# Cardiac Amyloidosis As a Reason for Heart Failure Exacerbation Among Older Adults: The Impact of its Increasing Diagnosis in PALTC

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## Disclosures

- Pfizer: Speaker, Consultant
- Alnylam : Consultant, Speaker
- BridgeBio: Consultant
- Ionis: Grant reviewer
- Astellas: Speaker (inactive)

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Diagnose, Differentiate, and Manage Cardiac Amyloidosis

## Learning Objectives

- Understand that amyloidosis has a broad range of clinical manifestations that makes recognition difficult
- Identify which cardiac patients have signs or symptoms consistent with cardiac amyloidosis
- Learn indications for non-invasive testing for cardiac amyloid and how to interpret results
- Understand the value of early diagnosis on treatment options and prognosis

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Q1. Which inheritedTTR gene variant is present in 3-4 of AfroAmericans is the most common in the US

- 1. Thr(60)Ala (T60A)
- 2 Val MET 30(V30M)
- 3. Val122Ie (V122)
- 4. Ike68Leu (I68L)

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Q2 Other than Endomyocardial Biopsy, Which of the Following Tests can be considered Diagnostic of wATTR

- CMR with increased ECV and Increased thickness
- Grade 3 PYP scan with negative clonal testing
- Grade 2 Pyp scan with elevated ntBNP and hs Troponin
- ECHO showing increased left ventricular thickness and abnormal longitudinal strain

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Q3.

* 3. You suspect cardiac amyloidosis based on heart failure and history of bilateral carpal tunnel syndrome. Echocardiogram shows classic findings with left ventricular wall thickening and abnormal longitudinal strain with an apical sparing pattern. Serum free light chain assay was abnormal with elevated Kappa light chains, normal lambda light chains and a highly abnormal Kappa to lambda ratio. The patient's renal function was normal. The next best test to perform is:

- 1) Cardiac Magnetic Resonance-CMR
- 2) Endomyocardial biopsy
- 3) 99mTC-PYP imaging
- 4) TTR genetic test
- 5) No further testing needed

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Q4. A 77yoman with HFpEF has an echo suspicious for cardiac amyloidosis. He has a history of bilateral carpal tunnel surgery. Which test of the following would you order?

- 1) Tc- PYP scan , SPEP, UIEP
- 2) Serum light chains and serum and urine immunoelectrophoresis
- 3) CMR
- 5) Tc-99m PYP scan with serum and urine electrophoresis

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## A Sad Story

- 76 yo Afro-Caribbean male with history of pacemaker 5 yrs prior. NO hx DM, HTN, CAD
- Saw Cardiologist two months prior. “Everything was good.”
- Stress test negative
- ECHO EF 48% , Bi-atrial enlargement
  Moderate concentric LVH

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## WW

- Presented to ER abdominal pain, 20 pound weight loss , SOB, inability to walk
- Long history of numbness in hands and toes.
- Attributed to cervical and lumbar radiculopathy
- Progressive decrease in ability to walk

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## WW – Data BAse

- BUN/CR =28/1.2
- Nt-BNP 3200
- Tn  0.66
- EF 38%

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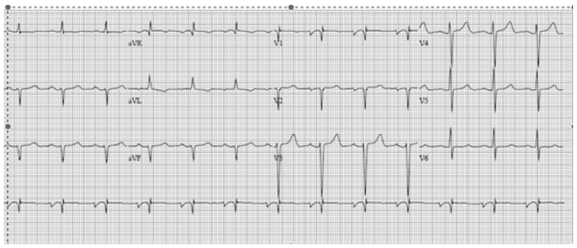
## ECG

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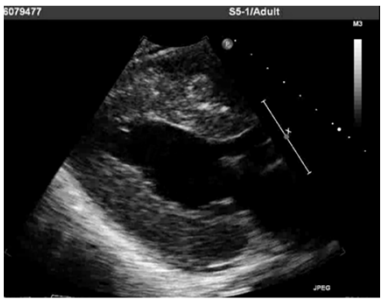
## ECHO

EF 38%

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## Clinical Impression

- Heart failure – chronic diastolic
- Profound weakness and ambulatory limitation -refer to Neurology
- Weight loss , cachexia – refer to GI
- No testing to evaluate etiology of cardiac disease

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## Neurology

- HX of C-spine fusion
- Bilateral arm weakness
- Atrophy of hand muscles
- Carpal tunnel
- Spine CT order , PT
- No other diagnostic test
- No explanation why he could not walk

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## Gastroenterology

- Mild weight loss possibly due to systolic heart failure
- Suggest nutritional support – ENSURE
- No workup or testing

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## Neurosurgery Consult

- Bilateral neuroforaminal spinal stenosis
- Not a candidate for surgery due to EF 38%

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## Returned to ER Six Weeks Later

- Weaker , SOB, unable to swallow , unable to walk without use of walker
- ECG = new Afib
- ECHO= EF 20%
- Imaging for Amyloid
- Genetic testing

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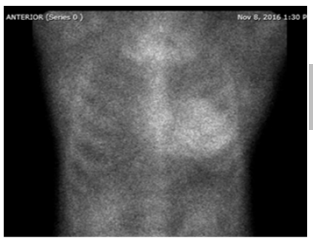
## PYP Planar




Cardiac Uptake greater than contralateral bone

Genetic Testing= Val122Il Mutation

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## Transferred to Subacute Rehab

- Returned to ER after two weeks – fluid overload and weak
- Hospitalized x 10 days
- Transferred to nursing home
- Died in hospice 6 weeks later

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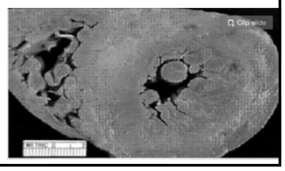
## Summary

- Chronic Diastolic Heart Failure- Progression to systolic
- Paroxysmal Atrial Fibrillation
- Abnormal ECG- Low voltage
- Abnormal ECHO - LVH, Bi-atrial enlargement
- Peripheral Neuropathy
- Edema
- GI Symptons –
- Bilateral CTS, spinal stenosis
- Weight loss and Cachexia

=

- Amyloidosis



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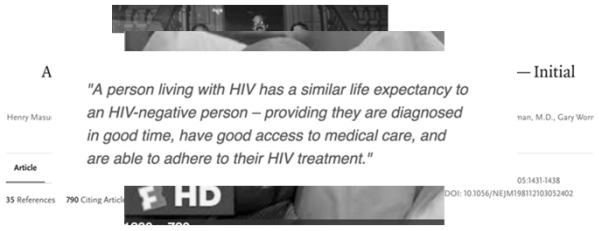
## A Long Story with a Good Ending

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# Clinician Understanding of Amyloid CCF Pilot Study

## Results

| | Not Confident | Somewhat Confident | Moderately Confident | Very Confident |
|---|---|---|---|---|
| How confident are you in **diagnosing** ATTR-CM? | 52 (59.1) | 19 (21.6) | 9 (10.2) | 8 (9.1) |
| How confident are you in **differentiating** the types of ATTR-CM? | 68 (77.3) | 8 (9.1) | 6 (6.8) | 6 (6.8) |
| How confident are you in **identifying the clinical presentations** of ATTR-CM (such as HFpEF)? | 40 (45.5) | 19 (26.1) | 15 (17.0) | 10 (11.4) |
| How confident are you in **identifying the soft tissue signs and symptoms** of ATTR-CM (such as lumbar stenosis)? | 40 (56.7) | 21 (23.9) | 13 (14.8) | 5 (5.7) |
| How confident are you in **identifying the GI signs and symptoms** of ATTR-CM (such as early satiety)? | 52 (59.1) | 21 (23.9) | 10 (11.4) | 5 (5.7) |
| How confident are you in **identifying the neurologic signs and symptoms** of ATTR-CM (such as carpal tunnel syndrome)? | 47 (53.4) | 20 (22.7) | 11 (12.5) | 10 (11.4) |
| How confident are you with **nuclear scintigraphy**? | 56 (63.6) | 22 (25.0) | 4 (4.5) | 6 (6.8) |
| How confident are you with **endomyocardial biopsy**? | 57 (64.8) | 16 (18.2) | 10 (11.4) | 5 (5.7) |
| How confident are you with **genetic testing** to determine if ATTR-CM is hereditary? | 59 (67.0) | 15 (17.0) | 8 (8.1) | 6 (6.8) |
| How confident are you in differentiating between light chain amyloidosis (**AL**) and **ATTR-CM**? | 54 (61.4) | 16 (18.2) | 11 (12.5) | 7 (8.0) |

Wolinsky, D and Sarkar, A Submitted for Publication

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# Epidemiology of HF

Diamond J .Curr Treat Options Cardio Med. (2022) 24:199.

- 6,000,000 Americans have Heart failure
- More than 1,000,000 hospitalizations per year
- 25% return in 30 days
- 50% return in 6 mo
- 700,000- new cases per year Half of them HFpEF

- HOSPITALIZATION IS A SENTINAL EVENT
- Recurrent hospitalizations are associated with increased mortality

Huusko ESC Heart Failure 2020; 7: 2406–2417

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# HFpEF

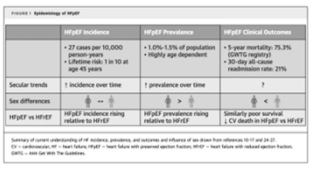
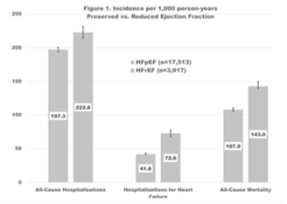


FIGURE 1 Epidemiology of HFpEF

| | HFpEF Incidence | HFpEF Prevalence | HFpEF Clinical Outcomes |
|---|---|---|---|
| | • 27 cases per 10,000 person-years<br>• Lifetime risk: 1 in 10 at age 45 years | • 1.0%-1.5% of population<br>• Highly age-dependent | • 5-year mortality: 75.3% (GWTG-registry)<br>• 30-day all-cause readmission rate: 21% |
| Secular trends | ↑ incidence over time | ↑ prevalence over time | ? |
| Sex differences | ♀ ≈ ♂ | ♀ > ♂ | ♀ < ♂ |
| HFpEF vs HFrEF | HFpEF incidence rising relative to HFrEF | HFpEF prevalence rising relative to HFrEF | Similarly poor survival. ↓ CV death in HFpEF vs HFrEF |

Summary of current understanding of HF incidence, prevalence, and outcomes and influence of sex drawn from references 16-17 and 24-27.
CV = cardiovascular; HF = heart failure; HFpEF = heart failure with preserved ejection fraction; HFrEF = heart failure with reduced ejection fraction; GWTG = Get-Get With The Guidelines.

(Borlaug B. Am Coll Cardiol 2023;81:1810–1834)




Nichols et al Eur Heart Jl 42 Suppl 1, 2021.

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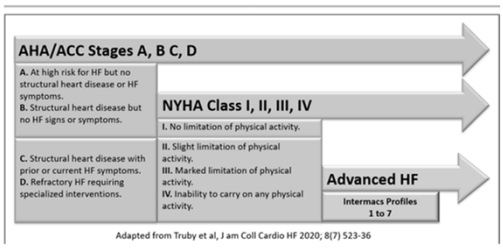
# Classification of Heart Failure




Roger V. Circulation Research. 2021;128:1421–1434.

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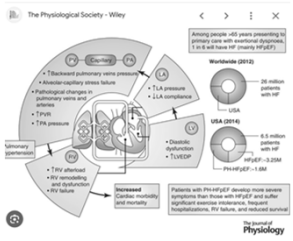
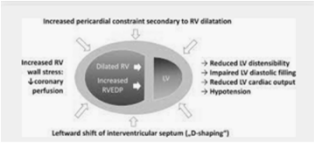
# HFpEF is Both "Forward" and "Backwards" Failure

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## What is amyloid?

- Amyloid is a protein folding disorder leading to the deposition of insoluble amyloid fibrils in the heart and other tissues
- Amyloid is a systemic disease
- Name derived from Latin amylum (starch)
- Histological diagnosis - aggregates of β–sheets that stain with Congo Red (green birefringence)

**R. Virchow, 1854**

Ruberg, *Circulation* 2012

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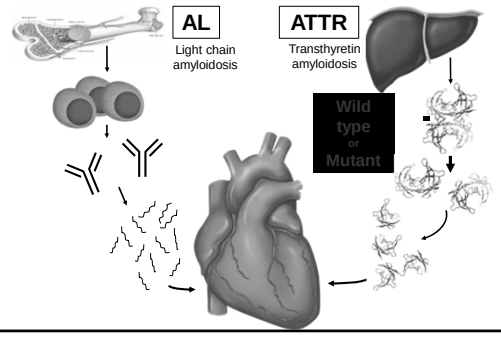
## Cardiac Amyloidosis

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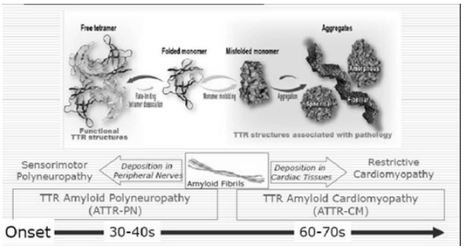
## Pathogenesis of ATTR Amyloidosis
## A Disease of Proteins




*Ruberg R JACC 2019;73:2872–91*

Eighty Percent of hATTR Patients Have Have Cardiac Involvement

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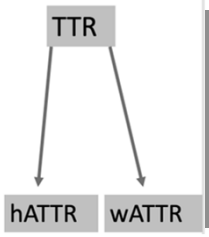
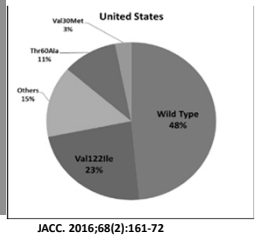
## ATTR Amyloidosis in United States:




Eighty Percent of hATTR Patients Have Have Cardiac Involvement

THAOS REGISTRY




JACC. 2016;68(2):161-72

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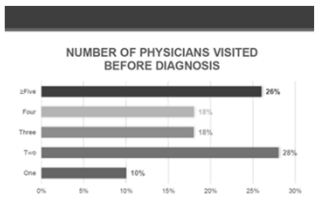
## Delayed Diagnosis of CA

- Time from Initial Sx → Dx is unacceptably high
  - AL-CA: 2 years, ~1/3 visited >5 physicians before Dx
  - ATTR-CA: there was a 3-year (median) delay in diagnosis (ATTR) amyloidosis.




Bishop, Emily E. (2018) Amyloid, DOI: 10.1080/13506129.2018.1498782
Maurer Circulation q2017;135:1357-1377.

Lousada et al., Adv Ther, 2015)

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## Prevalence wATTR

JOURNAL ARTICLE

**Wild-type transthyretin amyloidosis as a cause of heart failure with preserved ejection fraction**

Esther González-López, María Gallego-Delgado, Gonzalo Guzzo-Merello, F. Javier de Haro-del Moral, Marta Cobo-Marcos, Carolina Robles, Belén Bornstein, Clara Salas, Enrique Lara-Pezzi, Luis Alonso-Pulpon ... Show more

*European Heart Journal*, Volume 36, Issue 38, 7 October 2015, Pages 2585–2594, https://doi.org/10.1093/eurheartj/ehv338

**Published:** 29 July 2015 **Article history ▾**

**Conclusion**

ATTRwt is an underdiagnosed disease that accounts for a significant number (13%) of HFpEF cases. The effect of emerging TTR-modifying drugs should be evaluated in these patients.

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## We Cannot Afford Not to Look for and Treat ATTR-CA

**Heart Failure With Preserved Ejection Fraction**

Time for a Reset

Katherine A. A. Clark, MD, MBA[1]; Eric J. Velazquez, MD[1]

> Author Affiliations

*JAMA*. 2020;324(15):1506-1508. doi:10.1001/jama.2020.15566

Of the estimated 5 million patients in the US diagnosed with heart failure (HF), approximately 50% have HF with preserved ejection fraction (HFpEF),[1,2] and its prevalence is increasing by about 1% annually relative to that of heart failure with reduced ejection fraction (HFrEF).[3] The mortality associated with HF is substantial, and HF was estimated to account for more than 80 000 deaths annually in the US as of 2017.[4] In addition, because HF is projected to account for an estimated $69.8 billion in annual health care spending by 2030, HFpEF represents an important public health issue that will increase as the population ages, with a concurrent increasing prevalence of associated risk factors, including hypertension, obesity, and diabetes.[4]

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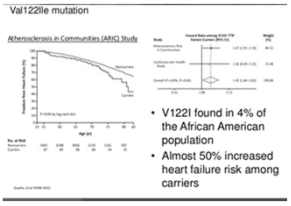
# V122I Mutation




Jacobson et al, NEJM 1997
Buxbaum et al, JACC 2006
Jacobson et al, Am J Cardiol 2011
Quarta et al, NEJM 2015

- General Profile
  - Age > 65 yrs
  - Heart failure symptoms
  - Severe symmetric "LV hypertrophy", Normal or mildly depressed LV ejection fraction
  - Normal or near normal QRS voltages
  - No or minimal neurologic impairment
  - Carpal tunnel syndrome (typically 8-10 years before heart failure symptoms
  - Low penetrance but increased risk of incident heart failure

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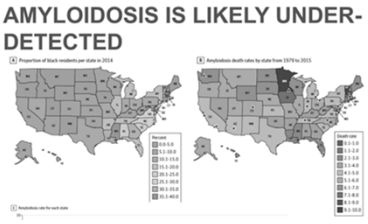
# Underdiagnosis




- Why do States with Highest Black Populations Have the Lowest Death Rates Due to Amyloid?
- Failure to Evaluate-Diagnose

**Alexander KM JAMA Cardiol. 2018;8654-870**

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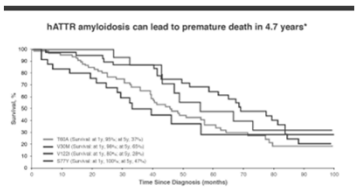
# Prognosis of ATTR CM- Historical




Swedicki AMYLOID 2015

HEREDITARY

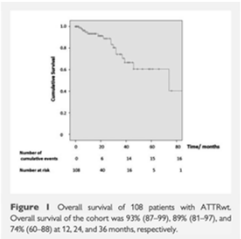



**Figure 1** Overall survival of 108 patients with ATTRwt. Overall survival of the cohort was 93% (87–99), 89% (81–97), and 74% (60–88) at 12, 24, and 36 months, respectively.

European Heart Journal (2017) 38, 1895–1904

WILD TYPE

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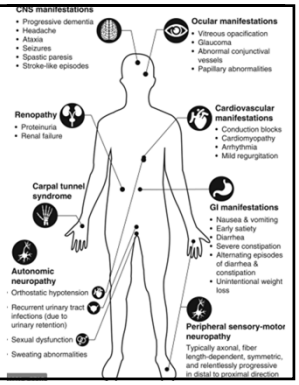
## Myriad of Symptoms in ATTR Amyloid

Stop, Look, Listen, then Test
Remove Your Preconceived Notions

Wiley OnLine Library

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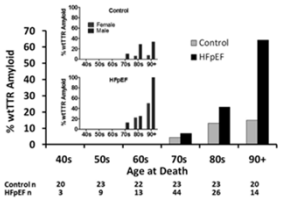
## HFpEF and ATTR




- The older you are the more you are likely to have it
- Does natural history change with age
- When You See HFpEF in a Male Above Age 70, You must consider ATTR

r Tanskanen, *Ann Med,* 2008; Cornwell, *Am J Med,* 1983; Mohammed, *JACC HF,* 2014

**Mohammed JACC Heart Fail 113-22**

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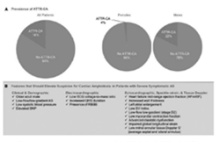
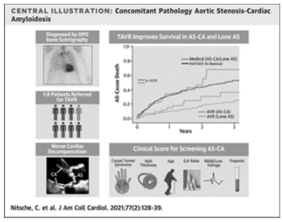
## Aortic Stenosis and ATTR 16 Per Cent



European Heart Journal (2017) 38, 2879–2887




Nitsche, *J Am Coll Cardiol* 2021

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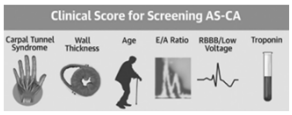
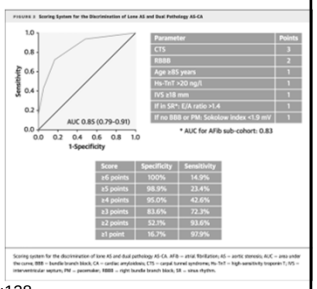
# RAISE SCALE




| Parameter | Points |
|---|---|
| CTS | 3 |
| RBBB | 2 |
| Age ≥85 years | 1 |
| Hs-TnT >20 ng/l | 1 |
| IVS ≥18 mm | 1 |
| If in SR*: E/A ratio >1.4 | 1 |
| If no BBB or PM: Sokolow index <1.9 mV | 1 |

* AUC for AFib sub-cohort: 0.83

| Score | Specificity | Sensitivity |
|---|---|---|
| ≥6 points | 100% | 14.9% |
| ≥5 points | 98.9% | 23.4% |
| ≥4 points | 95.0% | 42.6% |
| ≥3 points | 83.6% | 72.3% |
| ≥2 points | 52.7% | 93.6% |
| ≥1 point | 16.7% | 97.9% |

Nitsche JACC. 2001;77:128

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# Orthopedic Abnormalities

- 10% of pts with bilateral carpal tunnel syndrome have ATTR
- 50% of ATTR patients have Bilateral CTS
- Up to 1/3 of patients undergoing spinal stenosis stain positive for amyloid
- Trigger finger
- Multiple joint replacement
- History rotator cuff surgery

Nativi-Nicolai, J. Heart Failure Reviews (2022) 27:785–793Nicolai.

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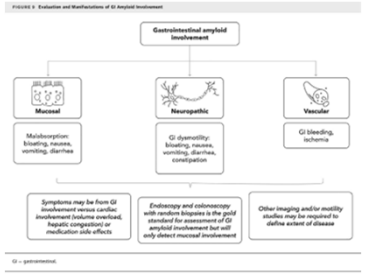
# GI Manifestations ATTR




*Kittleson et al*
*-2022:—- 2023 ACC Expert Consensus Decision Pathway on Cardiac Amyloidosis*

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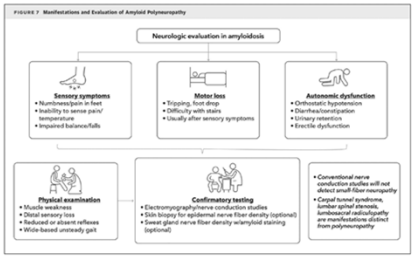
## Neurologic Manifestation of Amyloid




*Kittleson et al 2022:—- 2023 ACC Expert Consensus Decision Pathway on Cardiac Amyloidosis*

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## Most Common Confounding Diagnoses

- Hypertensive heart disease
- Hypertrophic Cardiomyopathy -40 % of LV increased thickening in A TTR-CMmay be asymmetric.
- Five percent of HOCUM patients may also have cATTR
- Infiltrative Cardiomyopathy
- Aortic Stenosis – 14% patients presenting for TAVR also have ATTR -CM

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## What is the “typical” ECG pattern cardiac Amyloid

Low voltage limb leads.
Poor R wave progression

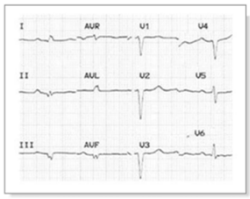


**Figure 1.** ECG of a patient with cardiac AL amyloidosis showing small QRS voltages (defined as ≤6 mm height), predominantly in the limb leads and pseudoinfarction pattern in the anterior leads.

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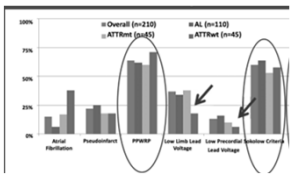
## Commonest ECG Findings




Am J Cardiol. 2014;114(7):1089-93

- Low Voltage present in 40%
- Associated with advanced disease
- Lack of low voltage should not dissuade amyloid workup in appropriate patient

Kittleson M. Circulation. 2020;142:e7–e22

46

## Clues to Cardiac Amyloid – LVEF

- HFpEF- But usually mildly reduced LVEF .
- Typical EF 45-50%.
- HFrEF 30-45% does not preclude consideration of amyloid
- Severe LV dysfunction EF 10-25% unusual in absence of severe disease
- Increase LV thickness on ECHO without LVH on ECG

47

## Electrophysiologic Findings

- Refractory atrial fibrillation- multiple cardioversions and ablations
- RBBB with first degree A-V block or LAHB
- Intolerance to RV pacing
- Clinical deterioration in setting of rhythm management

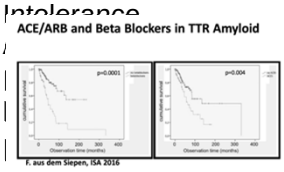
Rappezzi C. Circulation. 2009;120:1203-1212

48

## Clinical-hemodynamics- Low Output

Low- normal BP in setting of prior hypertension

Intolerance

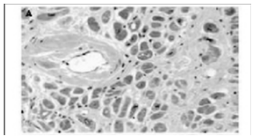


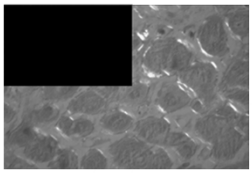

49

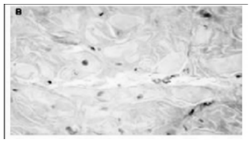
## Diagnostic Workup

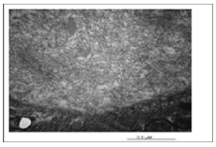
50

## "Gold Standard"-Endomyocardial Biopsy



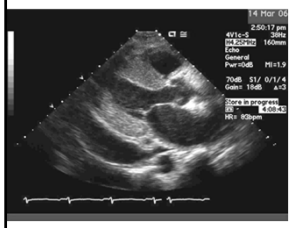






51

## Cardiac Amyloidosis - Echo Suspician



**Echo Findings:**

- Biventricular ↑ wall thickness
- "Granular sparkling pattern"
- ↑ RA and LA size / dyfn / stasis
- Mechanically silent Atria
- Thickened valves / atrial septum
- Pericardial effusion
- Pulmonary HTN
- Low stroke volume
- Abnormal diastolic function

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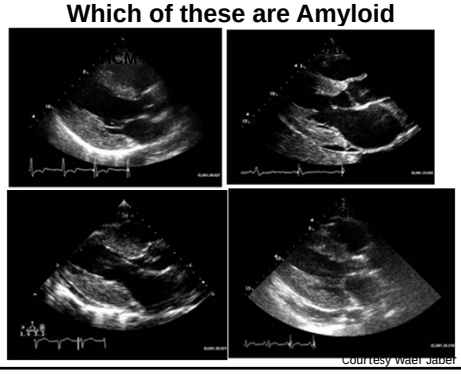
## Which of these are Amyloid



Courtesy Waef Jaber

53

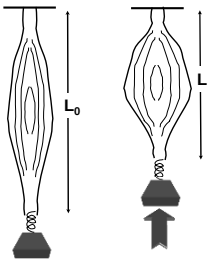
## What is Strain?

