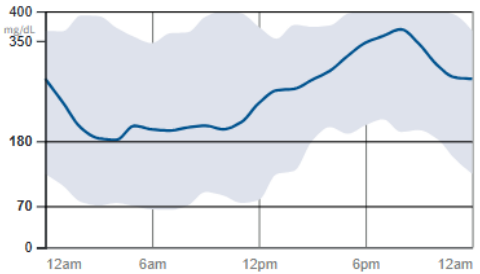
View glucose history below or click **Glucose Reports** to create customized reports you can view now or print/save as PDFs.

**Glucose Reports**

January 31, 2025 – **February 13, 2025**

**FreeStyle Libre 2**

| 252 | 100% | 5 |
|---|---|---|
| mg/dL Average Glucose | Days of Data | Hypo Events |



MRN: _____
DEVICE: FreeStyle Libre 3 + 7

New Kensington FHC
PHONE: 724-334-3640

Generated: 02/13/2025

# AGP Report

LibreView

January 31, 2025 - February 13, 2025 (14 Days)

## GLUCOSE STATISTICS AND TARGETS

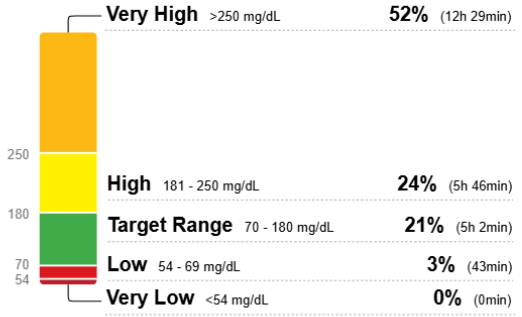
| | |
|---|---|
| **January 31, 2025 - February 13, 2025** | **14 Days** |
| **Time CGM Active:** | **80%** |

| Ranges And Targets For | Type 1 or Type 2 Diabetes |
|---|---|
| **Glucose Ranges** Target Range 70-180 mg/dL | **Targets** % of Readings (Time/Day) Greater than 70% (16h 48min) |
| Below 70 mg/dL | Less than 4% (58min) |
| Below 54 mg/dL | Less than 1% (14min) |
| Above 180 mg/dL | Less than 25% (6h) |
| Above 250 mg/dL | Less than 5% (1h 12min) |
| Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial. | |

| | |
|---|---|
| **Average Glucose** | **252** mg/dL |
| **Glucose Management Indicator (GMI)** | **9.3%** |
| **Glucose Variability** | **38.1%** |

**Defined as percent coefficient of variation (%CV); target ≤36%**

## TIME IN RANGES



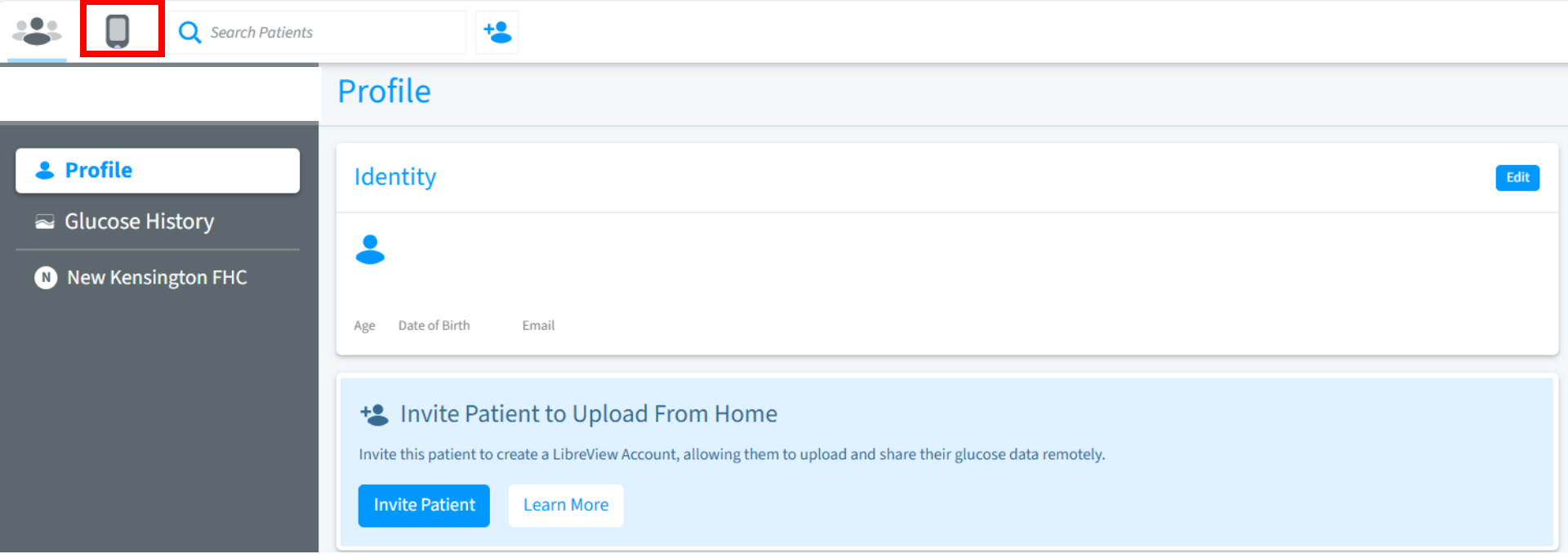

| | | | |
|---|---|---|---|
| **Very High** | >250 mg/dL | **52%** | (12h 29min) |
| **High** | 181 - 250 mg/dL | **24%** | (5h 46min) |
| **Target Range** | 70 - 180 mg/dL | **21%** | (5h 2min) |
| **Low** | 54 - 69 mg/dL | **3%** | (43min) |
| **Very Low** | <54 mg/dL | **0%** | (0min) |

## AMBULATORY GLUCOSE PROFILE (AGP)

*AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.*


Change Report End Date | 8 Data Sources | Report Settings

16 pages | Print/Save PDF


Search Patients
Profile
Profile
Glucose History
New Kensington FHC
Identity
Edit
Age
Date of Birth
Email
Invite Patient to Upload From Home
Invite this patient to create a LibreView Account, allowing them to upload and share their glucose data remotely.
Invite Patient
Learn More

# Upload a Device

1. Connect the device to your computer with the correct cable
2. Choose upload option below

The LibreView Device Drivers software is required to upload a device. Download the LibreView Device Drivers software


**Create 1-Time Report**

Upload a device to view and print a report now.

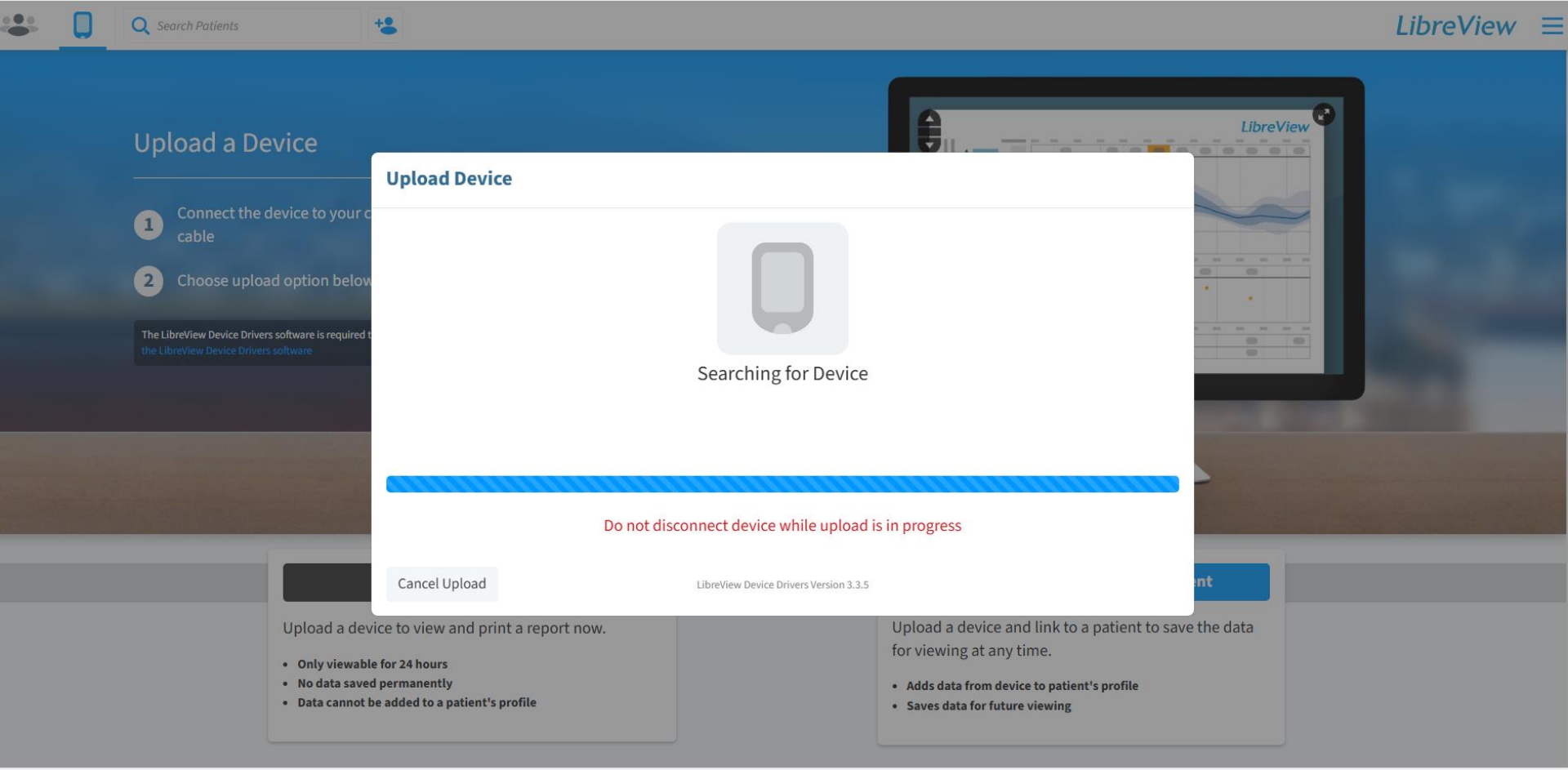
- **Only viewable for 24 hours**
- **No data saved permanently**
- **Data cannot be added to a patient's profile**

OR

**Create Report Linked to Patient**

Upload a device and link to a patient to save the data for viewing at any time.

- **Adds data from device to patient's profile**
- **Saves data for future viewing**


Search Patients
LibreView
Upload a Device
1 Connect the device to your c
cable
2 Choose upload option below
The LibreView Device Drivers software is required t
the LibreView Device Drivers software
LibreView
Upload Device
Searching for Device
Do not disconnect device while upload is in progress
Cancel Upload
LibreView Device Drivers Version 3.3.5
Upload a device to view and print a report now.
Only viewable for 24 hours
No data saved permanently
Data cannot be added to a patient's profile
Upload a device and link to a patient to save the data for viewing at any time.
Adds data from device to patient's profile
Saves data for future viewing

MRN: _____
DEVICE: FreeStyle Libre 3 + 7

New Kensington FHC
PHONE: 724-334-3640

Generated: 02/13/2025

# AGP Report

LibreView

January 31, 2025 - February 13, 2025 (14 Days)

## GLUCOSE STATISTICS AND TARGETS

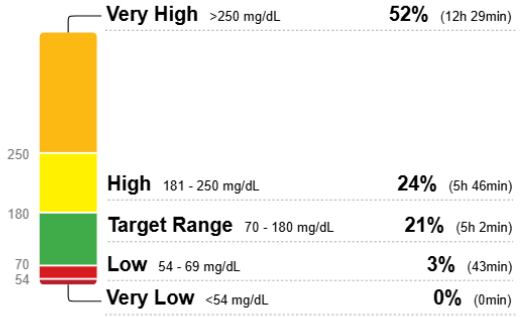
| | |
|---|---|
| **January 31, 2025 - February 13, 2025** | **14 Days** |
| **Time CGM Active:** | **80%** |

| Ranges And Targets For | Type 1 or Type 2 Diabetes |
|---|---|
| **Glucose Ranges** Target Range 70-180 mg/dL | **Targets** % of Readings (Time/Day) Greater than 70% (16h 48min) |
| Below 70 mg/dL | Less than 4% (58min) |
| Below 54 mg/dL | Less than 1% (14min) |
| Above 180 mg/dL | Less than 25% (6h) |
| Above 250 mg/dL | Less than 5% (1h 12min) |
| Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial. | |

| | |
|---|---|
| **Average Glucose** | **252** mg/dL |
| **Glucose Management Indicator (GMI)** | **9.3%** |
| **Glucose Variability** | **38.1%** |

**Defined as percent coefficient of variation (%CV); target ≤36%**

## TIME IN RANGES




| | | | |
|---|---|---|---|
| **Very High** | >250 mg/dL | **52%** | (12h 29min) |
| **High** | 181 - 250 mg/dL | **24%** | (5h 46min) |
| **Target Range** | 70 - 180 mg/dL | **21%** | (5h 2min) |
| **Low** | 54 - 69 mg/dL | **3%** | (43min) |
| **Very Low** | <54 mg/dL | **0%** | (0min) |

## AMBULATORY GLUCOSE PROFILE (AGP)

*AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.*


Change Report End Date | 8 Data Sources | Report Settings

16 pages | Print/Save PDF

# Goal: Flat, Narrow, In-Range

## GLUCOSE STATISTICS AND TARGETS

**September 4, 2024 - September 17, 2024** **14 Days**

**Time CGM Active:** **84%**

| Ranges And Targets For | Type 1 or Type 2 Diabetes |
|---|---|
| **Glucose Ranges** | **Targets** % of Readings (Time/Day) |
| Target Range 70-180 mg/dL | Greater than 70% (16h 48min) |
| Below 70 mg/dL | Less than 4% (58min) |
| Below 54 mg/dL | Less than 1% (14min) |
| Above 180 mg/dL | Less than 25% (6h) |
| Above 250 mg/dL | Less than 5% (1h 12min) |

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

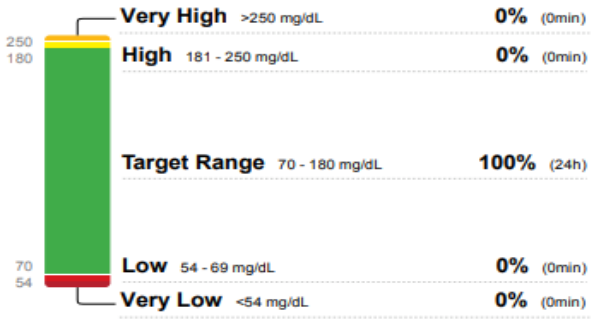
**Average Glucose** **112** mg/dL

**Glucose Management Indicator (GMI)** **6.0%**

**Glucose Variability** **14.0%**

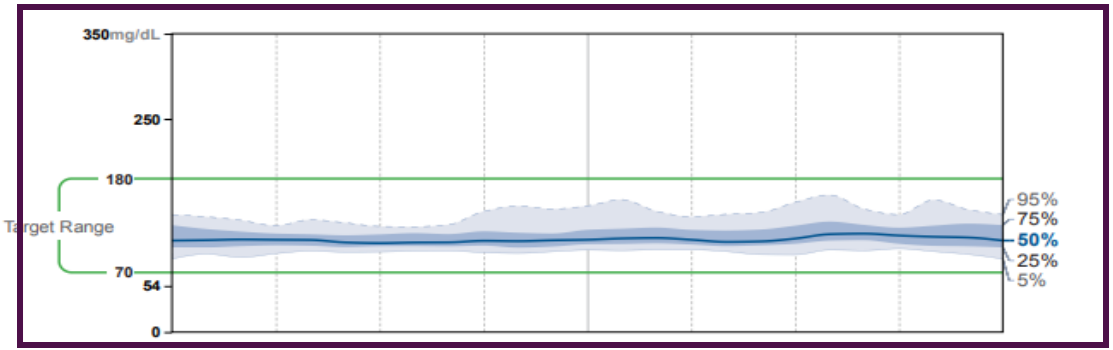
**Defined as percent coefficient of variation (%CV); target ≤36%**

## TIME IN RANGES

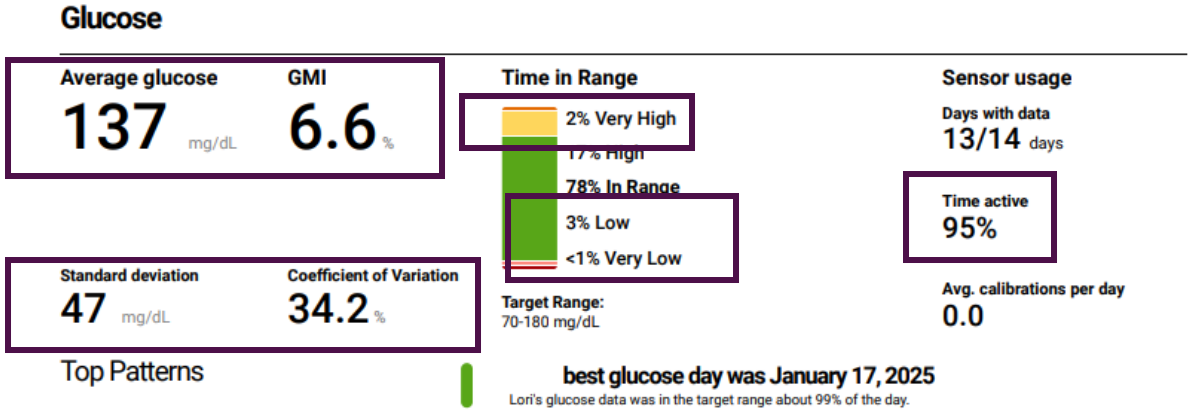


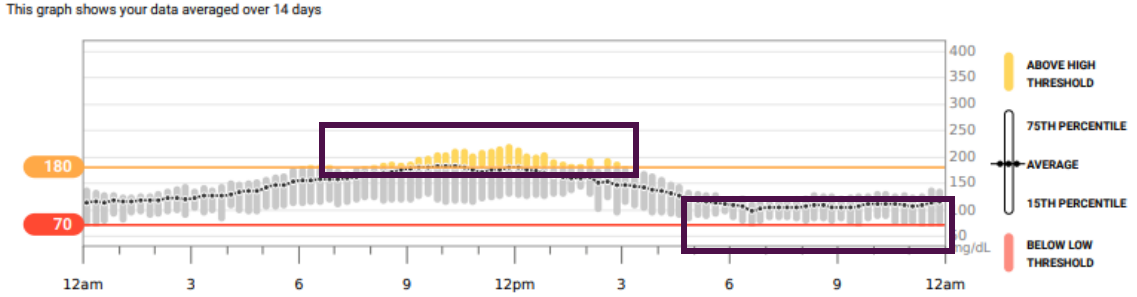

## AMBULATORY GLUCOSE PROFILE (AGP)

*AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.*



# Interpretation - Overview




UPMC
LIFE CHANGING MEDICINE
LET'S PRACTICE!

# Interpretation - Patient Case Example

CG is a 65 yo M pt with T2DM, obesity, HTN, and HLD comes into clinic for diabetes f/u.

**Pertinent Labs/Vitals:**

- A1c 2 months ago: 10.3%
- Last weight: 103 kg

**Current T2DM Regimen:**

- Metformin 1,000 mg BID
- Jardiance 25 mg daily
- Ozempic 2 mg weekly
- Lantus 30 units qHS
  - ~0.3 units/kg
- Humalog 10 units TID w/meals
- Dexcom G7

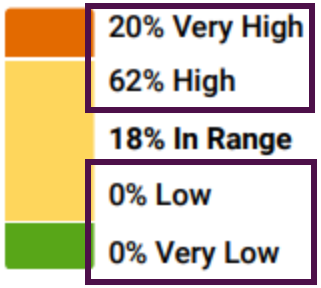
# Interpretation - Patient Case Example

UPMC
LIFE CHANGING MEDICINE

**Average glucose**
220 mg/dL

**GMI**
N/A

**Time in Range**



- 20% Very High
- 62% High
- 18% In Range
- 0% Low
- 0% Very Low

**Target Range:**
70-180 mg/dL

**Sensor usage**

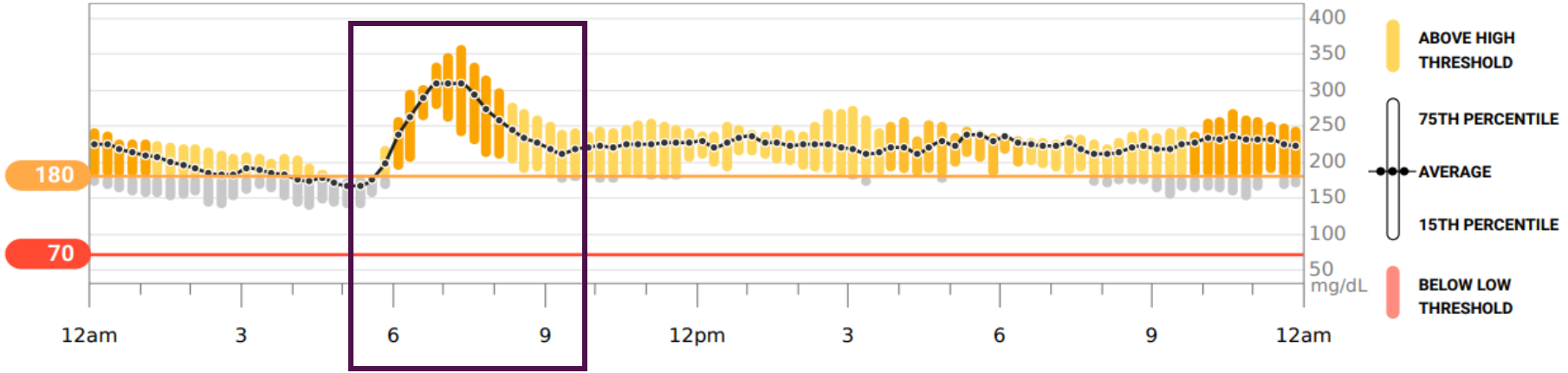
**Days with data**
4/14 days

**Time active**
67%

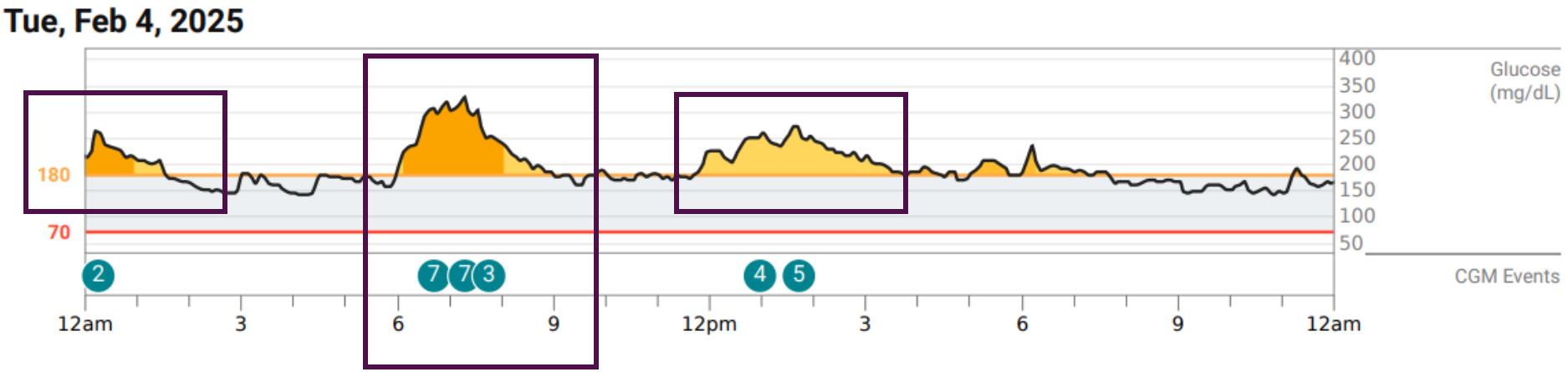
**Avg. calibrations per day**
0.0

**Standard deviation**
42 mg/dL

**Coefficient of Variation**
19.2 %



# Interpretation - Patient Case Example



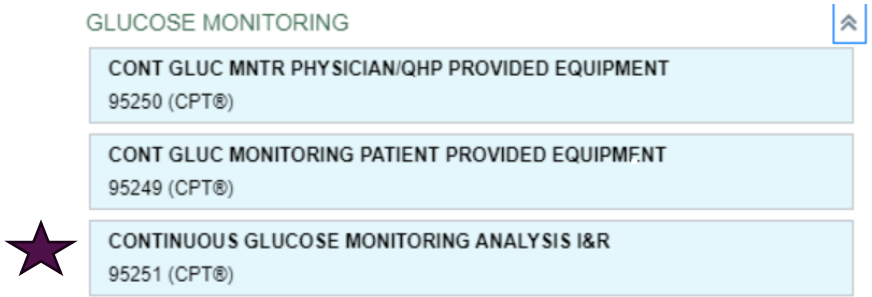

| | | | | | |
|---|---|---|---|---|---|
| 7:51 AM | CGM | Alert | High | -- | 250 mg/dL |
| 7:46 AM | CGM | Alert | High | -- | 252 mg/dL |
| 7:36 AM | CGM | Alert | High | -- | 272 mg/dL |
| 7:31 AM | CGM | Alert | High | -- | 302 mg/dL |
| 7:26 AM | CGM | Alert | High | -- | 294 mg/dL |
| 7:21 AM | CGM | Alert | High | -- | 302 mg/dL |
| 7:16 AM | CGM | Alert | High | -- | 328 mg/dL |
| 7:11 AM | CGM | Alert | High | -- | 314 mg/dL |
| 7:06 AM | CGM | Alert | High | -- | 306 mg/dL |

# What Would You Recommend For This Patient?

Our Recommendation:

- Lifestyle interventions
- Increase Humalog to 12 units with breakfast, 10 units with lunch and dinner
- Increase Lantus to 32 units qHS

**Don't Forget to Bill!**




Can only bill once every **30 days**!

# Key Points

CGMs are useful tools to monitor glycemic trends in patients with diabetes and assist in informing medication adjustments, particularly insulin

CGMs initial and interpretation visits utilize different billing codes, and the latter can only be billed once every 30 days

While different patient populations have different targets for glycemic control, the goal CGM trend is flat, narrow, and in-range

# References


1) American Diabetes Association Professional Practice Committee. Diabetes Technology: Standards of Care in Diabetes-2025. *Diabetes Care*. 2025;48:S146-S166. doi:10.2337/dc25-S007.

2) Abbott. FreeStyle Provider – Continuous Glucose Monitoring (CGM) Systems. Accessed February 10, 2025. https://www.freestyleprovider.abbott/us-en/home.html.

3) Dexcom Provider – Continuous Glucose Monitoring for Healthcare Providers. Accessed February 10, 2025. https://provider.dexcom.com.

UPMC
LIFE CHANGING MEDICINE

# Cracking the Code on Continuous Glucose Monitors (CGMs): A Practical Guide for Providers

UPMC St Margaret Pharmacy Residency Program

# Family Medical History in Primary Care

UPMC LIFE CHANGING MEDICINE

# Title Slide

Title of Course:

'PCPM: Family Medical History in Primary Care'

Course Presenter:

- Kevin C. Lee, DO

- No relationships with industry relevant to the content of this education activity have been disclosed for all parties

# Objectives

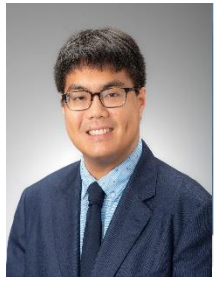
1. Understanding the role that family medical history plays in identifying genetically testable conditions and how primary care plays a key part in this role
2. Learning high-yield questions to help identify a genetically testable medical condition from the family history
3. Practice creating a medical pedigree in the context of patient care
4. Learning next steps to evaluate the concern for genetically testable conditions found in the family medical history

# Who are we?

- A consultant clinic in the UPMC Department of Family Medicine
- A multidisciplinary team of Family Medicine providers, Licensed Genetic Counselors, and Pharmacists
- Mission Aims:
  - Provide Precision Medicine care to the community
  - Research the integration of Precision Medicine into everyday Primary Care
  - Enhance access and equity for Precision Medicine services to the community

# UPMC Primary Care Precision Medicine Clinic

Mylynda Massart
MD, PhD



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DO

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DNP, CRNP, FNP-C

Lucas Berenbrok
PharmD, MS, BCACP

Natasha Berman
MA, MS, MPH, CGC

Christine Munro
MS, MPH, CGC

Lucy Galea
MS, CGC

# Key Components to Genetic Testing

1. Obtaining the personal/medical history (aka the phenotype)
   - As medical providers, this is our expertise
2. Obtain the Family History (aka the pedigree)
   - Providers: “What is your family history?”
3. Genetic counseling and consent
   - Key role of Genetic Counselors

# Importance of Family History

- Accurate family history is a well-established method to identify potential disorders and susceptibilities that may pose future health problems
- Family history is the first step to identify patients and start discussions about future health concerns
- Allows for personalized risk assessment
- Often encourages good rapport building with patients
- May open discussion for other concerns a patient may have

# Practitioner Approach Today for FMHx

- If a patient comes in for a new physical, how would you ask patients to describe their family history?

# Practitioner Approach Today for FMHx

- Most of the time we do not ask for precise questions that quickly identify a family history concern for a genetically testable condition
- We can do better
- And be more efficient!

# Quick Questions to Ask for FMHx ‘Red Flag’ Screening

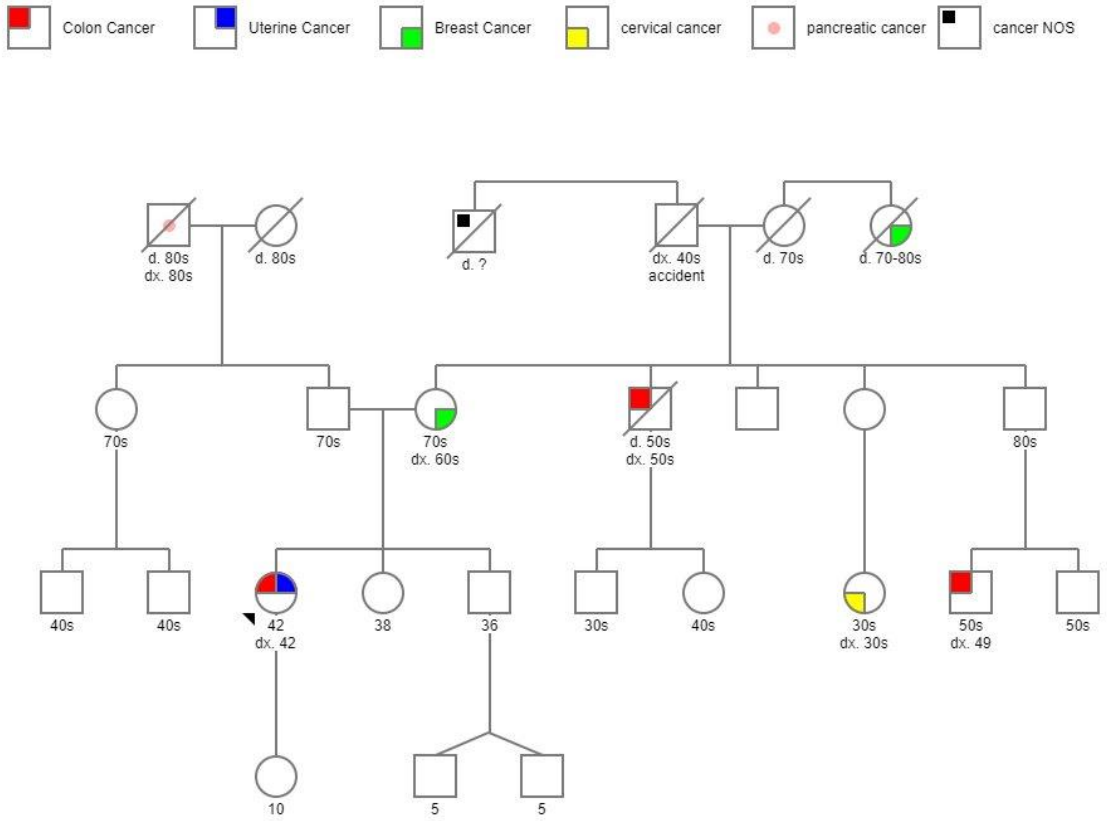
- Any family history of cancer diagnosed under the age of 50?
  - Ex. Hereditary Breast and Ovarian Cancer, Lynch Syndrome
- Any family history of developmental or intellectual delay in a family member?
  - Ex. Fragile X, Down Syndrome
- Any family history of dementia or neurocognitive decline before the age of 50?
  - Ex. ALS, Frontotemporal Dementia
- Any family history of 3 or more miscarriages, a history of stillbirths or infertility?
  - Ex. Turner Syndrome, Klinefelter Syndrome
- Any history of cardiomyopathy, spontaneous organ rupture, or arrythmia, sudden cardiac death?
  - Ex. Marfan's Syndrome, vascular Ehlers Danlos Syndrome, Familial hypercholesteremia, Brugada's
- How would you identify your ancestry or ethnicity?
  - Ex. Ashkenazi Jewish ancestry -> increased risk for BRCA

# ‘Red Flags’ of the Family History

- Cancer:
  - Onset of cancer before the age of 50
  - Cancer in at least 3 or more family members on the same side of the family
  - Rare cancers including pancreatic and ovarian, or metastatic prostate
  - Ashkenazi Jewish ancestry
  - Family history of genetic results (obtain and review the results!)
- Heart Disease
  - Heart Attack/Stroke/Aneurysm/Fatal Arrhythmia before the age of 50
  - Hyperlipidemia requiring medical therapy before the age of 50
  - Elevated LDL >190
  - Spontaneous organ rupture w/o trauma like aneurysms or pneumothorax
  - Spontaneous eye structural condition w/o trauma like lens detachment, vitreous detachment, retinal detachment, corneal rupture
- Genetic Conditions in general
  - Known conditions running in the family
    - Ex. Hereditary hemochromatosis, Alpha-1-antirypsin, thalassemia, malignant hyperthermia, Factor V Leiden, Familial Mediterrean Fever
  - Prior hx of positive genetic testing results in the family (obtain and review the results!)

# Medical Pedigree

# Example of a Medical Pedigree



# Steps to Making a Pedigree

1. Stop the patient! Tell them that you will go through a step-by-step approach addressing the family members of interest and that you will prompt the patient when you want more information.

2. Pick a Direction (siblings, parents, children). Stick with the generation until done.

3. For each person ask:
   - Alive vs Deceased
   - Current age vs Age deceased
   - Major medical conditions. You can be specific like conditions similar to the patient's presentation, or conditions that were diagnosed young in life like young onset of cancers, neurocognitive decline, or heart disease. If deceased, what did they die from?

4. When you move to the parents, pick a side (paternal or maternal), repeat step 2-3 until you finish a side, then go to the other side

5. Ask about ethnicity/ancestry on paternal and maternal side, and if there is any chance the parents are related to each other by blood (aka. consanguinity).