= tissue deformation as a function of applied force

= relative change of length of an object (e.g. myocardial fiber)

**********

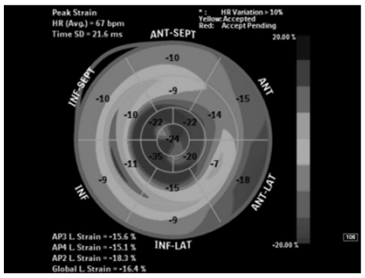
L0 = initial length
L = compressed length
Strain = $(L - L_0)/L_0$




Strain Rate= rate of change

54

## Apical Sparing

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## ECHO

- Suggestive not diagnostic or pathognomic
- Not all patients with typical echo findings have amyloid
- Not all patients with amyloid have all the echo findings
- CANNOT PRESCRIBE THERAPY BASED ON ECHO ALONE
- SUGGESTIVE ECHOES NEED FOLLOWUP

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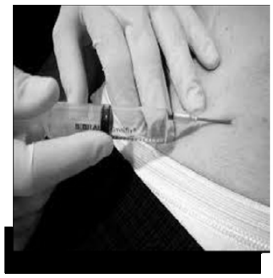
## Fat Pad Aspirate Poor Test for ATTR

- Sensitivity for AL amyloid of 70 % at best
- Positive in < 50 % of subjects with TTR cardiac amyloid



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## Potential Utility of CMR in Cardiac Amyloidosis

1. Increase suspicion of presence of disease
2. Diffuse late enhancement that can either be subendocardial or transmural, that does not follow coronary distribution,
3. poor myocardial signal nulling on PSIR LGE sequence
4. Marked increase in extracellular volume (>40%) or native (non-contrast) T1
5. Confers prognostic value
   - Transmural or high ECV, worst prognosis
   - Absence of LGE, best prognosis
6. Serial imaging for response to therapy

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ASNC
American Society of Nuclear Cardiology

ASNC
CARDIAC AMYLOIDOSIS
**PRACTICE POINTS**

**$^{99m}$Technetium-Pyrophosphate Imaging for Transthyretin Cardiac Amyloidosis**

https://www.asnc.org/Files/Practice%20Resources/Practice%20Points/ASNC%20Amyloid%20Practice%20Points%20FINALfeb26.pdf

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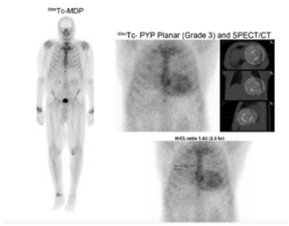
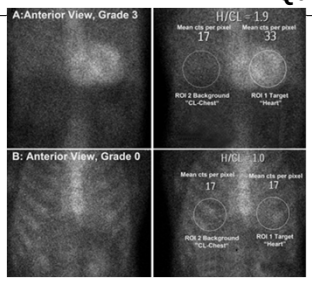
## Tc-PYP Scan

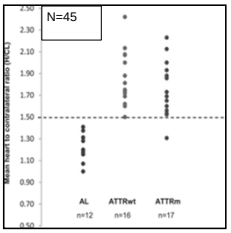
- PYP is calcium avid
- Bone imaging agent
- 1970's used to diagnose acute myocardial infarction
- Mechanism for binding to amyloid tissue unclear




60

## $^{99m}$Tc-PYP planar: Heart to contralateral ratio PLANAR **Quantitation**



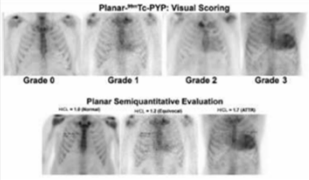




Bokhari S et al. Circ CVIM 2013;6:195-2013

61

## PYP UptakeGrading of 99m Tc

Planar imaging (qualitative and semiquantitative methods) and single-photon emission computed tomography (SPECT) imaging (without and with computed tomography)



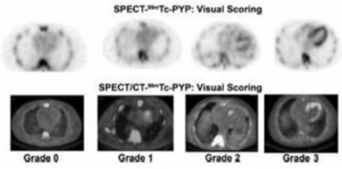




Table 2. Semi-quantitative Visual Grading of Myocardial $^{99m}$Tc-PYP Uptake by Comparison to Bone(rib) Uptake

| Grade | Myocardial $^{99m}$Tc-PYP Uptake |
|---|---|
| Grade 0 | no uptake and normal bone uptake |
| Grade 1 | uptake less than rib uptake |
| Grade 2 | uptake equal to rib uptake |
| Grade 3 | uptake greater than rib uptake with mild/ absent rib uptake |

ASNC

Hanna et al. JACC Vol. 75, N° 22 June 9, 2020: 2851-62

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## Tc PYP – Sensitivity and Specificity

Table 1.

Accuracy of Tc-pyrophosphate scan for detecting ATTR Cardiac amyloidosis based on semiquantitative and quantitative assessments

| | Sensitivity (%) | Specificity (%) | AUC (95% CI) |
|---|---|---|---|
| Semiquantitative visual Score | | | |
| 1-hour delay positive scan ≥ 2 | 95 | 79 | 0.938 (0.873-0.984) |
| 3-hour delay positive scan ≥ 2 | 58 | 100 | 0.980 (0.932-1.000) |
| Combined analysis | 88 | 88 | 0.945 (0.901-0.977) |
| Quantitative H/CL ratio | | | |
| 1-hour delay positive scan ≥ 1.5 | 92 | 97 | 0.971 (0.949-0.992) |
| 3-hour delay positive scan ≥ 1.3 | 88 | 86 | 0.935 (0.848-0.988) |
| Combined analysis | 91 | 92 | 0.960 (0.930-0.981) |

Open in a separate window

*Tc-PYP*, Tc pyrophosphate; *ATTR*, transthyretin amyloidosis; *AUC*, area under the curve; *CI*, confidence interval; *H/CL*, ratio = heart-to-contralateral lung ratio. Adapted from Castano et al.[12]

- If AL AMYLOID is ruled out
- Specificity preferred to Sensitivity

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# Clonal Testing for AL Amyloid

**TABLE 1 Serum and Urine Tests to Rule Out AL Amyloidosis***

| Test | What Does it Detect? | Most Sensitive Test for: | Normal Range |
|---|---|---|---|
| SPIE† | Clonal immunoglobulin and/or clonal light chain | Confirming clonal immunoglobulin production | No M-spike present |
| UPIE† | Clonal immunoglobulin and/or clonal light chain | Confirming clonal light chain production | No M-spike present |
| Serum free light chain assay | Ratio of serum kappa:lambda light chains | Detecting low-level clonal light chain production; clonality assumed if ratio is far from 1:1 | Kappa:lambda ratio = 0.26–1.65‡ |

**TABLE 3 Normal Values of Commonly Used sFLC Assays**

| Assay | Kappa | Lambda | sFLC Ratio | Renal Range* |
|---|---|---|---|---|
| Freelite | | | | |
| mg/dl† | 0.33-1.94 | 0.57-2.63 | 0.26-1.65 | 0.37-3.1 |
| mg/l | 3.3-19.40 | 5.71-26.30 | | |
| Siemens N-Latex | | | | |
| mg/dl | 0.82-2.89 | 0.91-3.26 | 0.53-1.51 | Not applicable |
| mg/l | 8.24-28.9 | 9.10-32.6 | | |

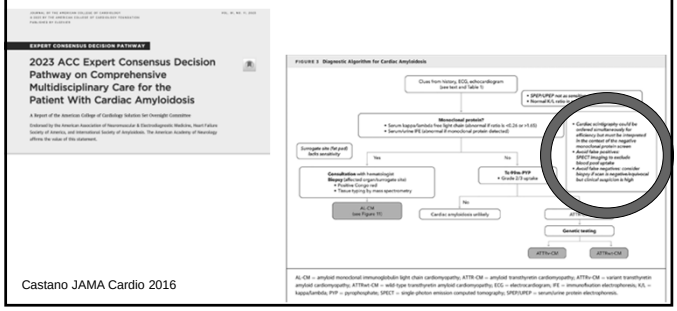
*Proposed extended range of sFLC ratio using the Freelite assay in patients with renal dysfunction, from The Binding Site, Inc. This correction is not applicable to Siemens N-Latex sFLC assay. †Units may be reported as mg/dl or mg/l, a cause of confusion when comparing results from different laboratories.
sFLC = serum free light chain.

- With age Kappa Levels increase
- With decreasing GFR =>0.48-3.38
- With GFR< 30-→0.54-3.30
- Ratio increases because of increased urinary spillage of lambda light chairs

Wittleles. JACC Heart Failure 20

64

# Diagnostic Algorithm- Suspect and Test




Castano JAMA Cardio 2016

65

# Management

- *The treatment of Heart Failure in patients with cardiac amyloidosis differs from the therapy generally recommended in patients with diastolic or systolic heart failure*

66

PATHOPHYSIOLOGY: Amyloid is not only a disease of abnormal cardiac filling , but also a disease of diminished cardiac output

Normal to small LV cavity (impaired filling secondary to decreased compliance)

Volume sensitive

**Late stage disease:**

LVEF is reduced

LV is unable to undergo compensatory dilation

Severely impaired atrial contraction

Further decrease in ventricular filling results in

- Decreased SV
- Decreased CO
- Marked elevation of intracardiac pressures

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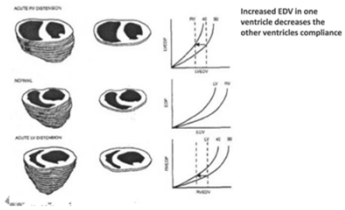
# Venticular Interdependence

Ventricular Interdependence: Diastole

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## Diuretics

- Diuretic - Use Torsemide, Bumetanide, They have better intestinal absorption
- PRN metolazone- do not delay- start with 3-5 lb weight gain
- Spironolactone + loop diuretic is generally well tolerated
- Adjust diuretics based on clinical status
- IV diuretics: Use with close monitoring as it may result in progressive azotemia and hypotension

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## Management

- Avoid ACE,ARB,ARNI:
  - *Safety and efficacy is uncertain (no clinical trials)*
  - *May provoke profound hypotension in AL amyloidosis (possibly by exposing a subclinical autonomic neuropathy)*
  - *Better tolerated in TTR amyloid (wild type)*
- Avoid digoxin:
  - *Amyloid fibrils bind to it and this interaction may increase risk for digitalis toxicity*

  ARNI
  - *No concrete data*

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## Management

- Av
  - *C* *ects may* *b* *R* *r*
- Av
  - *N* *diac* *a*


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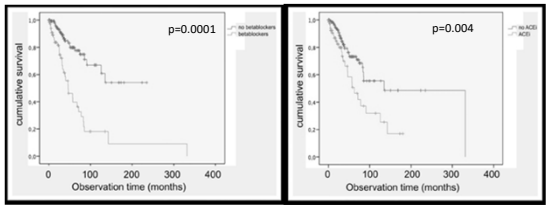
## ACE/ARB and Beta Blockers in Cardiac Amyloid




***F. aus dem Siepen, ISA 2016***

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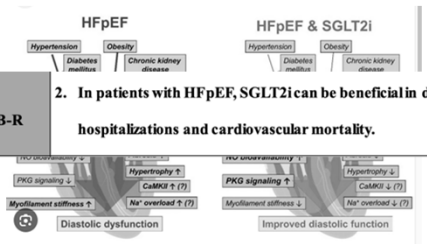
# SGLT-2 Inhibitors




| | |
|---|---|
| 2a | B-R |

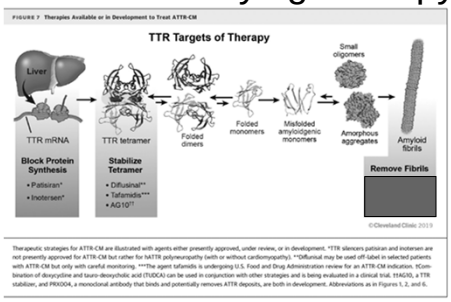
2. In patients with HFpEF, SGLT2i can be beneficial in decreasing HF hospitalizations and cardiovascular mortality.

Kittleson M .JACC 2023

Pabel IFrontiers Physiology 2021;

73

# Disease Modifying Therapy




Therapeutic strategies for ATTR-CM are illustrated with agents either presently approved, under review, or in development. *TTR silencers patisiran and inotersen are not presently approved for ATTR-CM but rather for hATTR polyneuropathy (with or without cardiomyopathy). **Diflunisal may be used off-label in selected patients with ATTR-CM but only with careful monitoring. ***The agent tafamidis is undergoing U.S. Food and Drug Administration review for an ATTR-CM indication. †Combination of doxycycline and tauro-deoxycholic acid (TUDCA) can be used in conjunction with other strategies and is being evaluated in a clinical trial. ††AG10, a TTR stabilizer, and PRX004, a monoclonal antibody that binds and potentially removes ATTR deposits, are both in development. Abbreviations as in Figures 1, 2, and 6.

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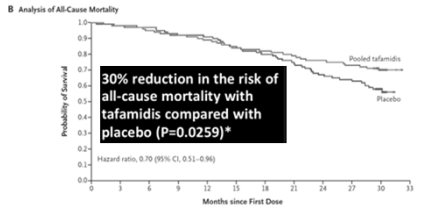
# Tafamidis

The NEW ENGLAND JOURNAL of MEDICINE




No. at Risk (cumulative no. of events)

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pooled tafamidis | 264 (0) | 259 (5) | 252 (12) | 244 (20) | 235 (29) | 222 (42) | 216 (48) | 209 (55) | 200 (64) | 193 (71) | 99 (78) | 0 (78) | | |
| Placebo | 177 (0) | 173 (4) | 171 (6) | 163 (14) | 161 (16) | 150 (27) | 141 (36) | 131 (46) | 118 (59) | 113 (64) | 51 (75) | 0 (76) | | |

Maurer MS,.. N Engl J Med 2018;379:1007-1016

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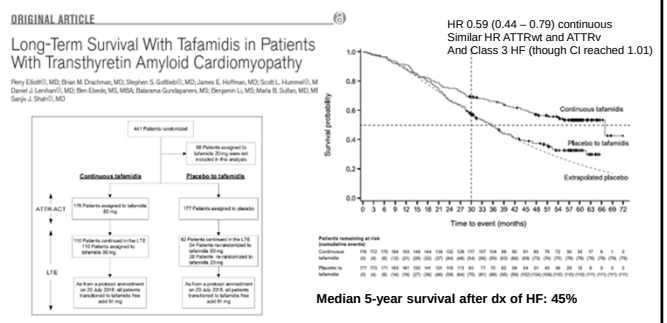





**Median 5-year survival after dx of HF: 45%**

Elliott, *Circ HF* 2022; Taylor, *BMJ* 2019

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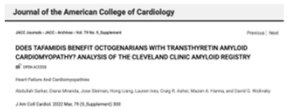
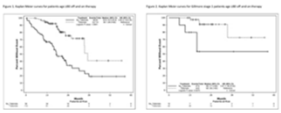
# Does Tafamidis Benefit the Elderly




DOES TAFAMIDIS BENEFIT OCTOGENARIANS WITH TRANSTHYRETIN AMYLOID CARDIOMYOPATHY? ANALYSIS OF THE CLEVELAND CLINIC AMYLOID REGISTRY

In our registry of unmatched patients, similar benefits of Tafamidis treatment for ATTR-CM appear to extend to octogenarian patients without advanced disease (Gillmore Stage 1).



Download Figure  Download PowerPoint

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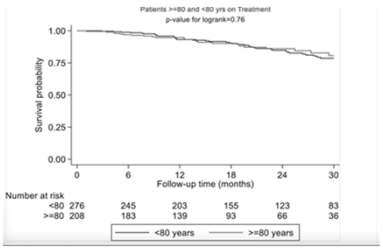
# Does Tafamidis Benefit the Elderly




Wolinsky DG et al Am Jl Card In Press

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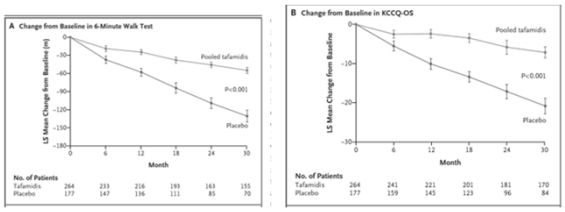
# Tafamidis – Reduces Rate of Clinical Deterioration




Maurer MS,.. N Engl J Med 2018;379:1007-1016

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ORIGINAL RESEARCH

HEART FAILURE AND CARDIOMYOPATHIES

## Improvements in Efficacy Measures With Tafamidis in the Tafamidis in Transthyretin Cardiomyopathy Clinical Trial

Maren Hanna, MD,[1] Nowell M. Fine, MD,[2] Balarama Gondapaneni, MS,[1] Marfa B. Sultan, MD,[1] Ronald M. Witteles, MD[1]

Improvements in ATTR-CM were more common with tafamidis than placebo

Throughout 2.5 years of treatment in the phase 3 ATTR-ACT, a higher proportion of patients who took tafamidis (n = 264) experienced improvement in ATTR-CM disease measures vs baseline compared with those who took placebo (n = 177)

Improvements with tafamidis vs placebo

- 6-minute walk test distance OR: 4.9 (95% CI: 2.28-10.69)
- NT-proBNP levels OR: 5.3 (95% CI: 2.66-10.73)
- KCCQ-OS score OR: 3.3 (95% CI: 1.85-5.78)
- Patient global assessment questionnaire OR: 2.9 (95% CI: 1.69-4.95)
- New York Heart Association functional class OR: 2.0 (95% CI: 0.88-4.62)

Hanna M, et al. JACC Adv. 2022;1(5):100148.

Hanna, *JACC Adv* 2022

80

## Repurposing Diflunisal for Familial Amyloid Polyneuropathy

### A Randomized Clinical Trial

John L. Berk, MD[1]; Ole B. Suhr, MD, PhD[2]; Laura Obici, MD[3]; et al

Author Affiliations | Article Information

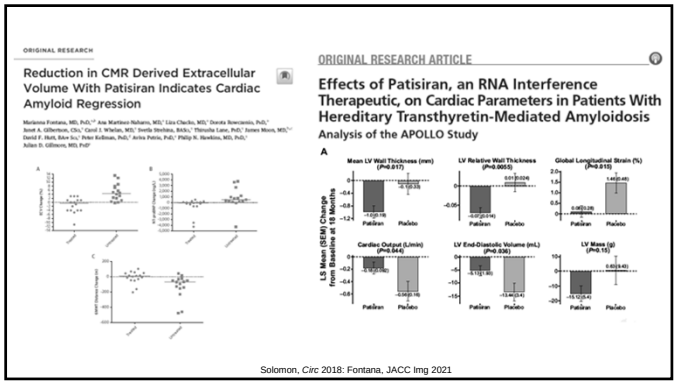
*JAMA*. 2013;310(24):2658-2667. doi:10.1001/jama.2013.283815

**CONCLUSIONS AND RELEVANCE** Among patients with familial amyloid polyneuropathy, the use of diflunisal compared with placebo for 2 years reduced the rate of progression of neurological impairment and preserved quality of life. Although longer-term follow-up studies are needed, these findings suggest benefit of this treatment for familial amyloid polyneuropathy.

| TTR stabilizers | | | | | | |
|---|---|---|---|---|---|---|
| Tafamidis | FDA approved for ATTRact-CM and ATTR-CM | 20*, 61, or 80 mg once daily | ATTR-ACT trial[17]<br>Inclusion:<br>End-diastolic septal thickness >12 mm<br>History of heart failure<br>NTproBNP ≥600 pg/mL<br>Exclusion:<br>6MWT <100 m<br>NYHA class IV symptoms<br>Liver or heart transplantation<br>eGFR <25 mL·min$^{-1}$·1.73 m$^{-2}$ | None | None | $225 000/y |
| Diflunisal | FDA approved as NSAID<br>Off-label use in ATTRwt or ATTRv with neuropathy/ cardiomyopathy | 250 mg orally twice daily<br>Administer with proton pump inhibitor | Diflunisal Trial Consortium[18]<br>Inclusion:<br>ATTRv with sensorimotor polyneuropathy (familial amyloid polyneuropathy)<br>Biopsy-proven amyloid deposits<br>Confirmed *TTR* mutation<br>Exclusion:<br>NYHA class IV symptoms<br>Estimated creatinine clearance <30 mL/min†<br>Anticoagulation | Fluid retention<br>Renal dysfunction<br>Bleeding | Renal function<br>Platelet count<br>Hemoglobin | +$60/mo |

Caveats:
CKD
AntiCoagulation

81




Solomon, *Circ* 2018: Fontana, JACC Img 2021

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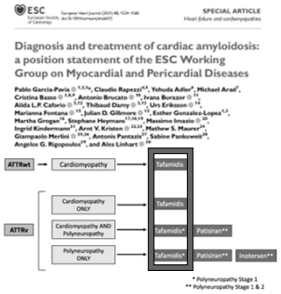
# Societal Guidelines for Treatment




Garcia-Pavia, *Eur H J* 2021

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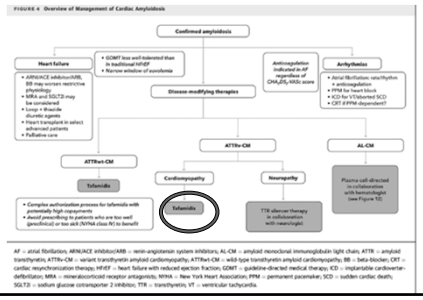
# ACC/AHA Guidleines

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JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. ■, NO. ■, 2022

PUBLISHED BY ELSEVIER

EXPERT CONSENSUS DECISION PATHWAY

## 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis

A Report of the American College of Cardiology Solution Set Oversight Committee

Endorsed by the American Association of Neuromuscular & Electrodiagnostic Medicine, Heart Failure Society of America, and International Society of Amyloidosis. The American Academy of Neurology affirms the value of this statement.

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# PROGNOSIS

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## Staging Systems ATTR Mayo and Gilmour (NAC)

Table 1 **Clinical staging systems for transthyretin amyloid cardiomyopathy**

| Grogan et al., 2016 (Mayo)[4] ATTRwt | | Gillmore et al., 2018 (NAC)[14] ATTRv and ATTRwt | | Cheng et al., 2020 (Columbia)[15] ATTRv and ATTRwt | |
|---|---|---|---|---|---|
| Staging parameters:<br>Troponin T >0.05 ng/mL<br>NT-proBNP >3000 pg/mL | | Staging parameters:<br>eGFR <45 mL/min<br>NT-proBNP >3000 pg/mL | | Scoring parameters:<br>Mayo or NAC score (0 to 2 points)<br>Daily dose of furosemide or equivalent:<br>0 mg/kg (0 points), >0–0.5 mg/kg (1 point), >0.5–1 mg/kg (2 points), and >1 mg/kg (3 points)<br>NYHA class I–IV (1 to 4 points) | |
| **Stage** | **Median survival** | **Stage** | **Median survival** | **Score** | **Mean survival** |
| Stage I (0 parameters) | 66 months | Stage I (0 parameters) | 69.2 months | Score 1–3 | 78 months |
| Stage II (1 parameter) | 40 months | Stage II (1 parameter) | 46.7 months | Score 4–6 | 48 months (Mayo)<br>45.6 months (NAC) |
| Stage III (2 parameters) | 20 months | Stage III (2 parameters) | 24.1 months | Score 7–9 | 26.4 months (Mayo)<br>22.8 months (NAC) |

ATTRv, variant transthyretin amyloid cardiomyopathy; ATTRwt, wild-type transthyretin amyloid cardiomyopathy; eGFR, estimated glomerular filtration rate; HF, heart failure; NAC, UK National Amyloidosis Centre; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association.