# Pedigree Demonstration

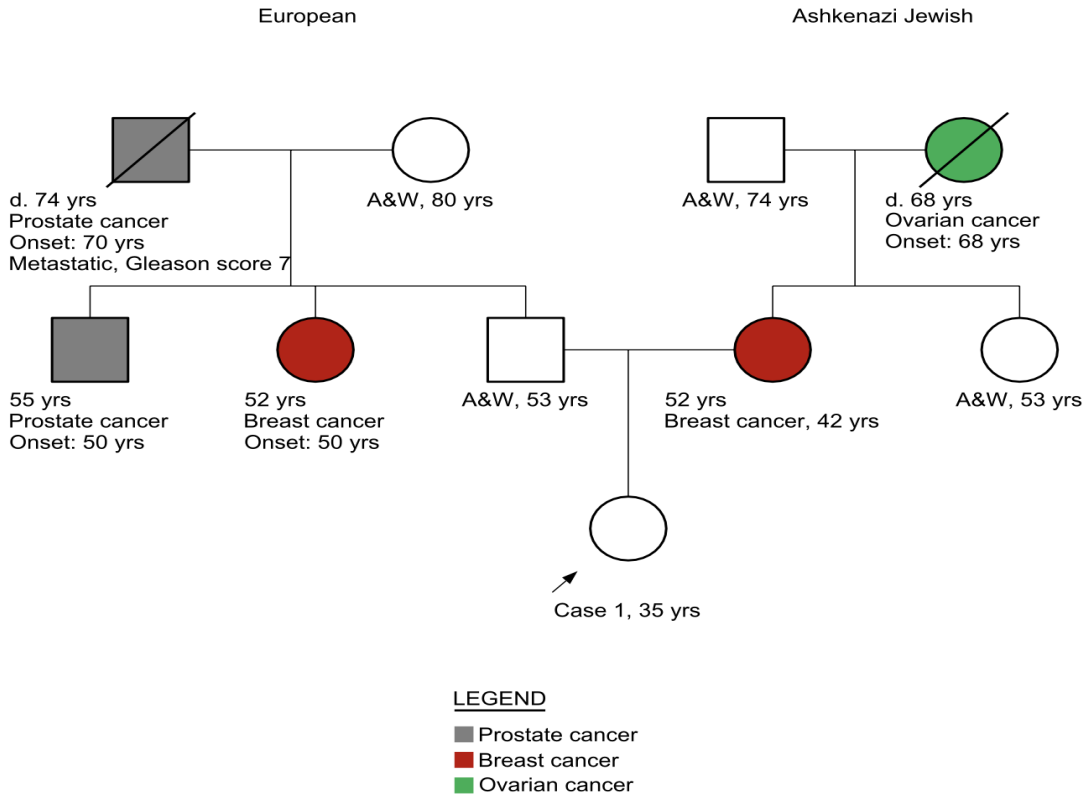
# Pedigree Demonstration

# Pedigree Practice

- With a partner, ask screening questions and draw a medical pedigree
- There are 2 cases, each partner will do one case and set of questions
- 5 minutes for each case (we will call out 'Switch!') for 10 minutes total
- There is a key for the pedigree symbols with each case

# Pedigree Case 1 Answer

**Patient Name**: Case 1 **MRN**: N/A **DOB**: 1990

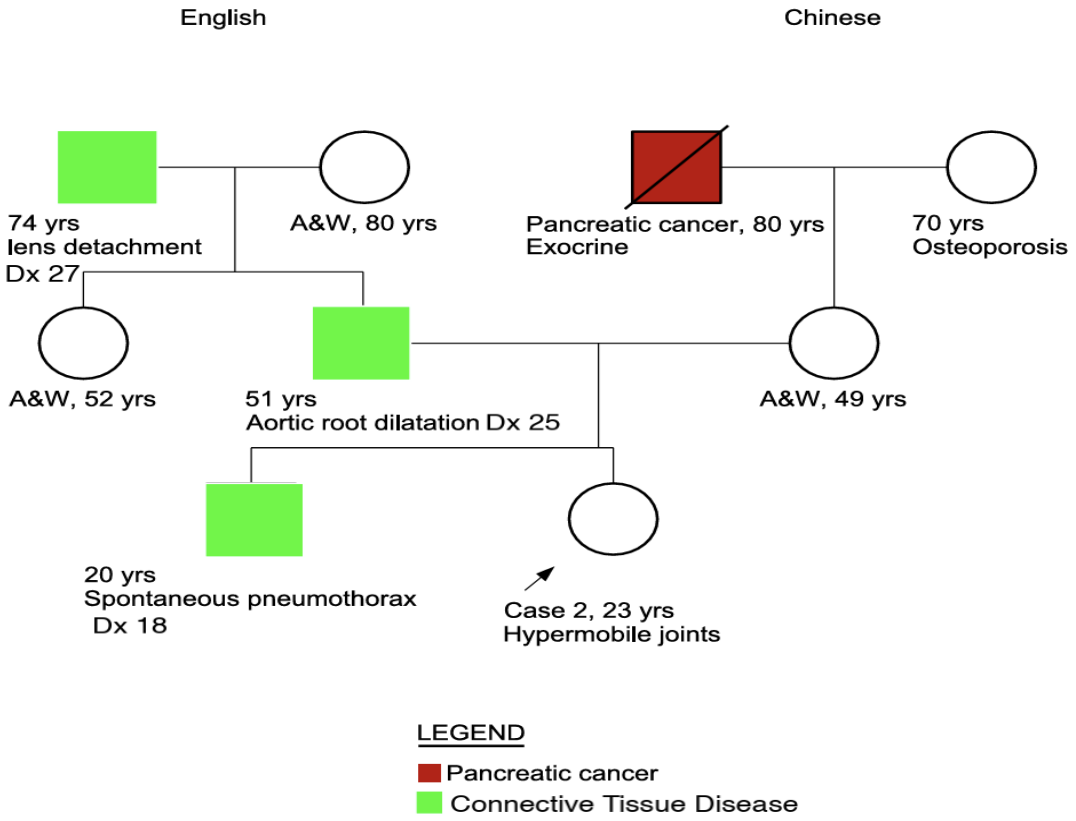


# Pedigree Case 1 Insights

- Patient qualifies for cancer genetic testing due to:
  - Mother with breast cancer dx age 42
  - Maternal Grandmother who had ovarian cancer
  - Paternal Grandfather who had metastatic prostate cancer
  - Paternal Uncle with prostate cancer dx age 50
  - Paternal Aunt with breast cancer dx age 50
  - Maternal ancestry being Ashkenazi Jewish

# Pedigree Case 2 Answer

**Patient Name**: Case 2 **MRN**: N/A **DOB**: 2002



# Pedigree Case 2 Insights

- Paternal history of connective tissue disease, (ex. Marfan's syndrome)
  - Father with aortic root dilation age 25
  - Paternal grandfather with lens detachment age 27
  - Best candidate for genetic testing would be father, then brother since they are the most affected
- Maternal history of exocrine pancreatic cancer
  - Patient would NOT meet NCCN guidelines for cancer genetic testing... but mother does due to be being the 1st degree relative from the affected maternal grandfather

# Can I bill for this?

- Yes!
- If positive on a screening question:
  - Z80.9 Family history of cancer
  - Z82.49 Family history of heart disease
  - Z84.89 Family history of genetic disease
- Bill by time

# What's Next?

1. Obtaining the personal/medical history (aka the phenotype) ✅
   - As medical providers, this is our expertise
2. Obtain the Family History (aka the pedigree) ✅
   - Providers: "What is your family history?"
3. **Genetic counseling and consent**
   - **Key role of Genetic Counselors**

# Genetic Counselors

"Genetic counseling is the process of helping people understand and adapt to the medical, psychological and familial implications of genetic contributions to disease. This process integrates the following:

- Interpretation of family and medical histories to assess the chance of disease occurrence or recurrence.

Education about inheritance, testing, management, prevention, resources and research.

Counseling to promote informed choices and adaptation to the risk or condition. "

- NSGC Definition Task Force 2006

# How to Consult PCPM

- UPMC
  1) Permission for patient being referred
  2) "Electronic Consult/Referral to Genetics" in Epic. Please write referral reason
     - Note that this will NOT be a formal electronic consult and will therefore not be billed, but a GC will reply to the consult you on whether or not we will accept the consult after chart review
  3) Use Smartphrase .pcpmreferral (Username: LEEKC2) to give instructions to the patient to call our central scheduling line (412-647-9304). Please indicate the referral reason in the instructions to remind the patient
     - Even if the consult is accepted by us, it is the patient's responsibility to call central scheduling themselves to schedule the appointment

- Non-UPMC

1) Permission for patient being referred

2) Referral order faxed to our office (412-863-5788)

3) Patient instructions to call our central scheduling line (412-647-9304)

# Consulting PCPM: Things to Note

- We do NOT provide continuity care, we will see patients on a consultant basis until the clinical question is adequately addressed
- We are board certified in Family Medicine, not in Medical Genetics, and therefore we may recommend referrals to specialists depending on the clinical case
- Please ensure that any relevant records especially genetic testing records from the patient and/or family members are available for us to review at the time of the visit. Failure to do so will likely result in delays in care such as additional appointments.
- We primarily operate in a telemedicine approach but we also offer in-person appointments.
  - Any patient whose home address is in PA may have their initial and subsequent visits via telemedicine regardless if they are a UPMC patient
  - Any patient whose home address is outside of PA AND are not active UPMC patients MUST have their initial appointment in person. Any subsequent visits can be facilitated via telemedicine.

# Thank you!

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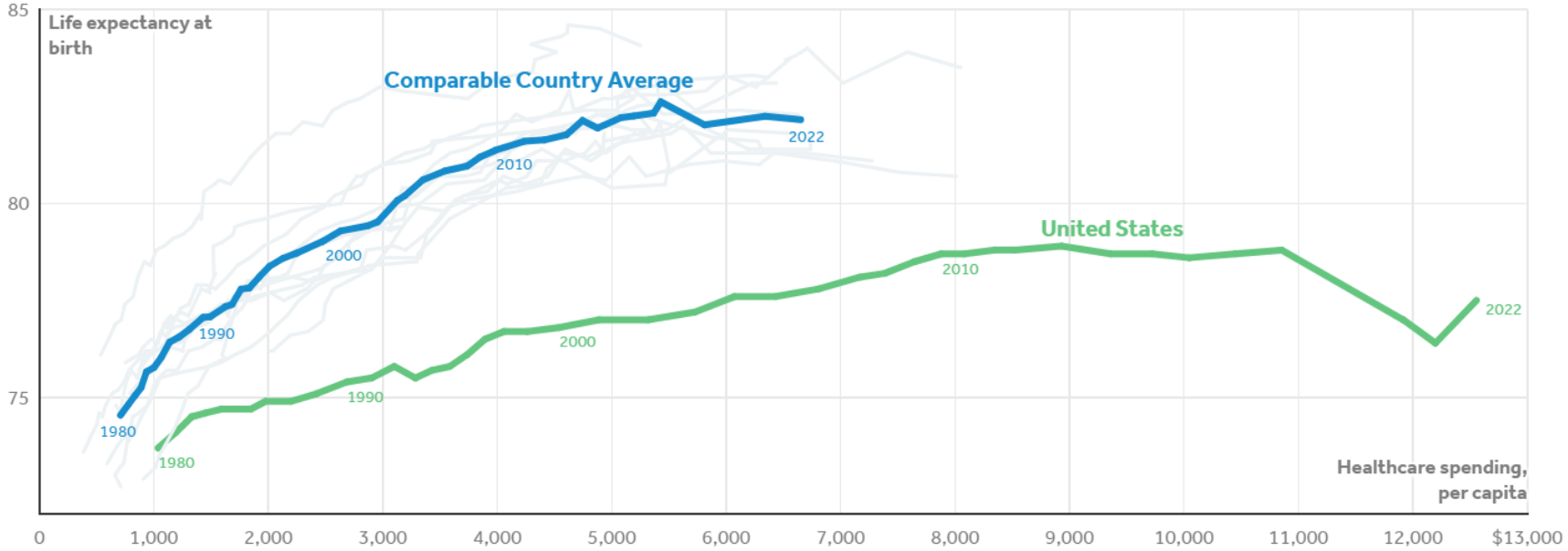
# Primary Care Investment

## A Discussion of Health Care in the U.S.

# Life expectancy and healthcare spending per capita, 1980-2022

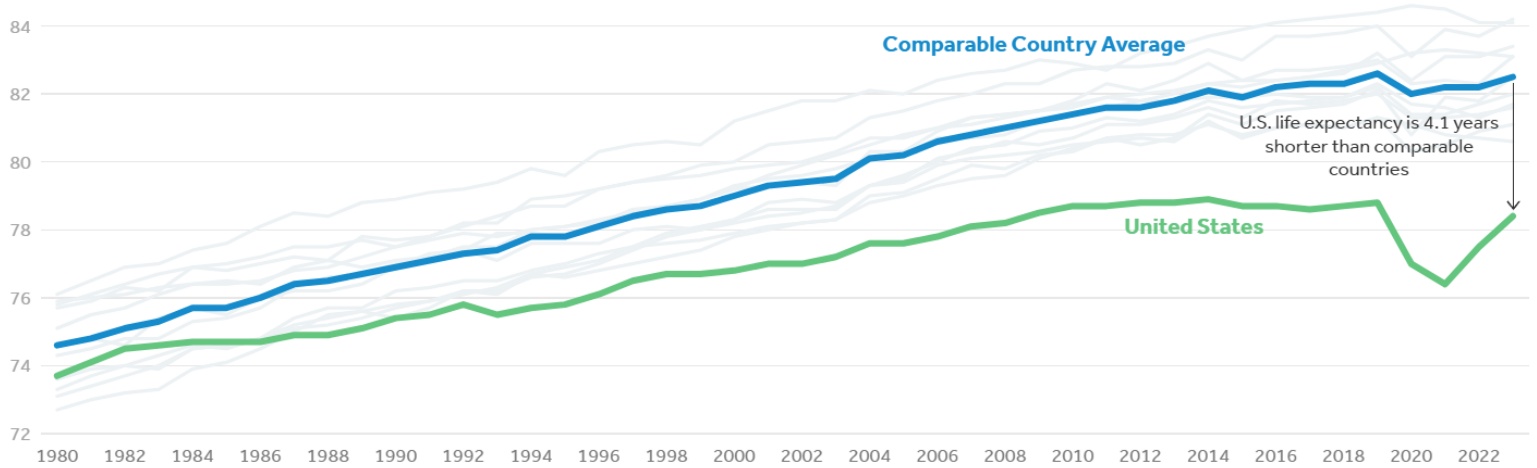



Notes: Comparable countries include: Australia, Austria, Belgium, Canada, France, Germany, Japan, the Netherlands, Sweden, Switzerland, and the U.K. See Methods section of "How does U.S. life expectancy compare to other countries?"

Source: KFF analysis of CDC, OECD, Australian Bureau of Statistics, Japanese Ministry of Health, Labour, and Welfare, Statistics Canada , and U.K. Office for National Statistics data • Get the data • PNG

Peterson-KFF
Health System Tracker

# US Life Expectancy vs OECD

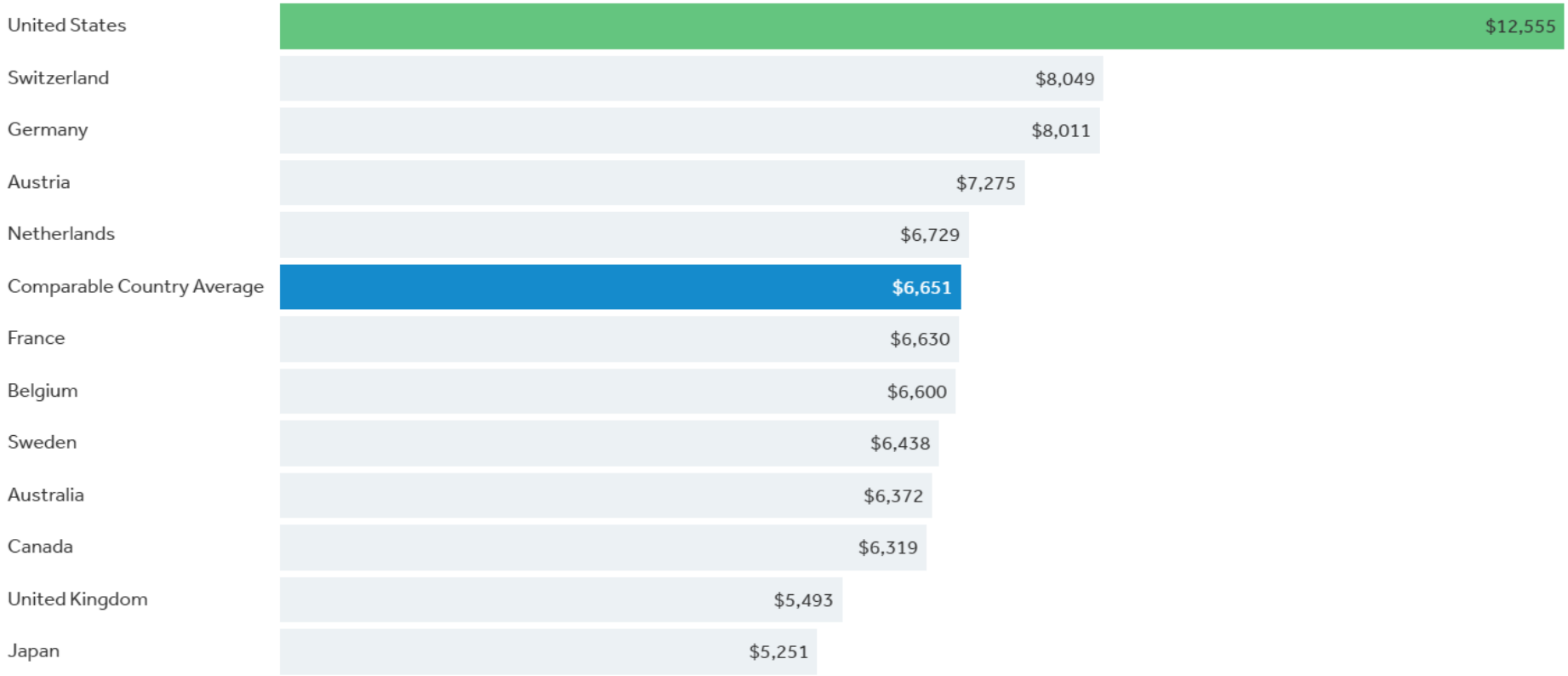



Notes: Comparable countries include Australia, Austria, Belgium, Canada, France, Germany, Japan, the Netherlands, Sweden, Switzerland, and the U.K. 2023 U.K. life expectancy data is only for England and Wales. See Methods section of "How does U.S. life expectancy compare to other countries?"

Source: KFF analysis of CDC, OECD, Australian Bureau of Statistics, German Federal Statistical Office, Japanese Ministry of Health, Labour, and Welfare, Statistics Canada, and U.K. Office for National Statistics data • Get the data • PNG

Peterson-KFF Health System Tracker

# Health expenditures per capita, U.S. dollars, 2022 (current prices and PPP adjusted)




Notes: Data from Australia, Belgium, France, Japan, Switzerland, and the U.S. are estimated. Data from Austria, Canada, Germany, the Netherlands, Sweden and the United Kingdom are provisional.

Source: KFF analysis of OECD data • Get the data • PNG

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Health System Tracker

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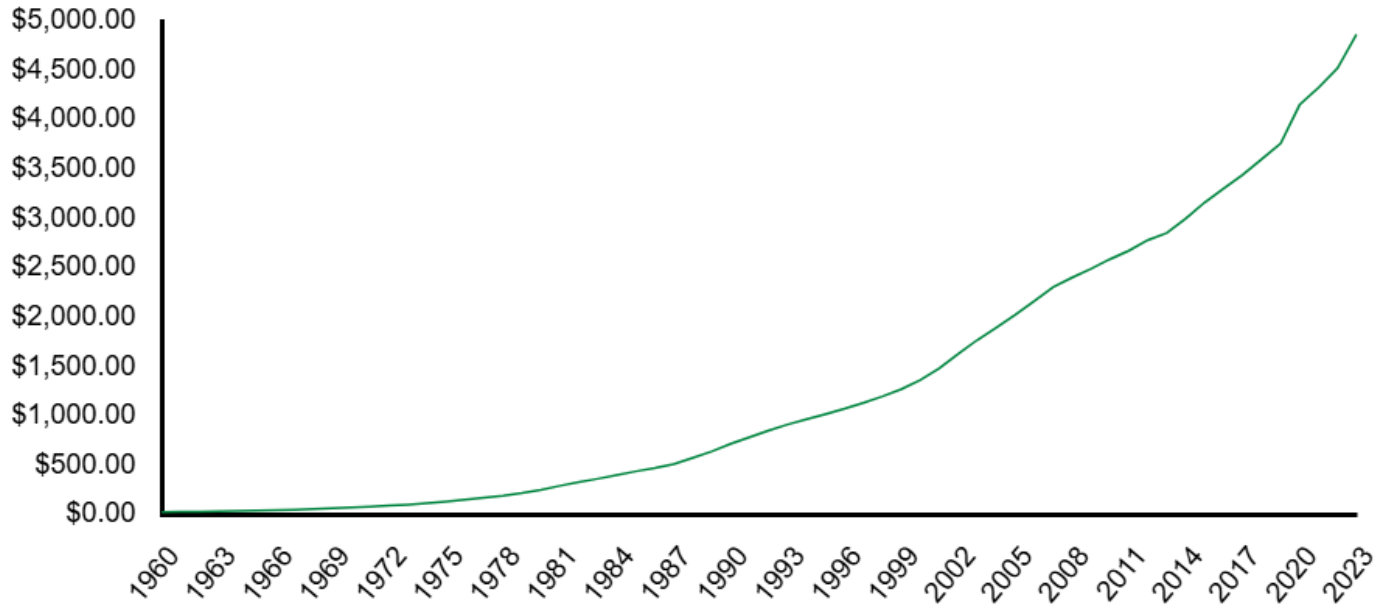
# HEALTH EXPENDITURES 1960 - 2023

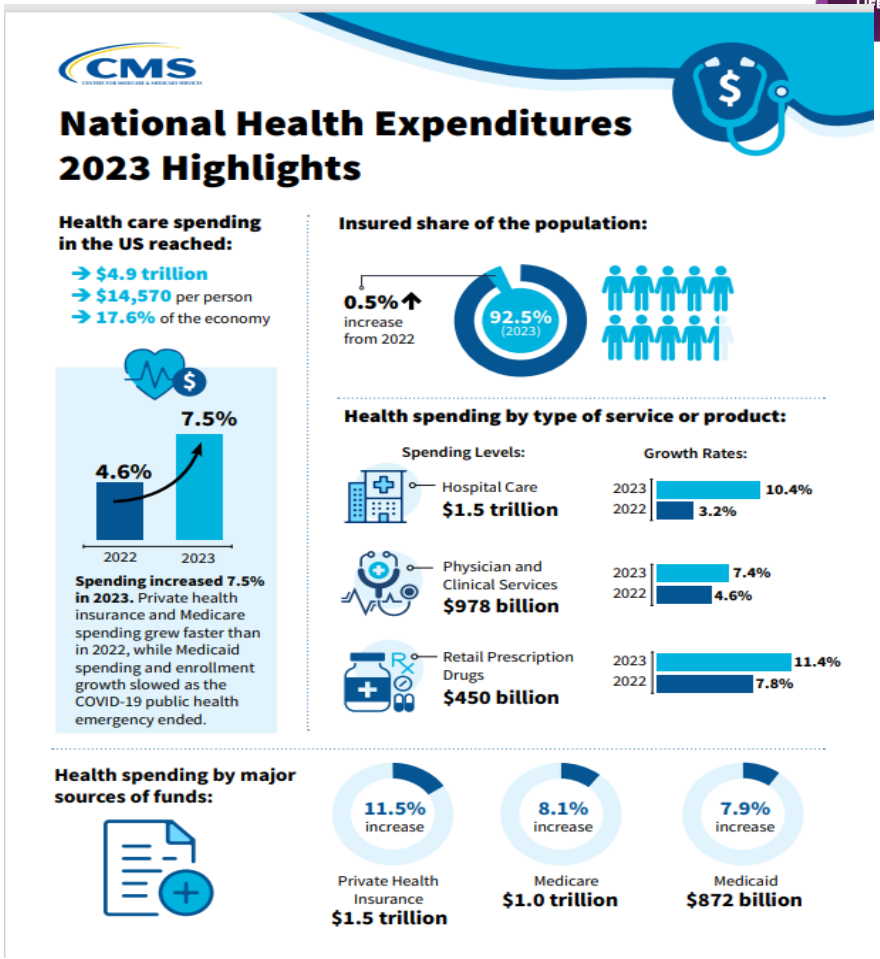
On All Types by All Sources

**U.S. $ Billions**

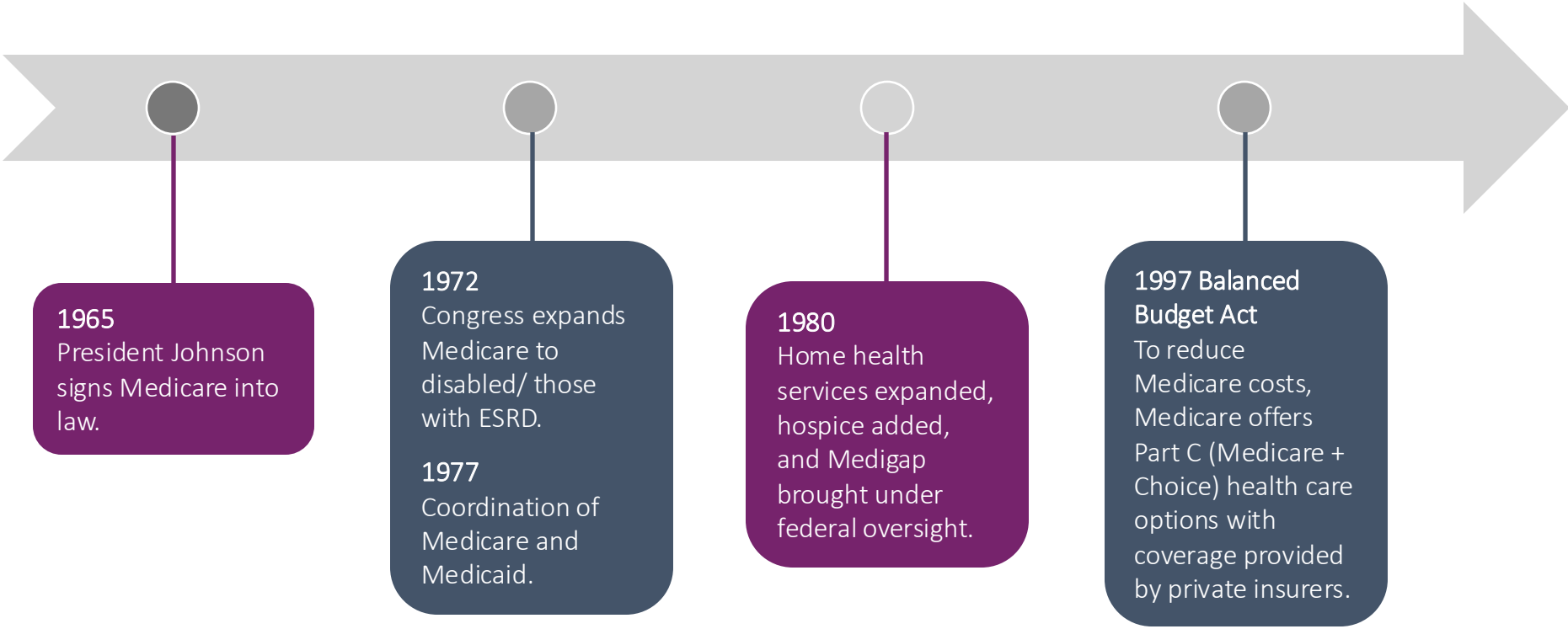


# Availability of Health Care continues to increase in the U.S.

- Inpatient care continues to lead spending
- Prescription coverage continues to drive trends
- Modest increase in physician spending and outpatient services



# The history of Medicare



# Medicare Advantage is born

**2000**
Congress approves the Medicare and Medicaid and State Children's Health Insurance Program (CHIP).

**2003**
Medicare becomes prevention-focused and allows private health plans to offer Part D prescription drug coverage beginning 2006

**2007-higher income recipients pay higher Part B premiums**
**2008-**MIPPA improves mental health, supplemental, and preventive care.

**2010**
The ACA establishes an exchange for health care, provides for Medicaid expansion, ensures no-cost for many preventive services, and prohibits insurers from denying coverage based on pre-existing conditions.

# Medicare continues to evolve

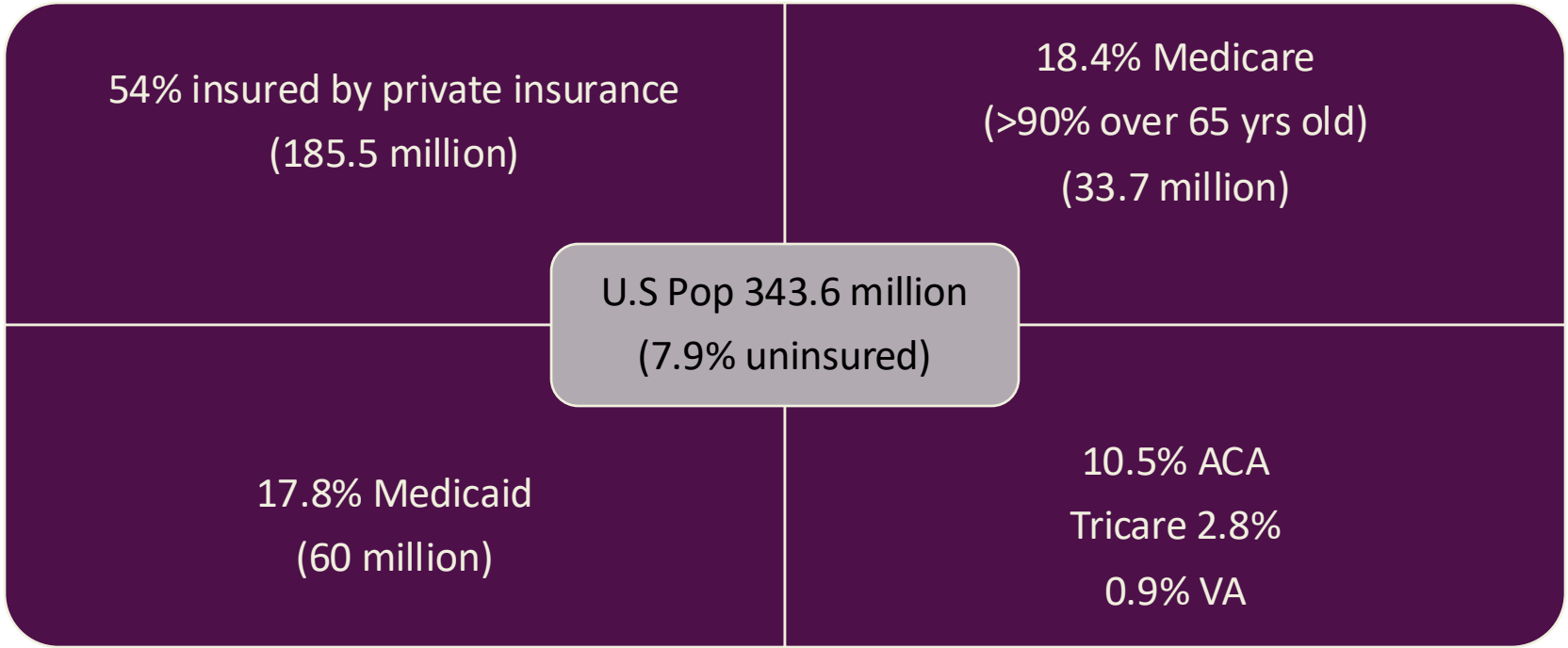
**2018**
The Bipartisan Budget Act allows Medicare Advantage plans to tailor benefits for those who are chronically ill, known as Special Supplemental Benefits for the Chronically Ill (SSBCI). Qualified members get coverage of traditionally non-health services like meals, food, transportation, pest control, indoor air quality, social need, adult day care, home based palliative care, and support for caregivers.

**2021-2022**
The ESRD Treatment Choices (ETC) Model is created and updated to decrease disparities in rates of home dialysis and kidney transplants.

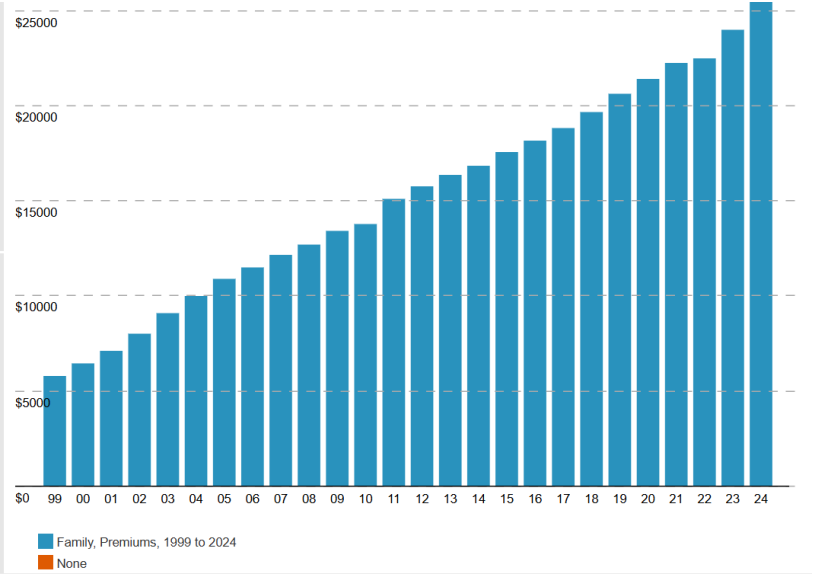
**2022**
The Inflation Reduction Act

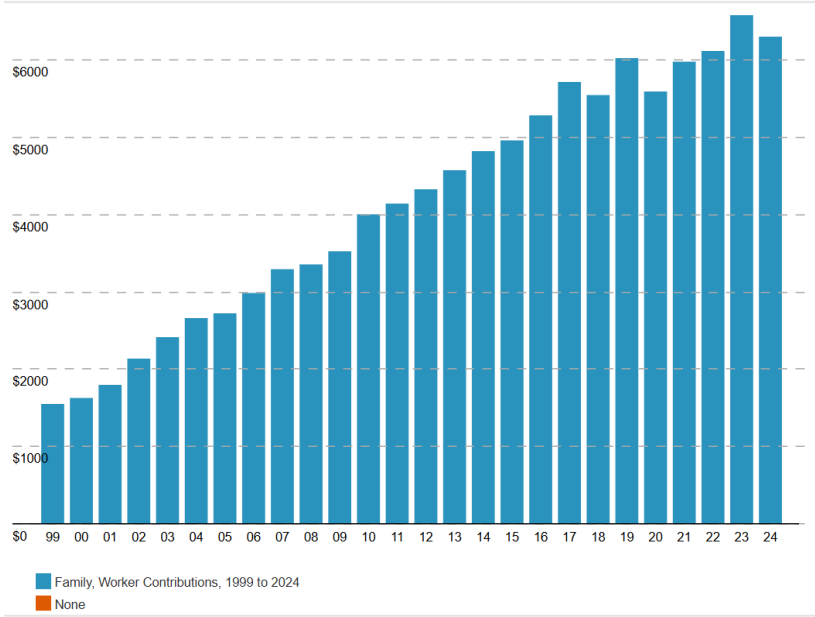
- Limits insulin to $35/month
- Immunizations $0 copay
- Closing coverage gap by year 2025
- Medicare able to negotiate pricing on more drugs
- Pharmaceuticals pay a penalty if the cost of a drug outpaces inflation
- LIS to 150% of FPL by 2025