Garcia-Pavia European Journal of Heart Failure (2021)23, 895–905

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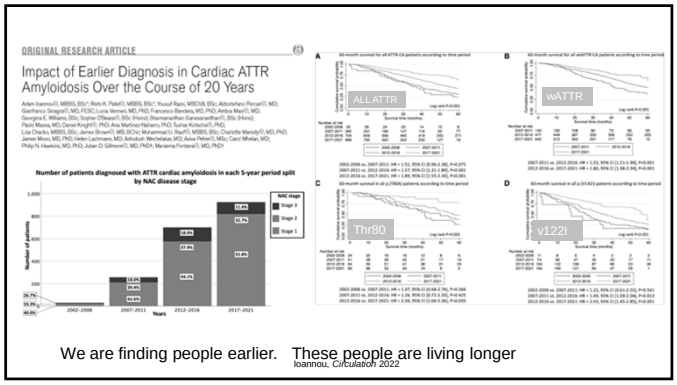
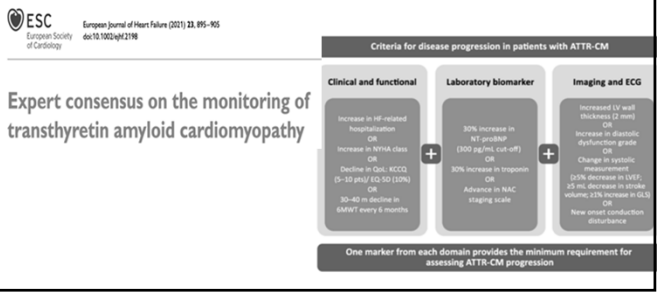



We are finding people earlier. These people are living longer

Ioannou, *Circulation* 2022

88

# Defining Disease Progression

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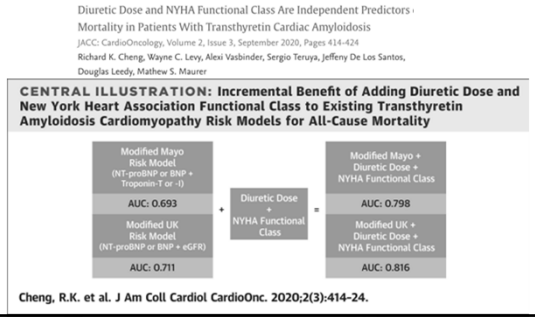
# Improved Risk Assessment

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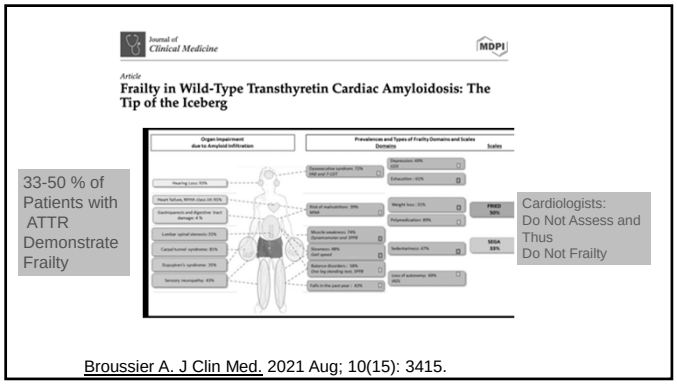


Broussier A. J Clin Med. 2021 Aug; 10(15): 3415.

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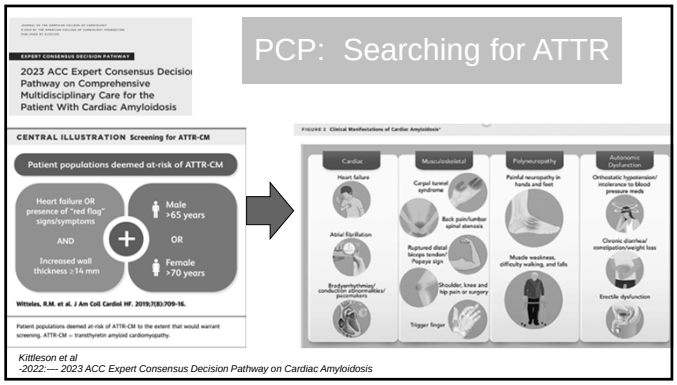


*Kittleson et al*
*-2022:–– 2023 ACC Expert Consensus Decision Pathway on Cardiac Amyloidosis*

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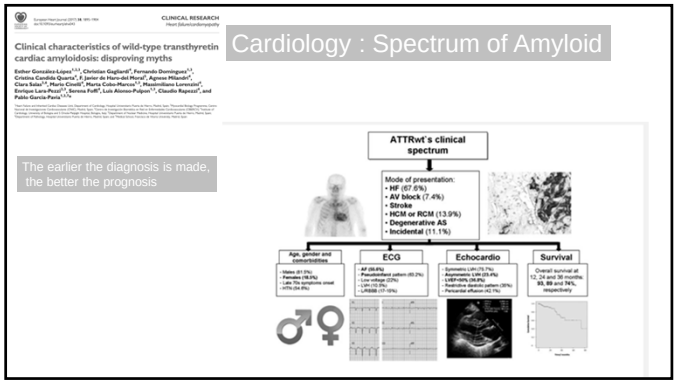


93

Q1. Which inheritedTTR gene variant is present in 3-4 of AfroAmericans is the most common in the US

- 1. Thr(60)Ala (T60A)
- 2 Val MET 30(V30M)
- 3. Val122Ie (V122)
- 4. Ike68Leu (I68L)

94

## Cardiac Amyloid

- If you don't think of looking for it , you won't find it


**But if you find it You can help**

95

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97

Q2 Other than Endomyocardial Biopsy, Which of the Following Tests can be considered Diagnostic of wATTR

- CMR with increased ECV and Increased thickness
- Grade 3 PYP scan with negative clonal testing
- Grade 2 PYP scan with elevated ntBNP and hs Troponin
- ECHO showing increased left ventricular thickness and abnormal longitudinal strain

98

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99

## Q3.

* 3. You suspect cardiac amyloidosis based on heart failure and history of bilateral carpal tunnel syndrome. Echocardiogram shows classic findings with left ventricular wall thickening and abnormal longitudinal strain with an apical sparing pattern. Serum free light chain assay was abnormal with elevated Kappa light chains, normal lambda light chains and a highly abnormal Kappa to lambda ratio. The patient's renal function was normal. The next best test to perform is:

- 1) Cardiac Magnetic Resonance-CMR
- 2) Endomyocardial biopsy
- 3) 99mTC-PYP imaging
- 4) TTR genetic test
- 5) No further testing needed

100

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101

Q4. A 77yo man with HFpEF has an echo suspicious for cardiac amyloidosis. He has a history of bilateral carpal tunnel surgery. Which test of the following would you order?

- 1) Tc- PYP scan , SPEP, UIEP
- 2) Serum light chains and serum and urine immunoelectrophoresis
- 3) CMR
- 5) Tc-99m PYP scan with serum and urine electrophoresis

102

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## SUMMARY

- Amyloidosis is a multisystem disorder caused by the deposition of abnormal proteins in myocardial tissue and other organs
- Cardiac Amyloidosis (ATTR-CM) is an underrecognized cause of heart failure in the elderly population
- ATTR-CM can be identified by invasive techniques in most patients
- AL amyloidosis must be ruled out before the diagnosis of ATTR-CM is made
- Disease modifying therapy is available to stabilize what was once felt to be a terminal disease

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## Speaker Disclosure

- Dr. Diane Sanders-Cepeda is a fulltime employee at UHG/UnitedHealthcare E&I Retiree Solutions

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## Enhancing our learning Experience Together

*WE ARE ALL LEARNING AND WE ARE ALL TEACHING EACH OTHER*

*WE WILL SPEAK UP IF WE HAVE QUESTIONS OR NEED CLARIFICATION ABOUT THE TERMINOLOGY*

*WE WILL ENGAGE IN THE SESSION AS BEST WE CAN*

*WE WILL LISTEN AND RESPOND RESPECTFULLY TO THE PRESENTERS REGARDLESS OF WHETHER WE UNDERSTAND OR AGREE WITH THE CONTENT OF THEIR PRESENTATION*

3

## Some Heavy Lifting?

| | |
|---|---|
| Describe | • Describe the impact of systemic racism on healthcare systems and care delivery |
| Review | • Review the impact of microaggressions and unconscious bias on care delivery in PALTC |
| Explain | • Explain how inequality and racial equity impact staff across the PALTC continuum |
| Discuss | • Discuss strategies that we as providers can implement to promote equity and address racial disparities in PALTC |

4

## What's Missing in the DEI equation?

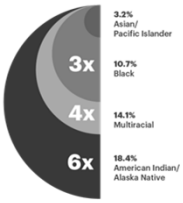

5

## Racial Disparities plagued Healthcare Before COVID

**Persistent disparities in race and ethnicity of those with chronic disease grew even larger in 2017-2019.**

Compared to Asian/Pacific Islander adults (3.2%), the percentage of adults with multiple chronic conditions was 6x higher for American Indian/Alaska Native adults (18.4%), 4x higher for Multiracial adults (14.1%), and 3x higher for Black adults (10.7%).

Source: CDC, Behavioral Risk Factor Surveillance System

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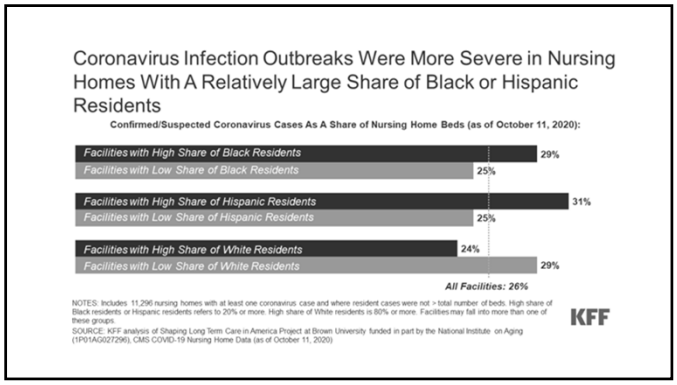
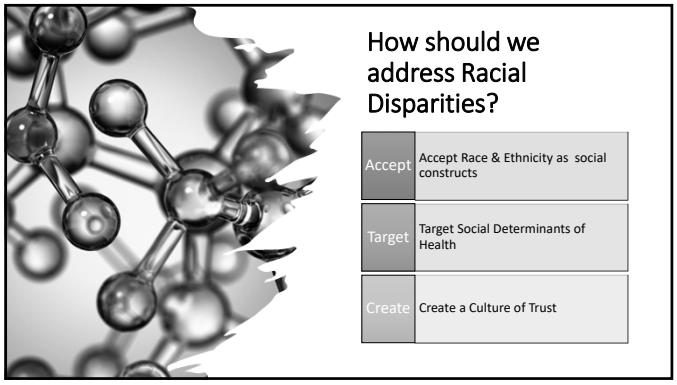

Coronavirus Infection Outbreaks Were More Severe in Nursing Homes With A Relatively Large Share of Black or Hispanic Residents
Confirmed/Suspected Coronavirus Cases As A Share of Nursing Home Beds (as of October 11, 2020):
Facilities with High Share of Black Residents
29%
Facilities with Low Share of Black Residents
25%
Facilities with High Share of Hispanic Residents
31%
Facilities with Low Share of Hispanic Residents
25%
Facilities with High Share of White Residents
24%
Facilities with Low Share of White Residents
29%
All Facilities: 26%
NOTES: Includes 11,296 nursing homes with at least one coronavirus case and where resident cases were not > total number of beds. High share of Black residents or Hispanic residents refers to 20% or more. High share of White residents is 80% or more. Facilities may fall into more than one of these groups.
SOURCE: KFF analysis of Shaping Long Term Care in America Project at Brown University funded in part by the National Institute on Aging (1P01AG027296), CMS COVID-19 Nursing Home Data (as of October 11, 2020)
KFF

7


LOCAL
In Baltimore, a struggling, black-owned nursing home keeps covid-19 at bay
By Rebecca Tan
July 24, 2020 at 7:00 a.m. EDT

8


How should we address Racial Disparities?
Accept
Accept Race & Ethnicity as social constructs
Target
Target Social Determinants of Health
Create
Create a Culture of Trust

9

"Of all the forms of inequality, injustice in health is the most shocking and the most inhuman because it often results in physical death."

Dr. Martin Luther King, Jr. (1966)

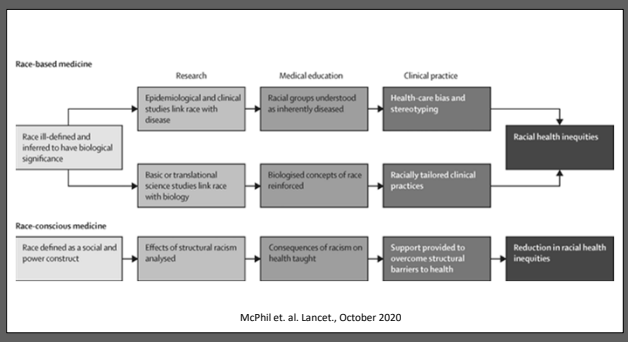

10

## The argument against Race & Ethnicity as a proxy for biological risk

- Concept based on centuries of colonialism, slavery, and race & ethnic superiority ideologies
- Racial and ethnic groups cause the differences seen in health outcomes and source of racial disparities
- Humans share 99.9% of DNA, so common with variations seen mainly within racial groups

Analysis of natural variation reveals no biological basis for racial classification

11




McPhil et. al. Lancet., October 2020

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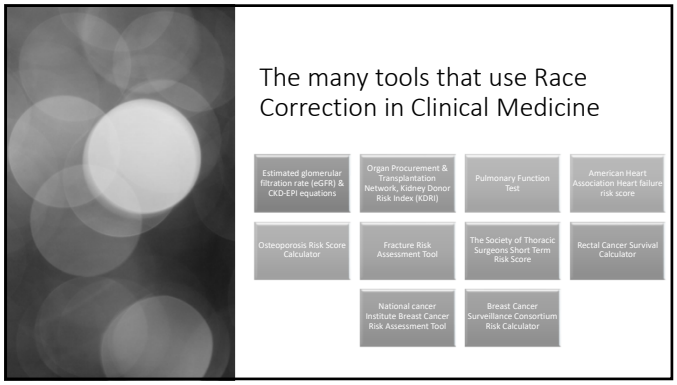
The many tools that use Race Correction in Clinical Medicine
Estimated glomerular filtration rate (eGFR) & CKD-EPI equations
Organ Procurement & Transplantation Network, Kidney Donor Risk Index (KDRI)
Pulmonary Function Test
American Heart Association Heart failure risk score
Osteoporosis Risk Score Calculator
Fracture Risk Assessment Tool
The Society of Thoracic Surgeons Short Term Risk Score
Rectal Cancer Survival Calculator
National cancer Institute Breast Cancer Risk Assessment Tool
Breast Cancer Surveillance Consortium Risk Calculator

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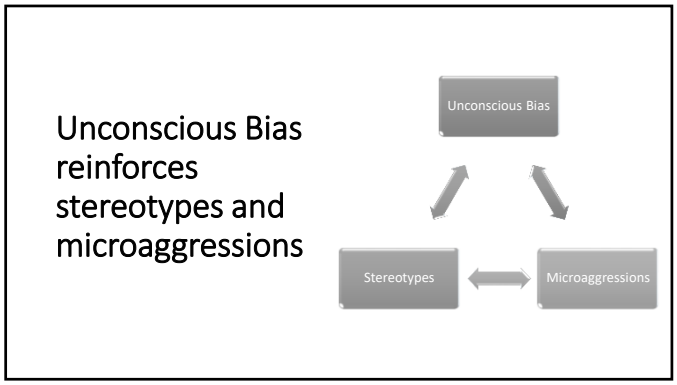
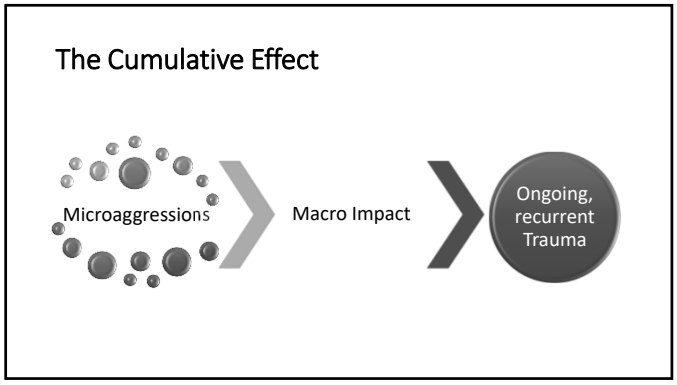

Unconscious Bias reinforces stereotypes and microaggressions
Unconscious Bias
Stereotypes
Microaggressions

14


The Cumulative Effect
Microaggressions
Macro Impact
Ongoing, recurrent Trauma

15

## Implicit bias during diagnosis

- Negative impact on physician-patient interactions
- Altering treatment plan and recommendations
- Perpetuate existing disparities in the healthcare system

16

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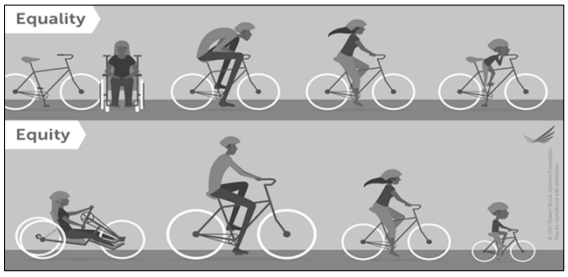
## Equality vs. Equity

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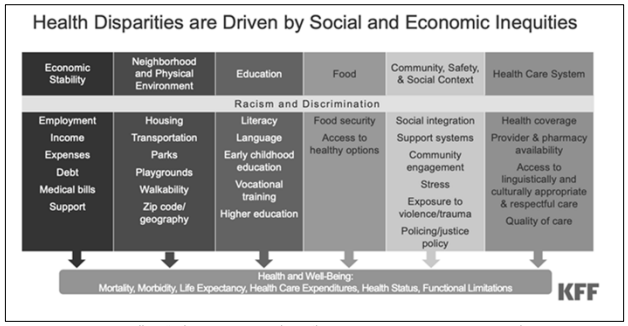


https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/

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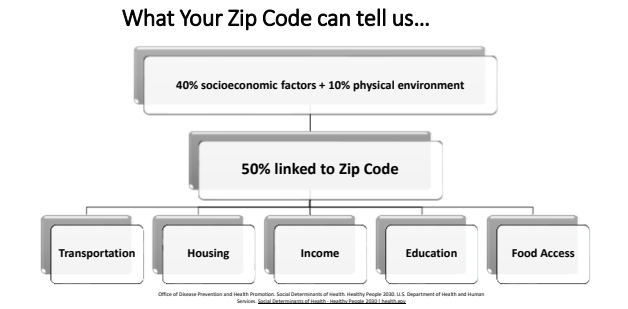


Office of Disease Prevention and Health Promotion. Social Determinants of Health. Healthy People 2030. U.S. Department of Health and Human Services. Social Determinants of Health - Healthy People 2030 | health.gov

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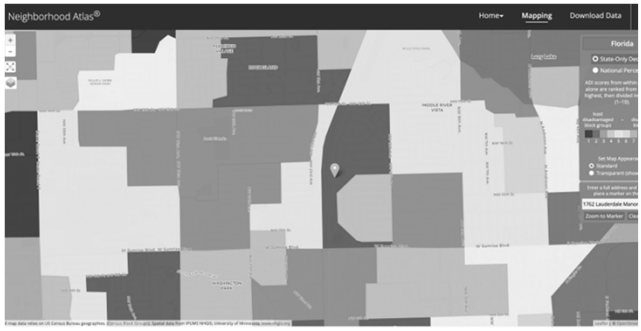


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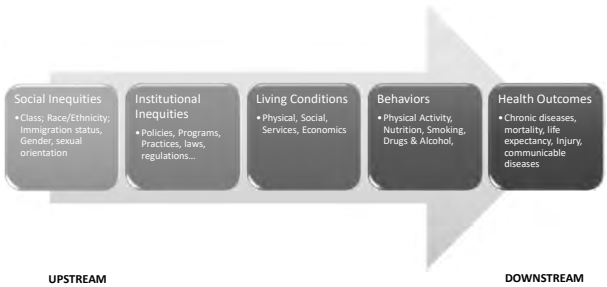
## Consider the impact of Social Determinants of Health

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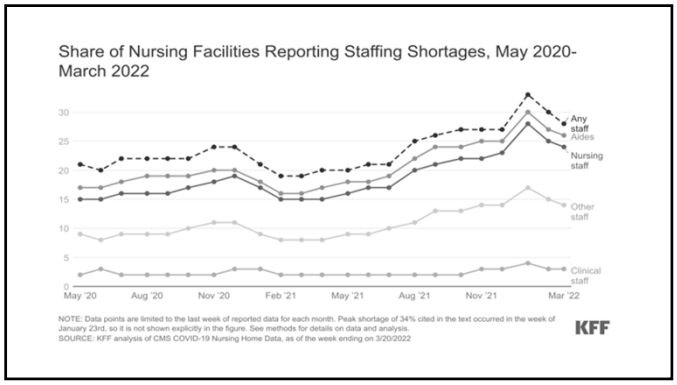


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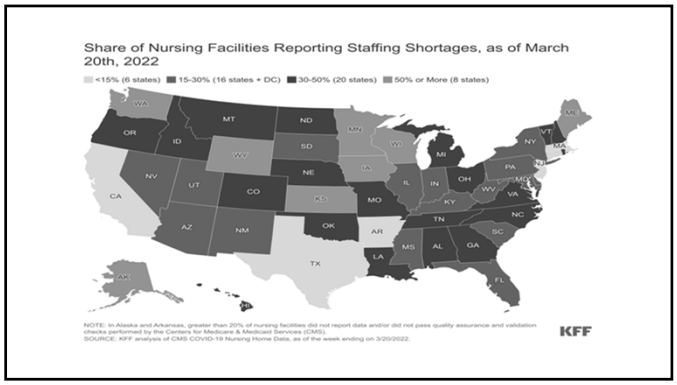


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## Staffing Challenges

Wages, pay inequities

Staffing shortages

Lack of Value

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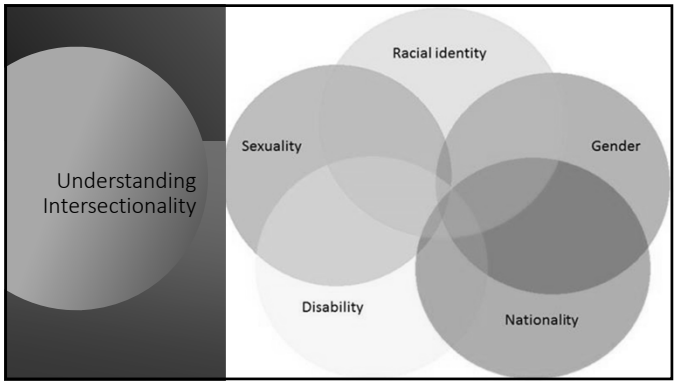


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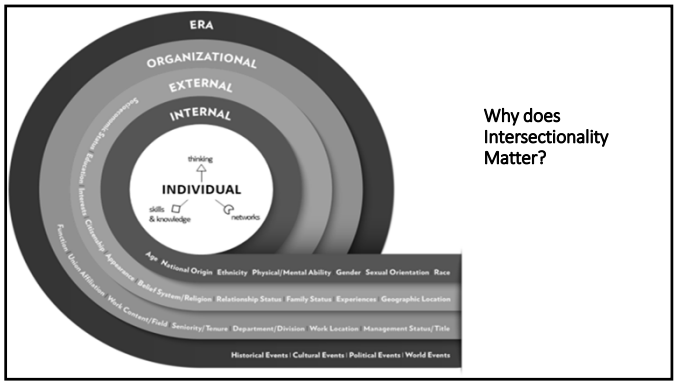


Why does Intersectionality Matter?

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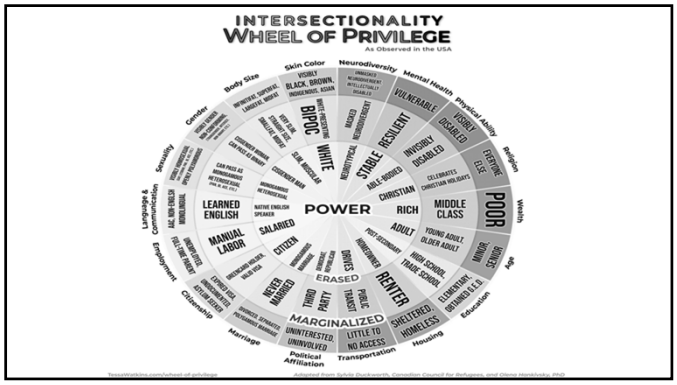


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## The Missing Part of The Equation….

Diversity + Equity + Inclusion = BELONGING

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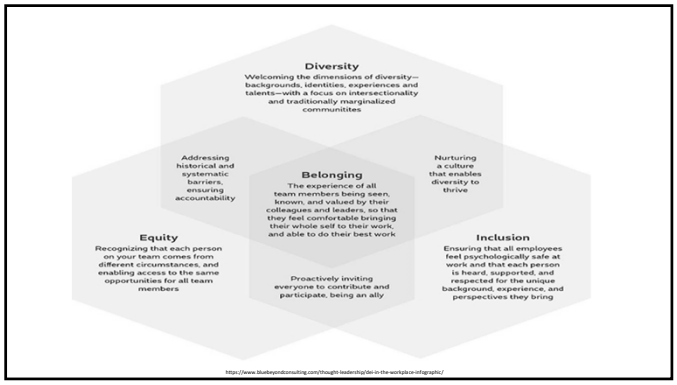
Diversity
Welcoming the dimensions of diversity—backgrounds, identities, experiences and talents—with a focus on intersectionality and traditionally marginalized communities
Addressing historical and systematic barriers, ensuring accountability
Belonging
The experience of all team members being seen, known, and valued by their colleagues and leaders, so that they feel comfortable bringing their whole self to their work, and able to do their best work
Nurturing a culture that enables diversity to thrive
Equity
Recognizing that each person on your team comes from different circumstances, and enabling access to the same opportunities for all team members
Proactively inviting everyone to contribute and participate, being an ally
Inclusion
Ensuring that all employees feel psychologically safe at work and that each person is heard, supported, and respected for the unique background, experience, and perspectives they bring
https://www.bluebeyondconsulting.com/thought-leadership/dei-in-the-workplace-infographic/

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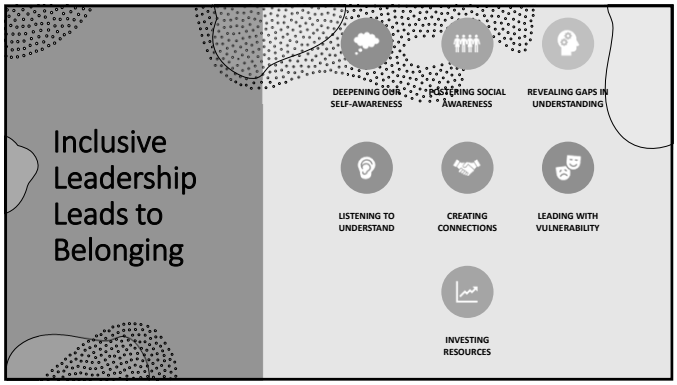
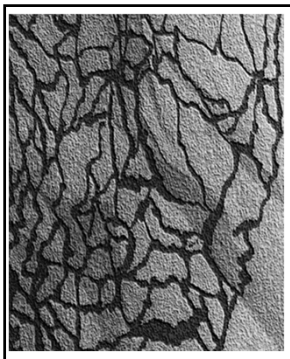

Inclusive Leadership Leads to Belonging
DEEPENING OUR SELF-AWARENESS
FOSTERING SOCIAL AWARENESS
REVEALING GAPS IN UNDERSTANDING
LISTENING TO UNDERSTAND
CREATING CONNECTIONS
LEADING WITH VULNERABILITY
INVESTING RESOURCES

35


Questions?