# 2025 U.S. Health Insurance Statistics

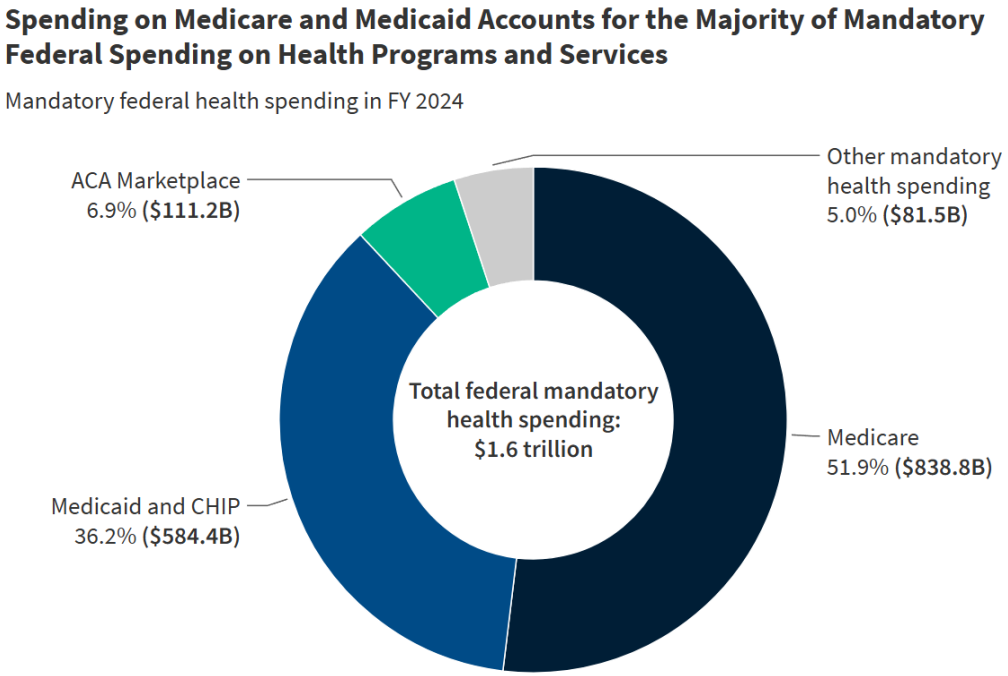


# Premium cost and employee contribution trends in private insurance

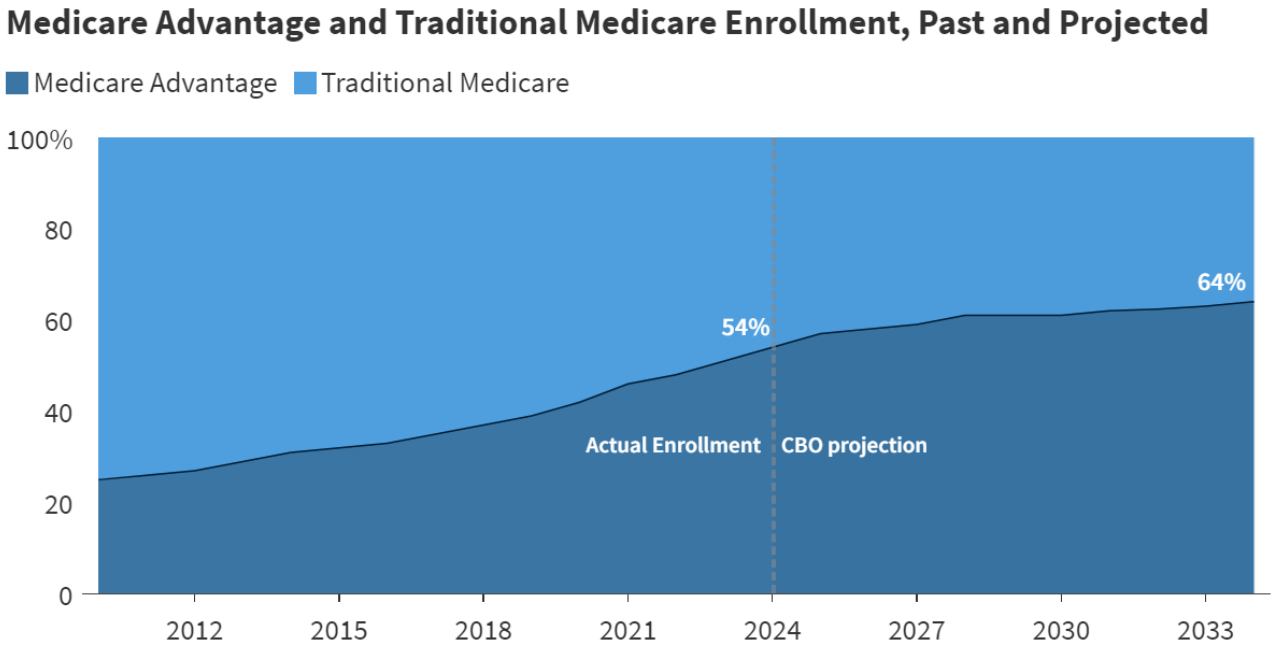


# U.S. investment in Healthcare



# Medicare US 2024-61.2 million Americans eligible for Medicare part A and Part B



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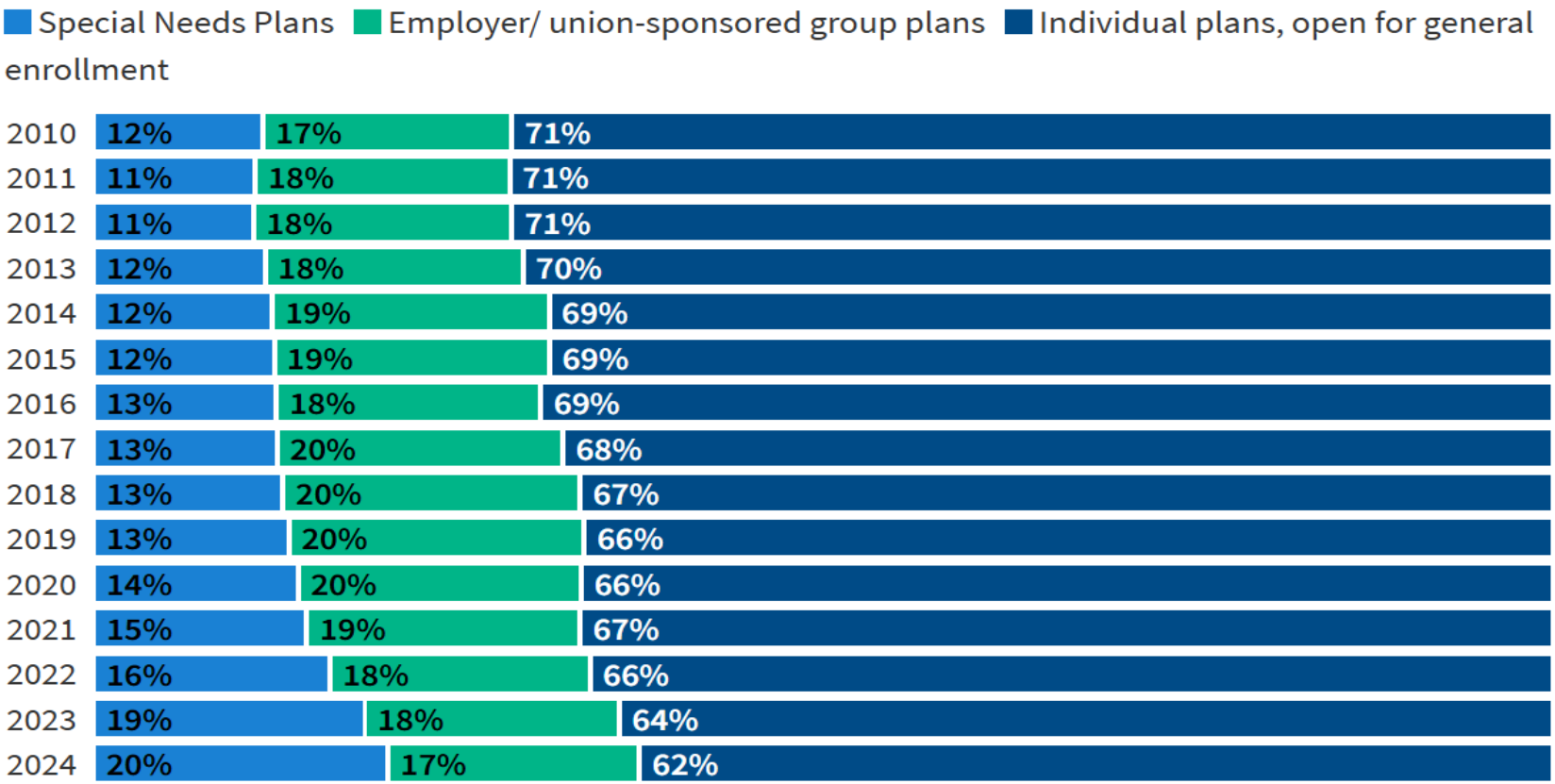
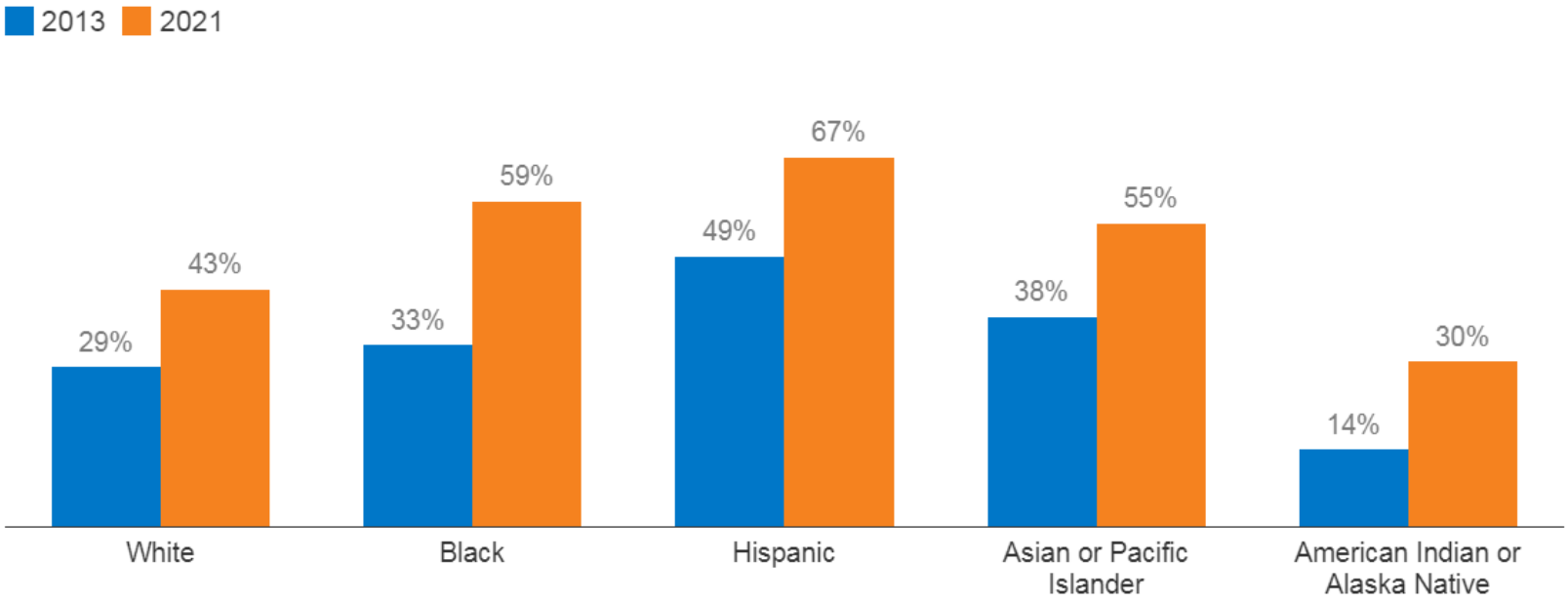
## Distribution of Medicare Advantage Enrollment, 2010-2024



# Over the Past Decade, Enrollment in Medicare Advantage Plans Has Increased More for People of Color than for White Beneficiaries

*Share of Medicare beneficiaries enrolled in a Medicare Advantage plan:*




NOTE: Persons of Hispanic origin may be of any race but are categorized as Hispanic; other groups are non-Hispanic. Figure does not include the small share of beneficiaries whose race/ethnicity is unknown or unspecified.

SOURCE: KFF analysis of 2021 Centers for Medicare & Medicaid Services (CMS) Program Statistics Data • PNG

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# 30.6%

of Medicare Advantage enrollees identify as Black, Latino, or Asian, compared to about **18.4%** of beneficiaries in FFS Medicare.[i]

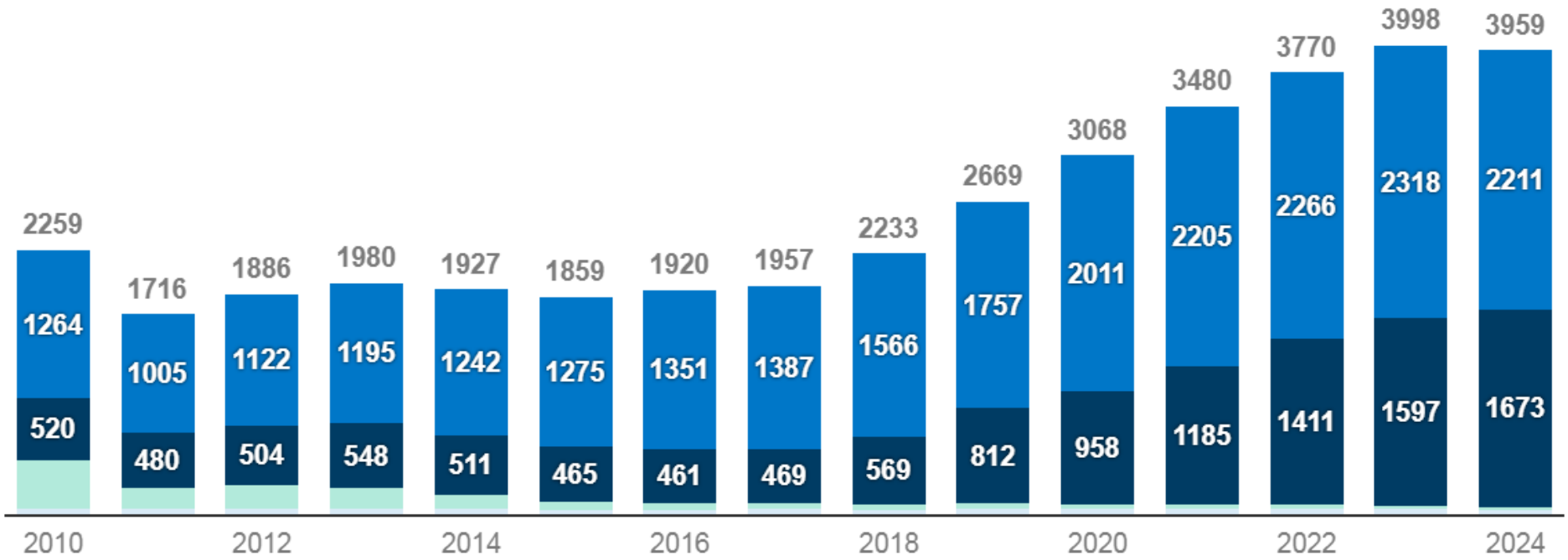
# 52%

of Medicare Advantage beneficiaries live below 200% of the federal poverty level, compared to **33%** of beneficiaries in FFS Medicare.[ii]

[i] Better Medicare Alliance, Analysis of the Centers for Medicare & Medicaid Services Monthly Enrollment Files, March 2024.
[ii] Better Medicare Alliance, Medicare Beneficiary Spending 2024, June 2024.

Number of Plans by Type | Share of Plans by Type

MSAs | Regional PPO | PFFS | Local PPO | HMO




NOTE: Excludes SNPs, EGHPs, HCPPs, PACE plans, cost plans and MMPs. Numbers may differ from previous publications in cases where the Landscape File for the year was updated after initial publication.

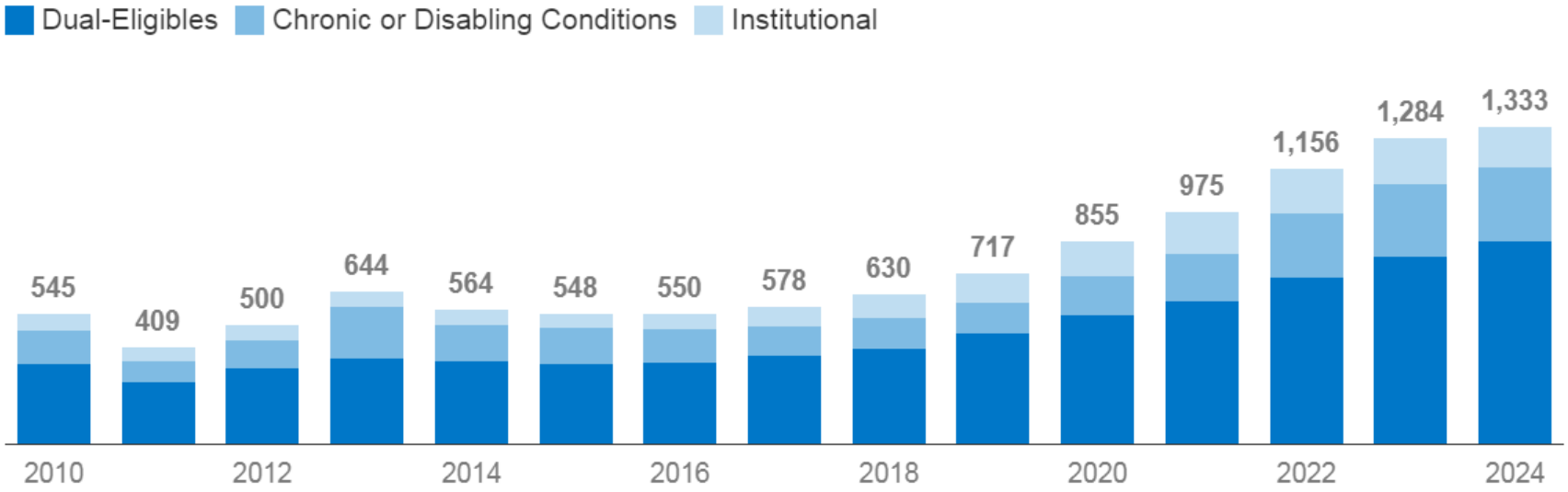
SOURCE: KFF analysis of CMS Landscape files for 2010-2024. • PNG

KFF

Figure 3

# The number of Special Needs Plans has nearly doubled since 2019

*Number of Special Needs Plans (SNPs), by plan type, 2010-2024*




NOTE: Includes only Special Needs Plans.
SOURCE: KFF analysis of CMS Landscape files for 2010–2024. • PNG

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# Options for Medicare Eligible individuals

| | Medicare FFS | Medicare Advantage | Traditional Medicare + Medigap |
|---|---|---|---|
| | | | |
| Part A | deductibles ($1,672 per inpt stay) | No deductible just copays | $1,672/inpt stay |
| Part B | Part B Premium ($185.00/mo) | Yes but some plans 'give back' part | $185/mo some deductibles |
| Maximum OOP spend | None | MOOP required (max $8,870/yr-average $4,875/yr | Variable, most capped |
| Monthly Premium | no | 69 % no monthly premium avg $17.00/month | Yes wide range $50-$500/mo (avg $128/mo) |
| Part D | No-need to purchase supplemental drug plan (avg $40.41/month) | 85% plans offer Part D $2,000 max) | No Must purchase –avg Part D supplement $55/month |

| | FFS | Medicare Advantage | Medigap |
|---|---|---|---|
| Vision | No | Yes | No |
| Dental | No | Yes | No |
| Hearing | No | Yes | No |
| Drug Formulary | No(broad cat's) | Yes | Sep drug plan |
| Gym | No | Yes | No |
| Quality req's | No | Yes –Medicare Stars | No |
| Prior Auth | No (LCD/NCD) | Yes | No |
| Care management | No | Yes | No |

# Protecting seniors from medical bankruptcy

## Maximum Out-of-Pocket Limits

All Medicare Advantage plans must have a maximum out-of-pocket limit (MOOP) at or below a maximum set annually by CMS—$8,850 in 2024 and $9,350 in 2025. In addition, plans with a MOOP at or below a lower, voluntary threshold—$3,850 in 2024 and $4,150 in 2025—gain additional cost-sharing flexibility for certain services.

In 2025, the median MOOP will increase by $400 to $5,400, an 8% increase from $5,000 in 2024. Meanwhile, 93.7% of plans have MOOPs below the maximum, a decrease from 97.4% in 2024 (Figure 5).

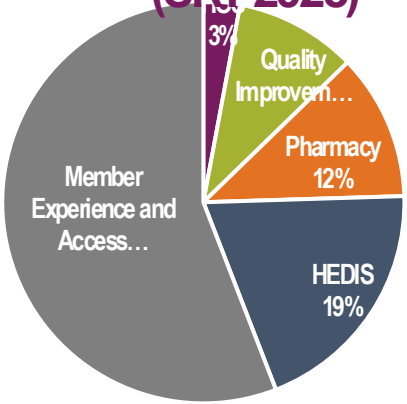
Figure 5: Median Maximum Out-of-Pocket Limit, Non-SNPs, 2024-2025

# Medicare Advantage stats

- Lower out of pocket costs for members- save an average of $2541/year oop costs
- A recent study by the Elevance Health Public Policy Institute (November 2024) estimates 10 yr savings to CMS for enrollees in MA plan of $144 billion-average $567 per enrollee per year
- 75% enrollees have $0 premiums
- 95% of enrollees have usual source of care
- JAMA study 2022 on utilization of members with complex medical issues showed lower inpatient utilization, ED visits and 30d readmissions in MA advantage subscribers compared to FFS counterparts
- 2022 study USC Schaffer institute showed MA enrollment costs taxpayers 22% more per enrollee than FFS

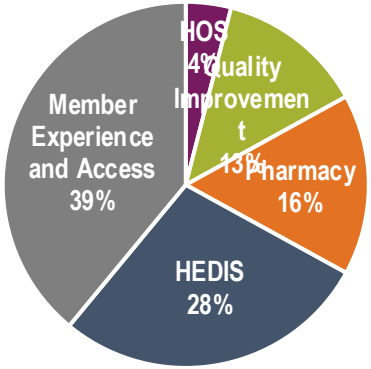
# Distribution of Measurement Changes in CMS Medicare STAR Rating Program

## 2023 Measurement Year (SRY 2025)



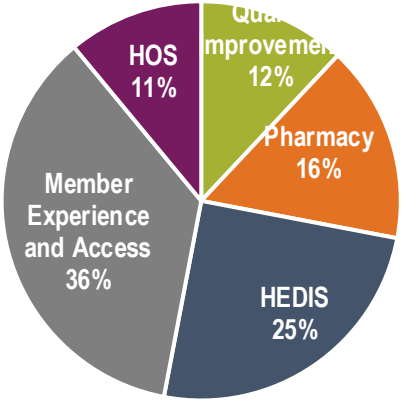

**Continued exponential increase in cut-points due to implementation of Tukey Outlier Deletion Methodology.**

## 2024 Measurement Year (SRY 2026)




**Member Experience decreases so now HEDIS and Pharmacy measures are more highly weighted.**

## 2025 Measurement Year (SRY 2027)

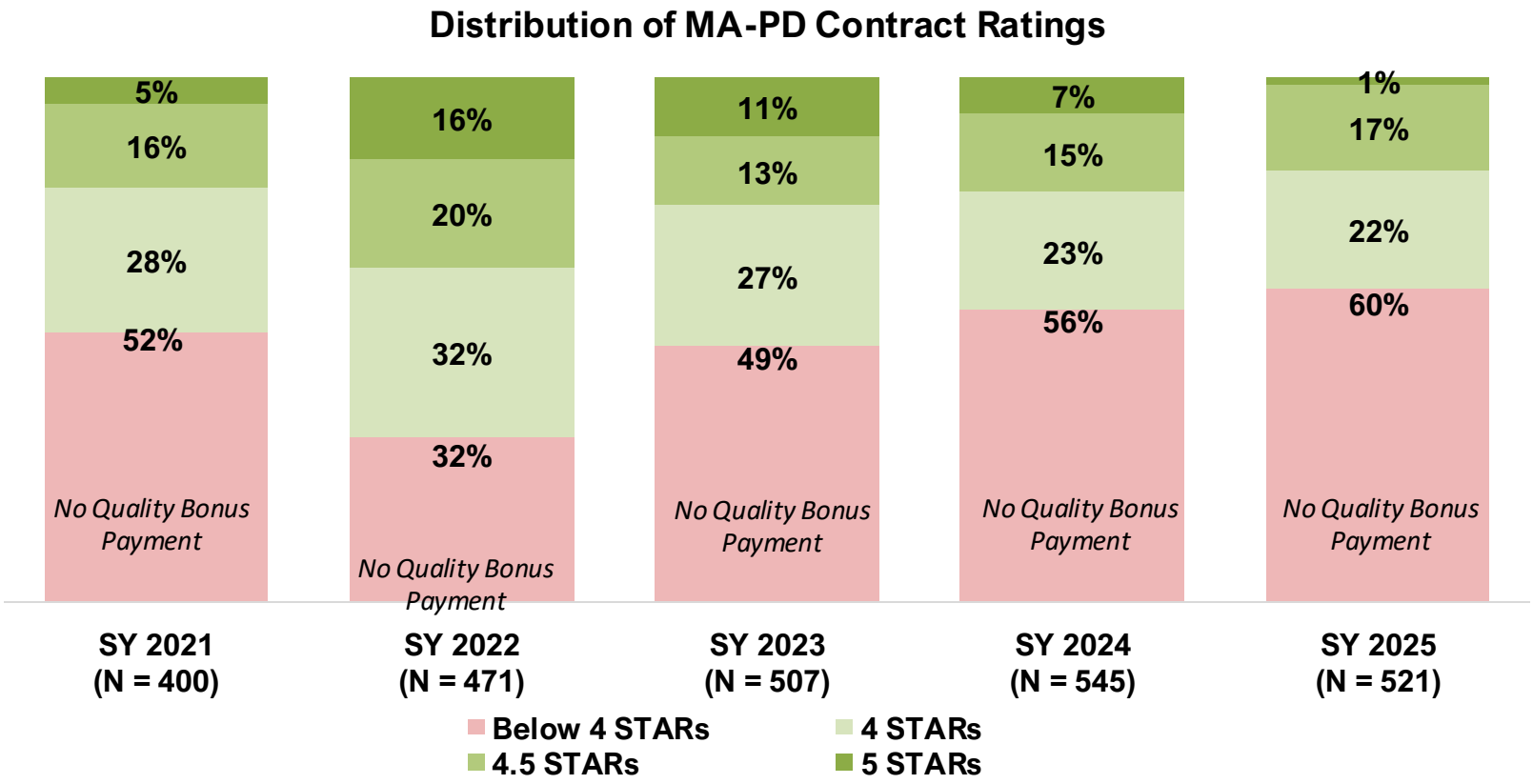



**Reward factor removed and Health Equity Index introduced.**

# CMS Medicare STAR Rating Upcoming Changes

| | MY 2022<br>2024 STAR Rating | MY 2023<br>2025 STAR Rating | MY 2024<br>2026 STAR Rating | MY 2025<br>2027 STAR Rating |
|---|---|---|---|---|
| **Method Changes** | • Tukey outlier deletion cut point methodology implemented | | | • Health Equity Index Reward Factor |
| **Measure Changes** | • Controlling Blood Pressure from weight of 1 to a 3 | • Plan All-Cause Readmissions from weight of 1 to 3. | • Member Experience and Access measures from weight of 4 to a 2<br>• Colorectal Cancer Screening no longer hybrid | • Colorectal Cancer Screening to include new age range (45+)<br>• Improving or Maintaining Physical Health from weight of 1 to 3<br>• Improving or Maintaining Mental Health from weight of 1 to 3 |
| **New Measures** | • Transitions of Care<br>• Plan All-Cause Readmissions<br>• Follow-up after ED Visit for People w/ Multiple Chronic Conditions | | • Kidney Health Evaluation<br>• Improving or Maintaining Physical Health<br>• Improving or Maintaining Mental Health | • Concurrent Use of Opioids and Benzodiazepines<br>• Polypharmacy Use of Multiple Anticholinergic Medications<br>• Care for Older Adults Functional Assessment |
| **Retired Measures** | • Kidney Disease Monitoring | | | • Care for Older Adults Pain Assessment |

# Medicare Star Rating Continues to Increase in Difficulty



# HEI Reward Factor

**Points are added to overall STAR Rating as a reward based on two factors:**

1. **Health Equity Index**
2. **Proportion of members with one or more Social Risk Factors** (Low Income Subsidy, Dual Eligibility, or Disability).

**The greater the proportion of members with Social Risk Factors, the greater the opportunity to earn a reward. Even if you have a high Health Equity Index, you cannot earn a large reward unless you also have a large population with Social Risk Factors in your contract.**

**Large** population with Social Risk Factors + **High** Health Equity Index = **Larger Reward**

**Small** population with Social Risk Factors + **High** Health Equity Index = **Smaller Reward**

# Health Equity Index (HEI) – Methodology

**Calculate each measure's performance of population with one or more of the following Social Risk Factors:**

1. Low Income Subsidy
2. Dual Eligibility
3. Disability

***Compare our performance on each measure to national performance.***

**Top 3rd** *National Performance*

**Middle 3rd** *National Performance*

***= 0 points***

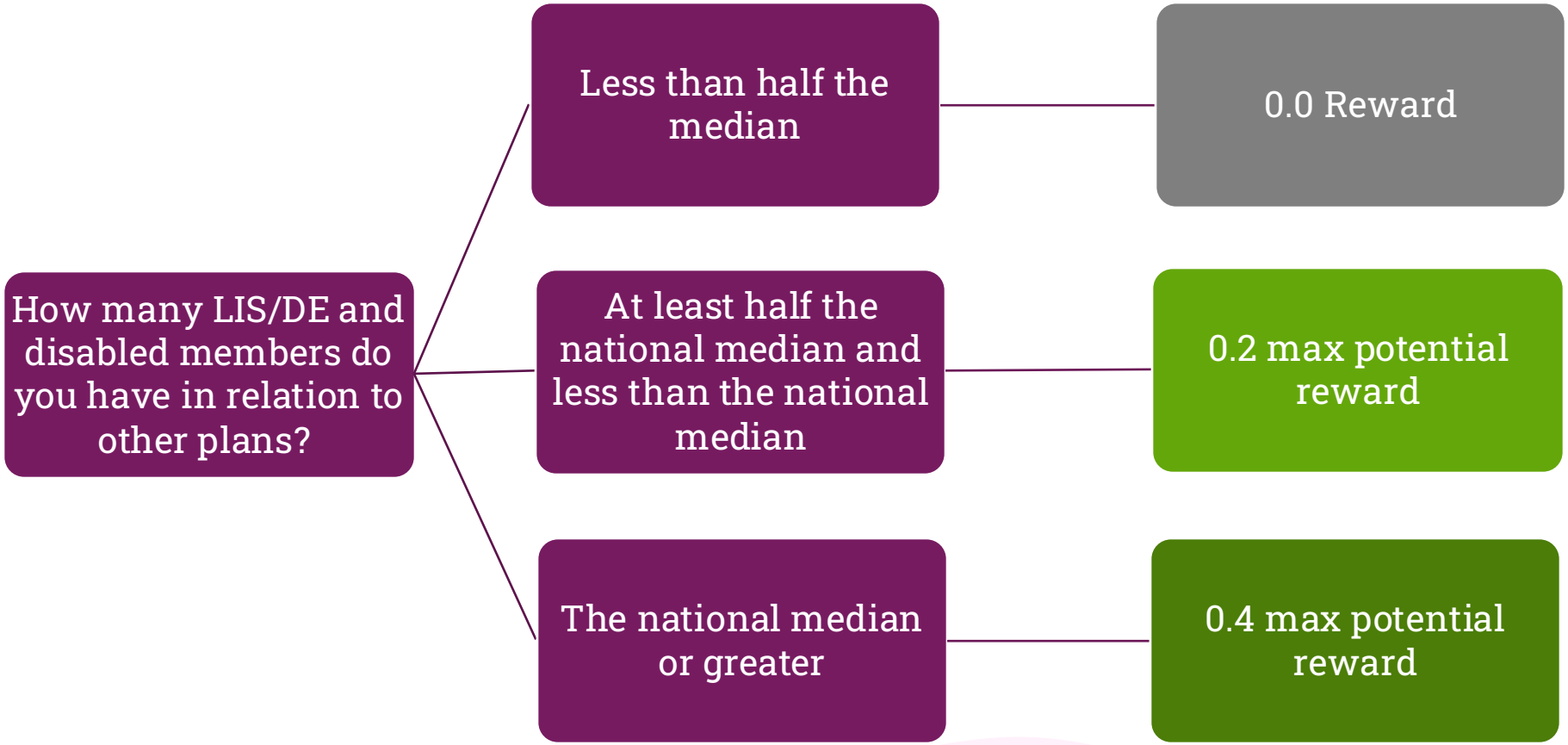
**Bottom 3rd** *National Performance*

***= -1 points***

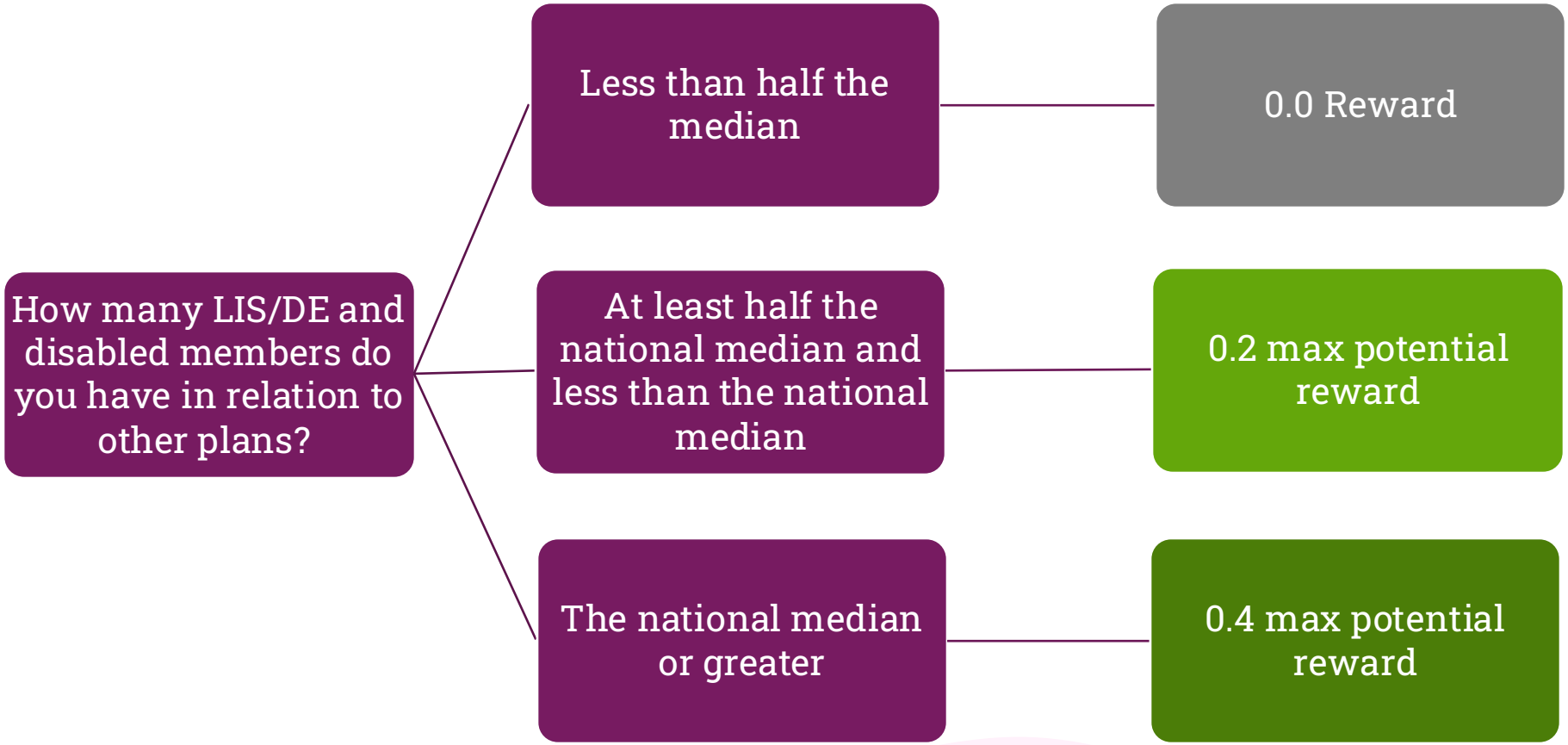
**Health Equity Index**

*Weighted average of points earned across all measures.*

# Health Equity Index (HEI) - Methodology



# Health Equity Index (HEI) - Methodology



# CMS plan for Medicare FFS recipients-the other 45%

In 2021, the Centers for Medicare & Medicaid Services (CMS) set a goal of having **100 percent of Medicare beneficiaries in an accountable care relationship by 2030**. Since then, CMS has been enthusiastically pursuing systemwide health care reform for whole-person centered, equitable, accountable care.

# ACO's -

- 53.4% of Medicare FFS enrollees in an accountable care relationship with a provider as of 01/25
- Medicare Shared Savings program -476 ACO's, 655,725 providers, 11.2 individuals receiving care in 10,455 FQHC's, RHC and critical access hospitals
- ACO Reach Model-103 ACO's, 161,765 providers 2.5 million individuals
- AIP model provides rural providers advanced payments to build infrastructure for VBC
- KCC model- 17 kidney contracting entities and 15 Kidney Care First practices serving 240,000 individuals with CKD and ESRD
- ACO flex model new in 2025- 24 ACO's serving 349,000 individuals testing new payment model for low revenue ACO's to increase participation in ACO's

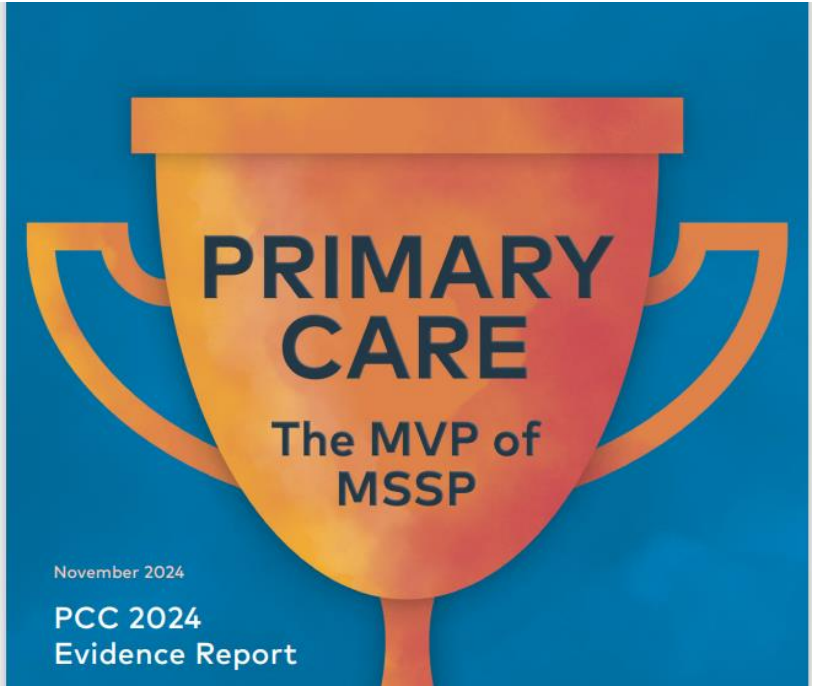
# CBO analysis on ACO's

"ACOs led by primary care clinicians had significantly higher net per capita savings than ACOs with a smaller proportion of primary care clinicians. These results continue to underscore how important primary care is to the success of the Shared Savings Program."

$2.1 billion net savings

- **Certain types of ACOs are associated with greater savings.** They include ACOs led by independent physician groups, ACOs with a larger proportion of primary care providers (PCPs), and ACOs whose initial baseline spending was higher than the regional average. (An ACO's baseline spending is generally the average spending per person in the Medicare fee-for-service, or FFS, program among beneficiaries that would have been assigned to the ACO over several calendar years before the start of the ACO's contract period.)
- **Some factors limit the savings from Medicare ACOs.** Those factors include weak incentives for ACOs to reduce spending, a lack of the resources necessary for providers to participate in ACO models, and providers' ability to selectively enter and exit the program on the basis of the financial benefits or losses they anticipate from participating.

# Deep dive resource on ACO's




Primary Care Collaborative

Table 1 highlights the consistency of relatively high performance of primary care centric ACOs over six years. Over the period 2017–2022, high primary care centric ACOs generated 2.4 times the savings as low primary care centric ACOs.

TABLE 1

**The Annual Savings Average of ACOs Based on Percentage of Participating Primary Care Physicians (PCPs), High (Greater Than 50 Percent) Compared to Low (Less Than 50 Percent)**

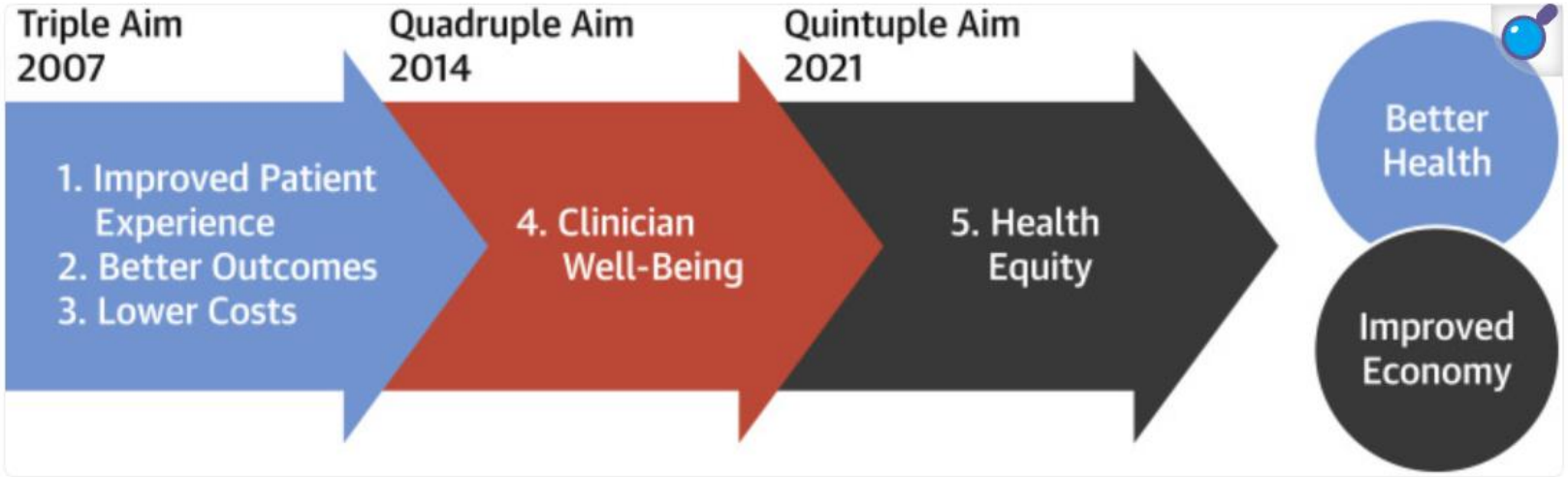
| Year | ACOs with less than 50 percent PCPs, percent savings | ACOs with greater than 50 percent PCPs, percent savings | Ratio of high percent PCP-to-low percent PCP savings |
|---|---|---|---|
| 2017 | 0.6 % | 2.4% | 4 |
| 2018 | 0.8% | 2.7% | 3.4 |
| 2019 | 1.4% | 4.5% | 3.2 |
| 2019.5 | 2.0% | 4.4% | 2.2 |
| 2020 | 3.0% | 5.5% | 1.8 |
| 2021 | 2.4% | 5.3% | 2.2 |
| 2022 | 2.5% | 5.9% | 2.4 |
| **Avg** | **1.8%** | **4.3%** | **2.4** |

# 2021 NASEM report on Primary Care

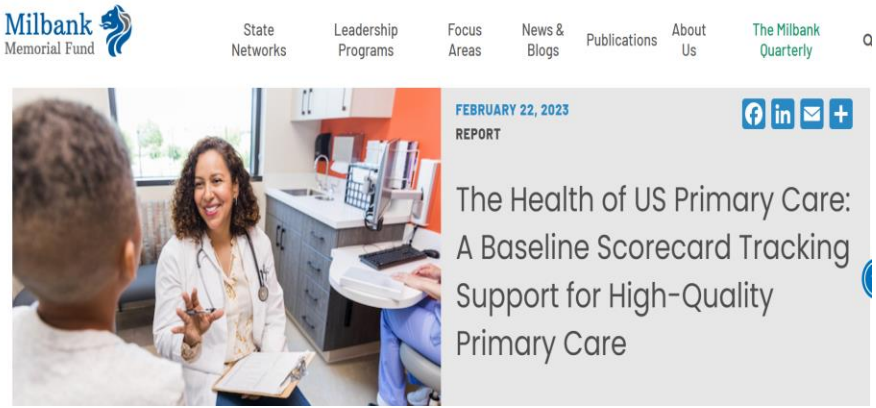

## WHAT IS HIGH-QUALITY PRIMARY CARE?

High-quality primary care is the provision of whole-person, integrated, accessible, and equitable health care by interprofessional teams who are accountable for addressing the majority of an individual's health and wellness needs across settings and through sustained relationships with patients, families, and communities.

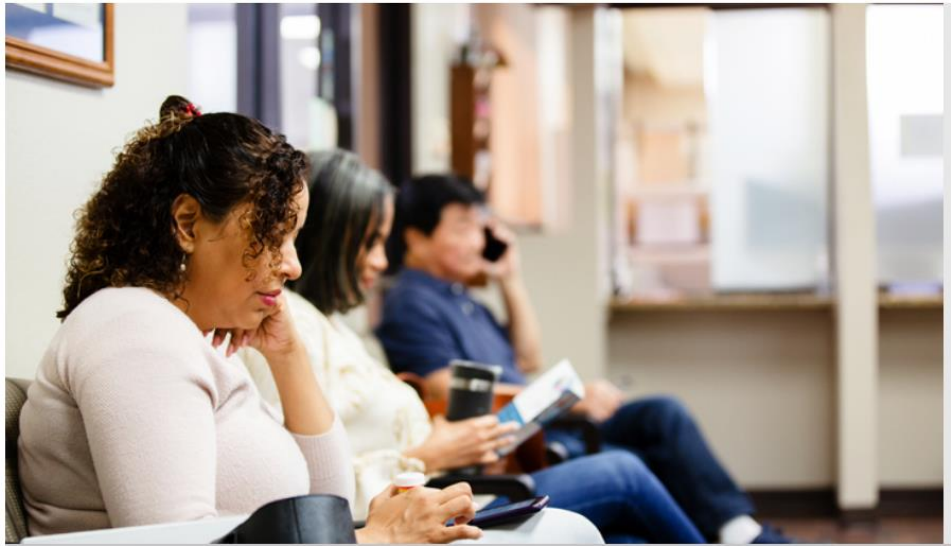
# Quintuple Aim



# Milbank primary care scorecards




- 1)Financing- underinvestment in primary care
- 2) Workforce-shrinking
- 3)Access- % of U.S. with USC declining
- 4) Training- less in community
- 5) Research-minimal funding for primary care research



FEBRUARY 28, 2024

REPORT

# The Health of US Primary Care: 2024 Scorecard Report — No One Can See You Now

# I. Financing: Declining investment and fee-for-service payment are hindering primary care clinicians' ability to meet growing patient needs

- Spending on primary care was under 5% in 2022 and continued its decline across all payers, with primary care spending in Medicare and Medicaid decreasing the most since the last Scorecard, down to 3.4% and 4.3% in 2022, respectively.
- Reimbursement rates for physician visits illustrate the way the US payment system rewards procedures over the comprehensive care of patients, undervaluing primary care. In 2022, primary care physicians' reimbursement per visit averaged $259, compared to $1,092 for gastroenterology. This relative lack of revenue limits practice capacity to provide high-quality primary care and hinders the field's ability to draw in new clinicians.

# II. Workforce/Access: Insufficient funding is diminishing the primary care workforce and access to care

- The number of primary care clinicians (PCCs), including physicians, physician associates (PAs), and nurse practitioners (NPs), dropped from 105.7 per 100,000 in 2021 to 103.8 per 100,000 in 2022. The number of primary care physicians (PCPs) per 100,000 population remained flat at around 67 while the number of advanced practice providers per 100,000 population in primary care fell slightly (from 38 in 2021 to 37 in 2022).
- The percentage of NPs and PAs in primary care dropped to new lows of 30% and 24.3% in 2022, respectively, compared with 34% and 29.7% in 2021, respectively. More than 30% of US adults lacked a usual source of care (USC) in 2022 — the highest level in a decade, despite historically high rates of insurance coverage during this period. The percentage of children without a USC dropped from 13.6% in 2021 to 12.4% in 2022.

# III. Training: Misdirected graduate medical education funding is not producing enough new primary care physicians, exacerbating access issues for patients

- The disparity in growth in medical residents per capita between primary care and all other specialties continued to widen, with the rate of primary care residents remaining stagnant at 17 per capita between 2020 and 2022, while the rate for all other specialties increased from 29 to 30 per capita.
- In 2022, the percentage of new physicians entering primary care dropped to 24.4% (or 19.8% when excluding hospitalists), marking its lowest rate in a decade. While the percentage has been steadily decreasing over the past decade, 2022 marked a steeper decline from 2021 compared to previous years.
- There was an inverse relationship between Medicare and Medicaid graduate medical education (GME) funding at the state level and the percentage of new PCPs entering the physician workforce; the more GME funding into the state, the fewer new PCPs in that state.

# GME- continued

- There was a marginal increase in the percentage of primary care residents training in community-based settings. Still, only 15.9% of primary care residents spent most of their training in a community-based setting in 2022 (compared with 15.2% in 2021). Only 5.1% of primary care residents were enrolled in either the Teaching Health Center program or a Rural Training Track — programs designed to provide training specifically in medically underserved communities. In addition, the FFS payment system does not provide for physician time to mentor trainees in community settings.

# IV. Technology: The lack of investment in EHRs has led to burdensome systems that drain clinicians' time, thereby reducing patient access to care

- Almost half of family physicians rated electronic health record (EHR) usability as poor or fair in 2023. Specifically, more than half found the usefulness of EHRs to be poor or fair, a growth of 4% since 2022. The ease of finding information remained stagnant in 2023, at 41%.
- Similarly, over one-quarter of family physicians remained "very dissatisfied" or "somewhat dissatisfied" overall with their EHR in 2023, with a slight increase in "very dissatisfied" respondents compared with 2022.
- While progress has been made throughout the realm of health information technology, primary care still seems to fall behind as progress is made in other sectors.[8, 9]

# V. Research: The lack of research dollars to study the practice of primary care is limiting evidence-based improvements in care

- The federal research investment in primary care remains well below 1%, although spending increased marginally from 0.31% of total federal health care research budget in 2022 to 0.34% in 2023.

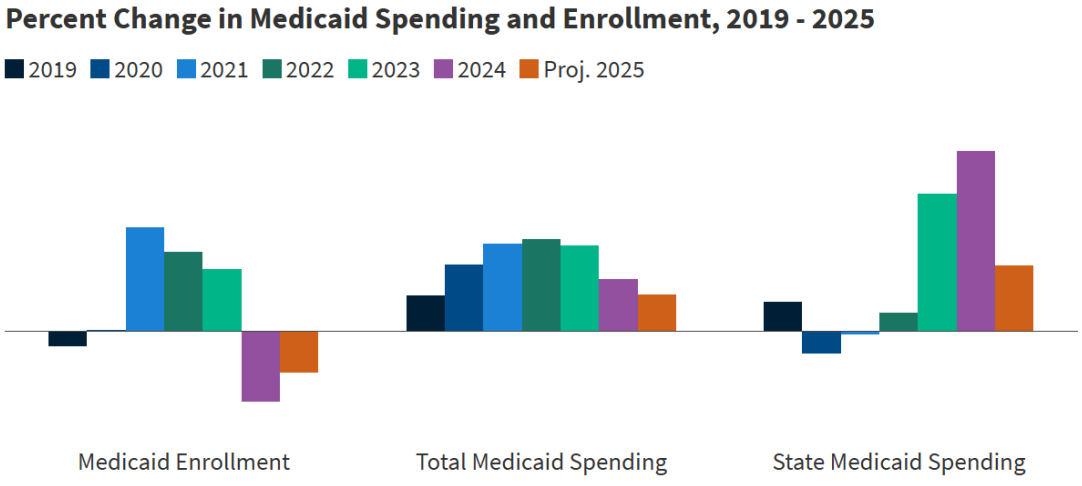
The fragility of primary care remains rooted in the lack of tangible progress on financing — specifically, how and how much primary care practices are paid. Yet, policy shifts at both federal and state levels have the potential to drive significant change in the years ahead. Recognizing the importance of these developments, this year's report introduces key enhancements:

The fragility of primary care remains rooted in the lack of tangible progress on financing — specifically, how and how much primary care practices are paid. Yet, policy shifts at both federal and state levels have the potential to drive significant change in the years ahead. Recognizing the importance of these developments, this year's report introduces key enhancements:

- **New measures:** We've added a measure that captures Medicare and Medicaid GME funding and primary care workforce production by state, providing critical insights into funding and capacity trends.
- **Enhanced dashboard:** Our improved Health of US Primary Care Scorecard Dashboard features interactive maps, state profiles, and now the ability to compare data across states. Users can also export data in various formats for deeper analysis.

Additionally, this report tracks progress on the policy recommendations outlined in the 2021 NASEM report. It also sheds light on issues affecting primary care that are not captured in the Scorecard, like the rise of private equity, as well as examples of strategic investments or state policies that are driving meaningful improvements. These enhancements illuminate a path forward toward a stronger, more sustainable primary care system that better serves communities.

# Trends in Medicaid




Note: Growth percentages refer to state fiscal year (FY). FY 2025 projections based on enacted budgets.

Source: FY 2024-2025 spending data and FY 2025 enrollment data are derived from the annual KFF survey of state Medicaid officials conducted by Health Management Associates, October 2024. 50 states submitted survey responses by Oct. 2024; state response rates varied across questions. Historic data reflects growth across all 50 states and DC and comes from various sources. See Methods of Medicaid Enrollment & Spending Growth: FY 2024 & 2025 for more information. • Get the data • Download PNG

KFF

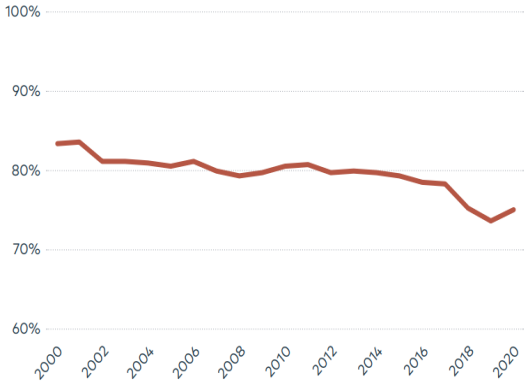
# Primary Care Collaborative

## Relationships Matter: How Usual is Usual Source of (Primary) Care?

2022 PCC Evidence Report


FIGURE 1

**Percent of U.S. Population with a USC**

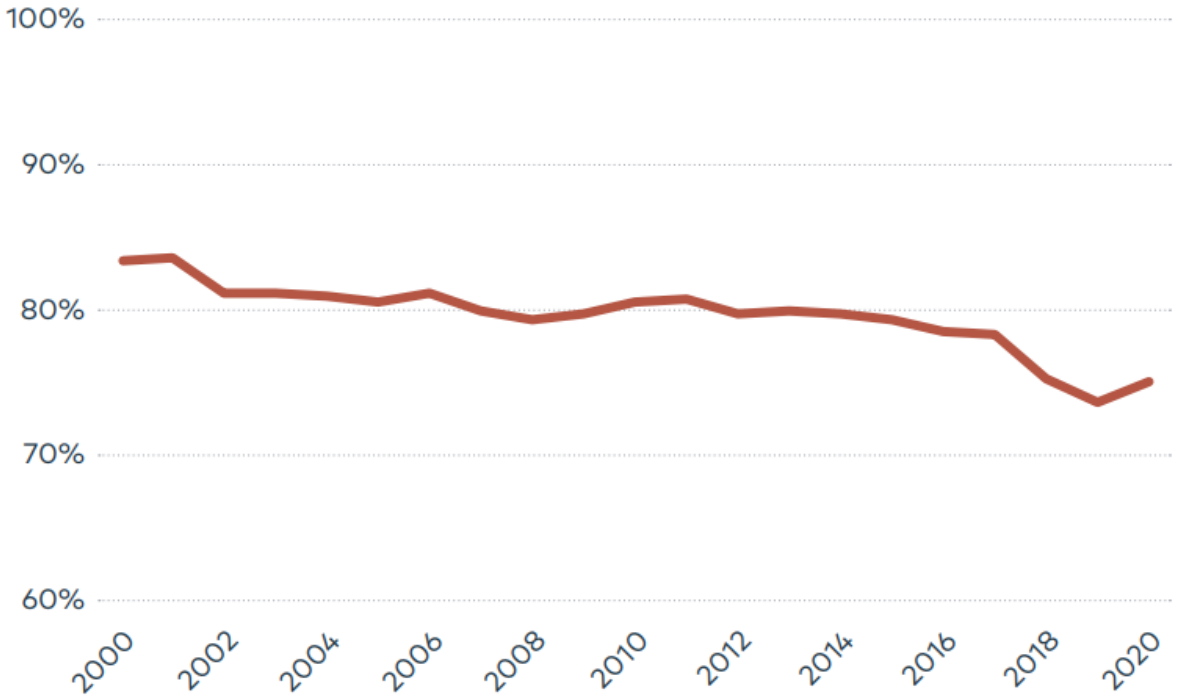



Data Source: Analyses of Medical Expenditure Panel Survey, 2000-2020.

Notes: HAVEUS42 and LOCATN42 were combined to construct a two-category USC measure. No USC includes respondents not having a USC and those who reported emergency department as the USC. Adjusted for gender, female, education, race-ethnicity, region, insurance coverage, and income.

FIGURE 1

## Percent of U.S. Population with a USC

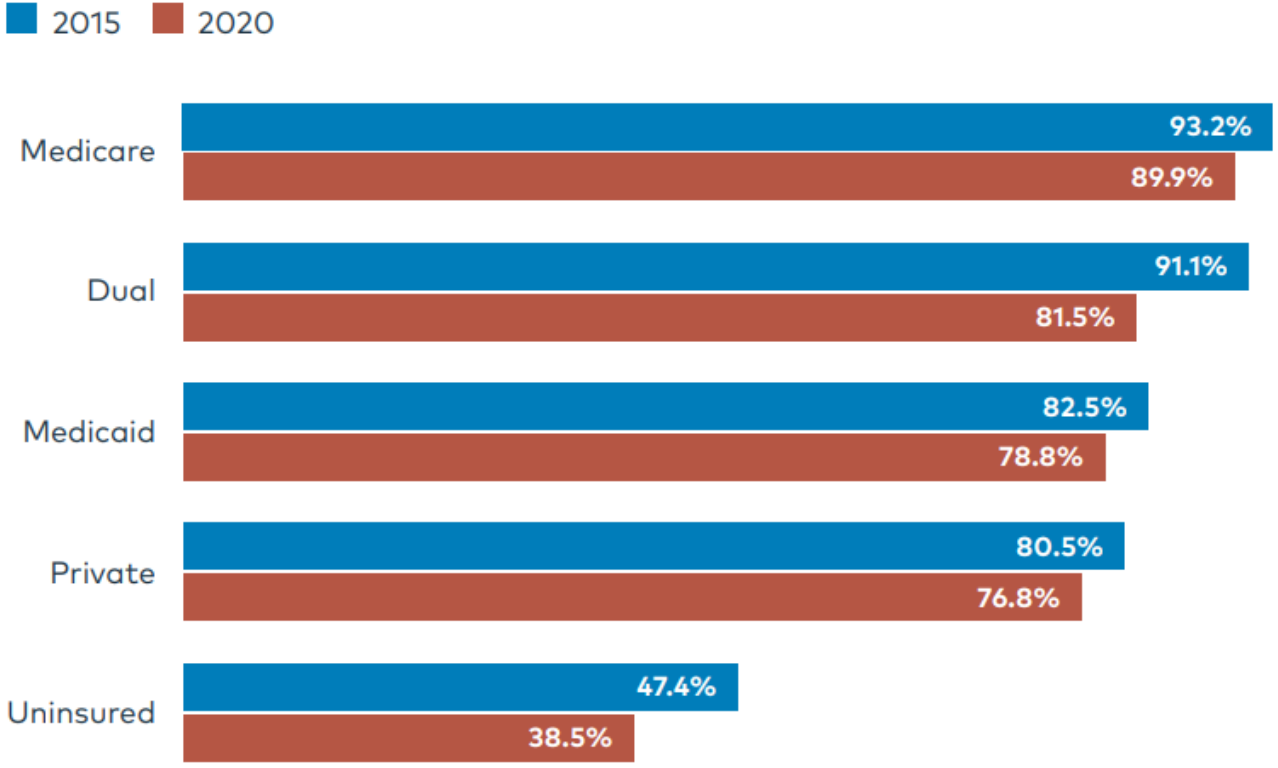



Data Source: Analyses of Medical Expenditure Panel Survey, 2000-2020.

Notes: HAVEUS42 and LOCATN42 were combined to construct a two-category USC measure. No USC includes respondents not having a USC and those who reported emergency department as the USC. Adjusted for gender, female, education, race-ethnicity, region, insurance coverage, and income.

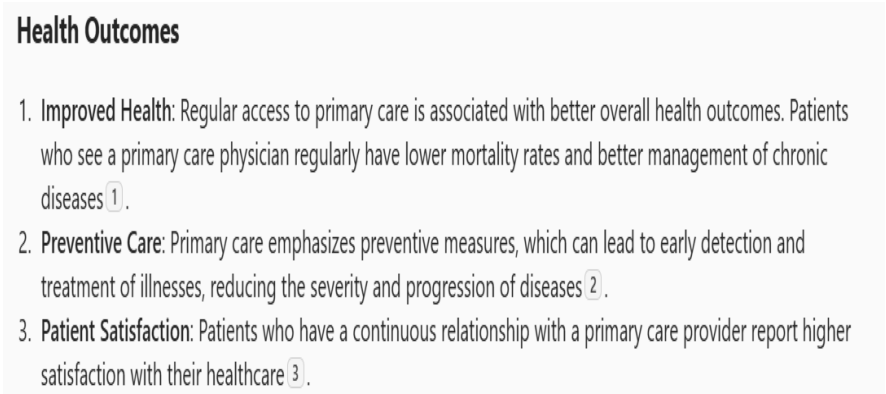
ABBREVIATED TABLE 1

## Trends in Percent U.S. Population with USC by Payer Type




Source: Analyses of Medical Expenditure Panel Survey, 2015 and 2020. Full results in Appendix Table 4.

# Barb’s Copilot

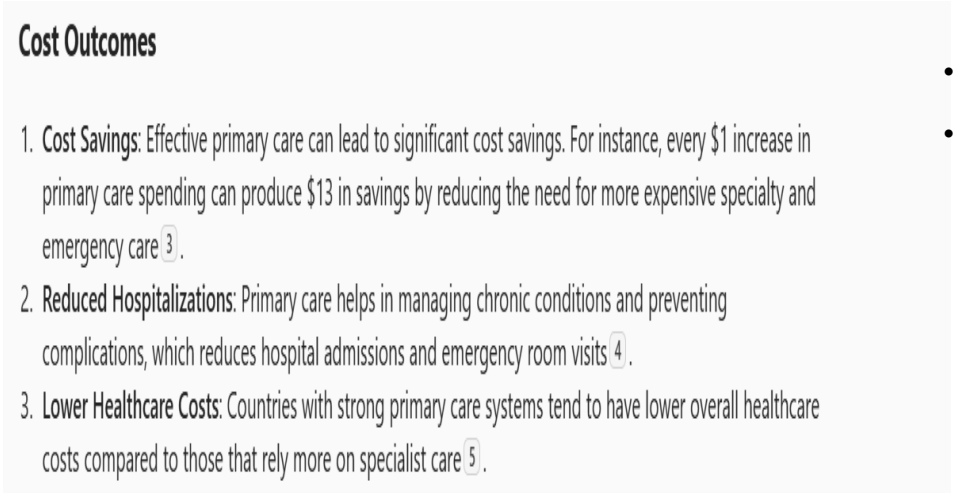


**Health Outcomes**

1. **Improved Health**: Regular access to primary care is associated with better overall health outcomes. Patients who see a primary care physician regularly have lower mortality rates and better management of chronic diseases [1].
2. **Preventive Care**: Primary care emphasizes preventive measures, which can lead to early detection and treatment of illnesses, reducing the severity and progression of diseases [2].
3. **Patient Satisfaction**: Patients who have a continuous relationship with a primary care provider report higher satisfaction with their healthcare [3].

- Hughes LS, Cohen DJ, Phillips RL. Strengthening Primary Care to Improve Health Outcomes in the US—Creating Oversight to Address Invisibility. *JAMA Health Forum*. 2022;3(9):e222903. doi:10.1001/jamahealthforum.2022.2903
- The Health of US Primary Care: 2025 Scorecard Report — The Cost of Neglect | Milbank Memorial Fund
- Using Primary Care’s Potential to Improve Health Outcomes < PBGH

# Barb’s Copilot (continued)



**Cost Outcomes**

1. **Cost Savings**: Effective primary care can lead to significant cost savings. For instance, every $1 increase in primary care spending can produce $13 in savings by reducing the need for more expensive specialty and emergency care [3].
2. **Reduced Hospitalizations**: Primary care helps in managing chronic conditions and preventing complications, which reduces hospital admissions and emergency room visits [4].
3. **Lower Healthcare Costs**: Countries with strong primary care systems tend to have lower overall healthcare costs compared to those that rely more on specialist care [5].

- Using Primary Care’s Potential to Improve Health Outcomes < PBGH
- HHS is Taking Action to Strengthen Primary Care
- Healthcare’s Cost Crisis: How Primary Care Can Deliver The Savings We Need

Medicare Advantage Costs Taxpayers 22% More Per Enrollee. Here's How Payment Reform Could Help Close the Gap. – USC Schaeffer
AMA Health Forum. 2022;3(10):e223451. doi:10.1001/jamahealthforum.2022.3451
CMS Moves Closer to Accountable Care Goals with 2025 ACO Initiatives | CMS
Medicare Advantage by the Numbers 2025 - Better Medicare Alliance
Medicare Accountable Care Organizations: Past Performance and Future Directions | Congressional Budget Office
Primary Care Evidence Report 2024
Primary Care Collaborative
Home - Peterson-KFF Health System Tracker
The Health of US Primary Care: 2025 Scorecard Report — The Cost of Neglect | Milbank

# Medical Cannabis for Chronic Pain: A Blunt Assessment of Efficacy and Risk

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Departments of Anesthesiology and Neurology
Division of Pain Management

University of Pittsburgh

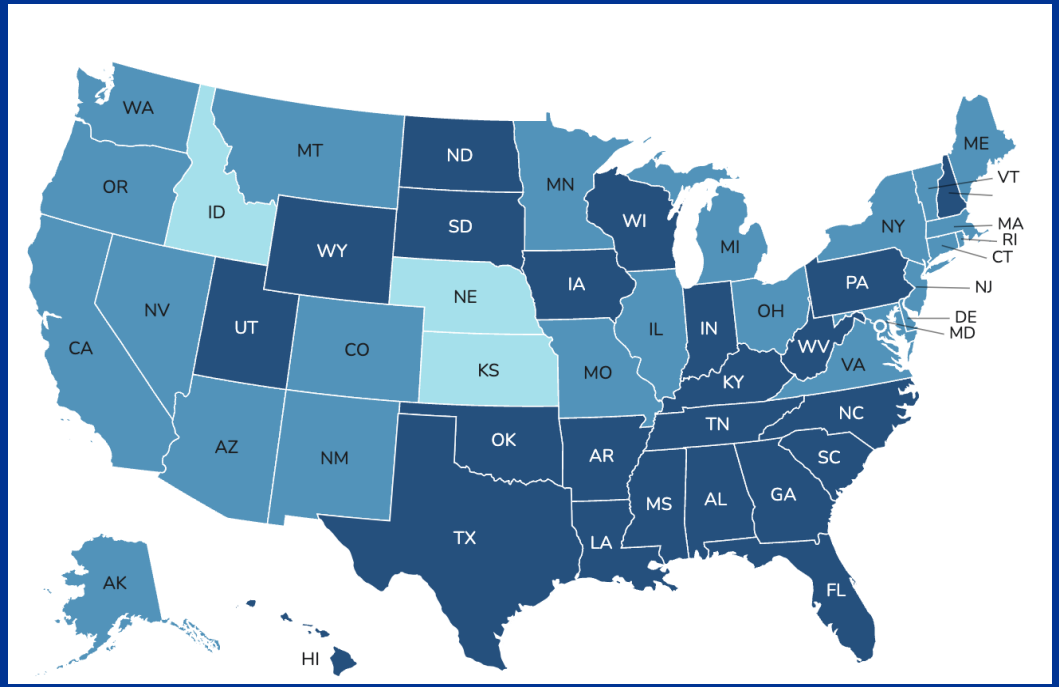
# Outline

- Background
  - Terminology
  - Medical Cannabis in PA
- Pathophysiology
  - Why medical cannabis for pain
- Certification process
  - Case Presentation
- Efficacy data from our division
- Safety data from our division

# Medical Cannabis Legislation

- April 2016 Medical Marijuana Act signed Pennsylvania
  - Governor Tom Wolf—medical cannabis for approved conditions
- 47 states legalized cannabis for medical use
- 24 states recreational use

# CDC Cannabis Laws Map

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# PA Medical Marijuana Program Data

**440,733** Active Patient Certifications

**1,936** Approved Practitioners

**1,003,834** Program-to-date patient registrations

**$904,341.61** MMAP Phase 3 Financial Benefit Given

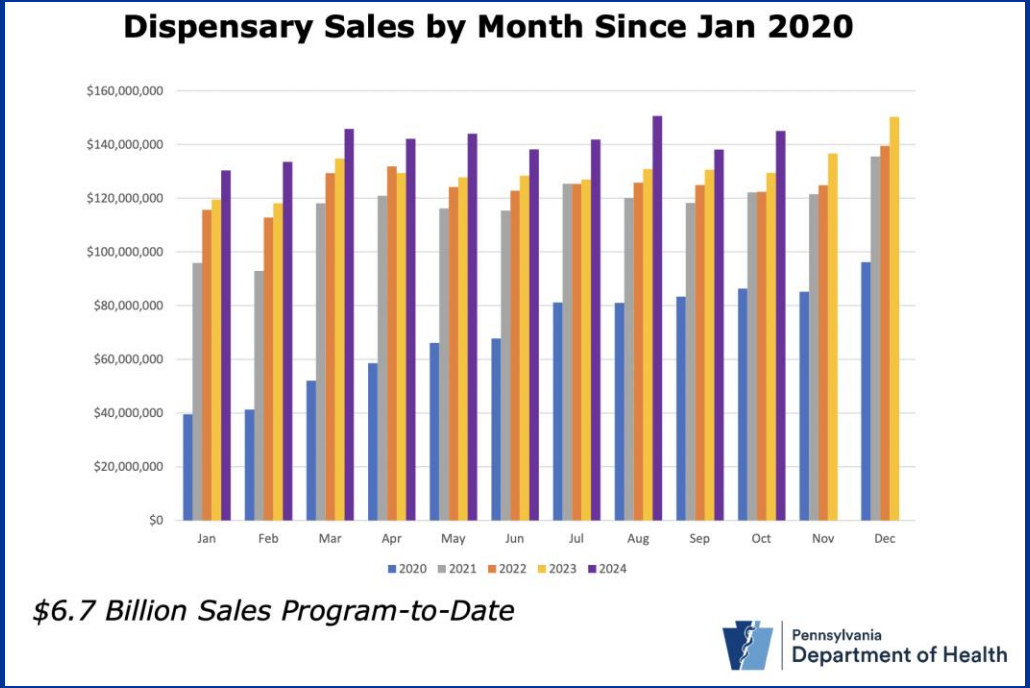
**32** Operational Grower/Processors

**186** Operational Dispensaries

Pennsylvania Department of Health

University of Pittsburgh

# PA Dispensary Data

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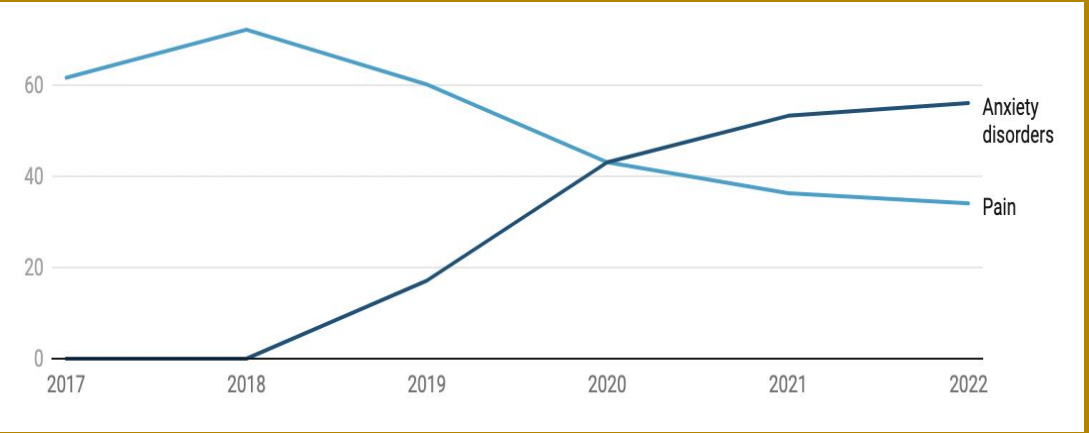
# Approved Conditions in PA

Certifications for Anxiety Increasing

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# Terminology

Cannabis (genus of flowering plants)
3 species
Indica, Sativa , Ruderalis

Hemp
Cannabis Sativa L.
Low THC < 0.3%
High CBD low THC

Marijuana
Indica and Sativa
THC >0.3%
High THC Low CBD

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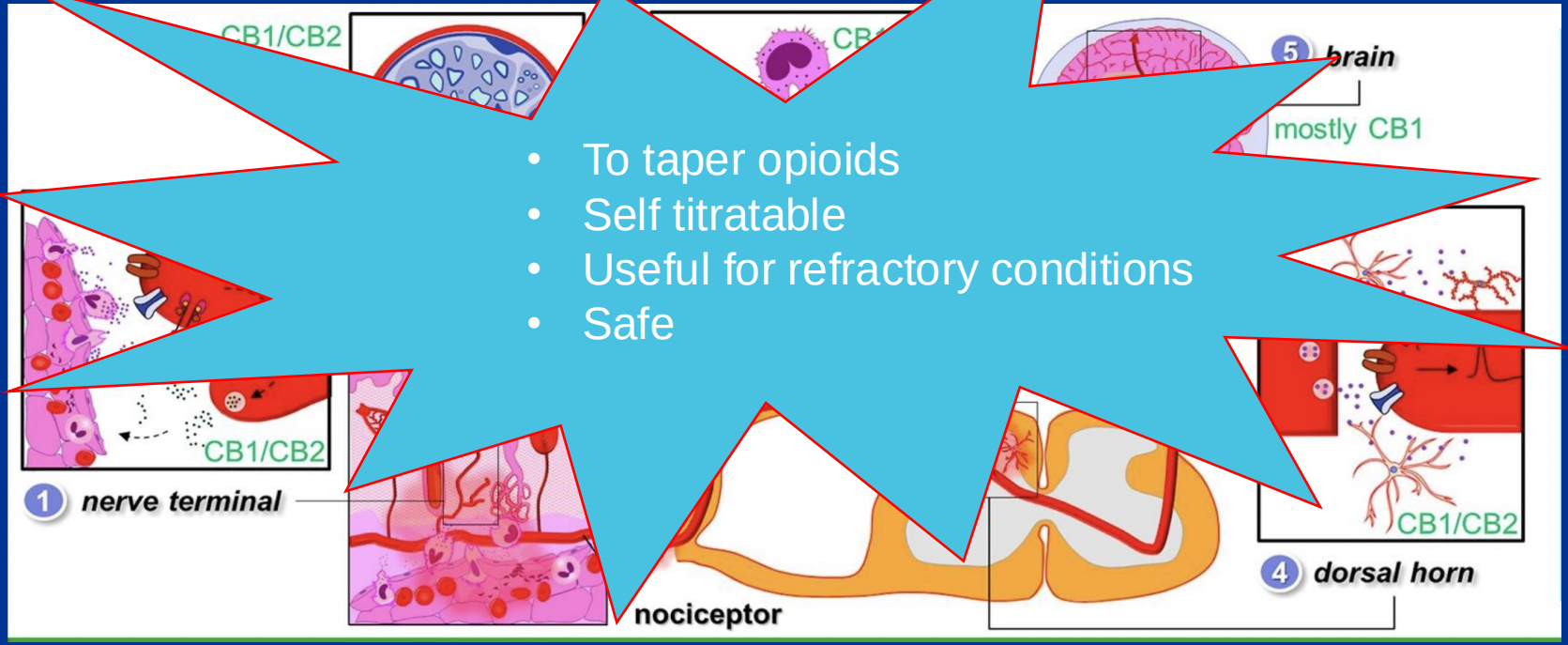
# CBD and THC

| | Cannabidiol (CBD) | Tetrahydrocannabinol (THC) |
|---|---|---|
| Overview | Hemp plant extract | Marijuana |
| Chemical Structure | Similar to the endocannabinoids | Similar to the endocannabinoids |
| Psychoactive effects | None (minimal binding to CB1 receptors) can dampen psychoactive effects of THC | Binds to CB1 receptors in brain and causes euphoria |
| Side effects | Well tolerated | Increased HR, dry mouth, CNS/psych effects, slow reaction time, memory loss |
| Drug testing | Should not be present on routine drug testing | Present days to weeks after use |
| Schedule | None | Schedule 1 |

# Why Cannabis for Chronic Pain




- To taper opioids
- Self titratable
- Useful for refractory conditions
- Safe

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Biochem Pharmacol. 2018 Nov;157:33-42

# Medical Cannabis and Chronic Pain

- One of the most common reasons given for medical cannabis
- Five fair-good quality systematic reviews supporting use[1]
  - Most studied neuropathic pain
- Efficacy is a controversial topic[2]
  - Other systematic reviews concluding no benefit

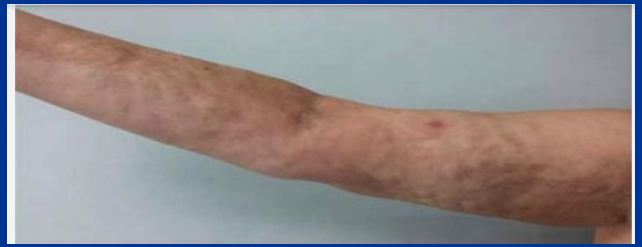
1. Abrams DI. Eur J Intern Med. 2018
2. Wasan AW. Pain 2025.