36



# Thank you for your time!

Diane Sanders-Cepeda, DO CMD
Diane_sanders-cepeda@uhc.com
linkedin.com/in/diane-sanders-cepeda-5430aa208

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FLORIDA MEDICAL
DIRECTORS ASOCIATION

# LEGAL UPDATE FOR PRACTITIONERS

September 19-22, 2023

GREGORY A. CHAIRES, ESQ.
BOARD CERTIFIED IN HEALTH LAW

CHAIRES, BROODERSON & GUERRERO, P.L.
283 CRANES ROOST BLVD., SUITE 165
ALTAMONTE SPRINGS, FLORIDA 32701
(407) 834-2777
www.chlawyers.com

1

## EDUCATIONAL OBJECTIVES

- Understand applicable laws and rules for licensees
- Knowledge of investigation and disciplinary process of the Department of Health and the various regulatory boards
- Where to find the laws and rules you may need
- New Laws affecting your professional practice and the care and treatment you provide to patients
- Ethics

2


3

## WHERE TO START THE ALPHABET SOUP

Dept. of Health (DOH) – licenses health care practitioners after approval from Board – also provides attorney prosecutors from the Prosecution Services Unit to prosecute cases

Agency for Health Care Administration (AHCA) – amongst other things, regulates facilities through the Bureau of Health Facility Regulation

Boards of Allopathic and Osteopathic Medicine, and Nursing (Board) – governs practice through rules, discipline

Attorney Generals Office (AGO) – provides legal counsel to each Board as its General Counsel

Div. of Administrative Hearings (DOAH) – hears certain disciplinary matters through Administrative Law Judges

District Courts of Appeal (DCA) – the appellate courts that consider appeals from the Boards

4

## ORGANIZATION OF THE DEPARTMENT OF HEALTH

- It is organized into seven divisions:
  - Administration
  - Emergency Preparedness and Community Support
  - Disease Control and Health Protection
  - Community Health Promotion
  - Children's Medical Services
  - Public Health Statistics and Performance Management
  - **Medical Quality Assurance (MQA)**

5

## ORGANIZATION - MQA

- MQA is responsible for regulatory activities of various health care practitioners, facilities and businesses. This is done through three Bureaus.
- Bureau of Enforcement –
  - inspections, analyzing companies, education the public, conducting complex investigations, issuing emergency restriction/suspension orders and monitoring compliance, enforcement of regulations and prosecution of unlicensed practice.
- Bureau of Operations –
  - Operation and infrastructure for MQA and the health care regulatory boards and councils. Background screening and practitioner notification services, licensure support services, operation support services, strategic planning and system support.

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## ORGANIZATION - MQA

- Bureau of Health Care Practitioner Regulation -
  - Policy making and programmatic activities related to licensure of health care practitioners and regulated facilities. Credential and license designated health care practitioners.
  - Regulates seven types of facilities and over 200 license types in over 40 healthcare professions through coordination through 22 boards and councils.
  - Board members share authority with the DOH for developing rules for licensure, establishing exams, setting fees, establishing guidelines for discipline, and reducing the unlicensed practice of healthcare professions.
  - The board offices evaluate applications for licensure and examination, conduct board meetings, administer policies, draft communications to licensees.

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## ORGANIZATION - BOARDS

Board Members are volunteers (unpaid) who are appointed by the Governor who are charged with upholding applicable practice acts – the Boards of Medicine, Osteopathic Medicine, and Podiatric Medicine.

Board of Medicine –

- 15 Members – 12 physicians and 3 consumer members

Board of Osteopathic Medicine

- 7 Members – 5 physicians and 2 consumer members

Board of Podiatric Medicine

- 7 Members – 5 podiatric physicians and 2 consumer members

Board of Nursing

- 13 Members – 7 RNs, 3 LPNs, and 3 consumer members

They license, monitor, discipline, education, rehabilitate, and quasi-legislate through rulemaking things such as standards of care, discipline, education. This power is delegated from the Florida legislature to the Boards.

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## LAWS AND RULES

Chapter 456, F.S. – Health Professions and Occupations applicable to all practice acts

Chapter 458, F.S. – Allopathic Medicine and PAs

Chapter 459, F.S. – Osteopathic Medicine and Pas

Chapter 464, F.S. – Nursing Practice Act

Chapter 465 – Pharmacy Practice Act

Chapter 893 – Controlled Substances Act

Chapter 120 – Administrative Procedures Act

Florida Administrative Code

Rule 64B9 – for M.D.s

Rule 64B15 – for D.O.s

Rule 64B9 – for Nurses

Rule 64B16 – for Pharmacists

Many other statutes and rules


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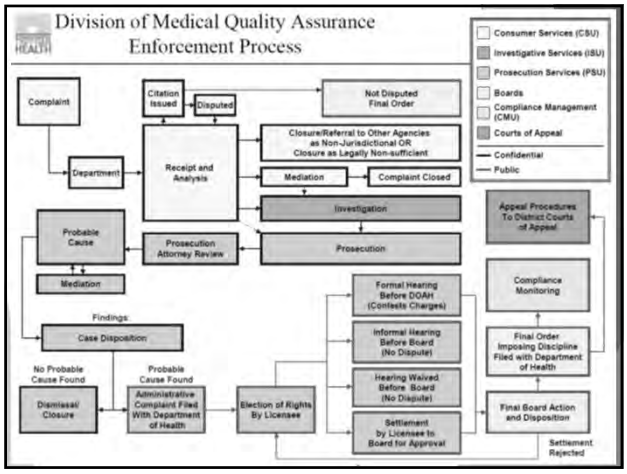
# Investigations

**FLORIDA**
**DEPARTMENT**
**OF HEALTH**
**BUREAU OF PRACTITIONER REGULATION**


10

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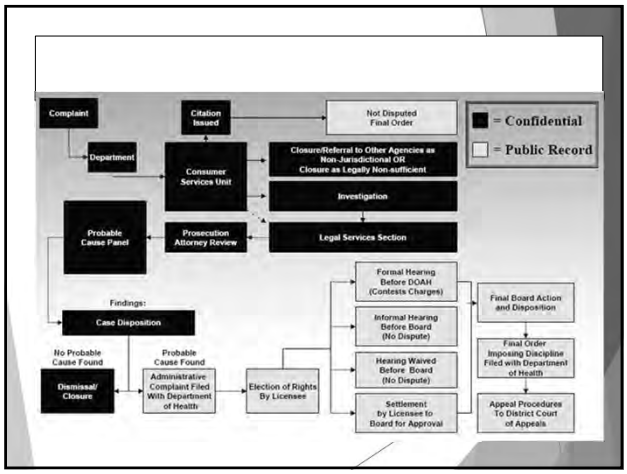


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# THE DISCIPLINARY INVESTIGATION PROCESS

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## HOW DO INVESTIGATIONS INITIATE?

- Complaints may be filed by:
  - A patient or a patient's family member
  - An attorney or law enforcement
  - A fellow practitioner or competitor
  - An anonymous source
  - Health care facility/entity (ex: Code 15 Report)
  - Closed Claim Report
  - Department of Children and Families
  - Department of Health inspectors for OSR or PM
  - Self Reports
  - Hospital Disciplinary Actions

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## CLOSED CLAIMS REPORTING

- **Reported**
  - **Final Judgments**
  - **Settlements**
  - **Final Dispositions not resulting in payments**
- **Report Includes**
  - **Name, Address & Specialty of Practitioner**
  - **Policy Number**
  - **Date of Incident**
  - **Date Reported to Carrier**
  - **Name & Address of Injured (confidential)**

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## DISCIPLINARY PROCESS

- It is governed by Section 456.073, F.S.
- The Department of Health is required to investigate any complaint that is filed if it is in writing and is legally sufficient.
- A complaint is legally sufficiency if it contains ultimate facts that show that a potential violation of the law, or any of the practice acts, or of any rule has occurred. The Department can request other information for that determination.
- The statute permits investigations of anonymous complaints so long as the written anonymous complaint is legally sufficient.
- The "complaint" are reviewed in the Consumer Services Unit.

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## CONSUMER SERVICES UNIT

- All complaints are funneled to the Consumer Services Unit ("CSU") which generally means one person is "analyzing" the complaint to determine legal sufficiency.
- CSU will either –
  - Issue a citation.
  - Dismiss the complaint because it is legally insufficient or there is no jurisdiction.
  - Refer it to mediation.
  - Refer the Complaint to the Investigative Services Unit.

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## INVESTIGATIVE SERVICES UNIT (ISU)

- ISU receives the complaint from CSU and a process then begins for the investigation.
  - You must be notified of the investigation.
  - You will be asked to be interviewed or submit a written response.
  - You can obtain the complete investigative file after the complaint of the investigation but must ask for it in writing.
  - You have the right to counsel.

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## A LETTER FROM THE DOH

- If a Complaint has been filed, you will receive a letter from the Department of Health. This letter will advise you that the Department has received a Complaint or has, on its own, initiated an investigation.
- With the letter, you will receive a Summary of Allegations, which will detail the specific allegations against your license.
- It will also assert statutory violations many of which are premature and may be inaccurate.

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## WHAT DO I DO IF I RECEIVE THIS LETTER?

- You have the right to respond to the allegations against your license, but for a limited time period detailed in the letter. You are not required to respond.
- Notify your insurance carrier.
- It is **strongly recommended** that upon receipt of the letter, you contact a health care attorney immediately that practices before the Boards and the Department.

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## CRITICAL DUE PROCESS RIGHTS

- Constitutional right to remain silent further to the 5th and 14th Amendments.
- State ex rel. Vining vs. Florida Real Estate Commission – seminal case regarding 5th Amendment right to remain silent
- Do not, do not, **do not** pick up the phone and contact the Department of Health or its personnel.
- You cannot be compelled to speak with the Department's investigators.
- You will not become a "red flag" if you do not speak with them – the Department is already reaching out to you.

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## WHY YOU SHOULD NOT TALK TO THE DEPARTMENT OF HEALTH INVESTIGATOR

- You do not know the rules.
- They do not make decisions regarding the viability or continuation of cases.
- They may inaccurately record or reflect what you say.

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## THE CONTINUING INVESTIGATION…

- The DOH will continue a field investigation, which will include interviewing witnesses, the patient or patient's family and gathering relevant medical records and documents.
- The DOH has subpoena authority and it will obtain records and seek information. It will seek your personnel file.
- Once documents and statements have been obtained, the matter will be reviewed by DOH attorneys and possibly an expert practitioner.
- A DOH matter can last from months to YEARS.

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## CASES RETURNED TO DOH AND SENT TO LEGAL

- Once a case is investigated in the field (though sometimes it is investigated in Tallahassee), it is forwarded to the Prosecution Services Unit of the Department of Health.
- They are Assistant General Counsels that are assigned to prosecute cases before the various Boards.
- They evaluate cases and ultimately make recommendations to a panel of the respective Board know as the Probable Cause Panel. This is done through submission of all the investigative materials, including where applicable expert opinions.

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## IMPORTANT RIGHT!!

You have the right to obtain the complete investigative file from the Department of Health.

That request must be in writing pursuant to Section 465.073, F.S. and should request everything.

You are permitted to respond a second time after review of the file.

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## PROBABLE CAUSE PANEL

- Example – Board of Medicine PCP:
- The Panel consists of two physicians and one layperson.
- The Panel will review all of the information collected in the investigation and will determine if probable cause exists.
- If no probable cause is found, the investigation will be dismissed or dismissed with a letter of guidance.
- All Medical Quality Assurance Boards have Probable Cause Panels – they are the screeners and hold the key between something becoming public record or not. What they say is recorded; Can request transcripts.
- The Panel directs the filing of an Administrative Complaint, Closure with a Letter of Guidance, Dismissal of the investigation, or a Referral back to DOH for further investigation.
- This process is confidential until ten days after probable cause is found.

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## WHAT IF PROBABLE CAUSE IS FOUND?

The Probable Cause Panel will recommend that the DOH file an Administrative Complaint against the practitioner's license. The matter, which was previously confidential up to this point, will then become a matter of public record and the DOH will then move the case forward to take disciplinary action.

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## CHOICES IF AN ADMINISTRATIVE COMPLIANT IS ISSUED.

- Charging document.
- Becomes public record.
- Attached to your Practitioner Profile for all to see.
- You will be given the choices to:
  - Dispute the allegations and have a formal hearing before an Administrative Law Judge. Must be done within 21 days.
  - An Informal Hearing where you appear before the Board and admit the allegations and address penalty.
  - Enter into a Settlement Agreement that must be approved by respective Board – generally with your appearance before it at the time of consideration of the settlement proposal.
  - Relinquish your license – a poor and permanent alternative.

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## ELECTION OF RIGHTS FORMAL HEARING

- Formal Hearings or Hearings of Disputed Facts
- Referred to the Division of Administrative Hearings
- Before an Administrative Law Judge
- Like a trial with no jury – heightened burden of proof
- Costly route and labor-intensive process.
- Still the Board's call on penalty, in other words, the Proposed Recommend Order issued by the Administrative Law Judge will be presented to the Board to adopt or reject and determine penalty.

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## ELECTION OF RIGHTS INFORMAL HEARING

- This is where you admit the allegations as alleged in the Administrative Complaint.
- Cannot dispute the allegations at any time and if you do the proceeding is canceled and the matter is referred to the Division of Administrative Hearings.
- Appear before the Board and present testimony/evidence regarding mitigation of any potential penalty.
- Should be represented by counsel.
- This is the least controllable outcome, and you are subject to any penalty issued by the Board within its penalty guidelines.

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## SETTLEMENT AGREEMENTS

- Negotiated between the licensee and the Department of Health prosecutor.
- Depending on the Board, may have to appear and answer questions at the time of consideration of the proposed Agreement.
- Board may accept or reject the Agreement after consideration of the investigative materials, and any testimony you may give. A count-offer can be offered to resolve the Administrative Complaint.
- The advantage to such a proceeding is that technically all the Board can do at your appearance is accept or reject the proposed Settlement Agreement. It cannot at that time, reject and issue a different penalty.

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## PENALTIES

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## PENALTIES MAY INCLUDE:

- Letter of Concern or Reprimand
- Fines up to $10,000
- Assessment of Costs
- Continuing Education
- Probation
- Suspension or Revocation
- UF CARES Program
- PRN

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## GROUNDS FOR DISCIPLINARY ACTION?

- Florida Statute 458.331 specifically sets forth the various grounds for disciplinary actions for allopathic physicians and physician assistants.
- Florida Statute 459.015 specifically sets forth the various grounds for disciplinary actions for osteopathic physicians.
- Florida Statute 465.016 specifically sets forth the various grounds for disciplinary actions for pharmacists.

**Be familiar with the law governing your license!**

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## FINAL ORDERS

Reported to National Practitioner Data Bank

Reported to the Federation of Medical Boards

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## IMPORTANT REMINDER

- There may be obligations to report discipline to facilities and other states in which you have a license.
- Need to check bylaws, management care agreements. Specialty Board rules, and other state laws where you have a license.
- How might it affect your participation in managed care plans, Medicare, etc.

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## IF YOU HAVE A DRUG OR ALCOHOL PROBLEM, PLEASE CONSIDER:

Physician's Recovery Network ("PRN") (http://www.flprn.org/)

or

Intervention Project for Nurses ("IPN") (http://www.ipnfl.org/)


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## WHAT CAN YOU DO TO PROTECT YOUR LICENSE?

- Follow the Rules which means know the Rules.
- Review your licensing Board's website weekly for updates.
- Also document thoroughly.
- Do you have broad form coverage? Some new carriers may not! In addition to coverage in the event of a malpractice claim, broad form provides coverage for your attorney fees should you be investigated by the Department of Health and sometimes, KEPRO, etc.
- Remember: It will cover your attorney fees, but it will <u>not</u> cover any potential fine or costs assessed against you by your licensing board.

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## REMEMBER YOUR RIGHTS

- You have a property right in your license
- Right to remain silent
- Proper notice and time to respond
- Review Department of Health investigative file – second bite at the apple
- Right to legal counsel

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# THE DAY TO DAY MUST KNOWS

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## MEDICAL DIRECTORS

- Each nursing home licensee must will have only one physician who is designated as Medical Director.
- The Medical Director must be a physician licensed under Chapter 458 or 459, F.S., the nursing home administrator may require that the Medical Director be certified or credentialed through a recognized certifying or credentialing organization.
- A Medical Director who does not have hospital privileges must be certified or credentialed through a recognized certifying or credentialing body, such as The Joint Commission, the American Medical Directors Association, the Healthcare Facilities Accreditation Program of the American Osteopathic Association, the Bureau of Osteopathic Specialists of the American Osteopathic Association, the Florida Medical Directors Association or a health maintenance organization licensed in Florida.

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## MEDICAL DIRECTOR
CONTINUED

- A physician must have his or her principal office within 60 miles of all facilities for which he or she serves as Medical Director. The principal office is the office maintained by a physician as required by Section 458.348 or 459.025(3)(c)1., F.S., and where the physician delivers the majority of medical services. The physician must specify the address of his or her principal office at the time of becoming Medical Director. A rural facility is a facility located in a county with a population density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other nursing home facility within the same county.

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## MEDICAL DIRECTOR
### CONTINUED

- (d) The nursing home licensee must appoint a Medical Director who must visit the facility at least once a month. The Medical Director must review all new policies and procedures; review all new incident and new accident reports from the facility to identify clinical risk and safety hazards. The Medical Director must review the most recent grievance logs for any complaints or concerns related to clinical issues. Each visit must be documented in writing by the Medical Director.

- A physician may be Medical Director of a maximum of 10 nursing homes at any one time. The Medical Director, in an emergency where the health of a resident is in jeopardy and the attending physician or covering physician cannot be located, may assume temporary responsibility of the care of the resident and provide the care deemed necessary.

- The Medical Director must meet at least quarterly with the risk management and quality assurance committee of the facility and participate in the development of the comprehensive care plan for the resident when he or she is also the attending physician of the resident.

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## PRACTITIONER PROFILES

- Pursuant to 456.02, F.S., a physician must update his or her Practitioner Profile within 15 days related to any of the following changes:
  - Address
  - Medical staff privileges
  - Medical malpractice settlements or judgments
  - Changes to financial responsibility
  - Matters related to Board Certification
  - Education matters
  - Disciplinary or criminal history

  Also, important to note that if you are disciplined in another jurisdiction, you have an affirmative obligation to notify the Board of Medicine within 30 days of any such disciplinary action. Failure to do so is grounds for discipline.

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## OTHER MUST KNOWS

- Do not pre-sign prescriptions no matter what good intentions you may have. Will be subject to discipline which could include a reprimand to your medical license, a $5,000 fine, payment of administrative costs, a laws and rules course, and probation.
- The Board Rules on Patient Record Retention –
  - Must maintain records at lease five years (but HIPAA and Medicare Managed Care Plans require longer).
  - Must notify patient by sign or letter of where records may be obtained if physician moves.
  - Newspaper notice and notify the Board within 30 before you move.

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## MEDICAL RECORDS MINIMUM WRITTEN CONTENT

- Written records shall contain, at a minimum, the following information about the patient –
  - Patient histories;
  - Examination results;
  - Test results;
  - Records of drugs prescribed, dispensed or administered;
  - Reports of consultations; and
  - Reports of hospitalization.

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## RECORDS MINIMUM CONTENT
(CONTINUED)

- Purpose for keeping complete and accurate medial records:
- To serve as a basis for planning patient care and for continuity in the evaluation of the patient's condition and treatment.
- To furnish documentary evidence of the course of the patient's medical evaluation, treatment and change in condition.
- To document communication between the practitioner responsible for the patient and other health care professional who contributes to the patient's care.
- To assist in protecting the legal interest of the patient, the hospital and **the practitioner responsible** for the patient. IT PROTECTS YOU.

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## SUPERVISION OF APRNS

- Frequently asked questions from the Board of Medicine website.
- According to Rule 64B8-35.002, F.A.C.:
  The number of persons to be supervised shall be limited to insure that an acceptable standard of medical care is rendered in consideration of the following factors:

  (a) Risk to patient;
  (b) Educational preparation, specialty, and experience of the parties to the protocol;
  (c) Complexity and risk of the procedures;
  (d) Practice setting; and
  (e) Availability of the physician or dentist
- This applies in the office setting and those exempt sections under 458.348. F.S.
- Must enter into a protocol with the supervising physician and must be maintained at the location where the APRN practices. Example protocol at the Board of Nursing website.

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## SUPERVISION OF PHYSICIAN ASSISTANTS

- Governed by Sections 458.347 and 459.022, F.S.
- Can supervise up to 10 PAs at a time and is not required to co-sign charts. However, third party payors may still require this. Remember the distinction between onsite and offsite supervision.
- Physician providing supervision must be qualified in the medical areas in which the PA is to perform and SHALL be individually and collectively responsible and LIABLE for the performance and the acts and omissions of the PA.

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## SUPERVISION OF PHYSICIAN ASSISTANTS (continued)

- Supervisory physicians may delegate to PAs the authority to prescribe or dispense any medication used in the supervising physician's practice unless prohibited by the formulary established by the PA Council.
  - PA must identify he/she is a PA to the patient.
  - The supervising physician must notify the Department of his or her intent to delegate before delegating any prescriptive privileges to the PA.
  - The PA can also procure medical devices.
  - The PA must complete a 10-hour CME course in the specialty practice, 3 of which regard safe and effective controlled substance medications.
  - PA, when delegate, can provide services in hospital and nursing homes.
  - The PA may sign DNRs, death certificates, physical exams, for PT, OT, SLP, home health and DME.
  - IMPORTANTLY, PAs now may supervise medical assistants.

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## WHAT CAN MEDICAL ASSISTANTS DO

- First – Under the direct supervision and responsibility of a licensed physician, a medical assistant may undertake the following duties:
- (a) 1. Performing clinical procedures.
  - 2. Taking vital signs.
  - 3. Preparing patients for the physician's care.
  - 4. Performing venipunctures and non-intravenous injections.
  - 5. Observing and reporting patients' symptoms.

  (b) Administering basic first aid.

  (c) Assisting with patient examinations or treatments.

  (d) Operating office medical equipment.

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## MEDICAL ASSISTANTS
(CONTINUED)

(e) Collecting routine laboratory specimens as directed by the physician.

(f) Administering medication as directed by the physician.

(g)Performing basic laboratory procedures.

(h) Performing office procedures including all general administrative duties required by physician.

(i) Performing dialysis procedures, including home dialysis.

They are not licensed by the state of Florida or the Department of Health and not required to have a national certification.

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## OTHER ISSUES THAT CAN CAUSE TROUBLE

- Misleading advertising including incorrect statements on your website. Also make sure your credentials are up to date, in particular your Board Certification.
- Financial relationships you enter into or other persons in your practice. Examples self-referral laws, anti-kickback statutes, patient brokering.
- Aiding the unlicensed practice of medicine. Be careful what you delegate and how you use medical assistants and other personnel.
  - Supervision required for MAs – law now allows physician assistants to supervise. Section 458.347(4)(j), F.S.

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## RECENT CHANGES IN FLORIDA LAW
PATIENT SELF-REFERRAL ACT

- SB 768 – significant change. The definitions of “direct supervision” and “present in the office suite” were removed from Florida’s Patient Self-Referral Act. In doing so, section (3)n3.f. was amended regarding the exceptions to the definition of referral stating that direct supervision is no longer required, but the supervision that will be required must comply with applicable Medicare payment and coverage services.
- This will impact any practice that provides designated health services. That includes practices that do things such as lab work, diagnostic imaging, etc.
- This took place on July 1, 2023

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## NEW LAWS

NURSING HOMES AND NURSES- QMAs

- SB 558 – A nursing home, may authorize an RN to delegate tasks, including medication administration, to a certified nursing assistant that meets certain requirements. Once the requirements are met, the CNA is designated a "Qualified Medical Aide." Those medications include oral, transdermal, ophthalmic, otic, inhaled, or topical prescription medication.
- Those requirements are set forth in Section 400.211(5), F.S., and include a 34 hour Nursing Board approved course in medication administration and associated tasks, including, blood glucose level checks, dialing oxygen flow meters to prescribed settings, and assisting with continuous positive airway pressure devices.
- There is an annual validation requirement and two hour in-service training required thereafter.
- The Board of Nursing is to write rules to implement this law.

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## NEW LAWS

MEDICAL MARIJUANA, TELEHEALTH, ASSAULT ON HEALTH CARE PROVIDERS AND PHYSICIANS ASSISTANTS.

- HB 387 – now permits physicians to renewal approval for medical marijuana via telehealth. There must be an in-person visit for the initial determination that approves a patient for medical marijuana.
- HB 267 – amends the definition of telehealth under Section 456.47, F.S., to now provide that audio-only phone calls are permitted and included in the provision of permissible telehealth services. Emails and faxes are still not permitted.
- HB 825 – changing assault on hospital personnel from a second-degree misdemeanor to a first-degree misdemeanor. Raising battery to a third-degree felony from a first-degree misdemeanor, aggravated assault to a second-degree felony from a third-degree felony, and aggravated battery to a first-degree felony from a second-degree felony.