# UPMC Guidelines for Medical Cannabis and Chronic Pain

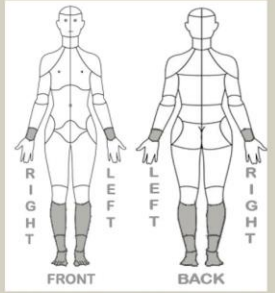
- Medical marijuana use for pain should not be a first-line treatment
- Use for chronic painful condition likely responsive to cannabis
- Absence of active cannabis use disorder or other substance use disorder
- No history of psychotic disorder
- Attempt to reduce or taper off chronic opioids in those certified

# Case Presentation

- 69 year old woman with bilateral LE > UE pain
  - Hx of scleroderma and eosinophilic fasciitis/overlap syndrome
  - Painful swelling and hardness of the distal limbs
  - Thickened skin
- Initial pain clinic visit 2/21/24
  - Patient seen by another physician in our division
  - Failed gabapentin 1200mg daily
  - Unable to tolerate duloxetine



# Baseline CHOIR Initial Visit




16 areas selected on the most recent body map

| PROMIS Outcomes Measures | Score | %ile | Category |
|---|---|---|---|
| Bank v1.2 - Physical Function * | 77 | 100 | |
| Bank v1.1 - Pain Interference | 78 | 100 | |
| Pain Behavior Bank | 66 | 95 | |
| Bank v1.0 - Sleep Disturbance | 64 | 92 | Moderate |
| Depression Bank | 71 | 98 | Severe |
| HEAL Bank v1.0 - Positive Outlook | 33 | 4 | Very Low |
| Anxiety Bank | 67 | 96 | Moderate |
| Post Traumatic Stress Disorder | 0 | 0 | |
| Initial Treatment Expectancy | 100 | | |
| Global Health - Physical * | 73 | 99 | |
| Global Health - Mental * | 56 | 73 | |

*Scores and percentiles have been inverted*

| Pain Intensity: 0=No Pain, 10=Worst Pain Imaginable | | |
|---|---|---|
| Worst | Average | Now |
| 8 | 7 | 9 |

| PainDETECT for Neuropathic Pain | |
|---|---|
| Score: 28 | 19-38: Neuropathic. A neuropathic pain component is likely (> 90%). |
| Radiating pain | No |
| Pain course | Pain attacks with pain between them |
| Burning pain | Very strongly |
| Tingling/Prickling pain | Very strongly |
| Light touching painful | Strongly |
| Sudden pain attacks | Very strongly |
| Hot/Cold painful | Moderately |
| Numbness | Hardly noticed |
| Slight pressure painful | Strongly |

| Pain Experience | |
|---|---|
| How long have you had your pain problem? | 5 Months |
| Briefly describe how your pain started | Swelling in my left leg. |
| Describe your current pain | Shooting, Stabbing, Sharp, Gnawing, Hot, Burning, Aching<br>Heavy, Tender, Tiring, Exhausting, Punishing, Cruel |
| Please describe the timing of your pain | Always there |
| What do you do to ease or relieve your pain? | Bedrest, Massage, Medications, Ice pack, Movement |

| Functional Assessment | |
|---|---|
| Please describe your activities in an average day | Going to school<br>Comments: Mostly can't do many activities anymore. Very frustrating. |

| Working Information | |
|---|---|
| Current or former occupation | Retired 2020 |
| Are you working now? | No |
| When was the last time you worked? | 2020 Years |

| Disability Information | |
|---|---|
| Are you receiving any kind of disability? | No |

| UPMC Opioid | |
|---|---|
| In the past 2 weeks, have you taken any opioid pain medication? Some examples are oxycodone, Percocet, hydrocodone, Norco, morphine, tramadol or buprenorphine | No |

| Cannabis Use | |
|---|---|
| Have you used any cannabis (marijuana, including medical marijuana) over the past six months? | No |

| PROMIS Depression Bank | |
|---|---|
| In the past 7 days<br>I felt depressed | Often |
| I felt hopeless | Often |
| I felt worthless | Often |
| I felt helpless | Always |

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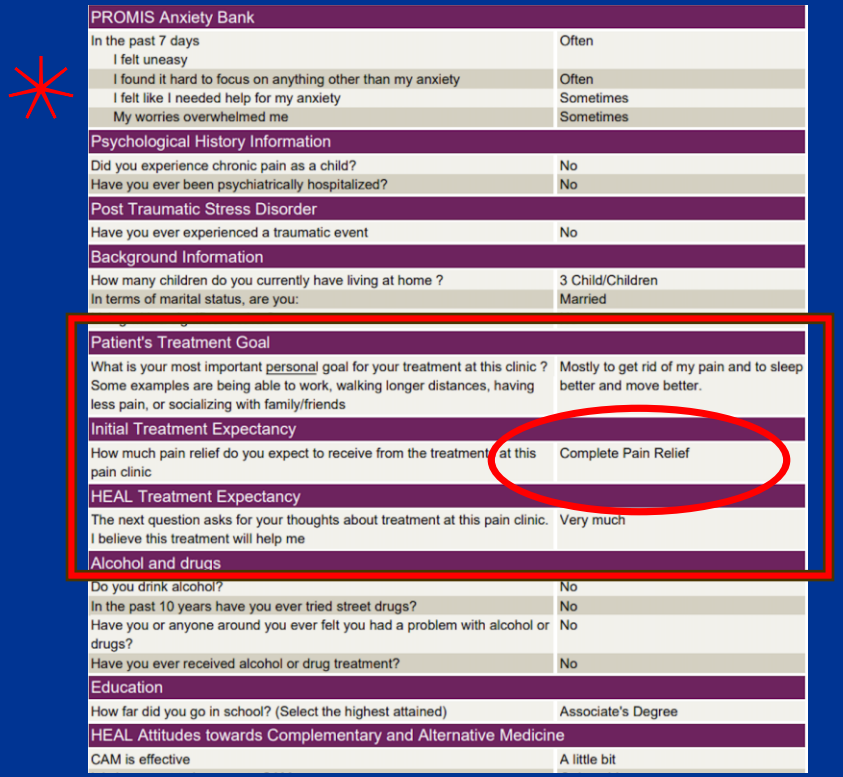
# Baseline Anxiety Treatment Goals

“Mostly to get rid of my pain and to sleep better and move better”



| | |
|---|---|
| **PROMIS Anxiety Bank** | |
| In the past 7 days I felt uneasy | Often |
| I found it hard to focus on anything other than my anxiety | Often |
| I felt like I needed help for my anxiety | Sometimes |
| My worries overwhelmed me | Sometimes |
| **Psychological History Information** | |
| Did you experience chronic pain as a child? | No |
| Have you ever been psychiatrically hospitalized? | No |
| **Post Traumatic Stress Disorder** | |
| Have you ever experienced a traumatic event | No |
| **Background Information** | |
| How many children do you currently have living at home ? | 3 Child/Children |
| In terms of marital status, are you: | Married |
| **Patient's Treatment Goal** | |
| What is your most important personal goal for your treatment at this clinic ? Some examples are being able to work, walking longer distances, having less pain, or socializing with family/friends | Mostly to get rid of my pain and to sleep better and move better. |
| **Initial Treatment Expectancy** | |
| How much pain relief do you expect to receive from the treatment at this pain clinic | Complete Pain Relief |
| **HEAL Treatment Expectancy** | |
| The next question asks for your thoughts about treatment at this pain clinic. I believe this treatment will help me | Very much |
| **Alcohol and drugs** | |
| Do you drink alcohol? | No |
| In the past 10 years have you ever tried street drugs? | No |
| Have you or anyone around you ever felt you had a problem with alcohol or drugs? | No |
| Have you ever received alcohol or drug treatment? | No |
| **Education** | |
| How far did you go in school? (Select the highest attained) | Associate's Degree |
| **HEAL Attitudes towards Complementary and Alternative Medicine** | |
| CAM is effective | A little bit |

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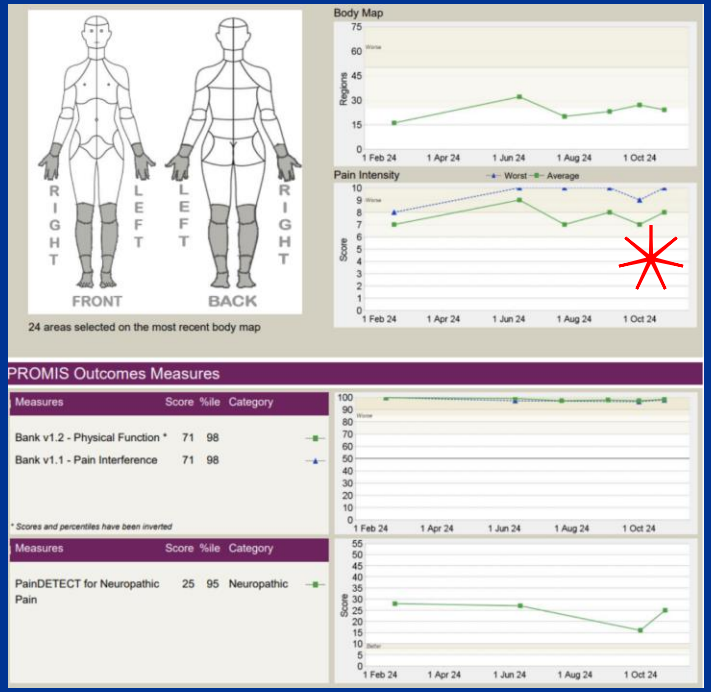
# Case Presentation

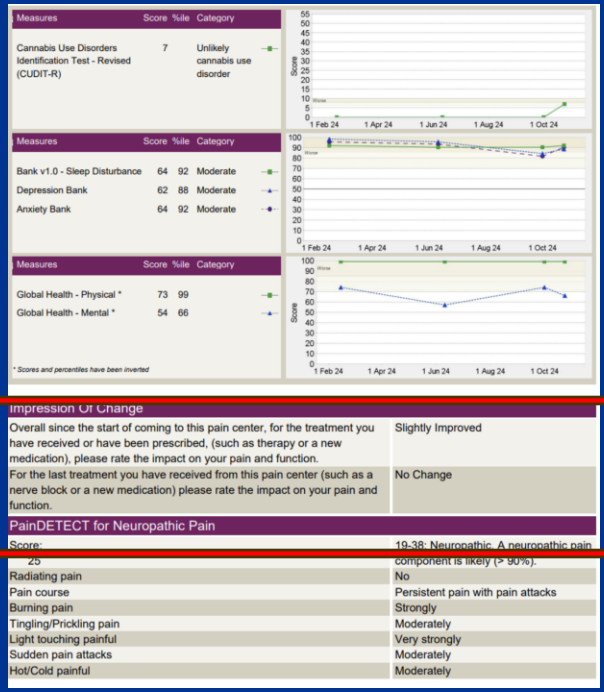
- Treatments tried prior to medical cannabis referral
  - Pregabalin
  - Tramadol
  - Topical compound cream
  - Hydrocodone (2 pills daily)
- Referred for medical cannabis certification 10/8/24
- Consent and urine toxicology documented
  - 3 month follow up

# Case Presentation

- 1st Follow-up shortly after certification 10/31/24
  - Reports using cannabis “gummy” at night with improvement in pain and sleep
  - Hydrocodone taper by more than 50%

# Follow-up CHOIR (apx 1 month post certification)

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# Follow-up CHOIR (1 month post certification)

| PainDETECT for Neuropathic Pain | |
|---|---|
| Numbness | Strongly |
| Slight pressure painful | Strongly |
| **Treatment Expectancy FollowUp** | |
| The next question asks for your thoughts about treatment at this pain clinic. I am confident in this treatment: | Somewhat |
| This treatment is right for me: | Somewhat |
| **UPMC Opioid** | |
| In the past 2 weeks, have you taken any opioid pain medication? Some examples are oxycodone, Percocet, hydrocodone, Norco, morphine, tramadol or buprenorphine | Yes |
| | No misuse reported. |
| **Cannabis Use** | |
| Have you used any cannabis (marijuana, including medical marijuana) over the past six months? | Yes |
| **Cannabis Use Disorders Identification Test - Revised (CUDIT-R)** | |
| Score: 7 | 0-7: Unlikely cannabis use disorder |
| How often do you use cannabis? | 2-4 times a month |
| How many hours were you intoxicated or "stoned" on a typical day when you had been using cannabis? | 1 or 2 |
| How often during the past 6 months did you find that you were not able to stop using cannabis once you had started? | Never |
| How often during the past 6 months did you fail to do what was normally expected from you because of using cannabis? | Never |
| How often in the past six months have you devoted a great deal of your time to getting, using, or recovering from cannabis? | Never |
| How often in the past six months have you had a problem with your memory or concentration after using cannabis? | Never |
| How often do you use cannabis in situations that could be physically hazardous, such as driving, operating machinery, or caring for children? | Never |
| Have you ever thought about cutting down, or stopping, your use of cannabis? | Yes, during the past six months |
| **UPMC Cannabis Use** | |
| In the past year while you were the driver, did you have a motor vehicle accident (MVA) or a moving traffic violation for which you were pulled over by the police? | No |
| Have you been certified for Medical Marijuana ? | Yes |
| When are you likely to use medical marijuana during an average day? Check all responses that apply. | Before Bed |

| PROMIS Depression Bank | |
|---|---|
| In the past 7 days I felt depressed | Sometimes |
| I felt hopeless | Sometimes |
| I felt worthless | Sometimes |
| I felt helpless | Sometimes |
| **PROMIS Anxiety Bank** | |
| In the past 7 days I felt uneasy | Rarely |
| I felt tense | Sometimes |
| My worries overwhelmed me | Sometimes |
| I found it hard to focus on anything other than my anxiety | Often |
| I felt like I needed help for my anxiety | Often |
| **UPMC Closing Comments** | |
| Is there anything else you would like your provider to know ? | Comments: Just that my pain is unbearable in the evenings the most. With the diagnosis I have my life is very hard to manage everyday, but I am grateful for this pain clinic |

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# Follow up (3 months after certification)

- Follow-up video visit 2/17/25
  - Continues to use ”gummy” only at night and reports sleep “very much improved”
  - Average pain score during daytime 4-5/10
  - Night pain 7-9/10 prompting cannabis use
  - “very much improved”
  - Rare use of hydrocodone (Tapered by over 50%)
  - No new CHOIR data

# Cannabis Efficacy

Research Paper

PAIN 00 (2025) 1–10

PAIN®

## The comparative effectiveness of medicinal cannabis for chronic pain versus prescription medication treatment

Ajay D. Wasan[a,*], Brian O'Connell[a], Rebecca DeSensi[a], Cheryl Bernstein[a], Elizabeth Pickle[a], Michael Zemaitis[b], Oren Levy[c], Jong-Hyeon Jeong[d], Gregory F. Cooper[e], Antoine Douaihy[f]

# Inclusion

- Patients certified for medical marijuana from 2018 to 2023
  - Baseline patient-reported outcomes data at the time of the certification visit and 3-month follow-up outcomes data.
  - 6 month follow up as well
- Control group
  - Prescribed a new medication treatment for chronic pain (nonopioid or opioid) during the same timeframe and were not certified for medical marijuana

# Study Objectives

- Efficacy of medical cannabis for pain versus other medications
- Used Patients Outcomes Repository for Treatment (PORT)
- CHOIR data
  - pain intensity and other measures
  - Functional improvement
  - Patient impression of change

# Study Design

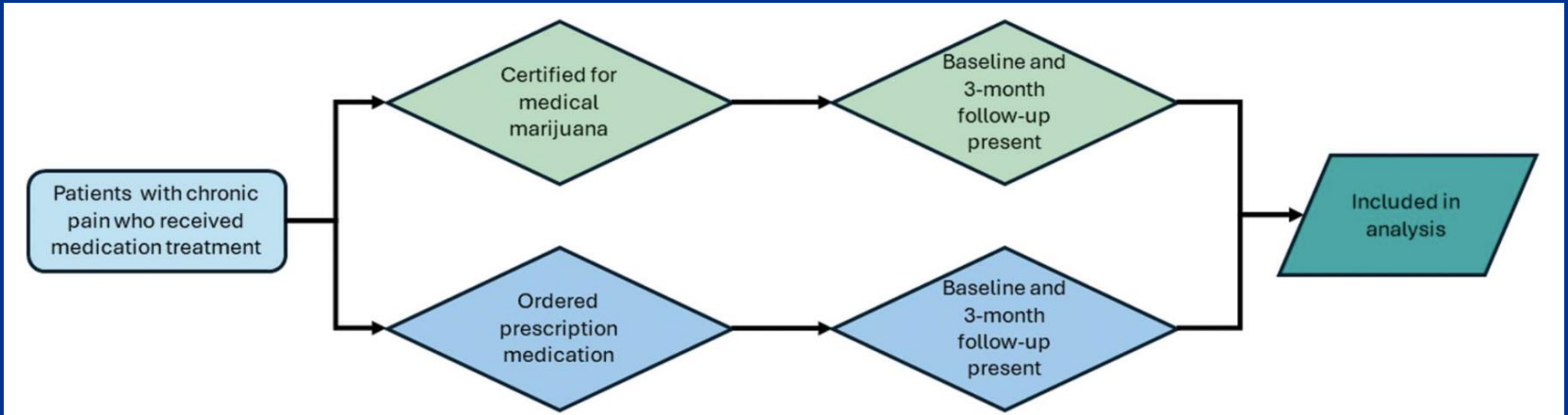


**Figure 1.** Creation of patient groups.

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# Responder Rates
# Cannabis vs. Other Medication

- Significant reduction in pain
- Clinically significant improvement in function
- Significant impression of change
- Combination of above

# Outcomes

A significantly higher percentage of patients certified for medical cannabis responded to treatment compared to control group.

**Table 2**

**Responder rates between groups.**

| Variable | Marijuana (N = 440) | Control (N = 8114) |
|---|---|---|
| Treatment responders (3 mo) | | |
| Pain intensity average, physical function, or impression of change for treatment responder (raw count [%]) | 170 (38.6%) | 2833 (34.9%) |
| Pain intensity average responder | 43 (9.8%) | 1052 (13.0%)* |
| Physical function responder | 73 (16.6%) | 1453 (17.9%) |
| Impression of change for treatment responder | 95 (21.6%) | 813 (10.0%)* |
| More than 1 domain of response | 39 (8.9%) | 472 (5.82%) |
| Treatment responders (6 mo) | | |
| Pain intensity average, physical function, or impression of change for treatment responder (raw count [%]) | 167 (38.0%) | — |
| Pain intensity average responder | 51 (11.6%) | — |
| Physical function responder | 71 (16.1%) | — |
| Impression of change for treatment responder | 79 (18.0%) | — |
| More than 1 domain of response | 32 (7.3%) | — |

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# Outcomes Medical Cannabis Group

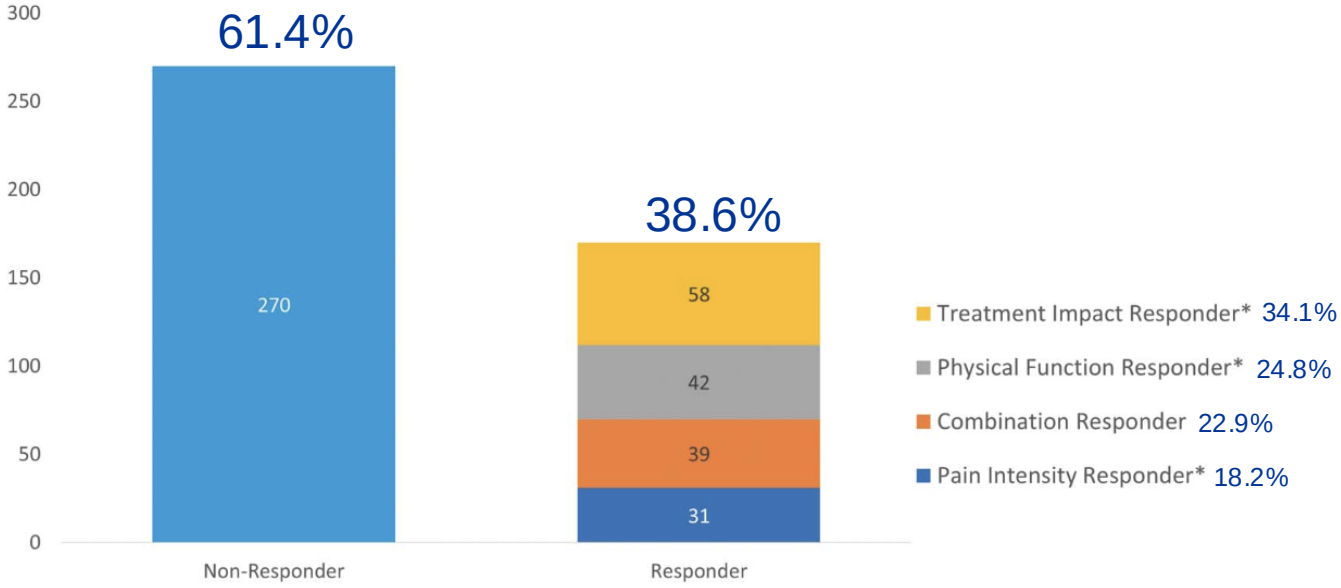


**Figure 2.** Three-month medical marijuana responder status for pain intensity average, physical function, and treatment impact. *Indicates that patients ONLY responded in this domain.

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# Medical Cannabis and Opioid Taper

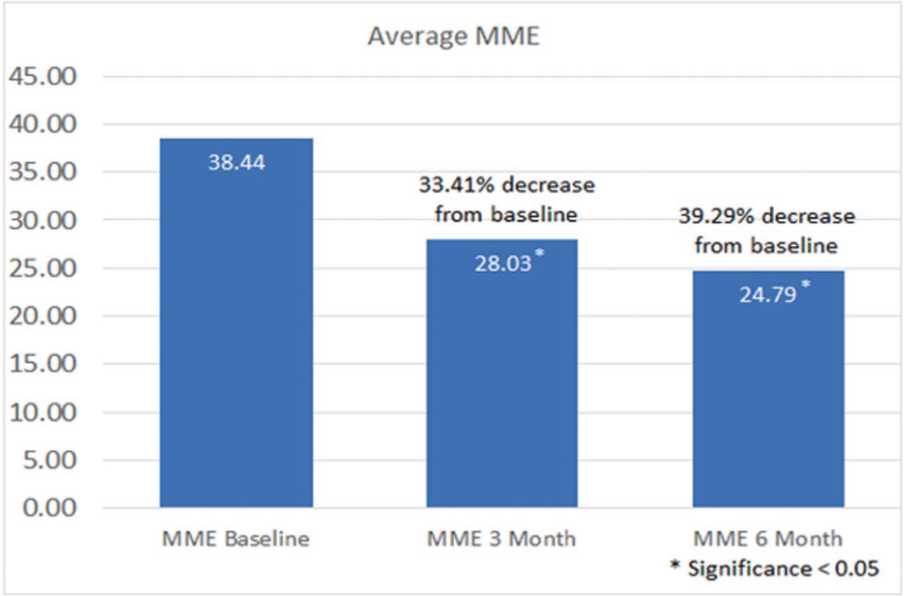


**Figure 3.** Changes in morphine milligram equivalents (MME), N = 157.

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# Study Conclusions

- Medical cannabis more effective than conventional medications
  - odds of responding 2.6 times higher in the medical marijuana group
  - response in the control group (34.9%) was very similar to the marijuana group (38.6%) at 3 months
- 9% in the marijuana group responded in more than one domain
- 39% reduction in prescribed MMEs over 6 months

# Risks of Medical Cannabis Use

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# Problematic Medical Cannabis Use in Patients with Chronic Pain

Cheryl D. Bernstein, Benedict J. Alter, Rebecca S. DeSensi Brian O'Connell, Maya Maurer, Ajay D. Wasan.

University of Pittsburgh

# Cannabis Use Disorder

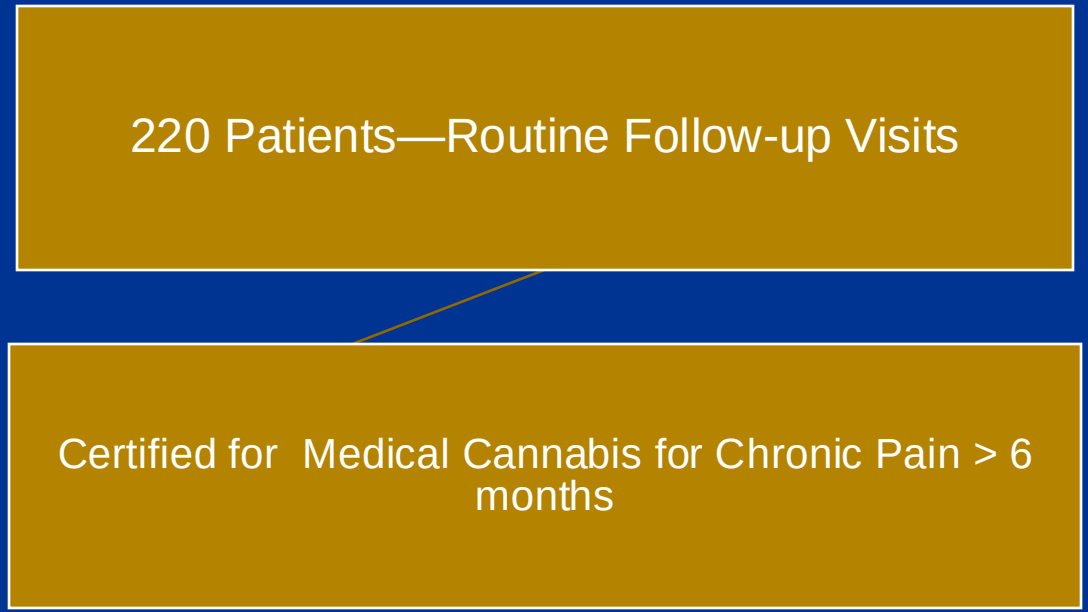
- Estimated to affect 1/3 adults using cannabis[1]
- Problematic use of cannabis defined by two of following[2]
  - Taken in larger amounts  than needed
  - Social or interpersonal problems
  - Inability to stop
  - Spending a great deal of time using
  - Cravings
  - Failure to fulfill obligations
  - Use in hazardous situations
  - Use despite physical or psychological harm
  - Tolerance
  - Withdrawal

1. *JAMA Psychiatry*. 2015;72(12):1235-1242
3. American Psychiatric Association. (2022). *Diagnostic and statistical manual of mental disorders* (5th ed., text rev.)

# Study Aims

- Identify problematic medical cannabis use in patients with chronic pain
- Identify patient factors that predict problematic use
- Study patterns of medical cannabis use
  - What form are patients using medical cannabis
  - When are patients typically using medical cannabis

# Study Design

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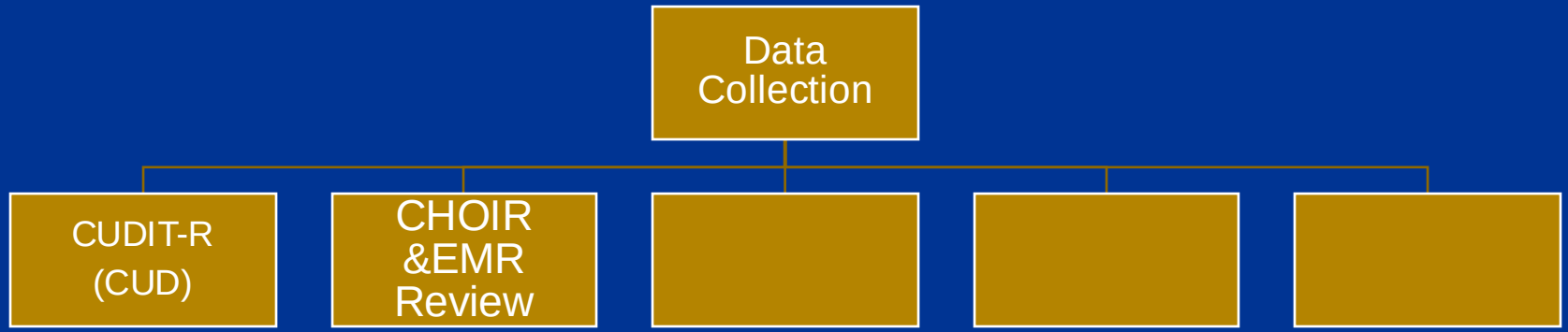
Approved by UPMC QI Review Committee with Waiver of Informed Consent

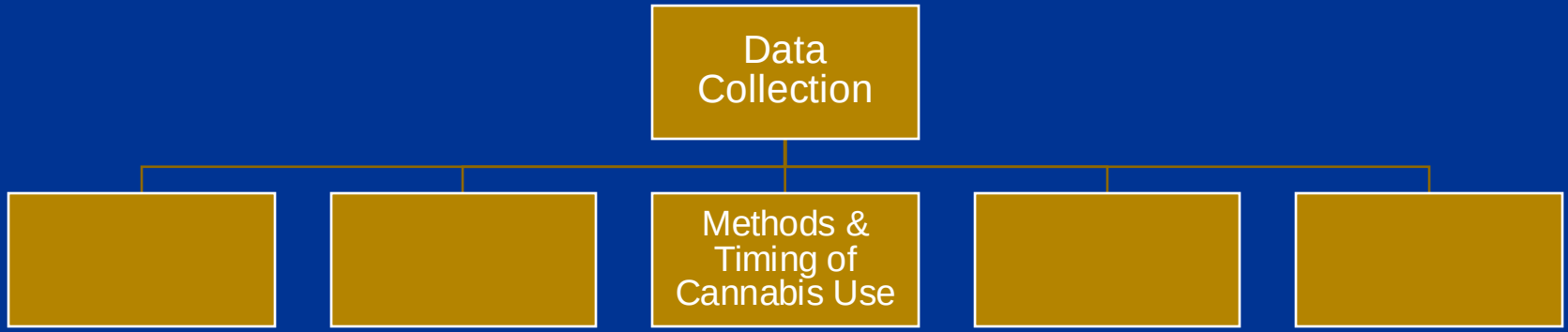



## Cannabis Use Disorder Identification Test—Revised (CUDIT-R)[1]

- Screen for cannabis use disorder (recreational use)
- Self reported 8-item questionnaire (0-4 points/question)
  - Score ≥ 8 indicates problematic use
  - Score ≥ 12 indicates CUD
- Assessment of:
  - Cannabis consumption
  - Abuse
  - Dependence
  - Psychological impact



Adamson SJ et al. Drug Alcohol Depend. 2010;110(1-2):137-143.




- Method of cannabis use
  - Predominantly inhaled (smoking or vaping)
  - Non-inhaled (tincture, pill, topical, mixed)
  - Topical only
- Timing of cannabis use
  - “When are you most likely to use cannabis on a typical day”

Morning
Afternoon
Evening
Before bed
Middle of night

} Indicate any that apply

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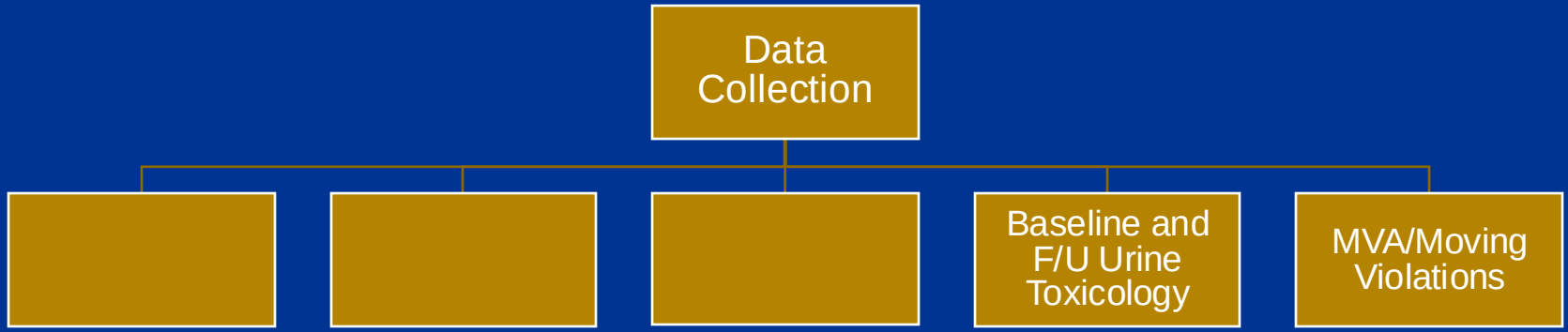


- Reviewed electronic medical records for baseline and follow up toxicology screen
  - Division policy to have baseline toxicology prior to certification
  - Follow-up toxicology at least once yearly
- Patients who drive were questioned about MVA or moving violation in past year

# CUDIT-R Scores (n=220)

- 76% CUDIT-R scores <8
  - 50% scored ≤ 4
- 24% patients ≥8
  - Only 3 patients scored ≥12 (possible CUD)

| CUDIT-R Scores<br>8-11 possible hazardous use<br>≥12 possible CUD | n (%) |
|---|---|
| CUDIT ≤ 4 | 111 (50) |
| CUDIT 5-7 | 57 (25.9) |
| CUDIT ≥ 8 (possible hazardous use) | 52 (23.6) |

# Patient Factors That Predict Problematic Use: High CUDIT-R Scores

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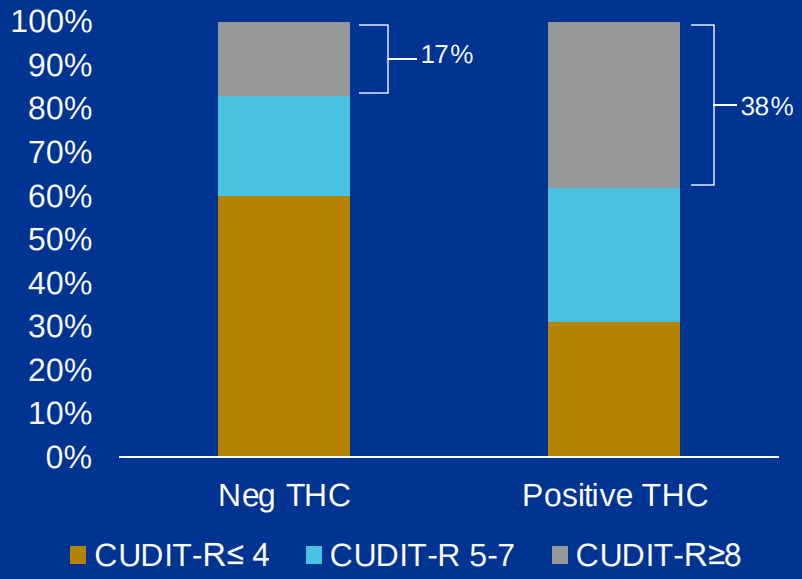
# Cannabis Use Before Certification and CUDIT-R Scores

- Patients using cannabis prior to certification (baseline positive  THC tox screen) had higher CUDIT-R scores (P<0.001).

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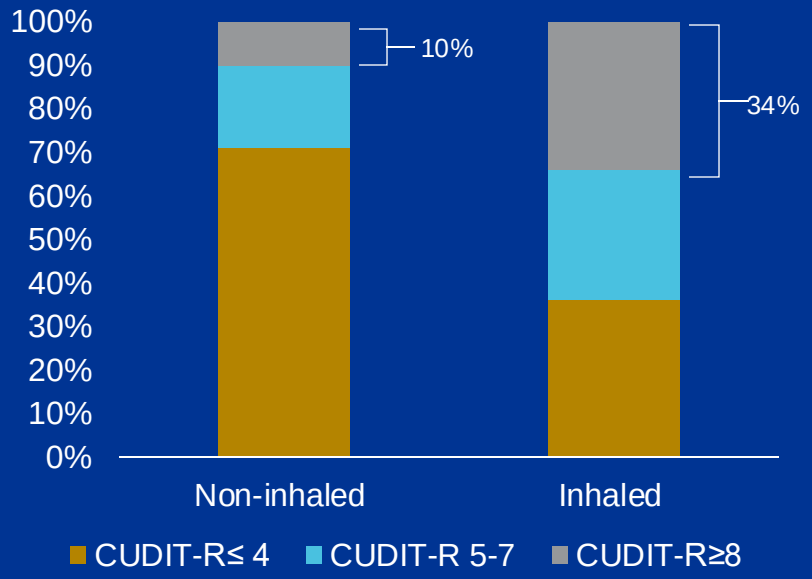
# Inhaled Cannabis Use and CUDIT-R Scores

- Patients using inhaled cannabis had higher CUDIT-R scores (P<0.001).

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# Several Factors Predicted Higher CUDIT-R Scores

- Linear Regression Models
- Multiple factors predicted higher CUDIT-R scores ($p<.05$)
  - Young age
  - Poor global mental health (CHOIR survey)
  - Inhaled use
  - Positive baseline THC (use prior to medical cannabis certification)

# Patterns of Use

- 53% of patients used inhaled forms of medical cannabis
  - Patients advised to avoid inhaled use at initial and follow up visits

| Method of Use (n=129) | n (%) |
|---|---|
| Non-inhaled | 60 (46.5%) |
| Inhaled | 69 (53.5%) |

- Over half of patients limited use to evening or later

| Timing of Use (n 218) | n (%) |
|---|---|
| Evening Only | 113 (52%) |

# Baseline and Follow-up Toxicology Screens

- 31% patients had baseline drug screens positive for THC
  - Patients using cannabis prior to medical cannabis certification

| Baseline Tox Screen (n=196) | n (%) |
|---|---|
| Negative for THC | 135 (68.9%) |
| Positive for THC | 61 (31.1%) |

- Almost all patients had consistent follow-up drug screens

| Follow-up Tox Screens (n 214) | n (%) |
|---|---|
| Consistent | 210 (98.1%) |
| Inconsistent | 4 (1.9) |

# Safety Conclusions

- Problematic use (CUDIT-R ≥8) in 24% of patients
  - Some patient factors increase risk of problematic use
- Over half of medical cannabis patients limited cannabis to evening or later
- Follow up urine toxicology was consistent

# Medical Cannabis Summary

- Effective option for chronic pain
  - May be more effective than other medications
  - Recommend as part of multimodal plan
- Recommend non inhaled options
    - Low dose ingestible forms and pills (5-10mg)THC
    - Tincture THC:CBD 1:1 option
    - Topical forms (salves and patches)
- Recommend no driving 6-8 hours after use
- Further studies on safety and efficacy needed

# A Joint Effort

Rebecca DeSensi, MS
Brian O'Connell, MS
Maya Maurer, MS
Benedict Alter, MD, PhD
Ajay D. Wasan, MD, MSc

University of Pittsburgh

# DYSLIPIDEMIA

UPMC Family Medicine Refresher Course

Alexandria Taylor, PharmD, BCPS
*Clinical Pharmacist Senior, Family Medicine*
*Director, UPMC St. Margaret PGY1 Pharmacy Residency Program*
*Faculty, UPMC St. Margaret Family Medicine*

# OBJECTIVES

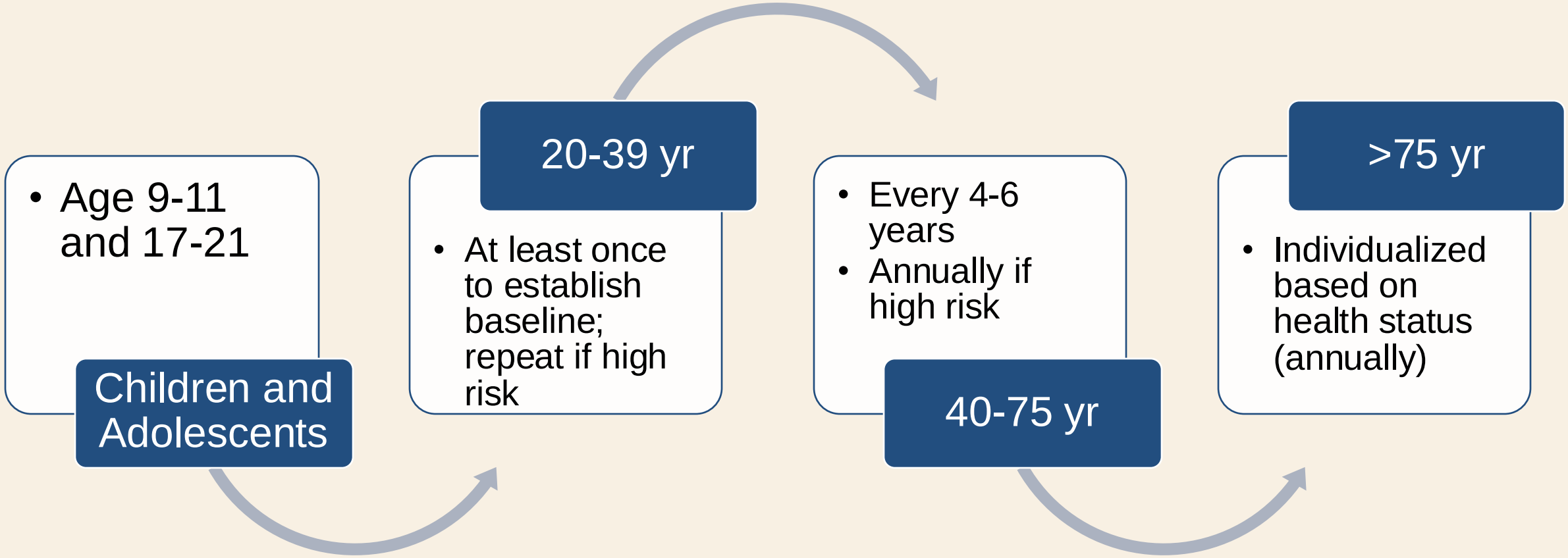
- **Identify** the target LDL-C levels for different risk categories according to the latest guidelines
- **Outline** the stepwise approach to initiating and adjusting lipid-lowering therapy based on patient response and tolerance
- **Analyze** recent clinical trial data on the efficacy and safety of novel non-statin therapies in reducing cardiovascular events

# ABBREVIATIONS

ABI- ankle-brachial index
ACS- acute coronary syndrome
ASCVD- atherosclerotic cardiovascular disease
BMI- body mass index
CABG- coronary artery bypass
CACS- coronary artery calcium scoring
CAS- coronary artery disease
CKD- chronic kidney disease
CVD- cardiovascular disease
DBP- diastolic blood pressure
DM- Diabetes mellitus
FH- familial hyperlipidemia
HF- Heart Failure
HTN- hypertension
MI- myocardial infarction
PAD- peripheral arterial disease
PCI- percutaneous coronary intervention
SBP- systolic blood pressure
UA- unstable angina
UACR- urine albumin-to-creatinine ratio

# LIPID GOALS

# When to Screen




Grundy SM, Stone NJ, Bailey AL, et al. J Am Coll Cardiol. 2019;73(24):e285-e350

# WHAT LDL GOAL DO YOU TARGET?

Scan the QR code to answer!

Join at menti.com | use code 7869 0614

Mentimeter

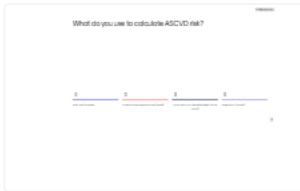
# What LDL goal do you target?

| 0 | 0 | 0 | 0 |
| --- | --- | --- | --- |
| None | <100 mg/dL | <70 mg/dL | <55 mg/dL |

Menti

Dyslipidemia FMRC

Choose a slide to present



# LDL-C TARGETS

| Guideline | Desired LDL-C |
| --- | --- |
| AHA/ACC Blood Cholesterol Guideline (2018) | **Primary prevention:**<br>≥30%-50% LDL-C lowering<br>**Secondary prevention:**<br>≥50% LDL-C lowering with high intensity statin and consider additional Rx if LDL-C ≥70 mg/dL in patient at very high risk |

Grundy SM, Stone NJ, Bailey AL, et al. J Am Coll Cardiol. 2019;73(24):e285-e350

# LDL-C TARGETS

| Guideline | Desired LDL-C |
|---|---|
| AHA/ACC Blood Cholesterol Guideline (2018) | **Primary prevention:**<br>≥30%-50% LDL-C lowering<br>**Secondary prevention:**<br>≥50% LDL-C lowering with high intensity statin and consider additional Rx if LDL-C ≥70 mg/dL in patient at very high risk |
| AACE/ACE (2020) | **Primary prevention:**<br><70 (very high risk), <100 (moderate or high risk), or <130 mg/dL (low risk)<br>**Secondary prevention:**<br><55 (extreme risk) or <70 mg/dL (very high risk) |

Grundy SM, Stone NJ, Bailey AL, et al. J Am Coll Cardiol. 2019;73(24):e285-e350
Handelsman Y, et al. *Endocr Pract*. 2020;26(10):1196-1224.

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| ACC ECDP on LDL-C Lowering (2022) | **Primary prevention:**<br>≥30%-50% LDL-C lowering, consider additional Rx when LDL-C exceeds <70, <100, or <130 mg/dL based on risk level/comorbidity<br>**Secondary prevention:**<br>≥50% LDL-C lowering with high intensity statin and additional Rx to target <55 (very high risk) or <70 mg/dL (not at very high risk) |

# AHA/ACC BLOOD CHOLESTEROL GUIDELINE (2018): *VERY HIGH RISK*

## Major ASCVD Events

- Recent ACS (past 12 mo)
- Hx of MI
- Hx of ischemic stroke
- Symptomatic PAD

## High-Risk Conditions

- Age ≥ 65 yr
- Heterozygous FH
- Hx of CABG or PCI
- DM
- HTN
- CKD
- Current smoking
- Hx of congestion HF
- Persistently elevated LDL-C (≥ 100 mg/dL) despite max statin + ezetimibe



Grundy SM, Stone NJ, Bailey AL, et al. J Am Coll Cardiol. 2019;73(24):e285-e350

# AHA/ACC BLOOD CHOLESTEROL GUIDELINE (2018): *VERY HIGH RISK*

| Major ASCVD Events | High-Risk Conditions |
| --- | --- |
| • Recent ACS (past 12 mo)<br>• Hx of MI | • Age ≥ 65 yr<br>• Heterozygous FH<br>• Current smoking<br>• Hx of congestion HF<br>• Persistently elevated LDL-C (≥ 100 mg/dL) despite max statin + ezetimibe |

Very High Risk: Meets 1 major ASCVD event + several high-risk conditions OR 2+ major ASCVD events



Grundy SM, Stone NJ, Bailey AL, et al. J Am Coll Cardiol. 2019;73(24):e285-e350

# AACE/ACE (2020): RISK DEFINITIONS

| Risk Category | Risk Factors | Treatment Goals (mg/dL) | | |
|---|---|---|---|---|
| | | LDL-C | Non-HDL-C | Apo B |
| **Extreme risk** | • Progressive ASCVD including UA<br>• Established clinical ASCVD + DM or CKD ≥ 3 or FH<br>• Hx of premature ASCVD (<55yr male, <65 yr female) | <55 | <80 | <70 |
| **Very high risk** | • Established clinical ASCVD, or recent hospitalization (for ACS, carotid, or peripheral vascular disease), or 10-year risk >20%<br>• DM with ≥ 1 risk(factors)<br>• CKD ≥ 3 w/ albuminuria<br>• FH | <70 | <100 | <80 |

Handelsman Y, et al. *Endocr Pract*. 2020;26(10):1196-1224.

# AACE/ACE (2020): RISK DEFINITIONS

| Risk Category | Risk Factors | Treatment Goals (mg/dL) | | |
|---|---|---|---|---|
| | | LDL-C | Non-HDL-C | Apo B |
| **High risk** | • ≥ 2 risk factors & 10-yr risk 10-20%<br>• DM or CKD ≥ 3 w/ no other risk factors | <100 | <130 | <90 |
| **Moderate risk** | • <2 risk factors & 10-yr risk <10% | <100 | <130 | <90 |
| **Low risk** | • No risk factors | <130 | <160 | NR |

**Risk factors**: advancing age, elevated non HDL-C, elevated LDL-C, low HDL-C, DM, HTN, CKD, smoking, family hx of ASCVD



Handelsman Y, et al. *Endocr Pract*. 2020;26(10):1196-1224.

# ACC ECDP ON LDL-C LOWERING (2022): RISK DEFINITIONS

| Major ASCVD Events | High-Risk Conditi |
| --- | --- |
| • Recent ACS (past 12 mo)<br>• Hx of MI<br>• Hx of ischemic stroke<br>• Very High R<br>sev | • Age ><br>ASCVD<br>• Hx of congestion HF<br>• Persistently elevated LDL-C (≥ 100 mg/dL) despite max statin + ezetimibe |

Same as AHA/ACC Blood Cholesterol Guideline (2018)

Lloyd-Jones, D, Morris, P. et al.. 2022 Oct, 80 (14) 1366–1418.

# WHAT DO YOU USE TO CALCULATE ASCVD RISK?

Scan the QR code to answer!

Join at menti.com | use code 7869 0614

Mentimeter

# What do you use to calculate ASCVD risk?

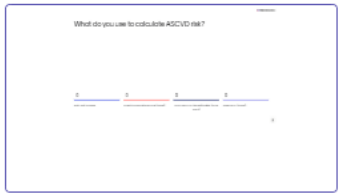
| 0 | 0 | 0 | 0 |
|---|---|---|---|
| Epic dot phrase | Framingham Risk Score (2008) | ACC ASCVD risk estimater (PCE 2013) | PREVENT (2024) |

AT

Menti

Dyslipidemia FMRC

Choose a slide to present



# CALCULATORS

- **Framingham (2008)**
  - Age (30-79 yo), sex, smoking status, total cholesterol, HDL-C, SBP, BP treated
- **ACC ASCVD Risk Estimator (PCE 2013)**
  - Age (**20**-79 yo), sex, **race**, smoking status, **diabetes**, total cholesterol, HDL-C, SBP, **DBP,** BP treated
- **PREVENT (2024)**
  - Age (30-79 yo), sex, smoking status, **diabetes**, total cholesterol, HDL-C, SBP, BP treated, **BMI, eGFR, lipid-lowering medication**
  - *Optional: UACR, A1C, zip code (social deprivation index)*

D'Agostino RB Sr, et al. *Circulation*. 2008;117(6):743-753.
Goff DC Jr, et al. 2014 Jun 24;129(25 Suppl 2):S74-5]. *Circulation*. 2014;129(25 Suppl 2):S49-S73.
Khan SS, et al. Circulation. 2024 Mar 12;149(11):e956.

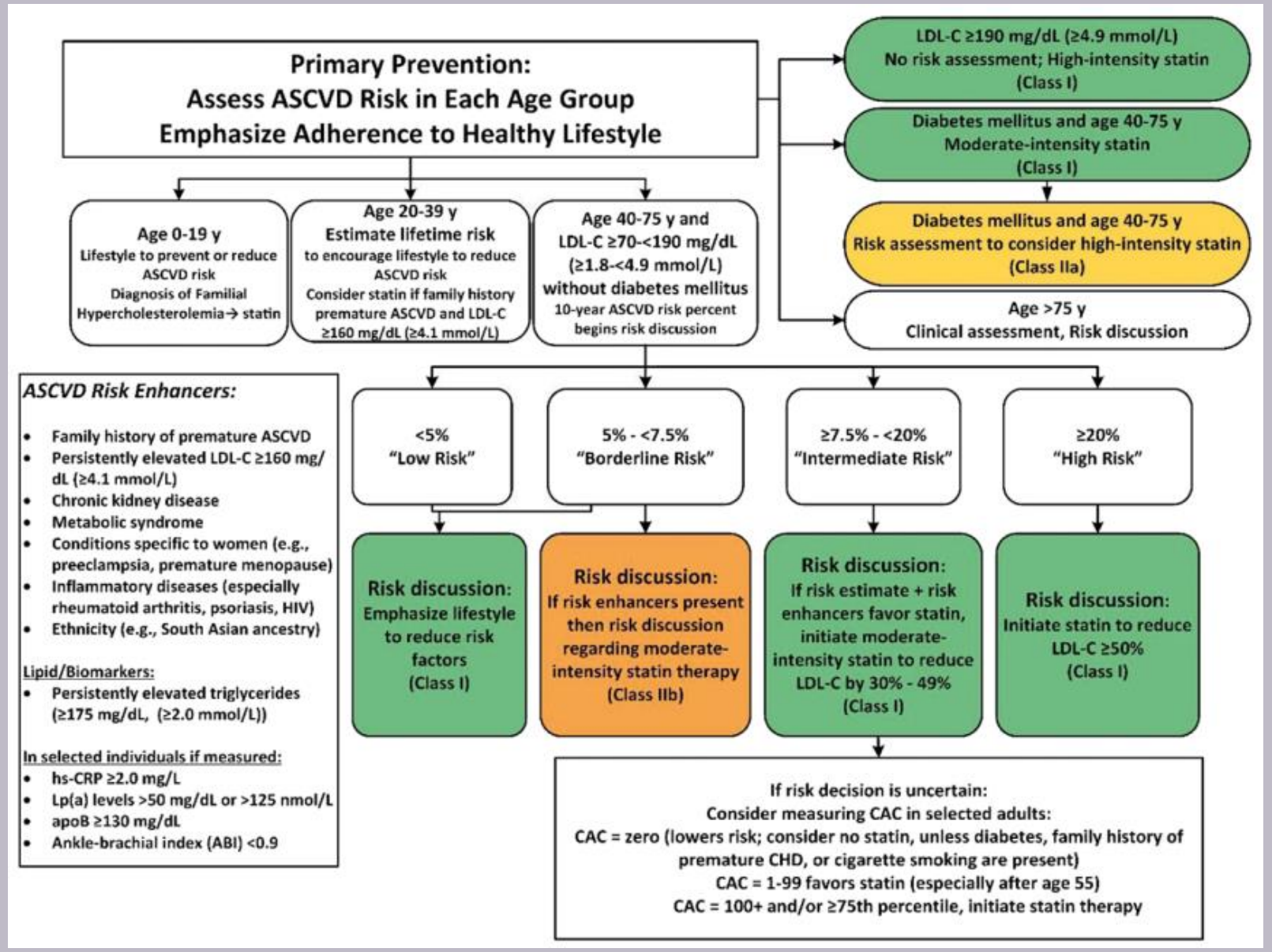
# HEALTH DISPARITIES ACROSS ASCVD RISK

- ACC/AHA 2013 ASCVD risk estimator race can have as much as 12% difference
  - Consider alternative risk factors
- Social determinants of health
- Undiagnosed or untreated comorbidities
- Delayed recognition of ACS events

Devareddy A, Sarraju A, Rodriguez F. *Curr Cardiol Rep*. 2022;24(9):1129-1137.
Gordon M, Di Bartolo IM. *Am Fam Physician*. 2021;104(3):292-294.

# TREATMENT APPROACH

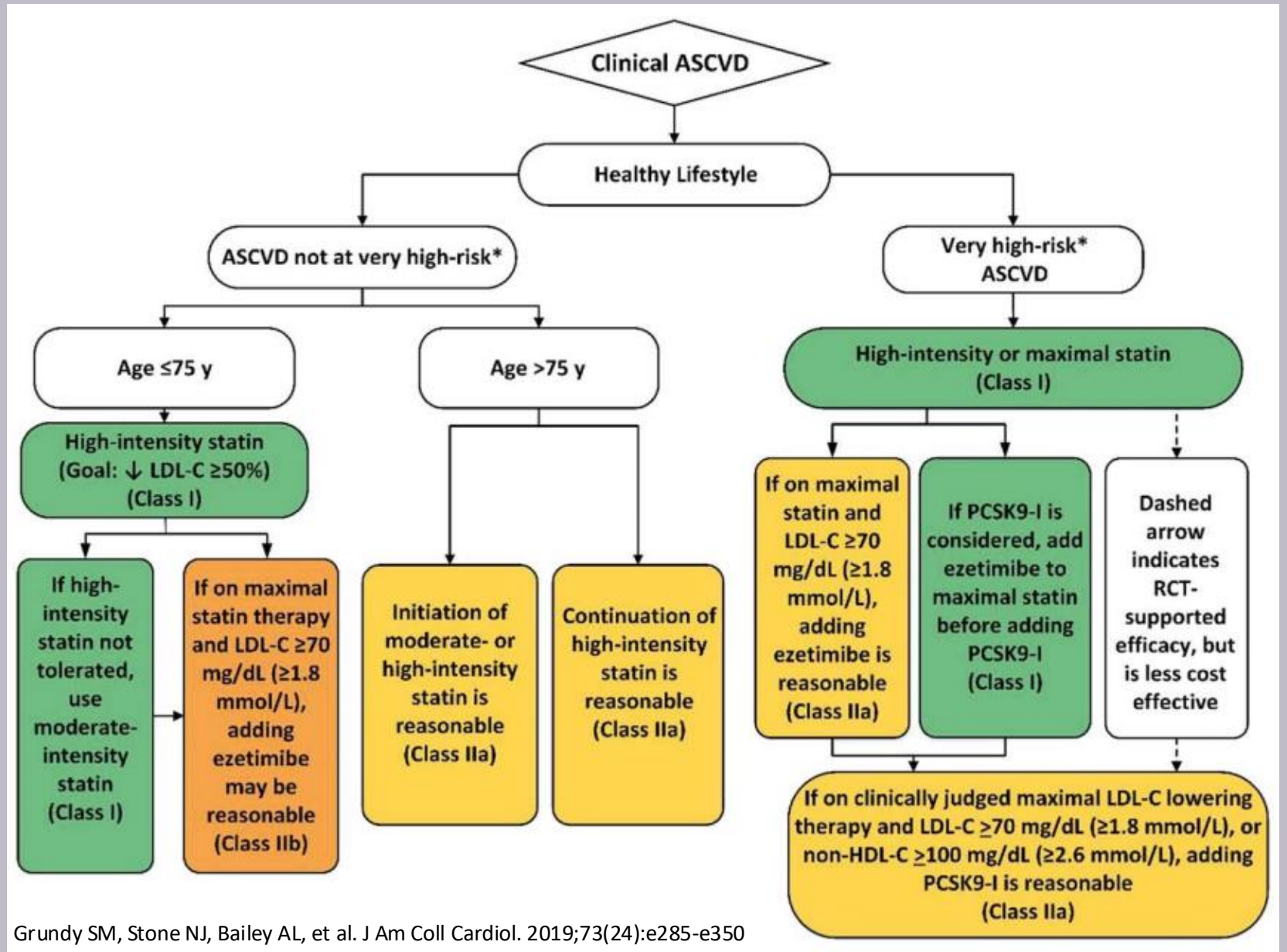
# AHA/ACC BLOOD CHOLESTEROL GUIDELINE (2018): *TREATMENT RECOMMENDATIONS*






Grundy SM, Stone NJ, Bailey AL, et al. J Am Coll Cardiol. 2019;73(24):e285-e350

# AHA/ACC BLOOD CHOLESTEROL GUIDELINE (2018): *TREATMENT RECOMMENDATIONS*




Grundy SM, Stone NJ, Bailey AL, et al. J Am Coll Cardiol. 2019;73(24):e285-e350

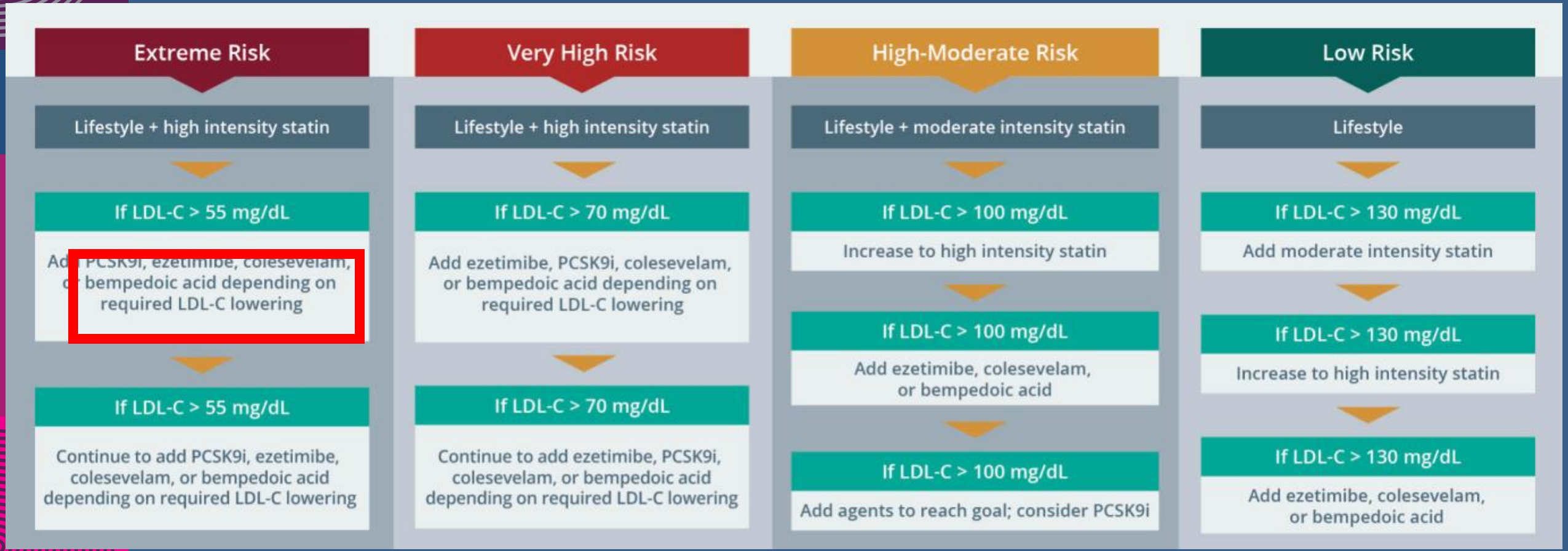
# AHA/ACC BLOOD CHOLESTEROL GUIDELINE (2018): *TREATMENT RECOMMENDATIONS*

| | |
|---|---|
| **Clinical ASCVD (ie CAD, stroke, PAD, etc)** | **ASCVD not at high risk (see below)**<br>≤ 75 yo: high-intensity statin<br>> 75 yo: moderate- or high-intensity statin<br>**ASCVD at high risk**<br>High-intensity or maximal tolerated statin<br>If on maximal tolerated statin & LDL≥ 70 mg/dL, can add ezetimibe |
| **Patients 20-75 yo with LDL ≥ 190 mg/dL** | Maximal tolerated statin<br>If on maximal tolerated statin & LDL ≥ 100 mg/dL, can add ezetimibe |
| **Patients 40-75 yo with diabetes** | Any patient in this group<br>Moderate-intensity statin<br>Additional risk factors*<br>High-intensity statin<br>***PMH T1DM ≥ 20 yrs, PMH T2DM ≥ 10 yrs, albuminuria ≥ 30 mcg albumin/mg creatinine; eGFR<60mL/min/1.73m2; retinopathy; neuropathy; ABI<0.9** |
| **Patients 40-75 yo with LDL 70-190 mg/dL** | Based on 10-year ASCVD risk score<br>< 5% Lifestyle changes<br>5-7.49% Lifestyle changes & potential moderate-intensity statin<br>7.5-19.9% Moderate-intensity statin<br>≥ 20% High-intensity statin |



Grundy SM, Stone NJ, Bailey AL, et al. J Am Coll Cardiol. 2019;73(24):e285-e350

# AACE/ACE (2020): TREATMENT RECOMMENDATIONS



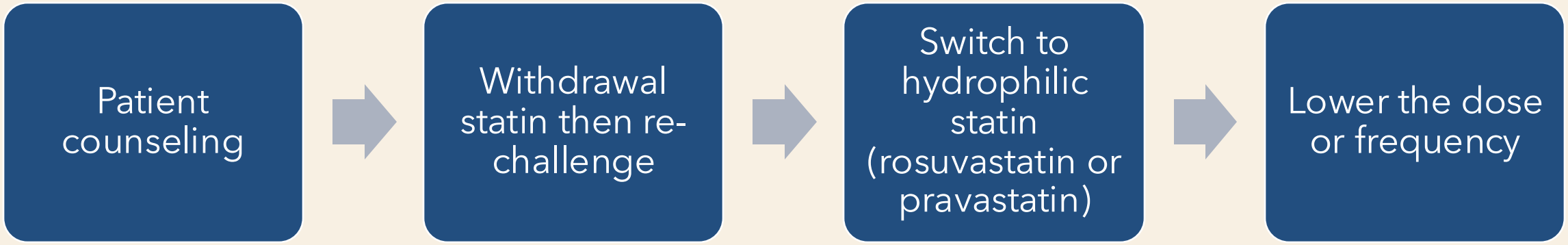

Handelsman Y, et al. *Endocr Pract*. 2020;26(10):1196-1224.

# ACC ECDP ON LDL-C LOWERING (2022): TREATMENT RECOMMENDATIONS

| | | | | |
|---|---|---|---|---|
| Clinical ASCVD at very high risk | Max statin | #1: Ezetimibe and/or PCSK9i, #2 bempedoic acid or inclisiran | | |
| Clinical ASCVD NOT at very high risk | Max statin | Ezetimibe | PCSK9i | Bempedoic acid or inclisiran |
| No clinical ASCVD, LDL ≥190 mg/dL | Max statin | Ezetimibe and/or PCSK9i | Bempedoic acid or inclisiran | |
| 40-75 yo w/ DM, w/o clinical ASCVD, LDL <190 mg/dL | Moderate-intensity statin | High-intensity statin | Ezetimibe | |

Lloyd-Jones, D, Morris, P. et al.. 2022 Oct, 80 (14) 1366–1418.

# STATIN INTOLERANCE




| **Adverse Effect** | **Exclusionary ICD-10 Code** |
|---|---|
| Myalgia | M79.1, M79.10, M79.11, M79.12, M79.18 |
| Myopathy | G72.0, G72.2, G72.89, G72.9 |
| Myositis | M60.80, M60.9 |
| Rhabdomyolysis | M62.82 |
| Other | T46.6X5A |

# NEW TREATMENT OPTIONS

# Which of the following medications do you currently prescribe for patients?

Scan the QR code to answer!

Join at menti.com | use code 7869 0614

Mentimeter

Which of the following medications do you currently prescribe for patients? Select all that apply.

| 0 | 0 | 0 | 0 | 0 | 0 |
|---|---|---|---|---|---|
| Statins | Ezetimibe | Bile acid sequestrants | PCSK9i | Bempedoic acid | Inclisiran |

Menti

Dyslipidemia FMRC

Choose a slide to present

# BEMPEDOIC ACID

| | |
|---|---|
| **Administration** | 180 mg 1 tablet by mouth daily |
| **Medication Class** | Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitor |
| **Warnings/precautions** | Hyperuricemia/gout, hx of tendon rupture |
| **Common side effects** | Bronchitis, anemia, elevated liver enzymes, back pain |
| **Mean LDL-C reduction** | 17-18% |
| **Cost Effectiveness** | Incremental cost-effectiveness ratio of $33,893 per QALY gained & $28,827 per year of life saved |


Perera K, Kam N, Ademi Z, Liew D, Zomer E. *J Clin Lipidol*. 2020;14(6):772-783.

# CLEAR-OUTCOMES (2023)

## Population

- 13,970 patients
- Age 18-85 yr
- LDL-C ≥ 100 mg/dL & 1 of 2 criteria for increased CVD risk (previous CVD event or clinical features placing at high risk of CVD event)

## Results

- Primary outcome: composite of death from CVD causes, nonfatal MI, nonfatal stroke, or coronary revascularization
- 11.7% vs 13.3% [HR 0.87; 95% CI 0.79-0.96]
- **NNT 43 patients for 3+ yr**

Nissen SE, Lincoff AM, Brennan D, et al. *N Engl J Med*. 2023;388(15):1353-1364.

# INCLISIRAN


| | |
|---|---|
| **Administration** | 284 mg as a single subq injection, again at 3 months, and then every 6 months by health care provider |
| **Medication Class** | Small Interfering Ribonucleic Acid (siRNA) |
| **Warnings/precautions** | None |
| **Common side effects** | Injection site reaction, arthralgia, urinary tract infection, diarrhea, bronchitis |
| **Mean LDL-C reduction** | 48-52% |

# INCLISIRAN


| | |
|---|---|
| **Administration** | 284 mg as a single subq injection, again at 3 months, and then every 6 months by |
| **Mean LDL-C reduction** | 48-52% |

CV outcomes trials not yet completed. ORION-4 currently in progress with estimated completion in 2026. VICTORION-2P currently in progress with estimated completion in 2027

# PCSK9i:Evolocumab & Alirocumab


| | |
|---|---|
| **Administration** | **Evolocumab**: 140 mg subq q2 weeks or 420 mg subq q1month<br>**Alirocumab**: 75 mg subq q2weeks or 300 mg subq q1month (can inc to 150 mg subq q2weeks) |
| **Warnings/precautions** | Hypersensitivity reactions |
| **Common side effects** | Nasopharyngitis, injection site reactions, influenza, back pain |
| **Mean LDL-C reduction** | 45-65% |
| **Cost Effectiveness** | Cost-effectiveness threshold $150,000<br>**Incremental Cost-Effectiveness Ratio** between $197,707 and $625,555, depending on the model used |


Azari S, Rezapour A, Omidi N, et al. *Heart Fail Rev*. 2020;25(6):1077-1088.

# FOURIER (2017) EVOLOCUMAB

## Population

- 24,081 patients
- Age 40-85 yr
- ASCVD + 1 major or 2 minor risk factors & LDL-C ≥ 70 mg/dL

## Results

- Primary outcome: composite of death from CVD causes, MI, stroke, hospitalizations for UA or coronary revascularization)
- 5.9% vs 7.4% [HR 0.80; 95% CI 0.73-0.88]
- **NNT 74 patients for 2 yr to prevent a CVD death, MI , or stroke**

Sabatine MS, Giugliano RP, Keech AC, et al. *N Engl J Med*. 2017;376(18):1713-1722.

# ODYSSEY OUTCOMES(2018) ALIROCUMAB

## Population

- 18,924 patients
- Age 40+ yr
- ACS hospitalization 1-12 months before randomization; LDL-C ≥ 70 mg/dL, non-HDL-C ≥ 100 mg/dL, or ApoB ≥ 80 mg/dL

## Results

- Primary outcome: composite of death from CVD causes, nonfatal MI, fatal/nonfatal stroke, or hospitalization for UA
- 9.5% vs 11.1% [HR 0.78; 95% CI 0.68-0.91]
- **NNT 43 (age 45 yr), 26 (age 75 yr), 12 (age 85 yr) for 3 yrs**

Schwartz GG, Steg PG, Szarek M, et al. *N Engl J Med*. 2018;379(22):2097-2107.

# NOVEL LP(A) THERAPIES

- **Antisense-Oligonucleotides (ASOs)**
  - Pelacarsen phase 3 trial Lp(a)-HORIZON anticipated May 2025
- **Small-Interfering RNA Agents (siRNAs)**
  - Lepodisiran phase 2 ALPACA trial
  - Olpasiran phase 3 OCEAN(a) trial anticipated late 2026
  - Zerlasiran phase 1 APOLLO trial, phase 2 ALPACAR-360 trial Dec 2024



# LIFESTYLE MEDICINE

- **Diet**
  - Whole-food, plant-based
  - Mediterranean
  - DASH
- **Physical activity**
  - ≥3 times/wk
  - 150 min/wk moderate-intensity or 75 min/wk high-intensity
  - Resistance training ≥3 2 times/wk
- **Familyheart.org**
  - Risk reduction strategies
  - Support and advocacy
  - Educational webinars and events
  - Printable materials
  - Nutrition guides
  - Genetic testing options

Ornish D, Scherwitz LW, Billings JH, et al.. *JAMA.* 1998;280(23):2001–2007.