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## NEW LAWS

PHYSICIANS ASSISTANTS AND CNAS

- HB 1133 – revised eligibility requirements for physician assistant licensure who matriculate through a program on or before 12/21/20 and permits the Boards to grant licensure if an applicant does not meet the statutory educational requirements but has passed the Physician Assistant National Certifying Examination.
- SB 558 – creates a new designation of "qualified medication aide" (QMA) for certified nursing assistants (CNA) who work in a nursing home and meet specified licensure and training requirements. It allows a nursing home to authorize an RN working in that nursing home to delegate medication administration to the QMA under direct supervision o the RN.
- HB 1317 – adds board-eligible or board-certified family medicine physicians as health practitioners eligible to certify brain death in certain situations.

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## NEW LAW - SB 1718

IMMIGRATION REFORM

- Employers may not knowingly employ, hire, recruit or refer workers who are not authorized to work in the United States. Florida employers with 25 or more employees and all Florida workers who contract with public agencies must use the E-Verify system with few exceptions.
- It requires hospitals accepting Medicaid to ask, on patient admission/registration forms, whether the patient is a U.S. citizen or lawfully present in the United States or is not lawfully in the U.S. The form is required to state that the response will not affect patient care or result in a report of patient's immigration status to immigration authorities. Patients can decline to answer.
- Hospitals must submit quarterly reports to AHCA. AHCA must submit an annual report to the Governor and Legislature that includes estimates of uncompensated care for those individuals not lawfully in the U.S.

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## NEW LAW – HB 1471

HEALTH CARE PROVIDER ACCOUNTABILITY

- Addresses health care provider accountability related to nursing home residents' rights, unlicensed facilities and standards of care for office surgeries.
- Sets forth an extensive list of resident rights that a nursing home must afford its residents, including the right to refuse medication and treatment, and be free from sexual abuse, neglect, and exploitation.
- Authorizes AHCA to seek ex parte temporary injunctions to prevent continued unlicensed activity by a provider that has received a cease and desist demand.

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## NEW LAW – SB 1580

CONSCIENCE BASED OBJECTIONS TO CARE

- SB 1580 – provides that health care providers (including physicians) and payors may make a "conscience-based objection" to the provision of certain "health care services" if such objection is based on a sincerely held religious, moral, or ethical belief. The statute which can be found at Section 381.00321, F.S., provides for the requirements for such an objection, including notice to a health provider's supervisor or employer, and documentation in the patient's chart (if applicable).
- This section does not allow a patient or payor to opt out of providing health care services to any patient or potential patient because of race, color, religion, sex or national origin.
- A health care provider may not be discriminated against or suffer adverse action because the health care provider declined to participate in a health service on the basis of a conscience-based objection.

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## NEW LAW - SB22

PROTECTION FROM DISCRIMINATION BASED ON HEALTH CARE CHOICES

- Prohibits business and governmental entities from requiring a person to provide documentation or requiring a COVID-19 test to gain access, entry or services or any relationship with the business or governmental entity.
- Prohibits mask mandates, vaccinations, mRNA vaccinations, as well as the requirement that a person wear a mask, face shield, or any facial covering or denying access to, entry to, services from, or admission to such entity based on the refusal to wear a mask (with an exception related to health care providers). AHCA is required to develop standards for the use of masks and that each health care provider adopt such similar rules.
- Prohibits hospitals from interfering with COVID-19 treatment options, requires health care practitioners obtain specific informed consent related to COVID-19 prescriptions, and prohibits pharmacists from being disciplined for properly dispensing COVID-19 medications.

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## NEW LAWS

DEA OPIOID TRAINING

- DEA new training requirement – a one time training requirement which is that practitioners take eight hours of training on treatment and management of patients with opioid or other substance abuse disorders.
- DEA requirement that beginning June 27, 2023, practitioners are required to check a box on their one DEA registration form, regardless of whether a registrant is completing their initial registration application or renewing their registration, affirming that they have complete the new training requirement.

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## CONTROVERSIAL LAWS

ABORTION AND TRANSGENDER TREATMENT

- SB 300 – prevents abortions after six weeks of pregnancy while allowing abortions up to 15 weeks for cases of rape, incest or human trafficking.
- SB 254 –Makes it a third-degree felony for health care providers to render gender-affirming treatments such as puberty blockers, hormone therapy or surgical procedures to minors. Requires that adults seeking such treatment must sign consent forms developed by the Boards of Medicine and Osteopathic Medicine.

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# ETHICS


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# ETHICS

Physicians are held to a high standard in our society. Patients need to be able to TRUST their physicians:

- Physician-patient relationship
- Financial
- Personal

The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare.

AMA Code of Medical Ethics Opinion 1.1.1

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# ETHICS CONTINUED

- Their historical development are reflected in:
- Local and state medical society records.
- AMA & AOA Code of Medical Ethics.
- AMA Journal of Ethics – Cases and Polls.
- Declaratory Statements from the Boards like the Board of Medicine and Boards of Osteopathic Medicine.
- Ethics are not laws and are not enforced in Courts of Law.
- They are actions that reduce trust.
- What you think is ethical may not be lawful.

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## ETHICS – THREE MAIN AREAS OF CONCERN

- Personal
- Economic
- Personal Issues

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## PHYSICIAN-PATIENT RELATIONSHIP

- Personal Physician–Patient Relationship
  - Communication – informed consent, its importance
  - Patient Rights – dignity and access to things like their medical records, right to privacy and continuity of care. Florida has a Patient Bill of Rights and there are many rights that can be gleaned from the various practice acts that regulate the practice of medicine.
  - Refusal of treatment and patient autonomy.
  - Boundary Issues – these occur all too frequently and some are legitimate, and others are not. Sexual misconduct is broadly defined and much more then you think it is. It includes verbal or sexual activity and is subjective as to how it is received by the patient.

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## IMPORTANT STATUTES IN THIS REGARDING SEXUAL MISCONDUCT.

- Exercising influence within a physician-patient relationship for purposes of engaging a patient in sexual activity. A patient shall be presumed to be incapable of giving free, full, and informed consent to sexual activity with his or her physician. 458.331(1)(j) and 459.015(i)(l), F.S.
- The physician – patient relationship is founded on mutual trust. Sexual misconduct in the practice of medicine violates the physician-patient relationship through which the physician uses said relationship to induce or attempt to induce the patient to engage in sexual activity outside of the practice or the scope of generally accepted examination or treatment of the Patient Sexual misconduct in the practice of medicine is prohibited.

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## BOARD RULES

(CONTINUED)

► (2) For purposes of this rule, sexual misconduct between a physician and a patient includes, but it is not limited to:

(a) Sexual behavior or involvement with a patient including verbal or physical behavior which:

1. May reasonably be interpreted as romantic involvement with a patient regardless of whether such involvement occurs in the professional setting or outside of it,

2. May reasonably be interpreted as intended for the sexual arousal or gratification of the physician, the patient or any third party, or

3. May reasonably be interpreted by the patient as being sexual.

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## SEXUAL MISCONDUCT

(continued)

(b) Sexual behavior or involvement with a patient not actively receiving treatment from the physician, including verbal or physical behavior or involvement which meets any one or more of the criteria in paragraph (2)(a), above, and which:

1. Results from the use or exploitation of trust, knowledge, influence or emotions derived from the professional relationship,

2. Misuses privileged information or access to privileged information to meet the physician's personal or sexual needs, or

3. Is an abuse or reasonably appears to be an abuse of authority or power.

► Rule 64B8-9.008, F.A.C.

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## WHEN IS THE PHYSICIAN-PATIENT RELATIONSHIP OVER

► The mere passage of time since the patient's last visit to the physician is not solely determinative of whether or not the physician-patient relationship has been terminated. Some of the factors considered by the Board in determining whether the physician-patient relationship has terminated include, but are not limited to, the following:

(a) Formal termination procedures;
(b) Transfer of the patient's case to another physician;
(c) The length of time that has passed since the patient's last visit to the physician;
(d) The length of the professional relationship;
(e) The extent to which the patient has confided personal or private information to the physician;
(f) The nature of the patient's medical problem; and,
(g) The degree of emotional dependence that the patient has on the physician.

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## BEST PRACTICES

- Best Practices would be to have someone else in the examination room with you at all times. It is not always realistic but best practices. Certainly, have someone present for any physical examination.
- The law requires that licensees report allegations of sexual misconduct to the Board. It does not say what time frame but does require a report. The fact that a practice conducts its own investigation and concludes that there was no "sexual misconduct" in and of itself does not mitigate the reporting requirement.

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## ETHICS – FINANCIAL/ECONOMIC

- Section 456.072(1), F.S. – Exercising influence on the patient or client for the purposes of the licensee or a third party, which shall include the promotion or selling of services, goods, appliances or drugs. Also, in Sections 458.331(1)(n) and 459,015(1)(q), F.S.
- Referrals
- Testing
- Billing
- Fee Splitting
- Kick-Backs
- Loans/Investments
- Gifts
- Products Sold
- Financial Responsibility

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## ETHICS – PERSONAL ISSUES

- Personal issues include –
- Being an expert witness and the potential influence associated with being compensated for your testimony.
- Impairment – inability to practice medicine with skill and safety due to any form of impairment.
- The Professional Resource Network (PRN) or the Intervention Project for Nurses (IPN) .
- Reporting obligations where a license may be disciplined for the failure to report to the Department any person who the licensee knows is in violation of the applicable practice act or Chapter 456, F.S. Those that are impaired can be reported to PRN or IPN rather than the Department for illness or use of alcohol, drugs, narcotics, chemicals or as a result of mental or physical condition.

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## OTHER RESOURCES

- Information vs. Advice – do your homework but do speak with competent and trained counsel. This is a unique area of the law, different from mainstream litigation, and thus, providers are urged to seek counsel from individuals who are experienced in this specific area of the law concerning licensure, board and health law matters.
- Read the Declaratory Statements issued by the Boards use such to obtain information on how certain activities or conduct are addressed by Boards.

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# Psychotropic Stewardship

## Navigating Phase 3 Guidance to Individualize Pharmaceutical Care

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Senior Manager, Clinical Services, Omnicare

1

**Dr Hidlebaugh has no disclosures**

**Dr Foley is a full-time employee of CVS/Omnicare**

2

## Learning Objectives

- **Understand Phase 3 guidance changes with respect to psychotropic medications**
- **Identify and develop a plan for addressing potential psychotropic medication irregularities**
- **Design and implement a psychotropic stewardship program**
- **Summarize keys to success to work as a team in a psychotropic stewardship program**

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## Case Study

JM is a 78 yo F admitted today for rehab s/p ORIF due to a ground-level fall at her ALF sustained one week ago.

Discharge Medication List

| Medication | Diagnosis |
|---|---|
| Lisinopril 20mg QD | Hypertension |
| Valproic Acid 500mg BID | Seizures |
| Gabapentin 300mg BID | Anxiety |
| Quetiapine 25mg HS | Schizophrenia |
| Metformin 500mg BID | Diabetes |
| Metoprolol XL 50mg QD | Hypertension |
| Donepezil 10mg QD | Alzheimer's Disease |
| Atorvastatin 40mg QD | Hyperlipidemia |
| Mirtazapine 15mg HS | Anorexia |
| Clonidine 0.1mg Q8h PRN SBP > 140 | Hypertension |
| Amlodipine 10mg once daily | Hypertension |
| Citalopram 20mg once daily | Depression |
| Aspirin 81mg once daily | Hx MI |

- Sentinel medications
- Sentinel diagnoses
- Where do we need more information?

4

## Discharge Medication List

| Medication | Diagnosis |
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| Lisinopril 20mg QD | Hypertension |
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| Gabapentin 300mg BID | Anxiety |
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| Amlodipine 10mg once daily | Hypertension |
| Citalopram 20mg once daily | Depression |
| Aspirin 81mg once daily | Hx MI |

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## Alzheimer's Disease & Related Dementias

- All-cause dementias: cognitive or behavioral symptoms that
  - Interfere with the ability to function at work or at usual activities; and
  - Represent a decline from previous levels of functioning and performing; and
  - Are not explained by delirium or major psychiatric disorder;
  - Cognitive impairment is detected and diagnosed through history taking and an objective cognitive assessment
  - The cognitive or behavioral impairment involves a minimum of 2 domains:
    1) impaired ability to acquire and remember new information;
    2) impaired reasoning and handling of complex tasks, poor judgement;
    3) impaired visuospatial abilities;
    4) impaired language functions;
    5) changes in personality, behavior, or comportment
- **Mild cognitive impairment** does not interfere with functioning

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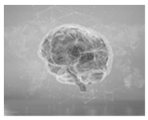
## Alzheimer's Disease & Related Dementias



- **Alzheimer's Disease dementia** diagnosed when:
  - Insidious onset
  - Clear-cut history of worsening of cognition; and
  - The initial and most prominent cognitive deficits are evident on history and examination in one of the following categories:
    - Amnestic presentation (learning and recall of recently learned information, and at least one other domain impairment)
    - Non-amnestic presentation: language (word-finding + 1 domain), visuospatial (spatial cognition + 1 domain), executive dysfunction (impaired reasoning, judgement, problem solving +1 domain)
  - No evidence of other disease (Lewy body, cerebrovascular disease, etc)

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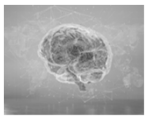
## Alzheimer's Disease & Related Dementias



- **Vascular Dementia**
  - Major cerebrovascular event -> stepwise decline/fluctuating course
  - Vs significant subcortical microvascular events -> gradual onset, slowly progressive
    - Deficits particularly in speed of information processing, complex attention and/or frontal-executive functioning + early gait disturbance/falls, or early urinary symptoms, or personality and mood changes

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## Alzheimer's Disease & Related Dementias

- **Dementia with Lewy bodies**
  - Fluctuating cognition/attention/alertness, well formed visual hallucinations, REM sleep behavior disorder, parkinsonism
  - Cognitive impairments appear before or around same time as parkinsonism
- **Frontotemporal dementia**
  - Behavioral variant: at least 3 of the following - behavioral disinhibition, apathy, loss of empathy, ritualistic behavior, hyperorality, executive dysfunction with relative sparing of memory and visuospatial functions
  - Primary progressive aphasia: difficulty with language, aphasia
    - Logogenic variant PPA, Non-fluent variant PPA, Semantic variant PPA

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## Objectives of Revised Guidance

- **Pharmaceutical Care and Services**
  - Evaluate psychopharmacologic use and Gradual Dose Reduction of medications that can affect brain activity
  - Document the medical history of an accurate psychiatric diagnosis

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## F658 and F659: Comprehensive Person-Centered Care Plans

**Guidance Overview**

- **New guidance on care planning and services provided, reporting practitioners not adhering to professional standards of quality**

**Rationale**

- **F658: CMS documented incidents of situations of potential misdiagnosis of schizophrenia, allowing for antipsychotic use and exclusion of resident's data from long-stay AP measures**
- **F659: Services provided and arranged "in accordance with the residents plan of care"**

**Implications for Non-Adherence**

- **Referral to State Medical Boards or Board of Nursing**

**Recommended Facility Action**

- **Review and update current policies and procedures**
- **Communicate changes with residents, families, staff and practitioners**
- **Confirm documentation of psychiatric diagnosis from past medical history**

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| Common Antipsychotics | Potential Approved (on-label) Uses |
|---|---|
| Haldol (haloperidol) | – Schizoaffective Disorder |
| Latuda (lurasidone) | – Schizophrenia |
| Risperdal (risperidone) | – Bipolar I Disorder |
| Seroquel (quetiapine) | – Bipolar Depression |
| Zyprexa (olanzapine) | – Major Depressive Disorder |

*****FDA-approved indications vary. Refer to prescribing information available at: https://dailymed.nlm.nih.gov/dailymed/**

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## Considerations for Adequate Indication for Use

Diagnosis **alone** may **not** warrant treatment with antipsychotics, but treatment may be justifiable when using a person-centered approach, especially when:

- Behavioral symptoms pose a **danger** to the resident or others
- Multiple attempts at **non-pharmacological approaches** failed to alleviate dangerous or distressful behavior
- The expressed behaviors are **distressful to the resident** (e.g., hallucinations)
- Symptoms returned following gradual dose reduction

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## Case for Adequate Indication of Use

- 78 yo M with significant history of dementia, CAD, hearing loss
- Admitted to memory care ALF due after hospitalization for agitation- on quetiapine 50 mg TID, memantine 5 mg daily
- Resident calm, no agitation -> slowly dose reduced until stopped
- Exhibited sexually inappropriate behaviors (bringing female residents into room and performing sexual acts, removing clothes)

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## Case for Adequate Indication of Use

- Started on aripiprazole 10 mg -> increased to 20 mg
- Memantine stopped (after quetiapine)
- Multiple interdisciplinary meetings: Director of nursing concerned about change from quetiapine to aripiprazole
  - Patient with unexplained LE edema and hyponatremia -> improved off of quetiapine
  - Started sertraline 25 mg, finasteride 5 mg, and medroxyprogesterone 2.5 mg daily
  - Wife was calling him from out of state often proceeding his behaviors

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## Pharmacy Services: F757 Unnecessary Drugs and F758 Psychotropic Drugs

**Guidance Overview**

- Facility may use LTC Pharmacist generated reports for QAPI on utilization of certain drug classes, allowing for trend identification which may prevent ADRs.
- Updated guidance stating that the medical record must show documentation of the "diagnosed condition" for utilization of prescribed psychotropics.
- CMS is also providing a list of other medication classifications for medications that affect brain activity and indicates that these fall under psychotropic requirements when being used as a substitute for another psychotropic rather than approved indication.
- CMS provides guidance regarding GDR to minimize withdrawal and meeting compliance with GDR requirements.

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## Pharmacy Services: F757 Unnecessary Drugs and F758 Psychotropic Drugs

**Recommended Facility Action**

- Review current policy and procedures
- Communicate regulatory changes with staff, family members, practitioners
- Utilize QAPI tracking tools provided by the consultant pharmacists as part of monthly and quarterly reporting
- Provide appropriate and documented diagnosis for psychotropic drug use
- Review the use of non-psychotropic medications that affect brain activity and document accordingly with emphasis on "substitute" medications as defined by CMS

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## F758 Psychotropic Drugs New Language

- Use of psychotropic medications, other than antipsychotics should not increase when efforts to decrease antipsychotic medications are being implemented.
- Risks are still evident with all psychotropics, regardless of their use (e.g., nausea, insomnia, itching)
- Requirements that pertain to psychotropic drugs apply to the four categories (antipsychotic, anxiolytic, antidepressant, sedative-hypnotic) without exception

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## Non-Psychotropic Medications

- Medications that are not normally categorized as psychotropic medications can also affect brain activity and should not be used as a replacement for another psychotropic medication unless prescribed with a documented clinical indication consistent with clinical standards of practice.
- The requirements pertaining to psychotropic medications apply to these types of medications when their documented use appears to be a substitution for another psychotropic medication rather for the original or approved indication


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## Discharge Medication List

| Medication | Diagnosis |
|---|---|
| Lisinopril 20mg QD | Hypertension |
| Valproic Acid 500mg BID | Seizures |
| Gabapentin 300mg BID | Anxiety |
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| Metoprolol XL 50mg QD | Hypertension |
| Donepezil 10mg QD | Alzheimer's Disease |
| Atorvastatin 40mg QD | Hyperlipidemia |
| Mirtazapine 15mg HS | Anorexia |
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| Amlodipine 10mg once daily | Hypertension |
| Citalopram 20mg once daily | Depression |
| Aspirin 81mg once daily | Hx MI |

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Is a GDR required?

| MEDICATION | DIAGNOSIS | GDR NEEDED? |
|---|---|---|
| Olanzapine | Schizophrenia | Yes |
| Lorazepam | Seizures | Yes |
| Duloxetine | Pain | Yes |
| Mirtazapine | Anorexia | Yes |
| Prochlorperazine | Nausea | **Yes** |
| Divalproex | Seizures | No |
| Divalproex | Mood Disorder | **Yes** |
| Gabapentin | Pain | No |
| Gabapentin | Anxiety | **Yes** |
| Meclizine | Vertigo | No |
| Meclizine | Anxiety | **Yes** |

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**Pharmacy Services: F757 Unnecessary Drugs and F758 Psychotropic Drugs- GDR and Required Monitoring**

**Gradual Dose Reduction**

"Dose reductions should occur in modest increments over adequate periods of time to minimize withdrawal symptoms and to monitor symptom recurrence."

**Required Monitoring**

"If the record shows evidence of prescribing multiple psychotropic medications or switching from one type of psychotropic medication to another category of psychotropic medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale."

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F758: Psychotropic Drugs - Summary of PRN Orders for Psychotropics*

| | PRN NON-ANTIPSYCHOTIC PSYCHOTROPICS | PRN ANTIPSYCHOTICS |
|---|---|---|
| TIME LIMITATION | 14 days | 14 days |
| EXCEPTION | Order may be extended beyond 14 days if the prescriber believes it is appropriate to extend the order | None |
| REQUIRED ACTIONS | Prescriber should document the rationale for the extended time period in the medical record and indicate a specific duration | If the prescriber wishes to write a new order for the PRN antipsychotic, they must first evaluate the resident to determine if the new order is appropriate |

* No change from previous guidance

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**F757/F758- Investigating Concerns Relating to MRR, Unnecessary Medications and Psychotropic Medications- Psychosocial Harm**

Surveyor interview to determine potential psychosocial harm due to side effects of medication therapy (e.g., sedation, lethargy, agitation, mental status changes, behavioral changes)

**Did these side effects:**

- affect the resident's abilities to perform activities of daily living or interact with others?
- cause the resident to withdraw or decline from usual social patterns?
- show that the resident has decreased engagement in activities?
- cause a diminished ability to think or concentrate?

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## Discharge Medication List

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| Metoprolol XL 50mg QD | Hypertension |
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| Citalopram 20mg once daily | Depression |
| Aspirin 81mg once daily | Hx MI |

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## Monitoring for Adverse Effects of Antipsychotics

- Observational monitoring should be ongoing. Other monitoring should be performed upon initiation, at least every 3 months, with any dose changes, following discontinuation, and as clinically appropriate.
- **Laboratory Monitoring and Vital Signs**
  - Weight, blood pressure, blood glucose
  - Lipid panel
  - Electrocardiogram at baseline and as clinically indicated
- **Observational Monitoring -** Observe for extrapyramidal symptoms (EPS) and consider the use of objective rating tools such as an AIMS assessment.
  - **Parkinsonism**: Tremors, drooling, muscle rigidity, shuffled gait
  - **Dystonia**: Painful, acute, muscle contracture commonly in the neck, eyes, and trunk
  - **Akathisia**: Restlessness, fidgeting, pacing, rocking

AIMS = Abnormal Involuntary Movement Scale
Jankovic M. Treatment of neuroleptic-induced tardive dyskinesia. Neuropsychiatr Dis Treat. 2015; 9:1371-1380.
Prescribing information obtained from DailyMed.
Stoop TLM et al. Management of common adverse effects of antipsychotic medications. World Psychiatry. 2018; 17(3):343-356.

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## Potential Adverse Effects of Antipsychotics

| | |
|---|---|
| **General** | Dry mouth, constipation, increased falls, sedation/drowsiness |
| **Cardiovascular** | Irregular heartbeat, changes in blood pressure |
| **Metabolic** | Weight gain, elevated cholesterol, elevated blood glucose |
| **Neurologic** | Uncontrollable movements, tardive dyskinesia, stroke, increased suicidality |

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## Identifying Overutilization and Misuse of Psychotropic Medications

It is important to recognize when a patient may benefit from a reduction in use of psychotropic medications in order to prevent or reduce the risk of adverse effects related to their use.

**What Overutilization and Misuse Looks Like**

- **Oversedation -** Resident requires assistance to wake up or stay awake
- **Toxicity of medications -** Elevated serum concentrations of medications
- **Inappropriate use or indication**
  - Anxiolytics and antipsychotics used for sleep
  - Not utilizing nonpharmacologic therapy
- **Duplicate therapy -** Multiple antidepressants without a clear rationale

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## Steps to Reduce the Risk of Psychotropic Use

It is important to develop a plan of care and share that plan with individuals, family, and other caregivers.

CBT = cognitive-behavioral therapy

- **Establish the goals of therapy and how they will be measured and documented**
  - Develop and reevaluate non-drug interventions (e.g., CBT, music, companionship)
  - Educate individuals and caregivers of potential side-effects and what to look for (e.g., falls, mood changes)
  - Formulate a plan for periodic reevaluation, including discussions regarding gradual dose reductions where appropriate

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## Prescribers Initial Steps to Reduce Psychotropic Use

**New admission:**

- Pay particular attention to psychotropic medications & why prescribed
- Devote a follow up visit to gathering more information, determining appropriateness, establishing non-pharmacologic management
- Enlist a family member/caregiver to communicate patient preferences, likes/dislikes to staff to help with non-pharmacologic management
- Reminder to reassess needed psychotropic medications in 1 or 2 weeks, etc.

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## Prescribers Initial Steps to Reduce Psychotropic Use

**Long term care resident:**

- At monthly or q2monthly routine visits, set aside few minutes to focus on psychotropics
- Inquire with CNAs, nursing staff, activities staff how patient is doing behaviorally, side effects
- Why -> How long -> What has improved, what hasn't -> Can we dose reduce/taper/stop -> If yes, set time for follow up -> If no, set time to reassess

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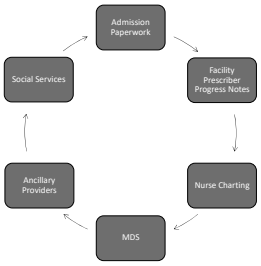
## Development of a Psychotropic Stewardship Program

- Comprehensive admission medication review
- Education of staff (prescribers, nursing, CNAs) of documentation requirements
- Education of caregivers and family members
- Development of psychotropic stewardship meeting involving all disciplines
- QAPI

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## Keys to Success to a Psychotropic Stewardship Program

- Regular meetings (biweekly or monthly)
- Bring everyone to the table (medical director, director of nursing, pharmacists, CNA representative, activities director)
- Make Phase 3 requirements clear (remind everyone of regulations quarterly and when new prescribers brought on)
- Make roles clear, have follow up plan
- Everyone's voice, in and out the meeting, is important
- If medication tapering/stopping not successful or possible, pharmacists can help keep prescribers accountable for documenting
- Celebrate wins

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## Pearls

- Psychotropic medications have consequences that providers must be aware of regardless of regulatory consequences
- Communicate with your consultant pharmacist and ensure they are completing thorough admission medication reviews. This is especially impactful in facilities with high Med-A populations.
- When determining the appropriateness of a dose reduction, make use of collateral information, including but not limited to, hospital H&P, previous admissions, potential prescribing cascades, psycho-social influences
- ALL PRN psychotropics require a stop date, regardless of indication. PRN antipsychotics CANNOT be auto-renewed and require direct evaluation by the prescriber.
- Have regular psychotropic stewardship program meetings with everyone in the care team- help keep each other accountable with appropriate documentation

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**Questions?**

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# A Script for Filling the Gap:
## The Importance of Medication Management and Best Practices in Transitions of Care

1

## Disclosures

- Faculty for this CE activity have no relevant financial relationship(s) to disclose

2

## This is Gary

3

## Objectives

- Describe the background and purpose of Transitions of Care (TOC)
- Discuss differences in medication management in the inpatient and long term care setting
- Investigate possible medication discrepancies during transitions of care process
- Review best practices of transitions of care for the interprofessional healthcare team
- Identify barriers related to care transitions and opportunities for development of transitions of care programs

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## Background and Purpose of Transitions of Care (TOC)

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## Transitions of Care (TOC)

"The movement of patients between healthcare locations, different providers or different levels of care within the same location as their needs change."

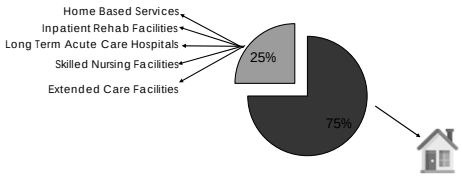
- *National Transitions of Care Coalition*


Consumers — NTOCC. (n.d.). NTOCC. https://www.ntocc.org/consumers
Image: https://nurseadvocates.com/ensuring-safe-transitions-care/

6

## TOC involves MANY care settings

- Approximately 75% of hospitalized patients are able to return home following discharge
- 25% go elsewhere




*An All-Payer View of Hospital Discharge to Postacute Care, 2013* 4205. (n.d.). https://hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp
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## What's the Problem?

- 20% of Medicare beneficiaries discharged from the hospital are readmitted within 30 days
- $15B of Medicare spending on 30-day hospital readmissions
- 1 in 5 patients discharged from the hospital who experienced an associated adverse event within 3 weeks
- 50% patients who experienced at least 1 medication discrepancy

Agency for Healthcare Quality and Research. Patient Safety Network. Readmission and Adverse Events After Discharge. https://psnet.ahrq.gov/primer/readmissions-and-adverse-events-after-discharge. Accessed June 11, 2022.
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8

## Hospital Readmission Reduction Program

- Established in 2012 as part of the Affordable Care Act
- Medicare value-based purchasing program that reduces payment to hospitals with excess 30-day readmissions
- Fiscal penalty up to 3% applied to all Medicare fee-for-service
- Targeted conditions/procedures
  - AMI; CHF; CABG; PNA; COPD; THA/TKA


*Hospital Readmissions Reduction Program (HRRP)* | CMS. (n.d.). https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/hospital-readmissions-reduction-program-hrrp

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## SNF Star Rating

| | SNF #1 | SNF #2 |
|---|---|---|
| | Save to Favorites | Save to Favorites |
| NURSING HOMES | | |
| Measures used to calculate the star rating – Short-stay residents | | |
| Percentage of short-stay residents who were re-hospitalized after a nursing home admission<br>↓ *Lower percentages are better*<br>National average: 22.1%<br>FL average: 25.2% | 22.2% | 21.7% |
| Percentage of short-stay residents who have had an outpatient emergency department visit<br>↓ *Lower percentages are better*<br>National average: 11.4%<br>FL average: 9.4% | 11.6% | 10.9% |

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 modified the Social Security Act requiring that SNFs be required to submit data for public reporting.

**Quality Measures for SNF Public Reporting**

- *Potentially Preventable 30-Days Post-Discharge Readmission Measure (PPR) for SNF*

*Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) Public Reporting | CMS.* (n.d.). https://www.cms.gov/medicare/quality/snf-quality-reporting-program/public-reporting

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## Medication Discrepancies in Transitions of Care

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## Contributors to Hospital Readmission

- Communication Barriers
- Patient Education Barriers
- Medication Errors
- Inappropriate Level of Care
- Lack of Follow up
- Social Factors
- Length of Stay

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## Medication Impact on Hospital Readmissions

- Omissions
- Unnecessary Additions
- Inappropriate Dosing, Directions, Duration
- Adverse Drug Events
- Patient Understanding
- Medications Not Optimized

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## Differences in Medication Management Between Settings

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## Differences in Medication Management

| Hospital | Facilities |
|---|---|
| • **Focus**: Acute Care<br>• **Formularies**: Restricted Medication Supply + Cost Containment<br>• **Staffing**: 24h coverage varying levels of RN+ MDs+ PharmDs<br>  • Pharmacy on-site+ integrated<br>• **Orders**: Lots of PRN orders, Order changes automatic for RN administration<br>• **Metrics**: Patient Safety, Abx Stewardship, Renal Dosing | • **Focus**: Recovery/Stabilization + Chronic care for LT residents<br>• **Formularies**: Cost Containment, possibly wide availability of commercial products<br>• **Staffing**: Limited<br>  • Pharmacy offsite/remote usually<br>• **Orders**: Limit PRN orders, decrease administration burden, order changes not automatic/delayed process<br>• **Metrics**: Lowering med burden, gradual dose reductions (ie antipyschotics), patient safety |

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## Gaps with Hospital & Skilled Facility Transitions

Campbell-Britton et. al. 2017

- *Care Transitions Between Hospitals and Skilled Nursing Facilities: Perspectives of Sending and Receiving Providers*
  - Focus: qualitative interviews assessing patient transfers and experiences with unplanned hospital readmissions
  - Setting: large, northeastern, urban, academic medical center & 2 local SNFs: Suburban for-profit facility and an urban non-profit facility
  - Participants: (*N* = 41) from medicine, nursing, social work, and consult services

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## Campbell-Britton et. al. 2017

**Four main themes emerged:**

- **1) Increasing patient complexity**
  - multiple co-morbidities; numerous medications; specialized medical equipment
  - psychosocial issues
  - rehabilitation expectations for patients with high illness burden may be unrealistic
- **2) Identifying an optimal care setting**
  - Hospitals: Pressure to optimize Length of Stay
  - SNF: relay on sustained volume but grapple with patient complexity
  - Structural differences in hospital vs SNF for patient care

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## Campbell-Britton et. al. 2017

- **3) Rising financial pressure**
  - Hospital: frustrated by patient declinations to SNFs
  - SNF: suggesting that payments drove discharges; have to consider the gain or loss for placement
  - Both Hospital and SNF recognize patient/family unaware or mistaken about their insurance coverage/options
- **4) Barriers to effective communication**
  - SNF: deeply concerned about the quality and consistency of the information sent from the hospital
  - Hospital: recognize concerned about barriers that delayed or disrupted communication efforts from facilities; identify differences in hospital physicians' documentation; high volume discharges as limiting the details put into discharge summaries
  - Lack of knowledge on both sides

18

## Opportunities

- Enhancing communication between clinicians
  - Direct communication channels
- Promoting provider understanding of post-acute care
  - Tours/visiting rotations through institutions
- Developing strategic opportunities to align facilities
  - Working collaboratively on care plans
  - Creative thinking to manage costs across the continuum of care

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## Transitions of Care Barriers and Opportunities

20

## Case of AO

- AO is a 78 year old male who presents to the ER being increasingly confused and weak. His wife is unable to care for him at home.
- **T:** 97.9 °F (Oral) **HR:** 111 (Pulse) **RR:** 22 **BP:** 134/90 **SpO2:** 97%
- PMH: CAD, Afib, HFmrEF (EF 45%), HTN, dyslipidemia, BPH, Falls
- DX Mild Cognitive Impairment and set to discharge to rehab
  - **But his BNP went to 1,349.8**

| Hospital Discharge Medication List | |
|---|---|
| Apixaban 5mg 2xdaily | Sacubitril-Valsartan 49-51mg 2xdaily |
| Clopidogrel 75mg daily | Tamsulosin 0.4mg daily |
| Isosorbide Mononitrate ER 30mg 0.5tablet daily | Metoprolol Succinate ER 50mg 2xdaily |
| **Misc Non-Medication (pt states there are more meds, unable to verify with him, family or pharmacy)** | |

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## AO Hospital Course

- Hospital Discharge Delayed
  - Treated with IV diuretics; strict ins and outs, daily weight, diuresed very well
  - TOC Pharmacist confirms missing home medications and provides medication recommendations for final discharge
- Pt stabilized for rehab
  - **Rehab does not receive updated medication list**

| Hospital Discharge Medication List | |
|---|---|
| Apixaban 5mg 2xdaily | Sacubitril-Valsartan 49-51mg 2xdaily |
| Clopidogrel 75mg daily | Tamsulosin 0.4mg daily |
| Isosorbide Mononitrate ER 30mg 0.5tablet daily | Metoprolol Succinate ER 50mg 2xdaily |
| *Alirocumab 150mg SQ q2weeks* | *Torsemide 20mg daily* |
| *Multivitamin daily* | *Fish Oil 1000mg 2xdaily* |
| *CoQ10 100mg daily* | |
| **NEW** dapagliflozin 10mg daily | **NEW** Daily weights/Low Salt Diet |

22

What barriers occurred for a successful discharge for AO?

23

Best Practices for TOC for the Interdisciplinary Team

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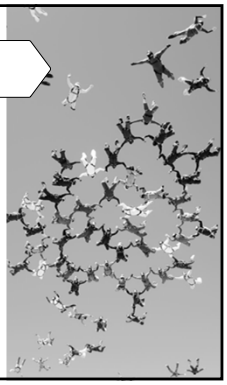
Best Practices for TOC for the Interdisciplinary Team

## Panelist Discussion

- Mary Lomberk, PharmD, CPh, BCACP
- Michael Samarkos, PharmD, CPh
- Mark Solomon, BS, MA, NHA
- Jacqueline Vance, RNC, BSN, CDONA/LTC, FADONA, IP-BC, CDP, ASCOM, LBBP



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## Assessment Question

- What area of opportunity exist to decrease the gap between acute care settings and skilled nursing facilities?
  A. Enhancing communication among clinicians
  B. Promoting provider understanding of post-acute care
  C. Developing strategic opportunities to align facilities
  D. All the above

26

## Assessment Question

- What area of opportunity exist to decrease the gap between acute care settings and skilled nursing facilities?
  A. Enhancing communication among clinicians
  B. Promoting provider understanding of post-acute care
  C. Developing strategic opportunities to align facilities
  **D. All the above**

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## Take Aways

- 30-day readmissions and transitions of care continue to be a focus for quality care in the United States
- Communication is key to working effectively with other teams buliding relationships and ensuring buy-in
- Leveraging pharmacist's knowledge and expertise can create high quality patient care

28

## Questions?


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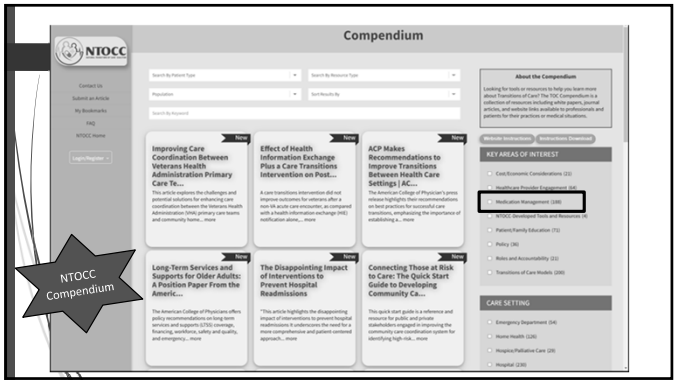


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EXTRA SLIDES

32

Baycare Health Systems Transitions of Care Efforts

Admissions Med Reconciliation performed by

- ER pharmacy technicians with focused training

Pharmacists-led Discharge Medication Reconciliation Planning

- Focus on guideline directed medication therapy, optimizing med list and patient safety

Bedside education

- RN led primarily Pharmacists-led specific units (CABG)

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Baycare Health Systems Transitions of Care Efforts

**Post-Acute Care Team (PACT)**

- Additional transitions of care support for preferred SNF network
- Increasing communication, identifying barriers, supporting SNF for successful patient discharge from SNF

**Post-discharge follow up calls**

- Supported from pharmacists, RN, SW

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## Discharge Medication Reconciliation (DCMR)

**Pre-discharge:**
Discharge medication reconciliation (DCMR)

Target Population: All Medicare patients ≥ 65yo

**Prospective:**
Pharmacist plans discharge medications

Physician reviews and signs DCMR prior to patient leaving

**Retrospective:**
Pharmacist reviews discharge medications after provider signs DCMR

Pharmacist contacts provider to recommend medication changes as needed

**Identification of patients**
- Hospital Census Reports

**Planning**
- Goal w/in 24-48hr of discharge
- Prospective vs retrospective

**Communicating with inpatient providers**
- Prospective vs retrospective

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## Post Acute Telephonic Follow up

- Calls
  - Targeted medication review
    - Focus on medication changes and disease state understanding
  - All eligible patients receive at least one call
- Communicating with outpatient providers
  - Faxes, calls

**Post-discharge:**
Telephonic follow-up

**0-5 day Post-discharge:**
Pharmacist completes a targeted medication review, clinical assessment, medication counseling, etc.

**14-21 day Post-discharge:**
Pharmacist provides further assessment/counseling if needed

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## PTOC Program Data

- Service Capture Rate
  - Goal > 90%

| Capture Rate: 2021 | |
|---|---|
| Group | All dx Medicare ≥ 65 yo |
| # Eligible for services* | 49,642 |
| # Receiving at least 1 service | 46,118 |
| % Pt receiving services | **92.9%** |

* Services include DCMR and/or post-acute telephonic follow-up

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## PTOC Program Data

- 30-day all cause readmission rate
  - O/E < 1 indicates better than expected

| 30-day All Cause Readmissions: 2021 | | |
|---|---|---|
| Group | ≥ 1 Service (DCMR and/or TMR call) | Both Services* (DCMR + TMR call) |
| Observed/Expected Readmissions (O/E) | 0.96 | 0.77 |

* Both Services for TMR eligible patients

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## Case of AO

- AO is a 66 year old male who presents to the ER with increased weakness and recurrent falls. He states that he was walking with his walker and felt like his legs were weak and "just gave out from underneath him"; EMS reports BP as low as 74/46.
- PMH: Cirrhosis with grade I esophageal varices + ascites (requiring paracentesis)+ hx hepatic encephalopathy, T2DM, depression; portal HTN, dyslipidemia, BPH
- Social History:
  - Stopped drinking in 2019
  - Manages his own meds
  - Lives with wife
  - Admits to forgetting to take medications sometimes

| Home Mediations Prior to Admission | |
|---|---|
| Insulin aspart 20units BID | Empagliflozin 10mg daily |
| Insulin glargine 10units daily HS | Rifaximin 550mg BID |
| Lisinopril 2.5mg daily | Ezetimibe 10mg daily |
| Nadolol 80mg daily | Gabapentin 300mg TID |
| Eplerenone 50mg BID | Solifenacin 10mg daily |
| Furosemide 80mg daily | Tamsulosin 0.4mg daily |
| Lactulose 30gm TID | Glimepiride 4mg daily |
| | |

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## AO Hospital Course

- Relevant Admission Labs/Vitals:
  - CT of head negative; Xrays negative for fractures
  - BP: 85/50; Orthostatic vital signs unremarkable
  - Scr: 1.4 (baseline 0.7); eGFR 47
  - US of ABD shows mild to moderate ascites
  - A1c 6.3%
- 11/1: ACEi and diuretics held on admission for AKI, Rifaximin missing (omission?), Lactulose titrated to QID to increase BMs, IR for paracentesis, which was done on 11/1 and 1800 mL was removed
- 11/2: had an episode of hypoglycemia in the evening (BG 50); PT eval and treat rec rehab; AKI resolved, Scr back to baseline 0.8
- 11/3: Reluctant but agreeable to rehab, Discharged with the following:

40

## AO Hospital Course

- DX: Fall, Ascites requiring paracentesis, AKI, Hypoglycemia

| Home Mediations Prior to Admission | |
|---|---|
| **Insulin aspart ~~20units BID~~ 10units BID** | Empagliflozin 10mg daily |
| Insulin glargine 10units daily HS | **~~Rifaximin 550mg BID~~** (missing) |
| **~~Lisinopril 2.5mg daily~~** | Ezetimibe 10mg daily |
| Nadolol 80mg daily | Gabapentin 300mg TID |
| Eplerenone 50mg BID | Solifenacin 10mg daily |
| Furosemide 80mg daily | Tamsulosin 0.4mg daily |
| **Lactulose 30gm ~~TID~~ QID** | **~~Glimepiride 4mg daily~~** |
| **Spironolactone 50mg BID** | **Insulin determir 10units BID** |

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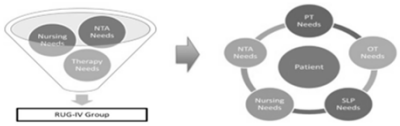
## Patient Driven Payment Model (PDPM) Review

- Goal is to improve the accuracy and appropriateness of payment based on the patient's specific needs
  - Replaced the previous RUG-IV (Resource Utilization Group) classification system
- In PDPM, the model considers all its components before a group daily rate is identified.
- The Patient Driven Payment Model (PDPM) provides an opportunity for a facility to maximize the services offered by their provider pharmacy.

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## Patient Driven Payment Model (PDPM) Review

- Anticipate an INCREASE ↑
  - In residents with multiple medical co-morbidities
  - In IV medication therapy orders and potentially requests for TPN therapy
  - Facility Part A medication costs due to more medications prescribed and more expensive medications used, particularly IV medications
  - Also , in reimbursements rates

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## AO 5 days later

- At rehab, patient's vitals are stable on admission:
  - BP 123/70, HR 65, O2 95% and FBG ~100s
- Pt participants with PT for first few days
- Consultant pharmacist reviews admission and **DC'd duplicate insulin and MRA order**
  - **Rifaximin still not administered**
- Therapist **notices increased confusion on day 5 and patient falls** during therapy
- Patient is sent back to ER

44

## AO 5 days later

- At rehab, patient's vitals are stable on admission:
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  - **Rifaximin still not administered**
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- Patient is sent back to ER

45

## Back to AO

- Evaluating AO's medication regimen
  - Duplicates were identified on SNF admission and corrected
  - On readmission, pharmacist identified that a previous home medication was missing on readmission, Rifaximin
  - Pt was restarted on medication and encephalopathy improved
- Assessment and Root Causes
  - Is this happening to other patients? Where is the error occurring? How can we lessen the risk of error?

46

## Challenges to TOC programs

**Accountability**
- Stakeholder engagement and communication
- Timely follow up for maximized impact
- Patient/Caregiver engagement

**Buy-in**
- Identify and enlist champions/leaders
- Identify areas to lessen workload for stakeholders
- Tracking/reporting outcomes or patient stories

**Technology limitations**
- Leverage IT team

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## Implementation strategies

- COLLABORATE CLOSELY WITH KEY STAKEHOLDERS
- BRAINSTORM FOR CREATIVE OPPORTUNITIES TO EXPAND TOC SERVICES
- LEVERAGE INFORMATION TECHNOLOGY TO EXPAND CLINICAL OPPORTUNITIES
- DOCUMENT ALL INTERVENTIONS IN A SYSTEM EASY TO TREND
- EVALUATE QUALITY AND PROCESS IMPROVEMENT ROUTINELY

48

# Beyond the diagnosis: An Update on Geriatric Syndromes in LTC

Milta Oyola Little, DO, CMD
Associate Professor, Geriatric Medicine
Duke University Medical Center

1

## Disclosures

- Dr. Little has no relevant financial conflicts of interest to report.
- Dr. Little will not be discussing any off-label or unapproved medications, devices, or therapeutics

2

## Objectives

1. Define geriatric syndrome
2. Distinguish syndrome-based from diagnosis-based approach to resident assessment
3. List and describe the 5Ms framework for resident-centered care
4. Apply short screening tools to assess for frailty, sarcopenia, falls, and incontinence
5. List the initial work-up and management of these geriatric syndromes

3

**The Story of Mr. C**

84 y/o cis-gender male, AL resident for the past 3 years, with PMH moderate stage Alzheimer's Disease, BPH, HTN, CAD, COPD, tobacco abuse, and CKD stage 3b. Moved into your secured memory care unit last week.

The Story of Mr. C.

Will he fall?

How strict should I be on his chronic disease targets?

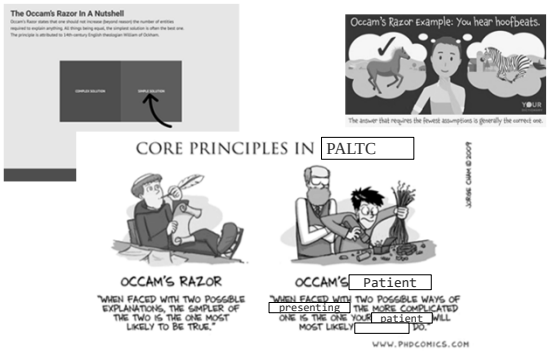
Will he die soon?

How can I keep him out of the hospital?

How quickly will he decline?

Should I get therapy involved?

4

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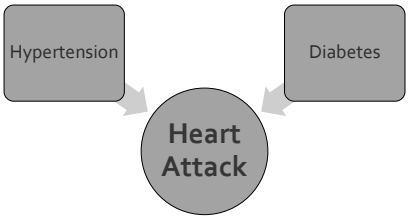
Co-Morbidity – How We Are Taught to Think

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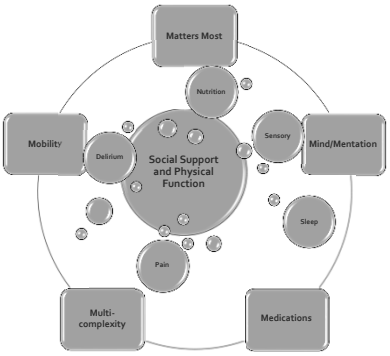
## The Geriatric Reality: 5Ms Framework

Multimorbidity: Many diseases of similar severity existing at the same time and overlapping in importance.

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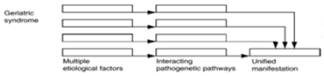
## Geriatric Syndromes



- From the Greek:
  - Syn = together
  - Dromos = running




OLDE RIKKERT M et al Neth J Med 2003; 61: 83-7

- Multifactorial health conditions that occur when the accumulated effects of impairments in multiple organ systems render an older person ***vulnerable*** to situational challenges.
- Syndromes are not underlying diagnoses (although they do have ICD-10 codes for billing)!

8

## Geriatric Assessment

- Geriatric Assessment is a systematic, interprofessional approach to the older patient
  - Diagnose **geriatric syndromes**
  - Develop targeted treatment plans
  - Improve patient outcomes
- Focus on function and quality of life
- Not based on chronological age but functional impairment and risk of future decline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## Examples of Geriatric Syndromes

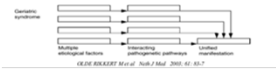
- **Frailty***
- **Sarcopenia***
- **Falls***
- **Incontinence***
- Weight loss/Anorexia of Aging
- Depression
- Delirium
- Dementia
- Polypharmacy



10

## Frailty Defined

- Frailty is a **medical syndrome** marked by reduced endurance, strength, and physiologic reserve, leading to increased **vulnerability** to functional decline, dependency, and death
- Lack of resilience when a stressor is applied to the system
- **Dynamic state,** influenced by a range of variables and losses within physical, psychological, or social domains, that increases the risk of adverse outcomes

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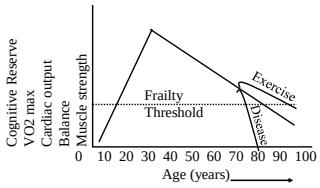


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Frailty Defined

[redacted]

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Frailty should be distinguished from disability

Diminished ability to carryout important ADL under stress.

Psychological Social Biological

FRAIL

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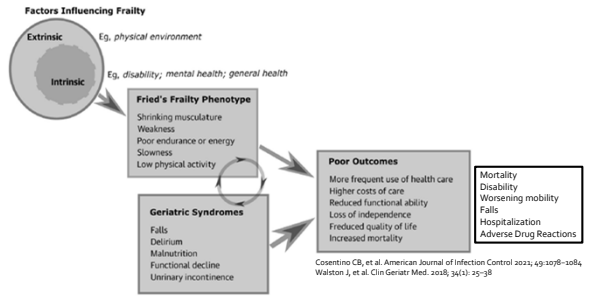


Cosentino CB, et al. American Journal of Infection Control 2021; 49:1078–1084
Walston J, et al. Clin Geriatr Med. 2018; 34(1): 25–38

**Fig. 1.** Frailty and geriatric syndromes usually interact. Either alone or in tandem, the outcomes are poor.

Visvanathan R and Yu Solomon. Clinical Implications of Research on Frailty. JAMDA 2021; 22:524-526

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## Value Based Care: Frailty as a vital sign

- Just as temperature, blood pressure, heart rate, and other conventional vital signs, frailty is a vital indicator of health.
- Clinicians need to be aware when an individual's Frailty Risk Score changes, identify what is driving those changes and generate a care plan to address those changes.