# TAKE AWAY POINTS

## Identify the target LDL-C levels for different risk categories according to the latest guidelines

- Different targets based on primary vs secondary and risk
- Secondary prevention <55 (extreme risk) or <70 mg/dL (very high risk)

## Outline the stepwise approach to initiating and adjusting lipid-lowering therapy based on patient response and tolerance

- Max statin→ ezetimibe →PCSK9i→ bempedoic acid (oral) or inclisiran

## Analyze recent clinical trial data on the efficacy and safety of novel non-statin therapies in reducing cardiovascular events

- CV benefits data with PCSK9i and bempedoic acid

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- Gordon M, Di Bartolo IM. Using Race with Caution in the ASCVD Calculator. Am Fam Physician. 2021;104(3):292-294.
- Perera K, Kam N, Ademi Z, Liew D, Zomer E. Bempedoic acid for high-risk patients with CVD as adjunct lipid-lowering therapy: A cost-effectiveness analysis. J Clin Lipidol. 2020;14(6):772-783. doi:10.1016/j.jacl.2020.08.013
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# THANK YOU

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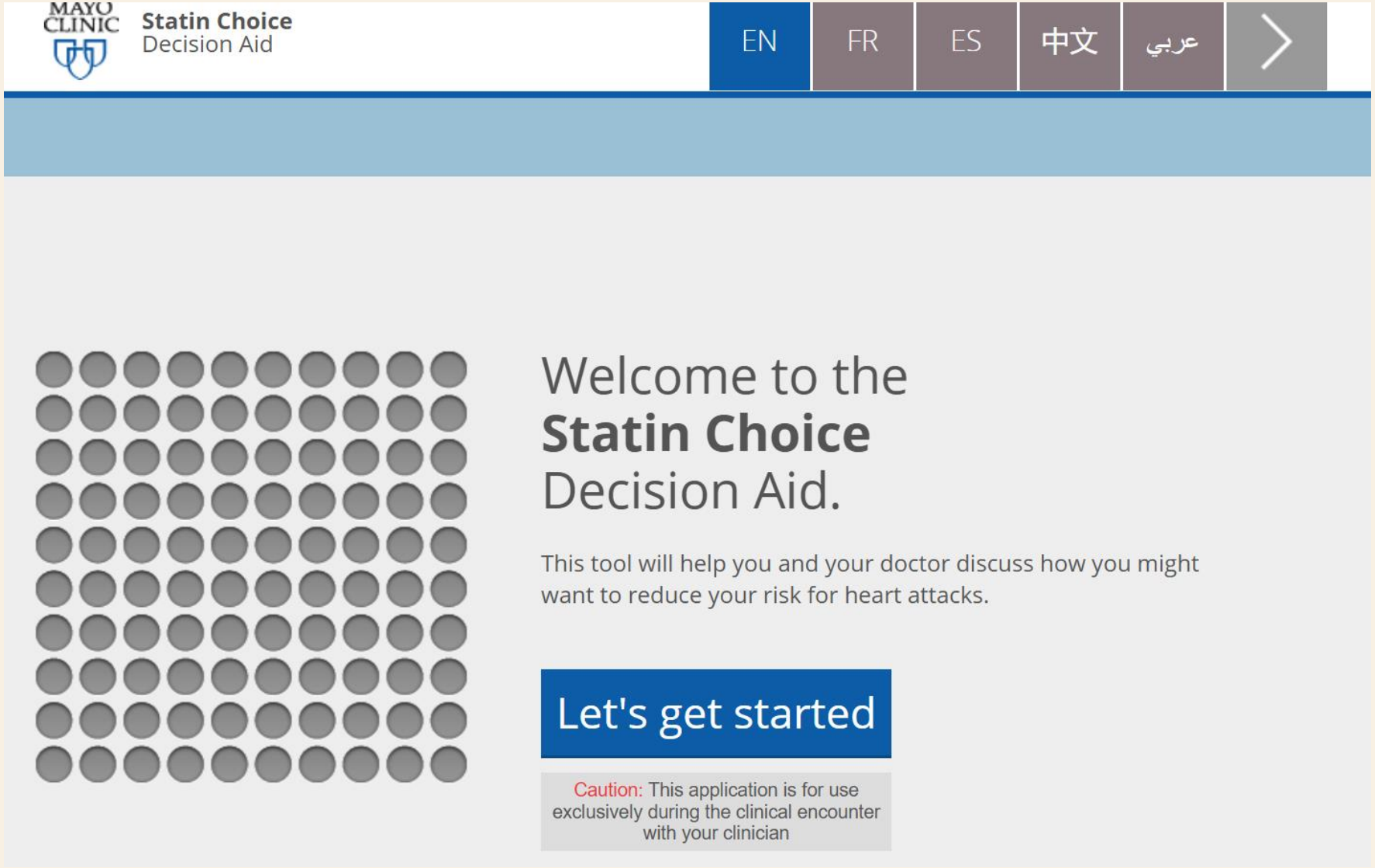
# CORONARY ARTERY CALCIUM SCORING

| CACS | Recommendations | LDL-C Desired |
|---|---|---|
| 1-99 AU and < 75$^{th}$ percentile for age/sex/race | Favor moderate-intensity statin therapy, especially in those ≥ 55 yr | 30%-49% LDL-C reduction, consider high intensity if <30% reduction or LDL-C remains ≥ 100 mg/dL |
| >100 AU and > 75$^{th}$ percentile for age/sex/race | Moderate to high intensity statin | LDL-C reduction, based on statin intensity |
| >300 AU and >75$^{th}$ percentile for age/sex/race | High intensity statin | ≥ 50% LDL-C reduction, consider ezetimibe if <50% LDL-C reduction or if LDL-C remains ≥ 70 mg/dL |
| >1000 AU | High intensity statin and possibly add on LDL-C lowering agent | ≥ 50% LDL-C reduction, consider adding PCKS9i to statin +ezetimibe if <50% LDL-C reduction or if LDL-C remains ≥ 70 mg/dL |

# MAYO CLINIC DECISION AID




Statin Choice Decision AID - Site

# RISK ENHANCERS IN THE 2018 ACC/AHA BLOOD CHOLESTEROL GUIDELINES

- ABI <0.9
- CKD
- Early menopause (age <40 yr)
- Elevated ApoB ≥ 130 mg/dL
- Elevated hs-CRP ≥ 2 mg/L
- Elevated Lp(a) ≥ 125 nmol/L
- Elevated TG ≥ 175 mg/dL
- Family history of premature ASCVD ( male <55 yr, female <65 yr)
- High-risk ethnic groups (South Asian ancestry)
- Inflammatory diseases (RA, psoriasis, HIV)
- Metabolic syndrome
- Persistently elevated LDL-C concentrations ≥ 160 mg/dL
- Preeclampsia

Annals of Internal Medicine

ORIGINAL RESEARCH

# Benefits and Risks Associated With Statin Therapy for Primary Prevention in Old and Very Old Adults

## Real-World Evidence From a Target Trial Emulation Study

Wanchun Xu, MPhil; Amanda Lauren Lee, MS; Cindy Lo Kuen Lam, MD; Goodarz Danaei, ScD; and Eric Yuk Fai Wan, PhD

JAMA Internal Medicine | Original Investigation | LESS IS MORE

# Evaluation of Time to Benefit of Statins for the Primary Prevention of Cardiovascular Events in Adults Aged 50 to 75 Years

## A Meta-analysis

Lindsey C. Yourman, MD; Irena S. Cenzer, MA; W. John Boscardin, PhD; Brian T. Nguyen, BA; Alexander K. Smith, MD, MPH; Mara A. Schonberg, MD, MPH; Nancy L. Schoenborn, MD, MHS; Eric W. Widera, MD; Ariela Orkaby, MD, MPH; Annette Rodriguez, MA; Sei J. Lee, MD, MAS

In older adults without CVD, treating 100 (NNT) persons with statins for **2.5 years time-to-benefit** prevented 1 MACE

# A NONINFERIOR RCT COMPARED TREAT-TO-TARGET VS HIGH-INTENSITY STATINS

- Patients with coronary artery disease in South Korea (n=4400)
- Intervention group LDL target 50-70 mg/dL
- Comparison group received high intensity statin (rosuvastatin 20 mg or atorvastatin 40mg)
- Primary end point was a 3-year composite of death, myocardial infarction, stroke, or coronary revascularization
  - 8.1% in treat to target
  - 8.7% in high intensity statin (mean LDL was 68.4 mg/dL)
- Noninferior treat-to-target vs high-intensity statins

Observational Study > CMAJ. 2020 Apr 27;192(17):E442-E449. doi: 10.1503/cmaj.190848.

# Calibration and discrimination of the Framingham Risk Score and the Pooled Cohort Equations

Dennis T Ko [1], Atul Sivaswamy [2], Maneesh Sud [2], Gynter Kotrri [2], Paymon Azizi [2], Maria Koh [2], Peter C Austin [2], Douglas S Lee [2], Idan Roifman [2], George Thanassoulis [2], Karen Tu [2], Jacob A Udell [2], Harindra C Wijeysundera [2], Todd J Anderson [2]

Affiliations + expand

PMID: 32392491 PMCID: PMC7207198 DOI: 10.1503/cmaj.190848

The predicted event rate of 5.78% by the Framingham Risk Score and 3.51% by the Pooled Cohort Equations at 5 years **overestimated** observed **event rates by 101% and 115%**, respectively

# STATINS

| Low Intensity | Moderate Intensity | High Intensity |
| --- | --- | --- |
| LDL lowering <30% | LDL lowering 30-49% | LDL lowering 30-49% |
| Simvastatin 10 mg | Atorvastatin 10&20 mg | Atorvastatin 40&80 mg |
| Pravastatin 10&20 mg | Rosuvastatin 5&10 mg | Rosuvastatin 20&40 mg |
| Lovastatin 20 mg | Simvastatin 20&40 mg | |
| Fluvastatin 20-40 mg | Pravastatin 40&80 mg | |
| | Lovastatin 40&80 mg | |
| | Fluvastatin XL 80 mg | |
| | Pitavastatin 1-4 mg | |

*Simvastatin, Fluvastatin must be taken at bedtime
**Lovastatin must be taken with evening meal

# Getting Back to Our "Why": Reclaiming the Joy in Medicine

Caitlin Matthis, DO, FAAFP
UPMC Washington Family Medicine Residency
March 7, 2025

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# Who do we have here today?

ⓘ Start presenting to display the poll results on this slide.

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# What is your happiness score?

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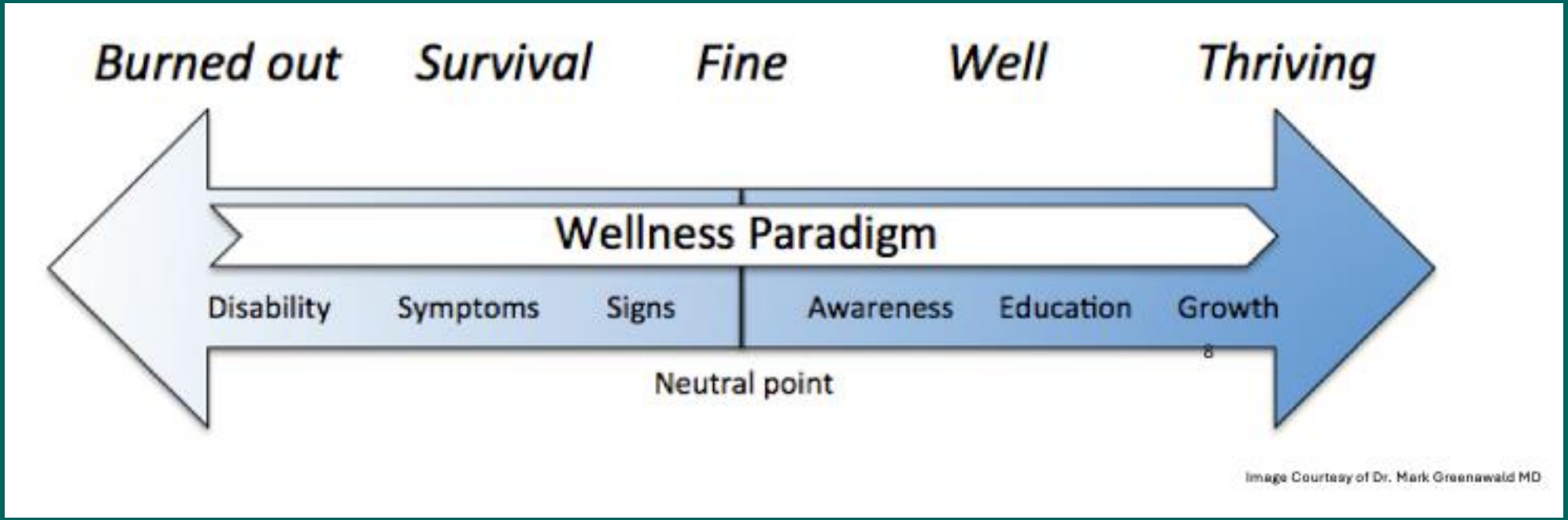
# Why I Am Here Today: My Burnout Story


# Where is your wellness currently?



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# Where is your wellness currently?

ⓘ Start presenting to display the poll results on this slide.

# Objectives

Describe the current landscape of family medicine.

Understand our “why” for choosing family medicine- including through the framework of our core values.

Learn the power of gratitude practices on our overall happiness.

# Objectives

Describe the current landscape of family medicine.

# Landscape of Medicine

AAFP CME

## Why Are We Here

### *The Burnout Impact on Physician Well-being*

**Margot Savoy, MD, MPH, FAAFP**

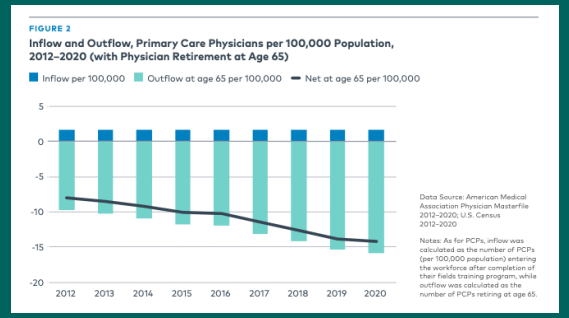
May 6, 2024 | Scottsdale, AZ

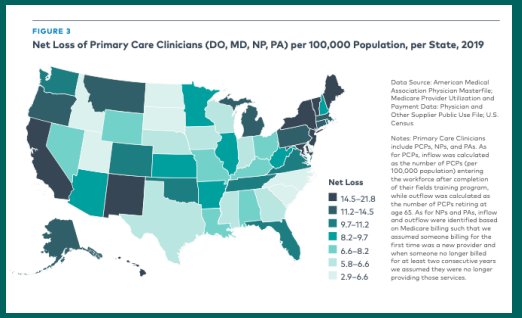
2024 Physician Health & Well-being Conference

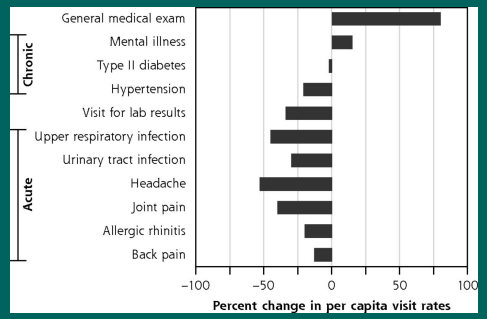
AAFP CME

# Struggle of Family Medicine

- There are less of us around
- We are seeing a lot of complex patients
- We are doing a lot of paperwork
- This is burning us out




| | 2008[a] | 2015[a] | Percent Change[b] | 8-Year Trend[c] (95% CI) |
|---|---|---|---|---|
| Mean visit duration, min[d] | 19.3 | 21.6 | 12 | 2.4 (1.1-3.8) |
| Mean diagnoses, No.[e] | 2.0 | 2.3 | 15 | 0.30 (0.16-0.43) |
| Mean medications, No.[f] | 3.1 | 3.9 | 26 | 0.82 (0.59-1.1) |
| Mean preventive services, No.[g] | 0.34 | 0.59 | 76 | 0.24 (0.12-0.36) |
| Mean procedures, No.[h] | 0.06 | 0.08 | 33 | 0.02 (0.01-0.03) |

NACMS = National Ambulatory Medical Care Survey.

**Table 3. Average Time Spent Per Day by EHR Task Category, Comparing Work Hours and After Hours**

| EHR Task Category | Time Spent per Day, min: Work Hours | After Hours | Ratio | Total Time Spent per Day, min (% of Daily Total) |
|---|---|---|---|---|
| Clerical | | | | |
| Documentation | 64 | 20 | 3.2 | 84 (23.7) |
| Order Entry | 35 | 8 | 4.4 | 43 (12.1) |
| Billing and Coding | 10 | 4 | 2.5 | 14 (3.9) |
| System Security | 8 | 2 | 4.0 | 10 (2.8) |
| Administrative | 4 | 2 | 2.0 | 6 (1.7) |
| Subtotal | 121 | 36 | 3.4 | 157 (44.2) |
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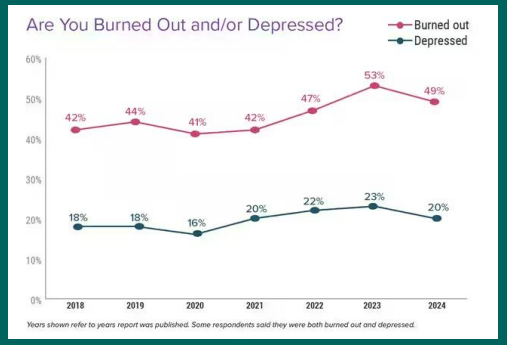


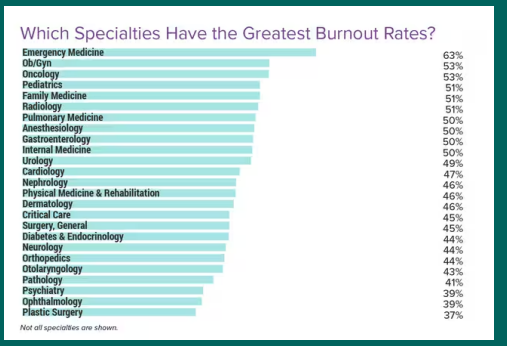


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# Struggle of Family Medicine

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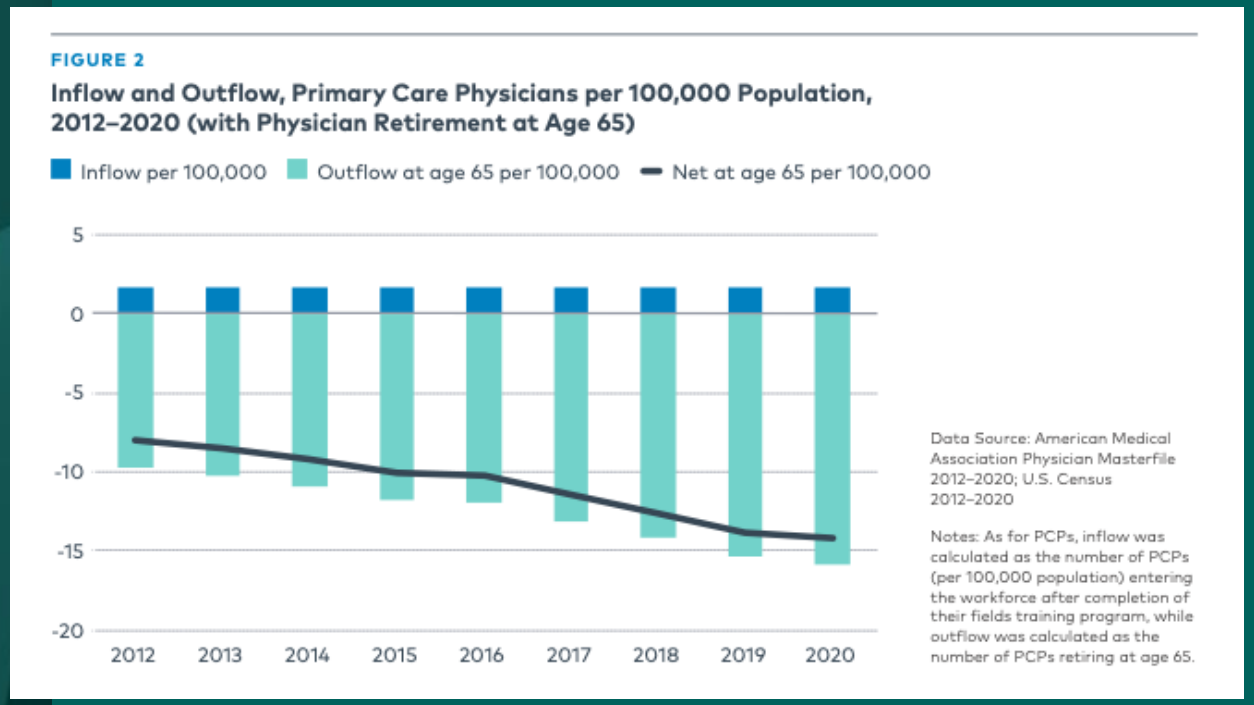


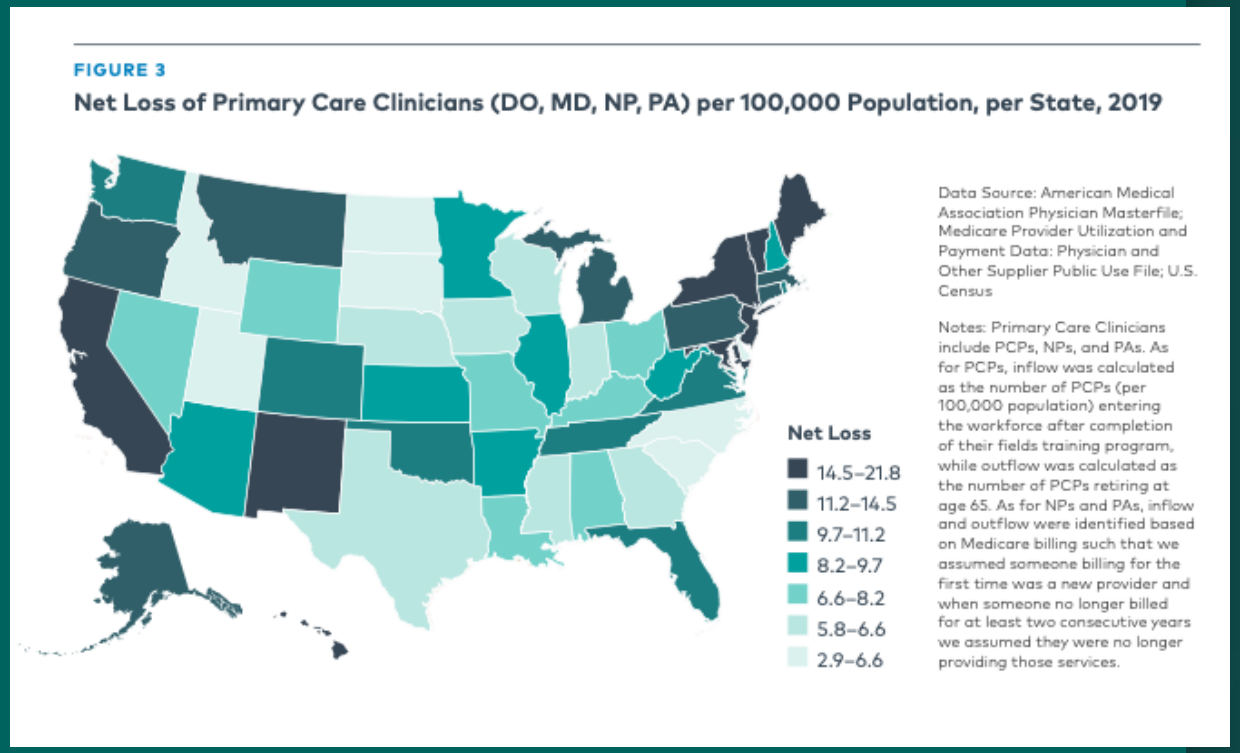


Huffstetler, A., A. Greiner, and A. Siddiqi. "Health is primary: charting a path to equity and sustainability." *Primary Care Collaborative and the Robert Graham Center. https://www. graham-center. org/content/dam/rgc/documents/publications-reports/reports/pcc-evidence-report-2023. pdf. Published* (2023).

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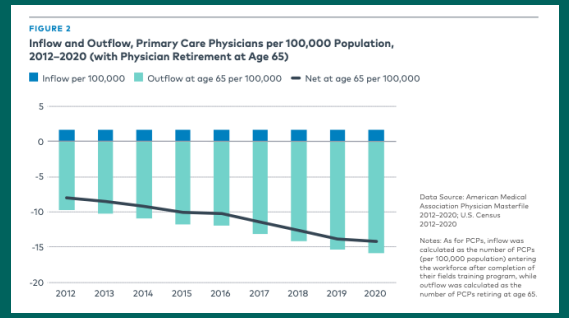


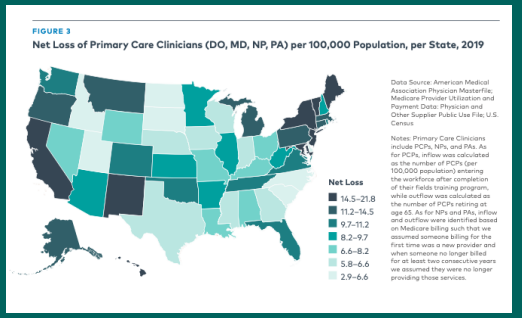


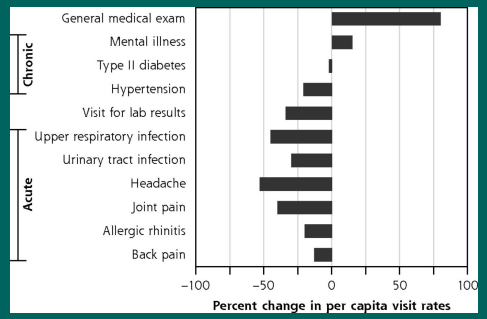


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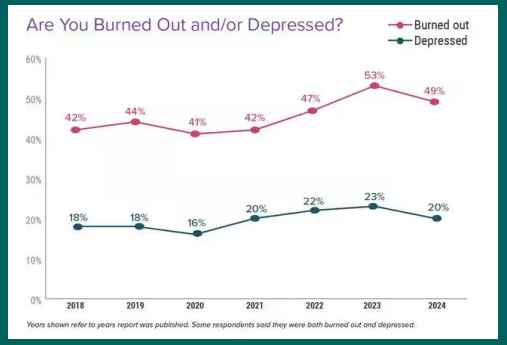


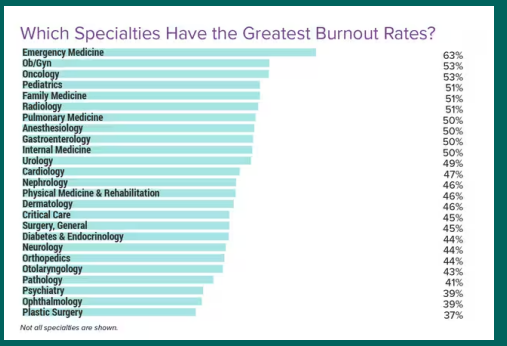


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# Struggle of Family Medicine

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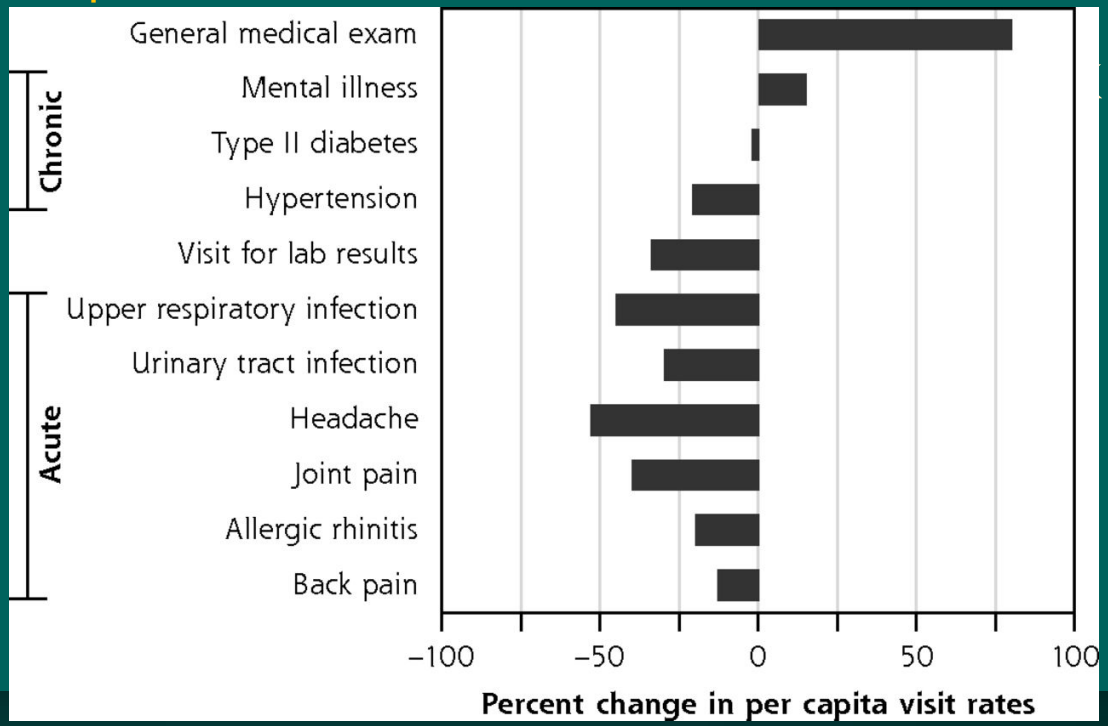


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Rao A, Shi Z, Ray KN, Mehrotra A, Ganguli I. National Trends in Primary Care Visit Use and Practice Capabilities, 2008-2015. Ann Fam Med. 2019 Nov;17(6):538-544. doi: 10.1370/afm.2474. PMID: 31712292; PMCID: PMC6846275.

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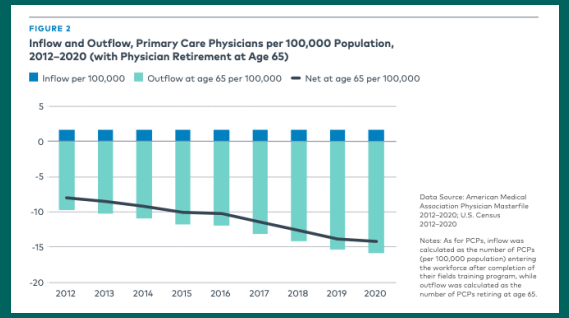


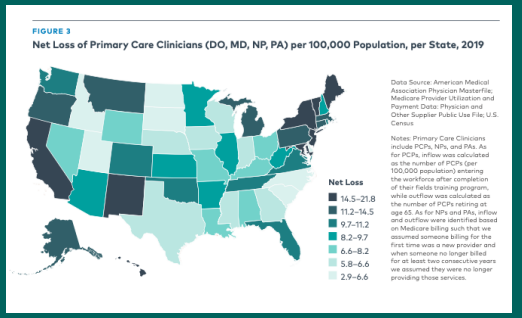


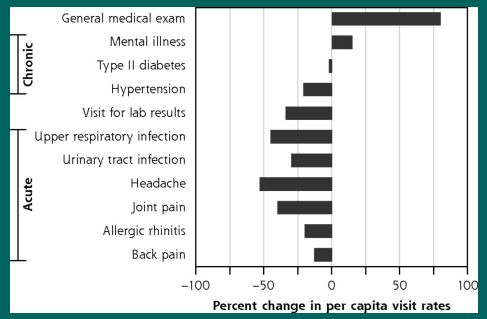


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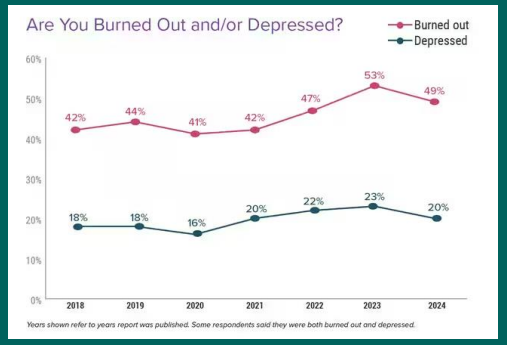


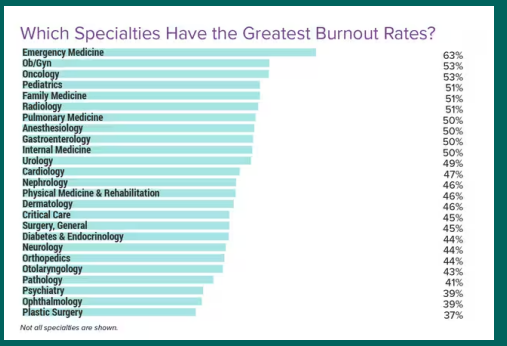


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# Struggle of Family Medicine

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-average 11.4-hour workday
-1/2 of this is spent in the EHR
-average of almost 1 ½ after hours EMR use

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Arndt, Brian G., et al. "Tethered to the EHR: primary care physician workload assessment using EHR event log data and time-motion observations." *The Annals of Family Medicine* 15.5 (2017): 419-426.