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## Clinical Utility of Frailty Screening

- Chronic disease targets differ based on frailty status
  - Less stringent glycemic control (well-established)
  - Less stringent blood pressure target levels (ongoing research)
- Identify individuals at high risk for adverse outcomes (delirium, weight loss, PI)
  - Pre-operative
  - Cardiovascular interventions
  - Hemodialysis and/or transplant
  - Oncological treatments


- Optimize medication management
- Timely ACP and palliative care services to avoid unnecessary hospitalizations and futile interventions towards end of life


- Limitations to frailty screening
  - Variation in screening instruments and agreement between them to identify risks, e.g. Healthcare Associated Infections with CFS or FI but not Frailty Phenotype
  - Research to date on frailty screening has been less useful for informing clinical practice or the development of clinical interventions to prevent or treat frailty.

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## Frailty Assessments

**Table 2**
Domains included in highly-cited frailty instruments.

| Highly-cited frailty instrument | Physical function? (includes disability?) | Physical activity? | Cognition? | Comorbidity? | Weight loss? | Other (social, sensory, demographic, etc) ? |
|---|---|---|---|---|---|---|
| Physical Frailty Phenotype | Yes (No) | Yes | No | No | Yes | No |
| Deficit Accumulation Index | Yes (Yes) | No | Yes | Yes | No | Yes |
| Gill Frailty Measure | Yes (No) | No | No | No | No | No |
| Frailty/Vigor Assessment | Yes (Yes) | Yes | Yes | No | No | Yes |
| Clinical Frailty Scale | Yes (Yes) | Yes | No | Yes | No | Yes |
| Brief Frailty Instrument | Yes (Yes) | No | Yes | Yes | No | No |
| Vulnerable Elders Survey | Yes (Yes) | No | No | No | No | Yes |
| FRAIL Scale | Yes (No) | No | No | Yes | Yes | No |
| Winograd Screening Instrument | Yes (Yes) | No | Yes | Yes | No | Yes |
| Total out of nine instruments | 9 (6) | 3 | 4 | 5 | 2 | 5 |

Buta BJ, Walston JD, Godino JG, et al. Ageing Res Rev. 2016; 26:53–61.

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Frailty Assessments

Selected instruments for frailty screening

| Instrument | Components | Scoring |
|---|---|---|
| Clinical Frailty Scale[14,21] | Clinical judgment, ranging from very fit to severely frail: 1 = Very fit, 2 = Well; 3 = Well, with treated comorbid disease, 4 = Apparently vulnerable; 5 = Mildly frail (some dependence on others for instrumental activities of daily living); 6 = Moderately frail (help needed with instrumental and non-instrumental activities of daily living); 7 = Severely frail (total dependence on others for activities of daily living, or terminally ill) | Physician assigns score of 1 to 7 based on clinical judgment. Physicians making the initial assessment given access to diagnoses and assessments related to these variables and other measures of comorbidity, function and associated features that inform clinical judgments about the severity of frailty.<br>A secondary review and scoring is performed by a multidisciplinary team. |
| FRAIL Scale[14,22] | Self-reported fatigue; resistance (ability to climb a single flight of stairs); ambulation (ability to walk one block); illnesses (more than five); loss of weight (more than 5%) | Score range 0 to 5.<br>No frailty = 0 deficits.<br>Intermediate frailty = 1 or 2 deficits.<br>Frailty = 3 or more deficits. |
| Frailty Phenotype[11,14] | Five (5) criteria: weight loss; measured weakness; self-report exhaustion; measured slowness; low activity questionnaire | Score range 0 to 5.<br>Frail: ≥3 criteria present.<br>Intermediate or pre-frail: 1 or 2 criteria present.<br>Robust or non-frail: 0 criteria present. |
| Gait Speed (as a single measure)[23,24] | Measured gait speed over 4 meters | Gait speed <0.8 m/s is cut point for increased risk of adverse health outcomes.<br>Gait speed <0.2 m/s is cut point for extreme frailty. |
| Géroutopôle Frailty Screening Tool[13,14] | Six questions to be answered by the practitioner/clinician about: 1) whether the patient lives along; 2) whether the patient has lost weight; 3) whether the patient has felt more tired; 4) whether the patient has memory problems; 5) whether the patient has found it difficult to get around; and 6) whether the patient has a slow gait (<1m/s) | If the practitioner/clinician answer yes to any one of the six questions, the screening questionnaire asks for their clinical judgment on whether the patient is frail. If yes, a follow-up question is to be completed as to whether the patient is willing to be fully evaluated for frailty. |
| PRISMA Questionnaire[24,34] | Seven yes or no self-reported questions about: 1) Age; 2) Sex; 3) Health problems that require a limit on activities; 4) Help needed from someone regularly; 5) Health problems that require one to stay at home; 6) Having someone to count on if needed; and 7) Regular use of an assistive device for walking. | Answering yes to three of more of the seven questions = potential disabilities/frailty |
| Timed-Up-and-Go Test[24,37] | Measures of functional mobility (chair stair, 10 foot walk, and return the chair) | Frail = taking greater than 10s to complete the test. |

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20

**The Simple "FRAIL" Questionnaire Screening Tool**
(3 or greater = frailty; 1 or 2 = prefrail)

**F**atigue: Are you fatigued?
**R**esistance: Cannot walk up one flight of stairs?
**A**erobic: Cannot walk one block?
**I**llnesses: Do you have more than 5 illnesses?
**L**oss of weight: Have you lost more than 5% of your weight in the last 6 months?

From Morley JE, Vellas B, Abellan van Kan G, et al. J Am Med Dir Assoc 2013;14:392-397.

21

[redacted]

22

## Physical Performance Thresholds for Frailty

| Physical Performance Measure | Threshold | Functional Correlates |
|---|---|---|
| Habitual Gait Speed | <0.4-0.6 m/s | Falls, Fractures, ↓ADLs, incontinance |
| Timed Chair Stands | > 14 sec | Falls, Fractures, ↓ADLs, incontinance |
| Tandem Stand | <3 sec | ↓ADLs |
| Grip Strength | <27 kg | ↓ADLs |

Guralnik, et al. J Geront:Med Sci 1994;49:M85-M94; Guralnik, et al. NEJM 1995; 332:556-561; Tinetti, et al. JAMA 1995;273:1348-1353; Judge, et al. J Am Geriatr Soc 1996;44:1332-1341.

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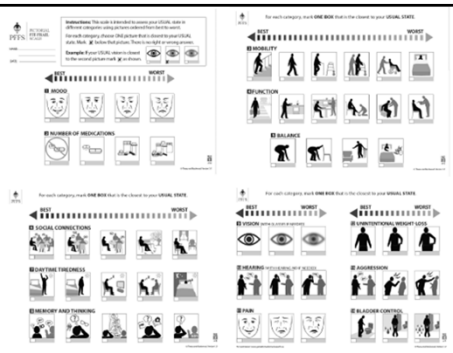

FIGURE A1. Pictorial Fit-Frail Scale—final prototype.

Note: Permission to use the copyrighted Pictorial Fit-Frail Scale can be obtained by visiting the website: www.geriatricmedicineresearch.ca

Theou O, et al. CANADIAN GERIATRICS JOURNAL 2019; 22(2):64-74

24

## FRAIL-NH

| | 0 | 1 | 2 |
|---|---|---|---|
| Fatigue | No | Yes | PHQ-9 ≥10 |
| Resistance | Independent Transfer | Set Up | Physical Help |
| Ambulation | Independent | Walker | Not Able/WC |
| Incontinence | None | Bladder | Bowel |
| Loss of Weight | None | yes | xxxx |
| Nutritional Approach | Regular Diet | Mechanically Altered | Feeding Tube |
| Help with Dressing | Independent | Set Up | Physical Help |
| Total | | | 0-13 |

**Nonfrail (0-5), Prefrail (6-7), Frail (≥8)**

Kaehr E, Visvanathan R, Malmstrom TK, Morley JE. Frailty in Nursing Homes: The FRAIL-NH Scale. *J Am Med Dir Assoc* 2015;16(2):87.

**The most frequent cut-off for defining frail and most frail residents were ≥2 and ≥6, respectively.**

When applying these definitions, between 15.1% and 79.5% of residents were frail, while 28.5% to 75.0% of residents were most frail.

Liau SJ, et al. J Nutr Health Aging 2021; 25(10):1205-16

25

## FRAIL-NH

J Nutr Health Aging. 2021;25(10):1205-1216
Published online October 27, 2021. http://dx.doi.org/10.1007/s12603-021-1694-3

Review

© Serdi and Springer-Verlag International SAS, part of Springer Nature

**The FRAIL-NH Scale: Systematic Review of the Use, Validity and Adaptations for Frailty Screening in Nursing Homes**

*S.J. Liau[1,2], S. Lalic[1,3], R. Visvanathan[2,4], L.A. Dowd[5], J.S. Bell[1,2]*

Overall, the FRAIL-NH scale demonstrated good agreement with other well-established but more complex frailty scales.

- ✓ Does not require use of specific instruments (e.g. dynamometer to measure handgrip strength) or gait speed
- ✓ Utilizes routinely collected data in NHs.
- ✓ Specialist training is not required to administer FRAIL-NH.
- ✓ Can be retrospectively applied to existing datasets

26

J Nutr Health Aging. 2021;25(10):1205-1216
Published online October 27, 2021. http://dx.doi.org/10.1007/s12603-021-1694-3

Review

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*S.J. Liau[1,2], S. Lalic[1,3], R. Visvanathan[2,4], L.A. Dowd[5], J.S. Bell[1,2]*

Over a median follow-up of 12 months, FRAIL-NH scores were predictive of
- mortality
- falls
- hospitalization
- length of hospitalization
- functional or cognitive decline

Clinically-relevant medication associations
- ➢ Multiple antihypertensive use was associated with increased mortality among most frail residents
- ➢ Statin use was associated with fall-related hospitalizations in mild moderate and most frail residents.
- ➢ Among *non-users* of statins, fall-related hospitalizations were *lowest* in the frailest subset.

**FRAIL-NH could guide development of individualized care plans to prevent falls, hospitalization and mortality**

**Using FRAIL-NH to detect pre-frail residents may help direct interventions to prevent functional dependence.**

27

## The Story of Mr. C

84 y/o cis-gender male, AL resident for the past 3 years, with PMH moderate stage Alzheimer's Disease, BPH, HTN, CAD, COPD, tobacco abuse, and CKD stage 3b. Moved into your secured memory care unit last week.

The
Mr.

FRAIL-NH

| | 0 | 1 | 2 |
|---|---|---|---|
| Fatigue | No | Yes | PHQ-9 ≥10 |
| Resistance | Independent Transfer | Set Up | Physical Help |
| Ambulation | Independent | Walker | Not Able/WC |
| Incontinence | None | Bladder | Bowel |
| Loss of Weight | None | yes | xxxx |
| Nutritional Approach | Regular Diet | Mechanically Altered | Feeding Tube |
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Gait Speed with walker 0.3 m/s

What next?

28

## Operationalizing Frailty Prevention and Treatment

- Education of residents and families – manage expectations, ACP
- Function and deficits focused, not disease focused
- Patient-focused care planning
- Manage and document unavoidable decline
- Frailty-based acuity scores to define facility case-mix

29

## PHYSICIAN PROGRESS NOTE WHEN DECLINE OCCURS

**Per state surveyor perspective**

- **Keep it simple.**
- If decline is occurring, **and,** upon your review of current frailty status-score, your own clinical assessment, and current treatment plan, and, per your best clinical judgment, you determine current decline is unavoidable, state that in your progress note.
- Mention key potential reversible frailty deficits treating for, efficacy of current plan. Mention any new treatments for potentially reversible deficits.
- Discuss current frailty status, current decline, and treatment plan with resident-family and mention this discussion in your progress note. Indicate in note, resident-family's level of understanding of current status and acceptance of treatment plan.

30

10/13/2023



PATHWAY HEALTH

30

## PHYSICIAN PROGRESS NOTE WHEN DECLINE OCCURS

**Per state surveyor perspective**

**Example:** This resident's most recent level of frailty has advanced with time, age. Most recent frailty score was 52 on the Frailty Index we have been using since her admission, up from 48. There is a decline in her mobility and transfer abilities. Current decline is unavoidable, per assessed frailty status. Will continue to try treatments to address those frailty deficits which are potentially reversible. The most pressing deficit is fatigue. Treating fatigue with new targeted PT program to increase muscle mass, adding additional calories to all meals, to enhance nutritional intake, and new C-PAP regimen for recently diagnosed sleep apnea. Discussed current frailty status with resident and family, discussed what deficits are potentially treatable. Resident and family, daughter, agreed to new plan of care.

31



31

## Operationalizing Frailty: Risk Meetings, Best Practices

- At least weekly discussion of highest risk residents in the population.
- Current status, progress;
  - Any new stressors (medical, infection, environmental, possible procedures etc.)
  - Changes in usual patterns: (sleep, oral intake, functional changes, cognitive changes)
- Input from Direct care and licensed nursing staff, resident, family, Medical Director, Pharmacist, Social Services, Dietary, Activities, Therapy input, true IDT team.

- Based on assessment-discussion above, as appropriate new interventions identified
- Any barriers to providing existing treatment plan identified
- *IDT Risk Note* written immediately in progress notes summarizing above
- Care plan, physician orders, updated immediately
- Care plan changes communicated to floor staff via huddles alert messaging, updating electronic care plan, electronic kardexes, other communication methods.

32



32

"…a logical path forward would embrace a "both-and" approach, rather than "either-or."
Measured by phenotype or index, frailty is highly predictive of adverse outcomes for older adults, including hospitalizations, falls, disability, institutionalization, and mortality.

Even if face-to-face clinical assessments outperformed EHR-based and other automated measures, there remains the question of scalability: the modest number of geriatricians in the United States cannot possibly assess the frailty status of the millions of adults aged 65 and older or even 75 years."

"I would propose nephrology as our metaphor. As a first-pass, automated tool, creatinine and estimated glomerular filtration rate (eGFR) guide much of our clinical decision-making, even without knowing the underlying nephropathology. Similarly, an EHR-based frailty index can identify which older adults merit a reapproach—consideration of our clinical even if the "cause" of frailty is not yet clear."

Kathryn E. Callahan MD, MS
Department of Internal Medicine, Section on Gerontology and Geriatric Medicine
Wake Forest School of Medicine
Winston-Salem, North Carolina
The future of frailty: Opportunity is knocking. J Am Geriatr Soc. 2022;70:78–80.

33

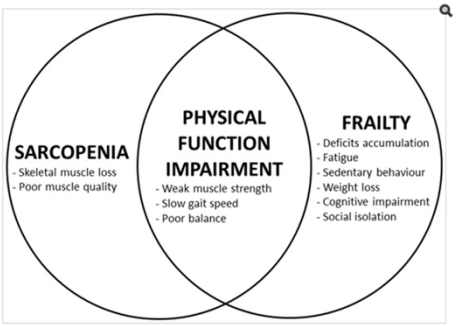
## Falls and Sarcopenia

- Sarc = flesh
- Penia = poverty

Decrease in muscle structure AND function




34




**Relationship among sarcopenia, frailty, and physical function impairment.**

Cesari M, et al. Front Aging Neurosci 2014; 6:192

35

## Falls and Sarcopenia

**Table I: SARC-F Screen for Sarcopenia**

| Component | Question | Scoring |
|---|---|---|
| Strength | How much difficulty do you have in lifting and carrying 10 pounds? | None = 0<br>Some = 1<br>A lot or unable = 2 |
| Assistance in walking | How much difficulty do you have walking across a room? | None = 0<br>Some = 1<br>A lot, use aids, or unable = 2 |
| Rise from a chair | How much difficulty do you have transferring from a chair or bed? | None = 0<br>Some = 1<br>A lot or unable without help = 2 |
| Climb stairs | How much difficulty do you have climbing a flight of ten stairs? | None = 0<br>Some = 1<br>A lot or unable = 2 |
| Falls | How many times have you fallen in the last year? | None = 0<br>1-3 falls = 1<br>4 or more falls = 2 |

From Malmstrom TK, Morley JE. J Frailty and Aging 2013;2:55-6.

Score > 4 is positive

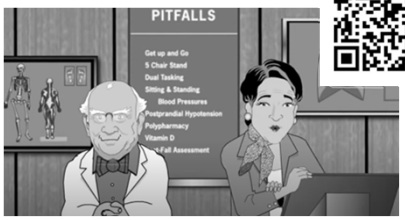
36

[redacted]

37

https://www.youtube.com/watch?v=xW-jYurjTBo&t=3s

Falls Risk Assessment




38

[redacted]

39

## The Story of Mr. C

84 y/o cis-gender male, AL resident for the past 3 years, with PMH moderate stage Alzheimer's Disease, BPH, HTN, CAD, COPD, tobacco abuse, and CKD stage 3b. Moved into your secured memory care unit last week.

Gait Speed with walker 0.3 m/s

FRAIL-NH 7 (Prefrail)

What next?

**Table 1: SARC-F Screen for Sarcopenia**

| Component | Question | Scoring |
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From Malmstrom TK, Morley JE. J Frailty and Aging 2013;2:55-6.

40

## Initial Work-up and Management of Frailty, Sarcopenia, and Weight Loss

**Fatigue**
- PHQ-9 or GDS for depression
- Do you stop breathing while asleep? Sleep apnea
- TSH for hypothyroid
- Vitamin B12
- Hemoglobin for anemia
- Blood pressure for hypotension/orthostasis

**Resistance / Aerobic** — **SARCOPENIA**
- Resistance exercise
- Aerobic exercise
- Protein supplement daily
- 1000 IU vitamin D daily

(Resistance exercise + Aerobic exercise: 3 to 5 x week)

**Illnesses**
- Review medication list for unnecessary side effects and drugs whose side effects may be contributing to frailty, e.g., anticholinergic drugs

**Loss of Weight**
- **M**edications producing anorexia
- **E**motional – depression
- **A**buse, elderly, alcoholism
- **L**ate life paranoia
- **S**wallowing problems
- **O**ral problems
- **N**osocomial infections, eg, *H Pylori*
- **W**andering and other dementia-related problems
- **H**yperthyroidism, hypercalcemia, hyperglycemia, hypoadrenalism
- **E**nteral problems, eg, celiac disease
- **E**ating problems
- **L**ow salt, sugar and cholesterol diets
- **S**tones - cholecystitis

+ Caloric Supplementation

41

Mobility | Mind | Medications | Multicomplexity | Matters Most

| Mobility | Medications | Matters Most |
|---|---|---|
| Group Exercise<br>PT evaluation<br>Restorative aides | Polypharmacy reduction<br>High-risk medication reduction<br>Consultant pharmacy review | Matching activities to interests<br>Providing choices<br>Advance car eplanning |

42

## The Story of Mr. C

In the first two weeks after admission, Mr. C had two non-injury falls in his room. One was in the middle of the night and one following lunch. Both times, he was found between his bed and the bathroom and had been incontinent of urine.

The
Mr.

**FRAIL-NH**

| | 0 | 1 | 2 |
|---|---|---|---|
| Fatigue | No | Yes | PHQ-9 ≥10 |
| Resistance | Independent Transfer | Set Up | Physical Help |
| Ambulation | Independent | Walker | Not Able/WC |
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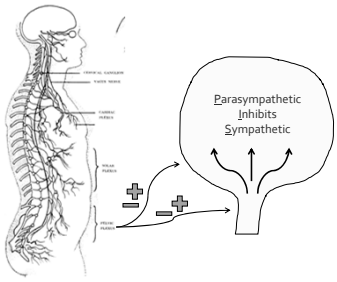
Gait Speed with walker 0.3 m/s

What next?

43

Incontinence

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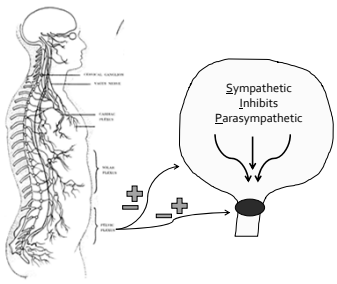
Incontinence

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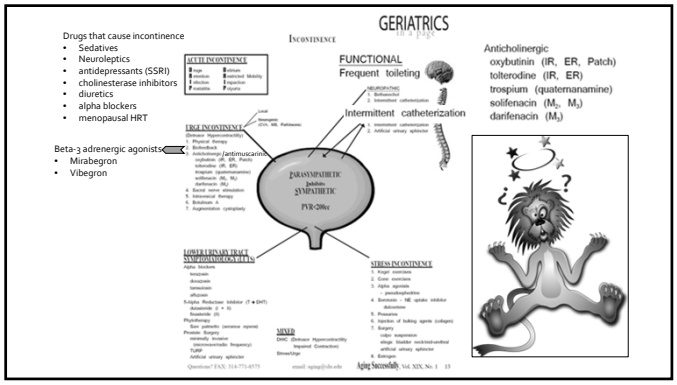



46

Kaplan's Pearls

- Screen for geriatric syndromes at least every 6 months in LTC
  - FRAIL-NH and SARC-F are quick screens
  - Anyone with high FRAIL-NH or SARC-F scores should have a fall reduction plan in place
  - Frailty status can help identify risk and guide decision-making
- Consider forming a high-risk Frailty interprofessional team meeting to prevent and address decline in high-risk residents
- Avoid antimuscarinics in urinary incontinence due to anticholinergic side effects. Instead…
  - Focus on deprescribing and non-pharmacologic management
  - Use Beta-3 adrenergic agonists as first line medications (Vibegron if risk of malignant hypertension)
- The 5Ms Framework belongs in PALTC too!

47

QUESTIONS?

48

# Policy and Clinical Issus Facing LTC in 2024

**David Gifford MD MPH**
***Chief Medical Officer***

1

## Who is AHCA

- Large National Trade Association
  - with state affiliate in all States (except MT)
- Represent
  - ~10,000 Skilled nursing centers
  - ~4,000 Assisted living communities
  - Provider owned I-SNPs
  - Clinically Integrated Provider Networks

Improving Lives *by* Delivering Solutions *for* Quality Care

2

## Policies Impacting Common Outcomes

**LTC Policies & Programs….**

- Reimbursement
  - PDPM
  - SNF VBP
  - Managed Care
  - SNPs
  - ACOs
  - Alternate payment models
- Five Star
  - Staffing
  - SNF QRP
- Changing patient mix
  - SMI & OUD
  - Advanced dementia
  - Increasing acuity

**Common Outcomes** →

- Hospitalizations/ED use
- Satisfaction
- Antipsychotic use
- Function
- Staffing
- Infection Control

Improving Lives *by* Delivering Solutions *for* Quality Care

3

## CMS Proposed Minimum Staffing

- Minimum HPRD for
  - RN: 0.55 HPRD
  - Nurse Aide (NA): 2.45 HPRD
  - No specific LPN requirement
- 24/7 RN
- If acuity needs of residents require more, higher RN and NA staffing level will also be required

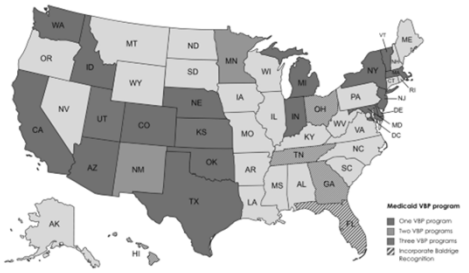
4

## Where We Are Today

- 49% do **not** meet 0.55 RN HPRD
- 72% do **not** meet 2.45 NA HPRD
- 19% meet both RN & NA HPRD
- Estimate <20% facilities have 24/7 RN hours
  - PBJ has per day, not shift-level data

5

## State Medicaid VBP programs incorporate Baldrige Recognition




6

## Managed Care is the Majority



https://www.chartis.com/insights/medicare-advantage-enrollment-continues-surge-increasingly-complex-and-competitive;
http://www.advancingstates.org/initiatives/managed-long-term-services-and-supports/mltss-map

7

## 2023/2024 Provider-Owned Networks

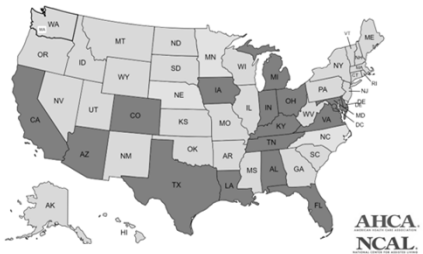
**Operating (1,130 Providers)**

- Iowa (181)
- Indiana (327)
- Ohio (168)
- Louisiana (141)
- Kentucky (113)
- Florida (200+)

**Launching Next 2023**

- Nebraska
- Minnesota
- North Carolina

**Exploring/2024**



AHCA
NCAL

8

## Factors Impacting: Clinical outcomes

| Non-Clinical | Clinical |
|---|---|
| • Mindset<br>• RN-MD communication<br>• End of life discussions<br>• Consistency with care delivery<br>• RNs & NPs<br>• Staff experience & competency<br>• Availability of services<br>• Transitions of Care | • Acute illness<br>• Healthcare Acquired infections<br>• Medications<br>o Anticoagulants<br>o Diabetic<br>o Antihypertensive<br>• Miss diagnosis<br>• Inappropriate treatment |

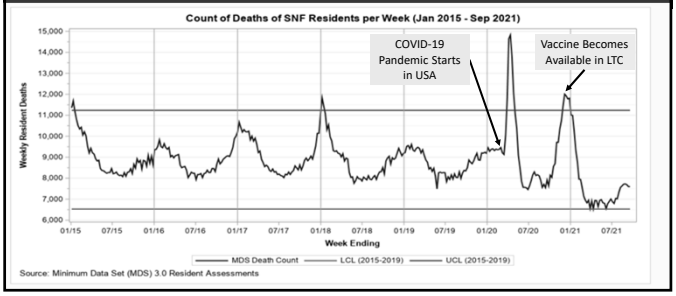
9

## RN-MD communication

- Communication between MD and RN is often the leading factor impacting
  - Hospitalization and ER use
  - Medication prescribing
  - Laboratory & radiology tests
  - Family satisfaction
  - Liability

10

## All Cause Deaths in LTC




11

JENNIFER KIM, DNP, GNP-BC, GS-C, FNAP, FAANP, FAAN

IMMEDIATE PAST PRESIDENT

GAPNA
Gerontological Advanced Practice Nurses Association

1

## GAPNA 2023 – 2043 BOARD OF DIRECTORS

President
Ann Kriebel-Gasparro

Immediate Past President
Jennifer Kim

President-Elect
George Peraza-Smith

Secretary
Kim Posey

Treasurer
Michele Talley

Director at Large
Sandi Vonnes

Director at Large
Aparna Gupta

2

## GAPNA

The premier professional organization that represents the interests of advanced practice nurses, other clinicians, educators, and researchers involved in the practice or advancement of caring for older adults.