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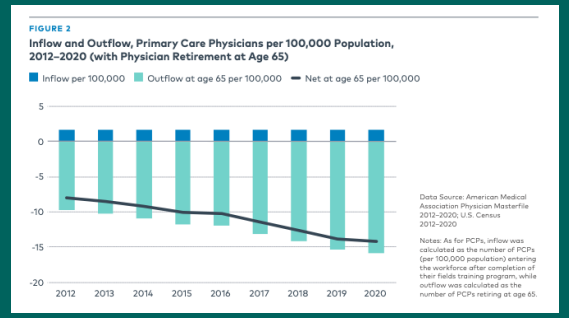


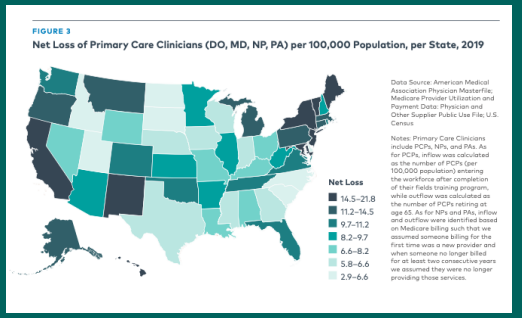


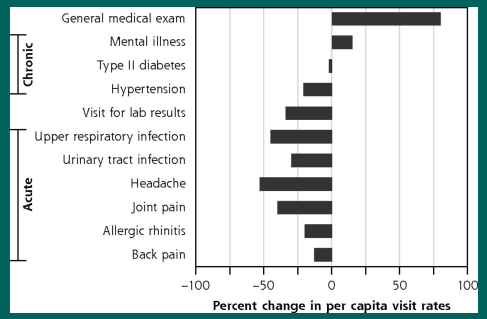


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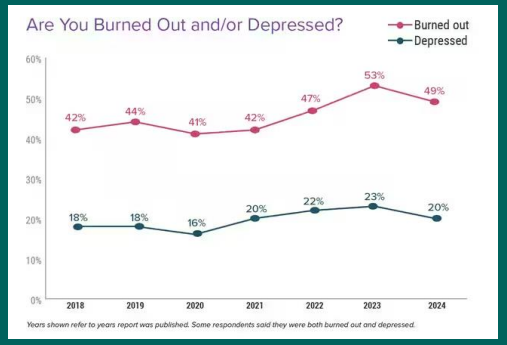


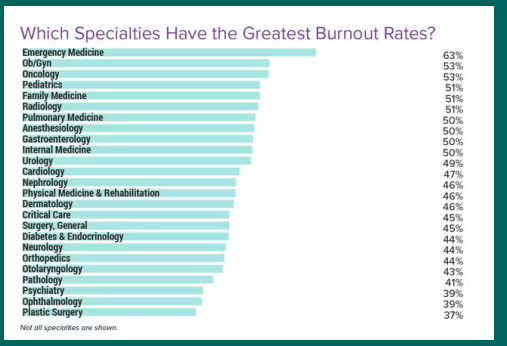


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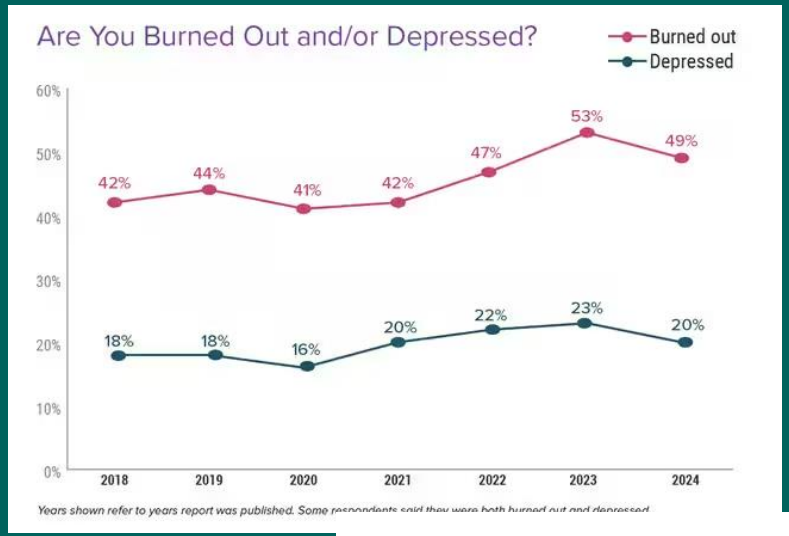
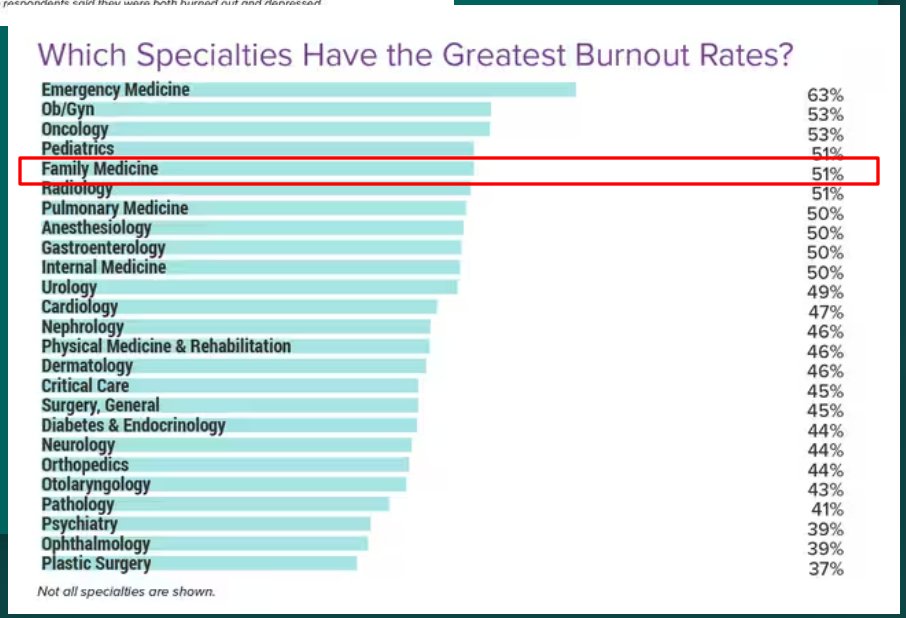
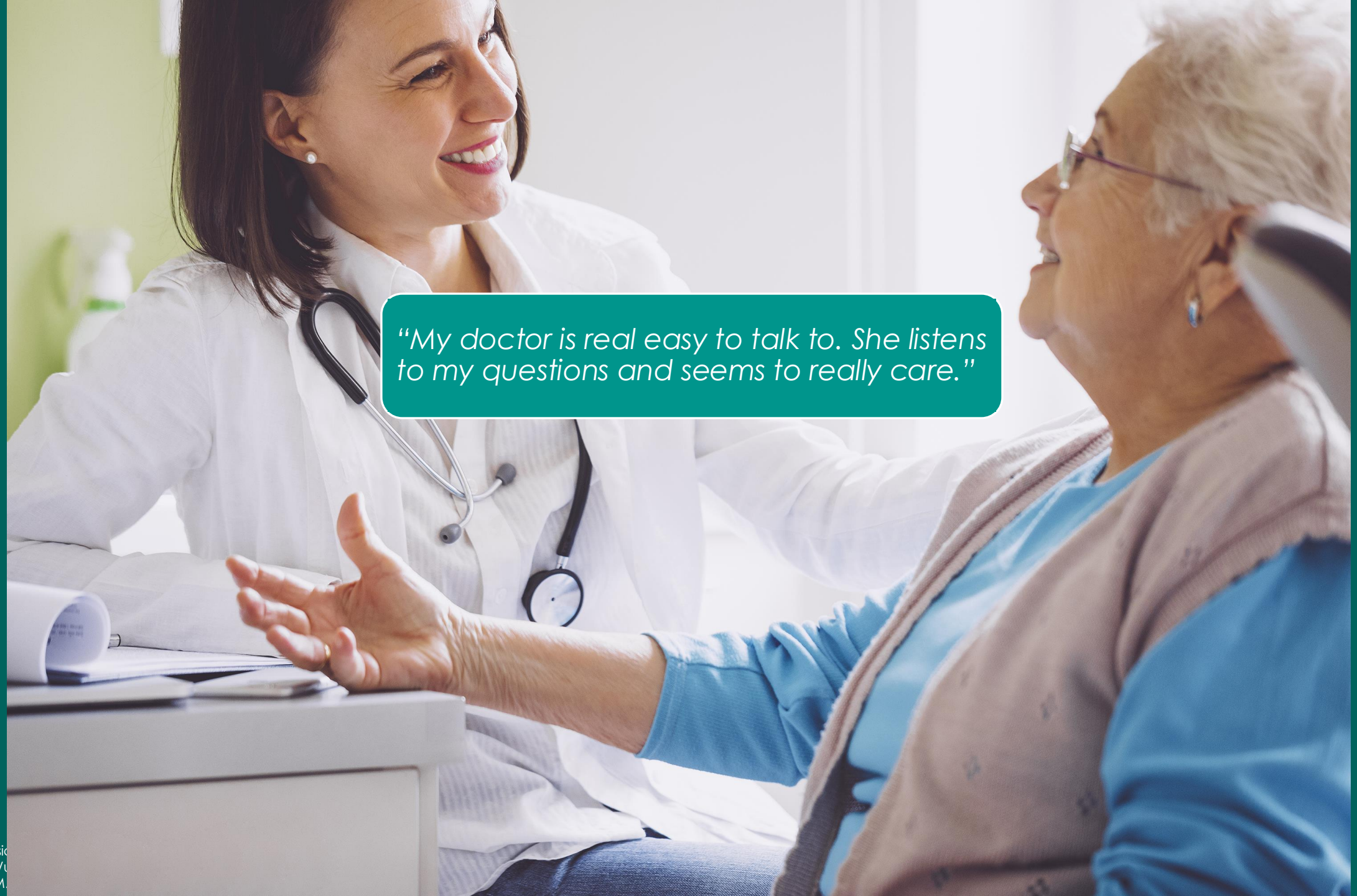



McKenna, Jon. Medscape Physician Burnout and Depression Report 2024: 'We Have Much Work to Do". 26 Jan 2024.

# WHAT WE DO MATTERS




The Physi
content/u
Savoy, M.

*"Because he is extremely knowledgeable and is responsible for my being alive today."*

The Physician's
content/uploa
Savoy, M., MD


"(The) doctor takes the time to converse and examine, striving to help me be healthier."

*"She is very pleasant and friendly. She always prescribes the right medicine the first time around."*

The Phys
content/
Savoy, M


*"Because he is an excellent doctor. He knows me and understands my medical needs."*

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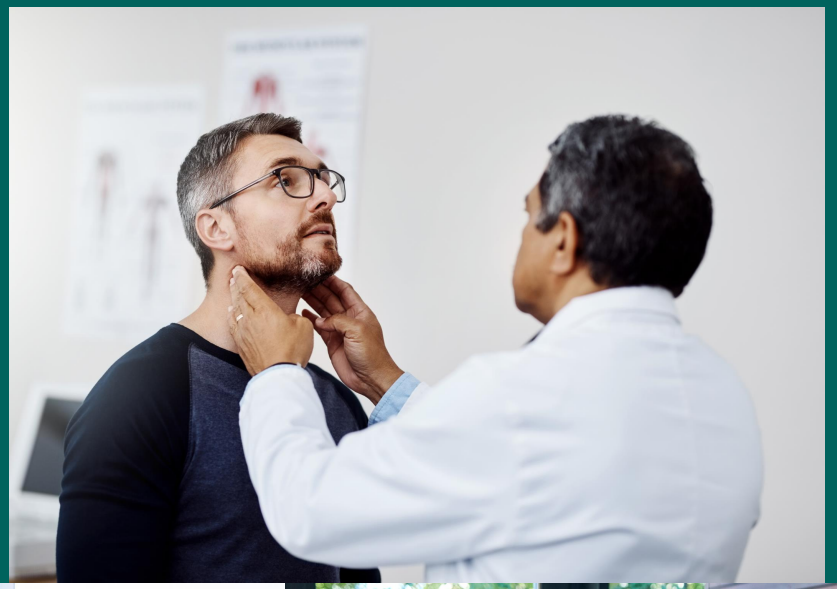


The Physician's Foundation (19 January 2022) *Consumer attitudes toward family / primary care physicians ...* Available at: https://physiciansfoundation.org/wp-content/uploads/2018/01/Physicians_Foundation_Consumer_Omnibus_Survey.pdf (Accessed: 28 February 2025).
Savoy, M., MD, MPH, FAAFP (2024, May 6). *Why Are We Here: The Burnout Impact on Physician Well-Being* [2024 Physician Health and Well-Being Conference Presentation].

# YOU LITERALLY GIVE US LIFE

Basu S, Berkowitz SA, Phillips RL, Bitton A, Landon BE, Phillips RS. Association of Primary Care Physician Supply With Population Mortality in the United States, 2005-2015. *JAMA Intern Med.* 2019;179(4):506–514. doi:10.1001/jamainternmed.2018.7624

Savoy, M., MD, MPH, FAAFP (2024, May 6). *Why Are We Here: The Burnout Impact on Physician Well-Being* [2024 Physician Health and Well-Being Conference Presentation].

# Objectives

Describe the current landscape of family medicine.

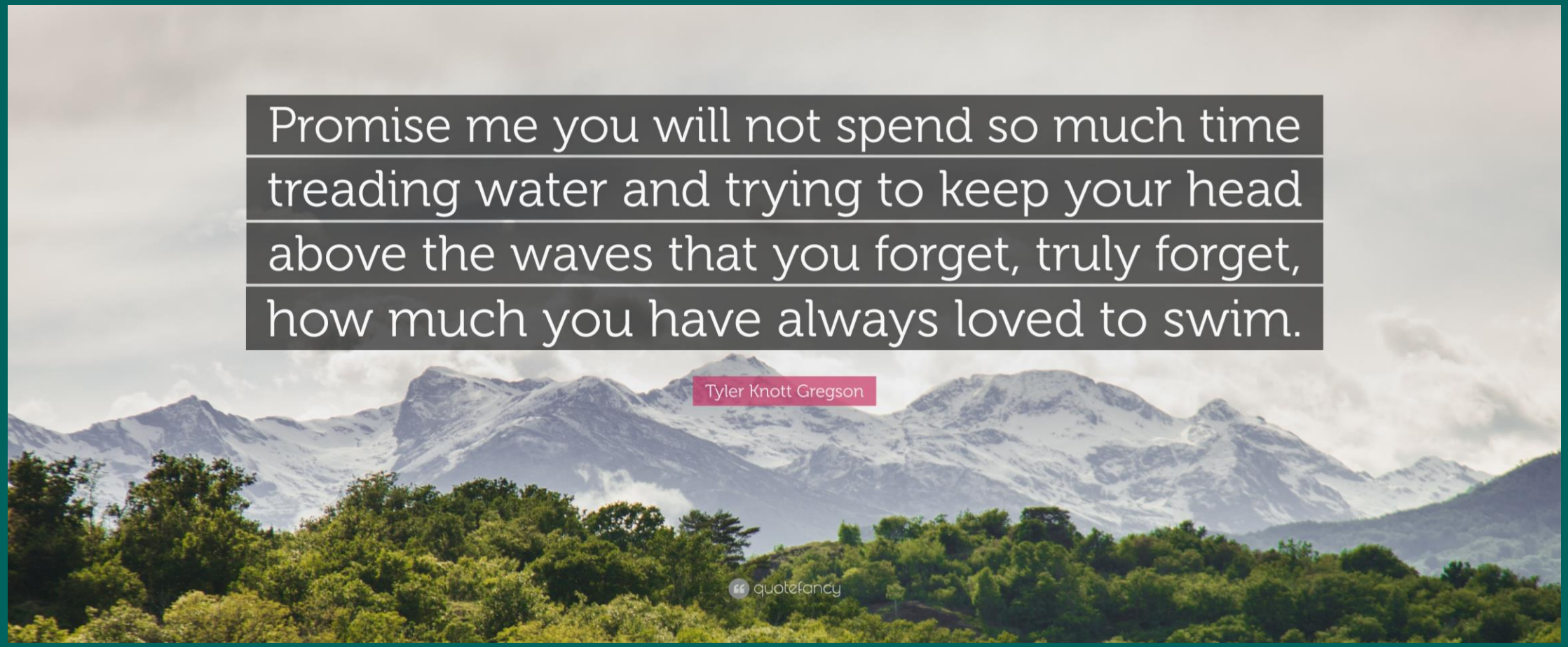
Understand our “why” for choosing family medicine- including through the framework of our core values.

Learn the power of gratitude practices on our overall happiness.

# Objectives

Understand our “why” for choosing family medicine- including through the framework of our core values.

# YOUR WHY


Promise me you will not spend so much time
treading water and trying to keep your head
above the waves that you forget, truly forget,
how much you have always loved to swim.
Tyler Knott Gregson
quotefancy

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# Why did you choose medicine?

ⓘ Start presenting to display the poll results on this slide.

# Core Values Exercise

- Circle the 10-15 that first come to mind
- Slowly narrow down to:

2

*Brown, Brené. Dare to lead list of values* (2023) *Brené Brown*. Available at: https://brenebrown.com/resources/dare-to-lead-list-of-values/ (Accessed: 27 February 2025).

dare to lead™

## *List of* VALUES

| | | | |
|---|---|---|---|
| Accountability | Ethics | Kindness | Self-respect |
| Achievement | Excellence | Knowledge | Serenity |
| Adaptability | Fairness | Leadership | Service |
| Adventure | Faith | Learning | Simplicity |
| Altruism | Family | Legacy | Spirituality |
| Ambition | Financial stability | Leisure | Sportsmanship |
| Authenticity | Forgiveness | Love | Stewardship |
| Balance | Freedom | Loyalty | Success |
| Beauty | Friendship | Making a difference | Teamwork |
| Being the best | Fun | Nature | Thrift |
| Belonging | Future generations | Openness | Time |
| Career | Generosity | Optimism | Tradition |
| Caring | Giving back | Order | Travel |
| Collaboration | Grace | Parenting | Trust |
| Commitment | Gratitude | Patience | Truth |
| Community | Growth | Patriotism | Understanding |
| Compassion | Harmony | Peace | Uniqueness |
| Competence | Health | Perseverance | Usefulness |
| Confidence | Home | Personal fulfillment | Vision |
| Connection | Honesty | Power | Vulnerability |
| Contentment | Hope | Pride | Wealth |
| Contribution | Humility | Recognition | Well-being |
| Cooperation | Humor | Reliability | Wholeheartedness |
| Courage | Inclusion | Resourcefulness | Wisdom |
| Creativity | Independence | Respect | |
| Curiosity | Initiative | Responsibility | *Write your own:* |
| Dignity | Integrity | Risk -taking | _____ |
| Diversity | Intuition | Safety | _____ |
| Environment | Job security | Security | _____ |
| Efficiency | Joy | Self-discipline | _____ |
| Equality | Justice | Self-expression | _____ |

# PAIR AND SHARE

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# Using your core values: Why did you choose medicine?

ⓘ Start presenting to display the poll results on this slide.

# Objectives

Describe the current landscape of family medicine.

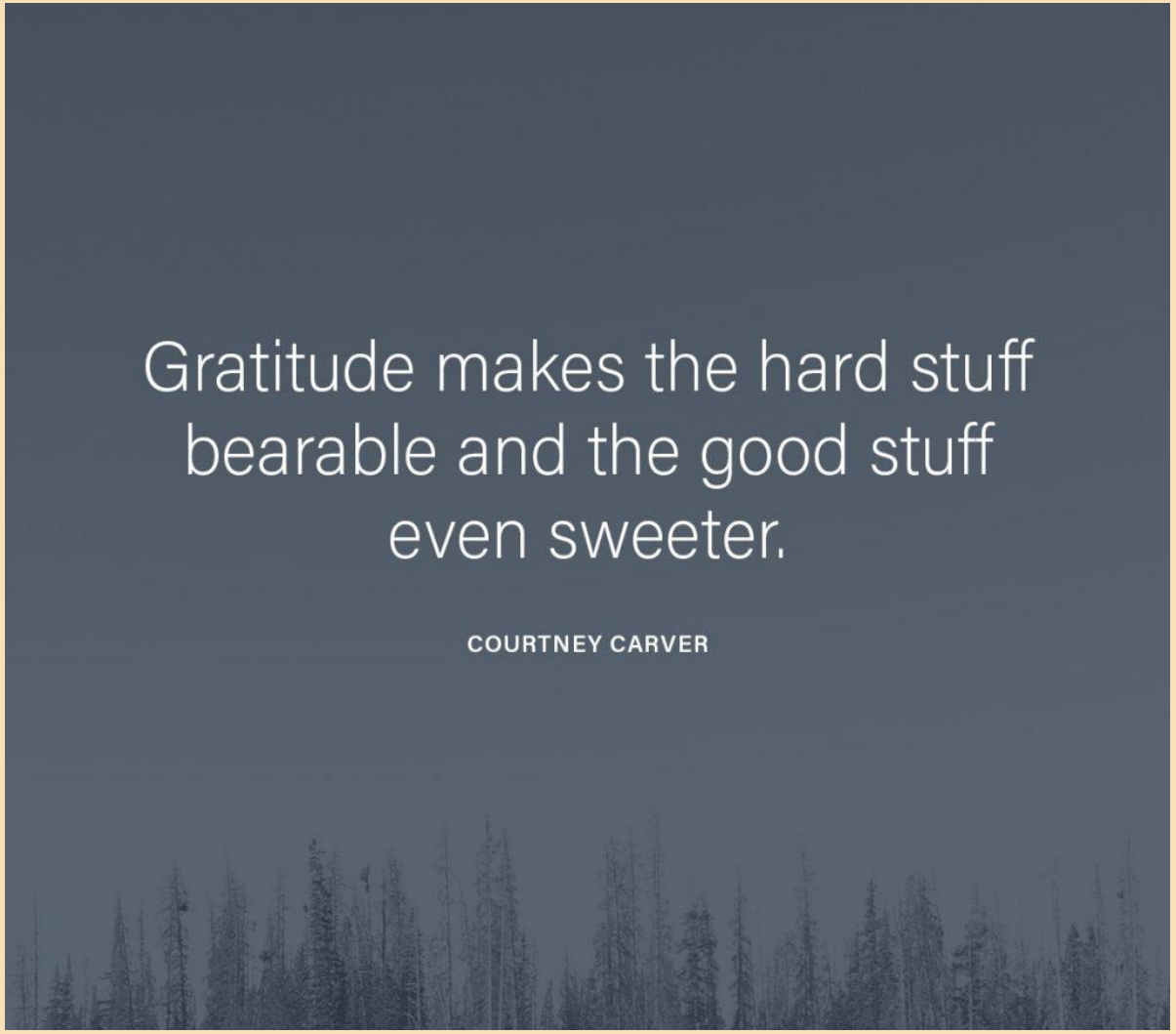
Understand our “why” for choosing family medicine- including through the framework of our core values.

Learn the power of gratitude practices on our overall happiness.

# Objectives

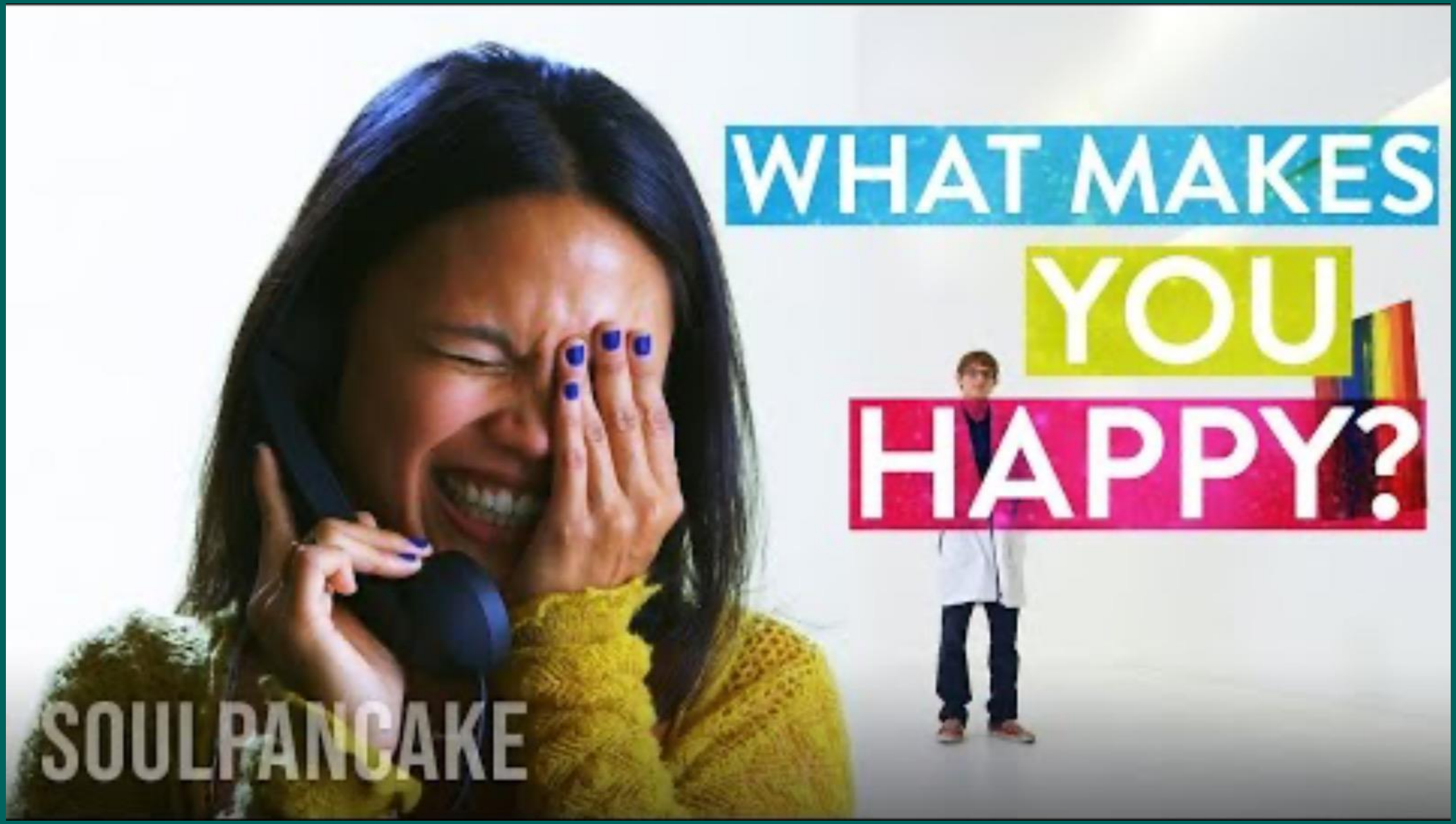
Learn the power of gratitude practices on our overall happiness.

# THE POWER (AND SCIENCE) OF GRATITUDE



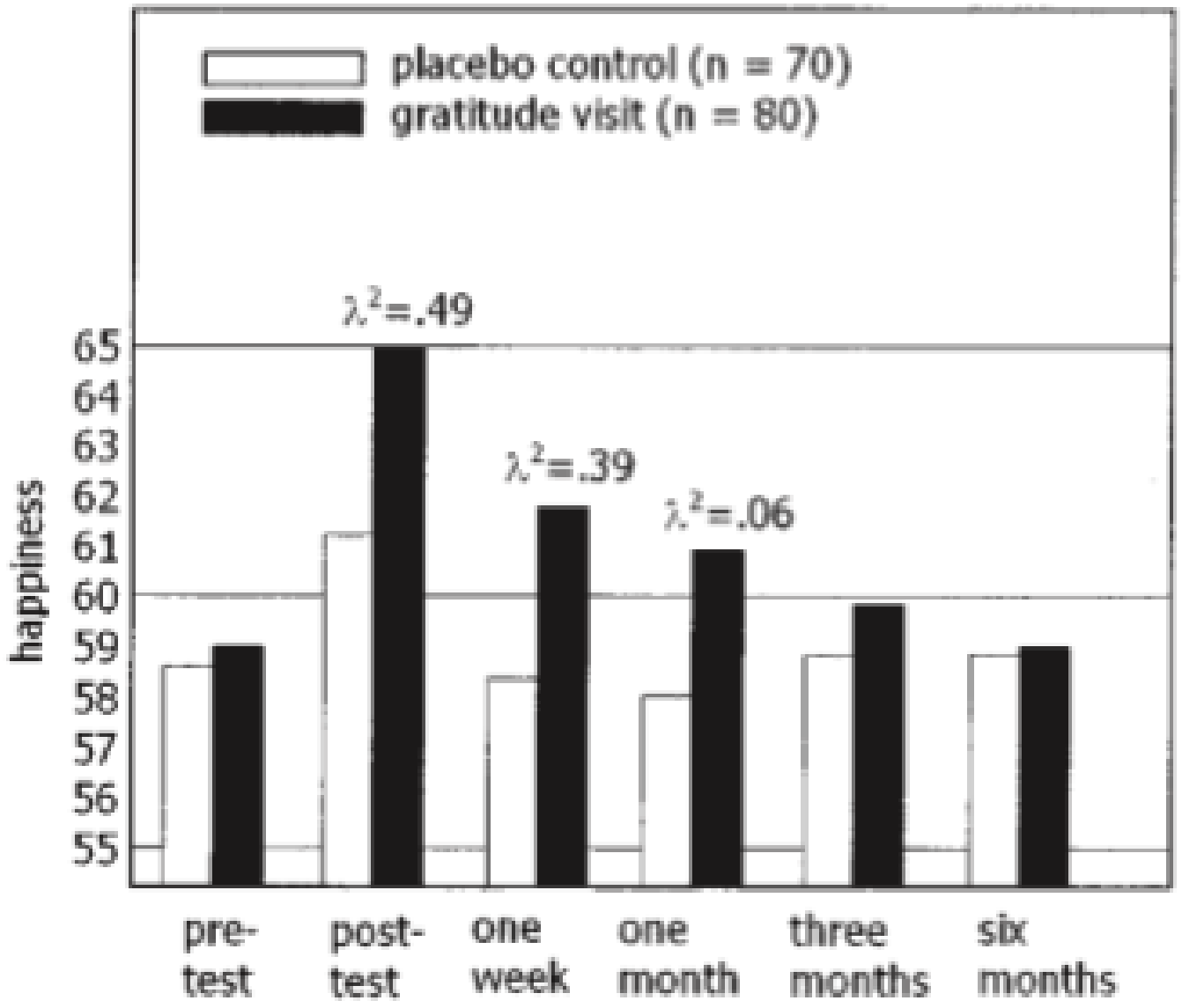
# Gratitude: Writing Activity

- Think of someone from your journey through medicine that you are grateful for
- Write a paragraph explaining why you are grateful for them.




*An Experiment in Gratitude | The Science of Happiness* (2013) *YouTube*. Available at: https://www.youtube.com/watch?start=17&feature=oembed&v=oHv6vTKD6lg (Accessed: 27 February 2025).

## Steen Happiness Index Scores



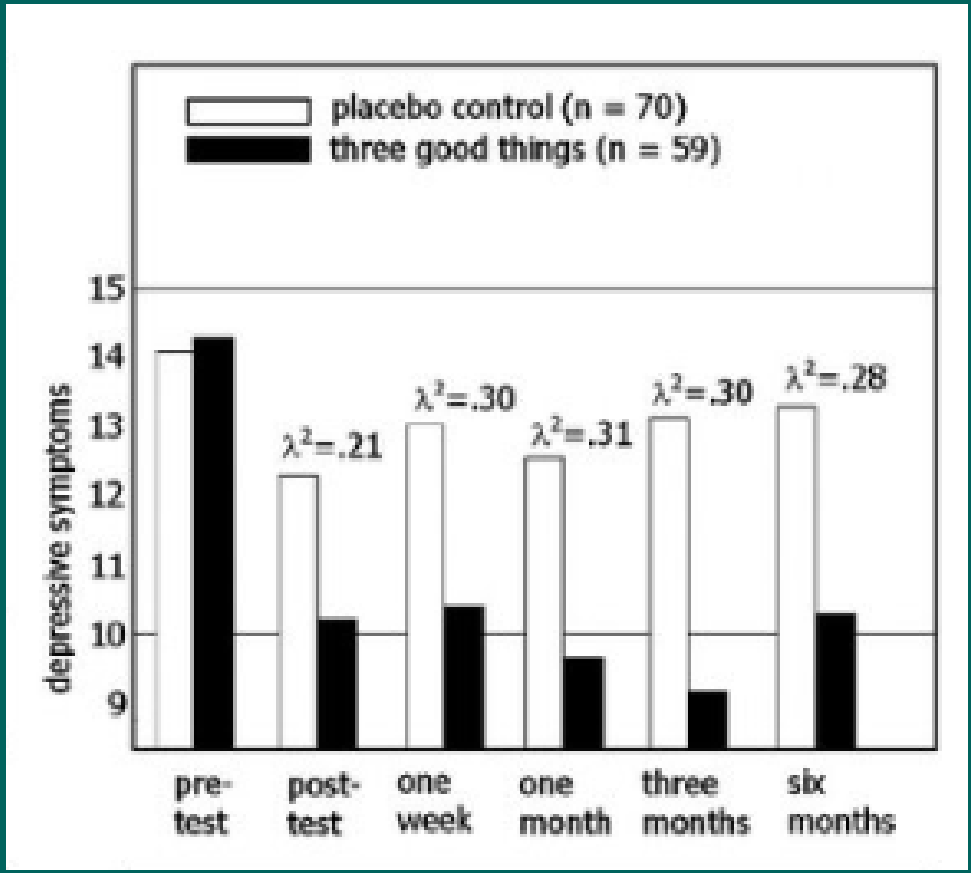

Seligman ME, Steen TA, Park N, Peterson C. Positive psychology progress: empirical validation of interventions. *Am Psychol*. 2005;60(5):410–421

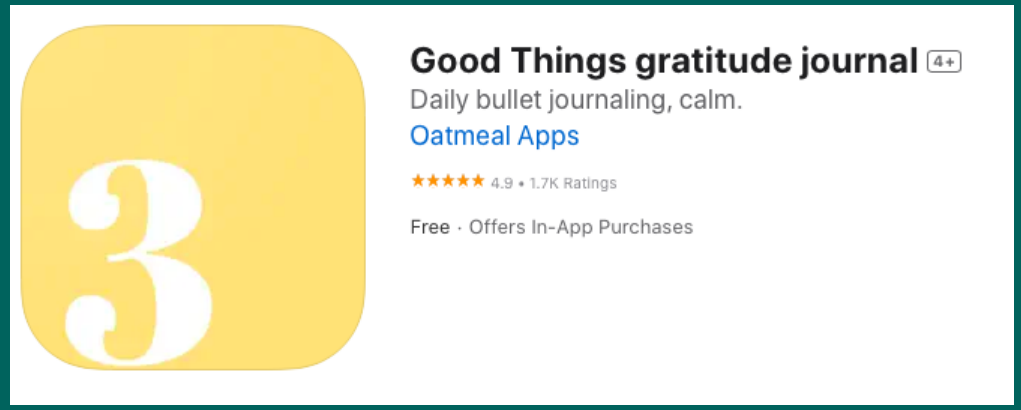
# 3 Good Things

- Reflect and write down 3 good things that happened yesterday.
- Write 1-2 sentences explaining why they were good.

Seligman ME, Steen TA, Park N, Peterson C. Positive psychology progress: empirical validation of interventions. *Am Psychol*. 2005;60(5):410–421

# 3 Good Things




Seligman ME, Steen TA, Park N, Peterson C. Positive psychology progress: empirical validation of interventions. *Am Psychol*. 2005;60(5):410–421

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# What are your 3 Good Things?

ⓘ Start presenting to display the poll results on this slide.

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# What is your happiness score?

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# Audience Q&A

ⓘ Start presenting to display the audience questions on this slide.

# Resources


1. *An Experiment in Gratitude | The Science of Happiness* (2013) *YouTube*. Available at: https://www.youtube.com/watch?start=17&feature=oembed&v=oHv6vTKD6lg (Accessed: 27 February 2025).
2. Arndt, Brian G., et al. "Tethered to the EHR: primary care physician workload assessment using EHR event log data and time-motion observations." *The Annals of Family Medicine* 15.5 (2017): 419-426.
3. Basu S, Berkowitz SA, Phillips RL, Bitton A, Landon BE, Phillips RS. Association of Primary Care Physician Supply With Population Mortality in the United States, 2005-2015. *JAMA Intern Med*. 2019;179(4):506–514. doi:10.1001/jamainternmed.2018.7624
4. *Brown, Brené. Dare to lead list of values* (2023) *Brené Brown*. Available at: https://brenebrown.com/resources/dare-to-lead-list-of-values/ (Accessed: 27 February 2025).
5. Huffstetler, A., A. Greiner, and A. Siddiqi. "Health is primary: charting a path to equity and sustainability." *Primary Care Collaborative and the Robert Graham Center. https://www. graham-center. org/content/dam/rgc/documents/publications-reports/reports/pcc-evidence-report-2023. pdf. Published* (2023).
6. McKenna, Jon. Medscape Physician Burnout and Depression Report 2024: 'We Have Much Work to Do". 26 Jan 2024.
7. Rao A, Shi Z, Ray KN, Mehrotra A, Ganguli I. National Trends in Primary Care Visit Use and Practice Capabilities, 2008-2015. Ann Fam Med. 2019 Nov;17(6):538-544. doi: 10.1370/afm.2474. PMID: 31712292; PMCID: PMC6846275.
8. Savoy, M., MD, MPH, FAAFP (2024, May 6). *Why Are We Here: The Burnout Impact on Physician Well-Being* [2024 Physician Health and Well-Being Conference Presentation].
9. Seligman ME, Steen TA, Park N, Peterson C. Positive psychology progress: empirical validation of interventions. *Am Psychol*. 2005;60(5):410–421


Images:

1. Gratitude Image: https://bemorewithless.com/grace-gratitude/

2. Swim Image: Images from Quotefancy.com

3.Wellness Continuum: Dr. Mark Greenawald

# Thank You

Caitlin Matthis, DO, FAAFP
matthiscc@upmc.edu

# PEP and PrEP

St Margaret Family Medicine Refresher Course
Jesse Gordon D.O.
March 7 2025

# Outline

HIV statistics
PEP Criteria, Meds, Barriers
PrEP Criteria, Meds, Monitoring, Barriers
Doxy PEP
Contact info

# HIV statistics

**World** 40 million people living with HIV

**US** 1.2 million people living with HIV

**Pennsylvania** 36,000 people living with HIV

**Allegheny County** 4000 people living with HIV.

66 new cases in 2023. In 2015 139 new cases.

# Who is at risk?

- Gay, bisexual, and other men who have sex with men, in particular Black, Latino, and American Indian/Alaska Native men
- Transgender women
- People who inject drugs
- Black women
- Youth aged 13–24 years
- People with STI in past year
- People with an HIV+ partner
- Anyone who requests PrEP

# nPEP Criteria


Rapid HIV testing

Pregnancy testing for people with uterus

Determining need for empiric treatment for other STIs

Initiation within 72 hours of exposure

OK for exposure to HIV+ partners or partners of unknown HIV status

# PEP meds

CDC recommends

Tenofovir disoproxil fumarate-emtricitabine (TDF-FTC) or TAF-FTC

Plus

Dolutegravir

But many clinicians use other one tablet 3 drug regimens like Biktarvy

- Bictegravir (an integrase inhibitor)
- Emtricitabine (a nucleoside reverse transcriptase inhibitor)
- Tenofovir alafenamide (a nucleoside reverse transcriptase inhibitor)

Continue for 28 days

# Barriers to PEP use

Patient awareness

Access within 72 hours

Clinician knowledge and experience

# PrEP Criteria

Rapid HIV testing (resulted before starting)

HBV surface antigen, surface antibody, and core antibody.

Full STI –include throat and rectal swab if using those parts for sex

Serum Creatinine

Pregnancy testing

# PrEP Meds

Oral options

Daily or as needed (211 or PrEP on demand)

-Truvada-Tenofovir disoproxil fumarate-emtricitabine (TDF-FTC)

-Descovy-tenofovir alafenamide-emtricitabine (TAF-FTC)

Every 2 month injection

-Apretude-cabotegravir

Every 6 month injection-*coming soon*

-Lencapavir an HIV 1 capsid inhibitor


# PrEP Monitoring

| | |
|---|---|
| HIV testing (HIV RNA) | Q3 months oral<br>Q2 months inj* |
| STI testing | Q3 months oral<br>At least Q4 months inj* |
| Lipids and Wt monitoring | Annual with Descovy |
| Renal Function | Annual or<br>Q6 months >50yrs or CrCl <90ml/min |
| Hep C | Annual for MSM, transwomen who have sex with men, IVDU |
| Pregnancy Testing | every 3 months |

# PrEP Barriers

Clinician knowledge and experience

Difficulty with frequency of appointments or lab testing

# Doxy PEP

Doxy PEP (given as 200mg doxycycline within 72 hours of condomless sex) can reduce the rate of chlamydia, syphilis, and possibly  gonorrhea

Who to offer Doxy PEP to?

- Men and transgender women who have sex with men
- Men and transgender women with history of STI in past year
- Men and transgender women with multiple partners

# Contact info

JesseDawn@gmail.com

773 241 0077