Mission Statement:

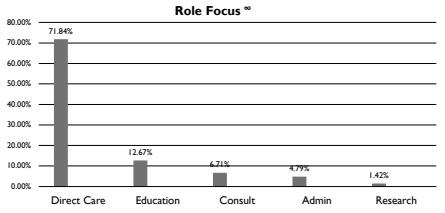
Promoting excellence in advanced practice nursing for the well-being of older adults.

Vision:

To continue to be the trusted leaders for the expert care of older adults.

3

## GAPNA MEMBERSHIP PROFILE*

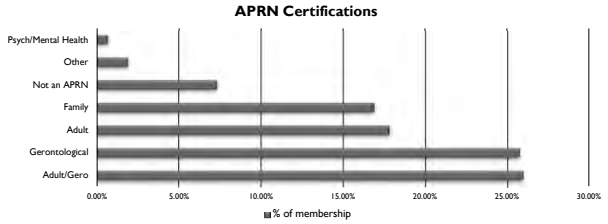



∞ at least 60% of APP position

* End of December 2022

4

## GAPNA MEMBERSHIP PROFILE

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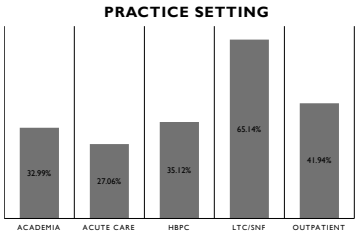
## GAPNA MEMBERSHIP PROFILE



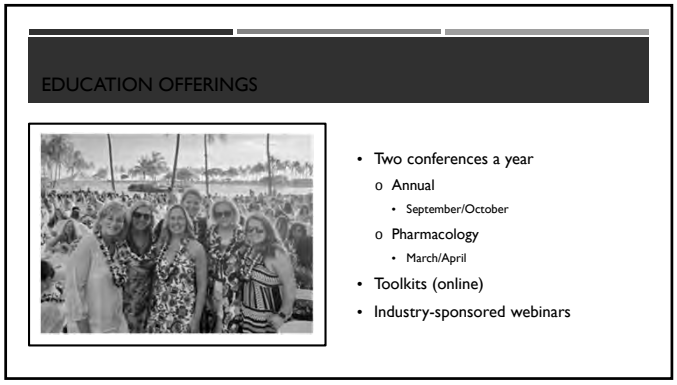

6


MEMBER ENGAGEMENT
• State Chapters (18)
• Committees (9)
• Special Interest Groups (6)
• GAPNA Exchange
• Social Media - "We Are Your People" Campaign
• GAPNA Chat podcast
KEEP CALM AND CALL THE GERO APRN

7


GAPNA
We Are Your People
Ladsine Taylor, MSN, APRN, GNP-BC, CDP
Sarah Ryan, MSN, AGPCNP-BC
Joan Michelle Moccia, DNP, ANP-BC, GS-C
Brette Svensson, DNP, MSN, AGPCNP-BC

8


EDUCATION OFFERINGS
• Two conferences a year
o Annual
• September/October
o Pharmacology
• March/April
• Toolkits (online)
• Industry-sponsored webinars

9

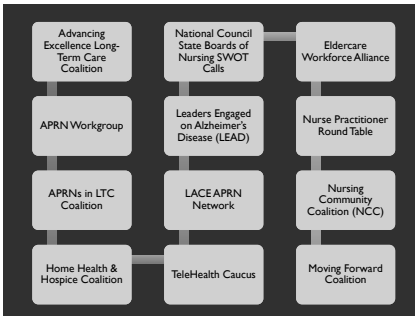
## GAPNA'S STRATEGIC PARTNERS






10

## ADVOCACY




11

## SECURING GAPNA'S FUTURE


- Cohort #5 starts October 2023
- Program extended to 18 months
- Past fellows assuming GAPNA leadership roles

12

## NEW IN 2023


Diversity, Equity, & Inclusion Taskforce

13

## GERONTOLOGICAL SPECIALIST CERTIFICATION

GNCC
Gerontology Nursing Certification Commission

- Specialty exam for APRNs with 2500 hours experience caring for older adults within the past 5 years
- *A Practical Guide for Gerontological Specialist*
- First cohort eligible for recertification in March 2023

14

## IMPLEMENTING GAPNA'S STRATEGIC PLAN (2022-2025)


GOALS

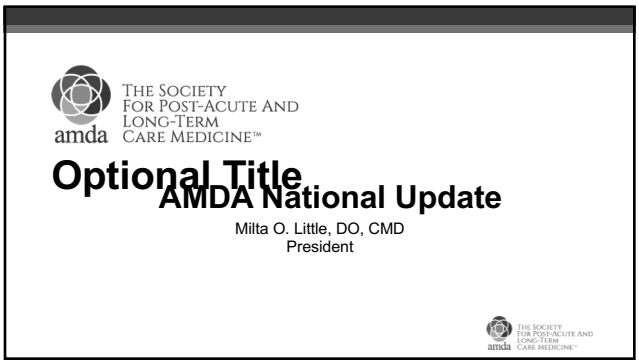
- To improve patron experience as they are the foundation of the organization and cultivate our culture and growth.
- To be a clear, recognizable brand that is reflective of who we are and who we serve.
- To continue to evolve GAPNA to better serve all those who interact with our organization.

15

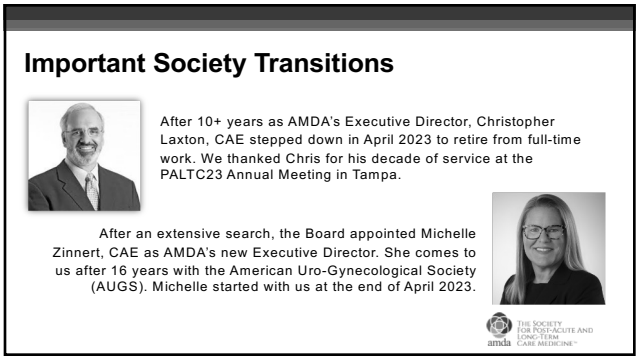
*"The world is changed by your example, not your opinion."*

- Paulo Coelho

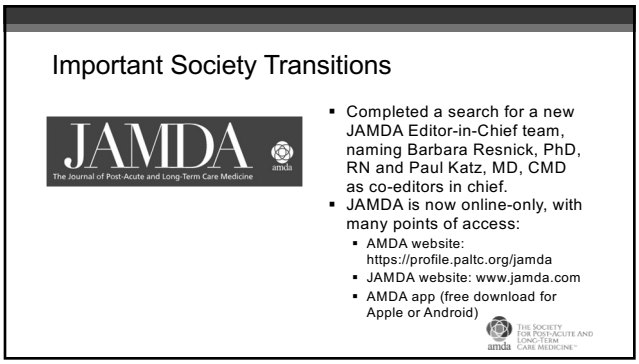
16


THE SOCIETY FOR POST-ACUTE AND LONG-TERM CARE MEDICINE™
amda
Optional Title
AMDA National Update
Milta O. Little, DO, CMD
President

1


Important Society Transitions
After 10+ years as AMDA's Executive Director, Christopher Laxton, CAE stepped down in April 2023 to retire from full-time work. We thanked Chris for his decade of service at the PALTC23 Annual Meeting in Tampa.
After an extensive search, the Board appointed Michelle Zinnert, CAE as AMDA's new Executive Director. She comes to us after 16 years with the American Uro-Gynecological Society (AUGS). Michelle started with us at the end of April 2023.

2


Important Society Transitions
JAMDA
The Journal of Post-Acute and Long-Term Care Medicine
Completed a search for a new JAMDA Editor-in-Chief team, naming Barbara Resnick, PhD, RN and Paul Katz, MD, CMD as co-editors in chief.
JAMDA is now online-only, with many points of access:
AMDA website: https://profile.paltc.org/jamda
JAMDA website: www.jamda.com
AMDA app (free download for Apple or Android)

3

## Strategic Initiatives

**Advocacy**
*Protect and advance the clinician voice to ensure optimal and equitable outcomes for PALTC medicine*

**Organization Vitality**
*Preserve and align resources with AMDA's mission*

**Education & Clinical Affairs**
*Provide widespread access to education, training, and clinical best practices*

**Stakeholder Expansion**
*Grow and engage all clinicians working in PALTC medicine*

4

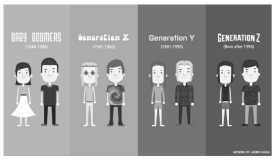
## Emerging Issues

- Workforce/Staffing – physician, APP, medical director
- Transparency – focus on medical director transparency (e.g. H.R. 177)
- COVID/RSV/Infection control
- Equity, inclusion, and belonging
- Telehealth for medical care and medical direction
- Schizophrenia diagnosis and antipsychotic measure

5

## Big Future Goal – Membership Growth

- Guided by members' needs, providing relevant and timely resources
- Transform our structures and procedures to be nimble and responsive to member's needs



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6

## Big Future Goal – Workforce Expansion

- Attract the next generation of clinicians-in-training to PALTC medicine and AMDA
- Continue to grow and enhance the Futures Program
- Develop trainee/student specific educational resources to develop a stronger pipeline of clinicians working in PALTC medicine
- **More of a Good Thing Series** returns with roundtable discussions focusing on the role of leadership in retention and recruitment of PALTC staff.
  - 8 leadership modules led by JoAnne Reifsnyder, PhD, MSN, MBA, Professor of Health Services and Leadership Management, Univ. of Maryland School of Nursing

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7

SAN ANTONIO ●TEXAS

paltc 24 ANNUAL CONFERENCE

**NEW DATES:**

SATURDAY, MARCH 9 -
TUESDAY, MARCH 12, 2024

Registration opens Nov. 1
Call for Papers Deadline – Nov. 6

**paltc.org/annual-conference**

8

Thank you for all you do!

**Milta Oyola Little, DO, CMD**
**Milta.little@duke.edu**

9

Date
Time

# Updates from AMDA

THE SOCIETY FOR POST-ACUTE AND LONG-TERM CARE MEDICINE™

1

## Join AMDA Today! (paltc.org)

**Member Community**
Tap into a wealth of knowledge and support with our vibrant online community.

**Volunteer Opportunities**
Serve on committees or work groups, and contribute to our esteemed House of Delegates.

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JAMDA - the Society's scientific peer-reviewed journal (valued at $399).

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Free live and archived webinars (valued at $49/webinar).

**Weekly e-Newsletters**
Access to *Weekly Round-Up* (Society and policy news) and *PALTC Pulse* (industry news consolidator).

**Caring for the Ages**
News and commentary on clinical developments and the impact of health care policy on LTC medicine.

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Caring for the Ages

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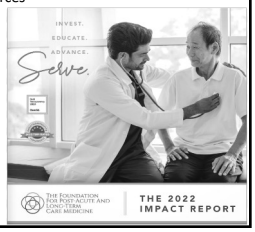
3

**Founded in 1996, the Foundation for PALTC Medicine is the only philanthropic entity dedicated exclusively to supporting and enabling professionals and clinicians working in the post-acute and long-term care field of medicine.**

◊ Expanding the geriatric workforce
◊ Advancing PALTC research, education & clinical resources
◊ Demonstrating the value of the PALTC clinician

**Funding / Donation Areas:**
- ◊ Education & Training
- ◊ Futures Program
- ◊ Clinical Resources
- ◊ Research




The Foundation For Post-Acute And Long-Term Care Medicine

**To learn more or donate**
**Paltcfoundation.org**

4

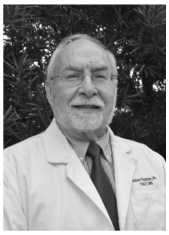
## 2023 Foundation Impact Report

- $50,000 Research Award to Dr. Brian McGarry and David Grabowski for "Certified Medical Directors In Nursing Homes: An Evaluation of the Current Landscape, their Association with Quality, and Early Impacts of California Law AB749
- $25,000 Award to Dr. Charles Semelka for research focused on "The Post-Acute Care Utilization and Outcomes in Frail Older Adults"
- $25,000 Co-Sponsored funding requests in review
- $95,000 – 2023 Futures Program, 87 participants (5 attendees from Florida!)
- Established Named Endowed Funds:
  - Chris Laxton Excellence in Leadership Fund
  - Kenneth Brubaker Fund – benefitting Research & Education
  - Susan Levy Futures Scholarship Fund

The Foundation For Post-Acute And Long-Term Care Medicine

5

## Robert Kaplan Memorial Endowment Fund



The Foundation and the FMDA are working collectively and with the support of the Kaplan family to establish a named endowed fund preserving Dr. Kaplan's passion and commitment to post-acute and long-term care education.

All donations and the sentiments expressed will be shared with the Kaplan Family and will be designated toward this effort of establishing an annual scholarship for the benefit of a Future's Program participant.

Donations may be made at paltcfoundation.org and by designating your gift to the Dr. Robert Kaplan Memorial Fund.

The Foundation For Post-Acute And Long-Term Care Medicine

6

Thank you!

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7

# Trends in Post-Acute & Long-Term Care

**October 21, 2023**

**Rhonda L. Randall, D.O.**
EVP & Chief Medical Officer
UnitedHealthcare Employer & Individual

Director
**UnitedHealth Foundation**

Chair of the Board
**FMDA - The Society for Post Acute & Long-Term Care**

1

**Welcome to Florida:**
By 2030, 57% of new residents will be 65+

2

# Aging Demographics: USA & FL

3

## Which US State is currently home to the largest % of people over the Age of 65?

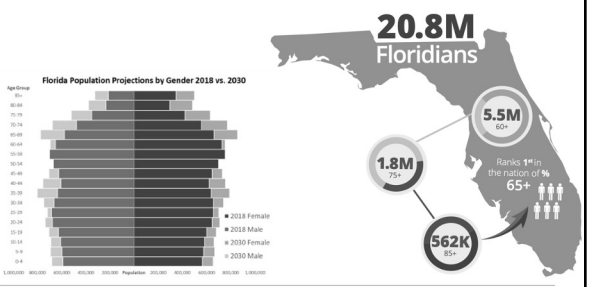
A) Florida

B) Maine

C) Vermont

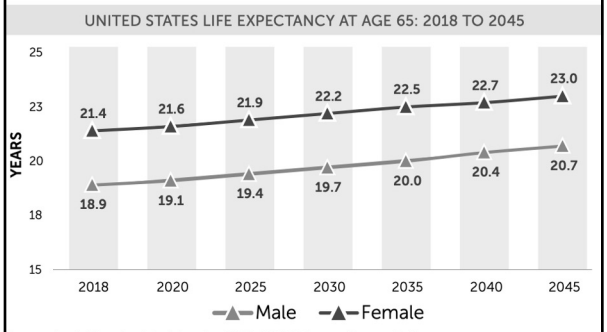
D) West Virginia

4




*Florida Population Projections by Gender 2018 vs. 2030 Source: Bureau of Economic and Business Research, 2010 Census Counts, and Projections of Florida Population by County and Age, Race, Sex, and Hispanic Origin, 2020-2045, With 2018 Estimates (Released June 27, 2019)*

5




*Source: Social Security Administration 2019 OASDI Trustees Report. Table V.A5. Cohort Life Expectancy—Intermediate Projections*

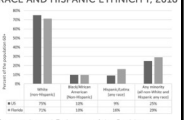
6

COUNTIES IN FLORIDA WHERE 40 PERCENT OR MORE OF THE TOTAL POPULATION IS 60 OR OLDER, 2018

| County | Total Population (All) | Total Population 60+ | Percent 60+ |
|---|---|---|---|
| Sumter | 124,935 | 76,168 | 61.0% |
| Charlotte | 177,987 | 82,860 | 46.6% |
| Citrus | 145,721 | 63,747 | 43.7% |
| Sarasota | 417,442 | 178,361 | 42.7% |
| Highlands | 102,525 | 43,032 | 42.0% |

*Source: Office of Economic and Demographic Research (2019). Demographic Estimating Conference Florida Demographic Forecast. Tallahassee, FL. Retrieved from edr.state.fl.us/content/conferences/population/ComponentsofChange.pdf*

U.S. AND FLORIDA PERCENT OF PERSONS AGE 60 AND OLDER BY RACE AND HISPANIC ETHNICITY, 2018




*Source: Annual Estimates of the Resident Population by Sex, Age, Race Alone or in Combination, and Hispanic Origin for the United States and States: April 1, 2010 to July 1, 2018. U.S. Census Bureau, Population Division https://www.census.gov/data/tables/time-series/demo/popest/2010s-national-detail.html*

2 U.S. Census Bureau, Population Estimates Program (PEP), updated annually. census.gov/quickfacts/FL; retrieved April 28, 2020. American Community Survey Product, 2018: ACS 1-Year Estimates Subject Tables "Population 60 Years and Over in Florida;" TableID: S0102

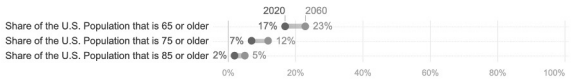
3 Department of Elder Affairs calculations based on Florida Population Data and 2012-2016 American Community Survey Data provided by AGID agid.acl.gov/customtables/acs/year

7

Figure 10

An Aging Population Will Use More Long-Term Services and Supports.

Over half of people ages 65+ will use paid LTSS at some point, with 39% using care provided in a nursing home.




SOURCE: KFF analysis of U.S. Census Bureau's Projected 5-Year Age Groups and Sex Composition: Main Projections Series for the United States, 2017-2060 • PNG

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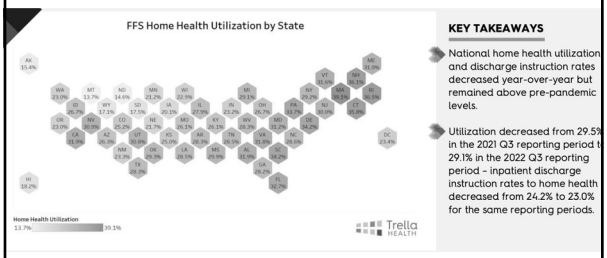


10

# International PALTC

11

## Which OCED Nation has the highest% of people living in a Nursing Home?

**A) USA**

**B) Iceland**

**C) UK**

**D) Denmark**

**E) Japan**

12

# U.S. and Global Approaches to Financing Long-Term Care: Understanding the Patchwork

13

Table 1.

Government regulations and public policies for medical services in NHs.

| | Level and type | Level of detail | NHs covered |
|---|---|---|---|
| Norway | Federal authority allocates responsibility and oversight to local municipalities | Unspecified/framework act/interpretive | All NHs |
| Germany | Federal authority allocates responsibilities to district jurisdictions | Unspecified/interpretative | All NHs with public funding (provision contracts) |
| US | Federal regulations and state licensing regulations | Specified (for instance, type and frequency of visits and documentation)/prescriptive. Requirements have increased over time | All NHs who receive federal funds (96%). State regulations cover all other NHs |
| Manitoba | Provincial | Provincial standards ensure that each resident's medical care is supervised by a physician, that residents are seen by a physician as often as their condition requires, and that both professional NH staff and residents have access to a physician for advice and input 24 h a day | All licensed NHs |
| British Columbia | Provincial | General standard that a resident needs to be attached to an MD to be admitted to an NH. Some variation in credentialing of MDs who work in private (contracted nonprofit and for-profit vs public facilities) | All licensed NHs |

Abbreviations: MDs, Medical Directors; NHs, nursing homes.

14

Table 3. Percentage of people ≥65 years living at home and in institutions (prevalence data; different years in the early 1990s)

| Place of residence | Country USA | Japan | Iceland[a] | Sweden | Denmark | Netherlands | UK | France | Italy |
|---|---|---|---|---|---|---|---|---|---|
| Own home, independently or with informal and/or formal care (including domestic help and home nursing) | – | 94.0 | 87.0 | 94.0 | 85.0 | 90.0 | 93.0 | 94.0 | 96.0 |
| Residential homes, homes for the aged, old people's homes (low levels of care) | 1.5[b] | 0.5 | 5.0 | 3.0 | 10.5[c] | 6.5 | 3.5[d] | 4.0 | 1.0 |
| Nursing homes (high levels of care) | 5.0 | 1.5 | 8.0 | 2.0 | 4.0 | 2.5 | 2.0 | –[e] | <2.0 |
| Hospitals (intensive medical care) | – | 4.0 | – | <1.0 | <1.0 | <1.0 | 1.5 | – | 1.0 |

Source: Postal questionnaires to RAI-study participants; NIVEL report; fact sheets on Sweden [6, 7].
[a]Including only elderly of ≥67 years.
[b]Including only residential care homes and not group facilities such as board and care homes.
[c]Including some sheltered housing and other special dwellings for elderly.
[d]Including some young disabled.
[e]No facilities described as nursing homes; 2% of elderly reside in nursing-home-like facilities.

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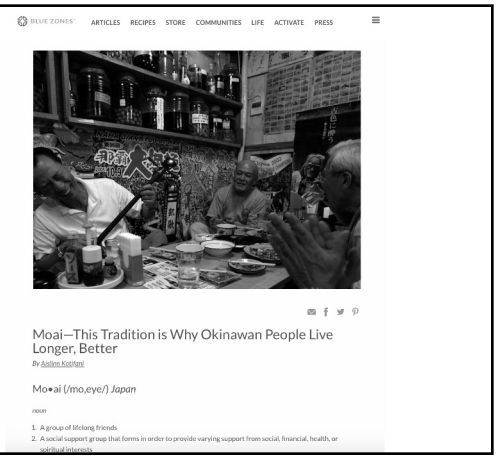


16

# Utilization
# Site of Service

17

## About how many Nursing Home residents are there win the USA?

**A) <1.0 Million**

**B) 1.3 Million**

**C) 1.7 Million**

**D) 2.1 Million**

18

**Table XII. Post-acute and long-term care users, by selected characteristics and sector: United States, 2017–2018**

| Characteristic[1] | Adult day services center | SE | Home health agency | SE | Hospice | SE | Inpatient rehabilitation facility | SE | Long-term care hospital | SE | Nursing home | SE | Residential care community | SE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number | | | | | | | | | | | | | |
| Users[2] | 251,100 | 7,080 | 4,940,270 | --- | 1,562,524 | 47,679 | 380,430 | 10,956 | 115,822 | 4,448 | 1,321,205 | 6,640 | 918,708 | 33,620 |
| | Percent distribution | | | | | | | | | | | | | |
| Age | | | | | | | | | | | | | | |
| Under 65 | 39.4 | 2.1 | 17.3 | 0.0 | 5.2 | 0.1 | 12.1 | 0.2 | 25.7 | 0.5 | 16.9 | 0.0 | 7.5 | 1.2 |
| 65 and over | 60.6 | 2.1 | 82.7 | 0.0 | 94.8 | 0.1 | 87.9 | 0.2 | 74.3 | 0.5 | 83.1 | 0.0 | 92.5 | 1.3 |
| 65–74 | 17.8 | 1.4 | 27.5 | 0.0 | 17.6 | 0.1 | 31.9 | 0.2 | 34.3 | 0.3 | 19.5 | 0.0 | 12.1 | 1.6 |
| 75–84 | 24.1 | 1.7 | 29.9 | 0.0 | 29.2 | 0.1 | 33.5 | 0.1 | 26.5 | 0.2 | 27.2 | 0.0 | 25.5 | 2.4 |
| 85 and over | 18.6 | 1.5 | 25.2 | 0.0 | 48.0 | 0.2 | 22.5 | 0.3 | 13.5 | 0.5 | 36.4 | 0.0 | 54.9 | 2.6 |
| Sex | | | | | | | | | | | | | | |
| Man | 43.5 | 1.9 | 39.4 | 0.1 | 41.6 | 0.1 | 45.8 | 0.2 | 51.8 | 0.3 | 36.7 | 0.0 | 32.6 | 2.1 |
| Women | 56.5 | 1.9 | 60.6 | 0.1 | 58.4 | 0.1 | 54.2 | 0.2 | 48.2 | 0.3 | 63.3 | 0.0 | 67.4 | 2.1 |
| Race and ethnicity | | | | | | | | | | | | | | |
| Hispanic | 22.2 | 1.9 | 7.0 | 0.2 | 6.5 | 0.4 | 5.8 | 0.4 | 9.7 | 0.9 | 5.7 | 0.0 | 1.9 | 0.6 |
| Non–Hispanic White | 44.8 | 2.1 | 76.8 | 0.3 | 82.3 | 0.5 | 79.9 | 0.6 | 66.3 | 1.1 | 73.9 | 0.0 | 89.4 | 1.8 |
| Non–Hispanic Black | 16.8 | 1.4 | 12.1 | 0.2 | 8.3 | 0.2 | 10.8 | 0.4 | 19.8 | 0.9 | 14.9 | 0.0 | 5.9 | 1.4 |
| Other[3] | 16.3 | 1.9 | 4.1 | 0.1 | 3.0 | 0.2 | 3.5 | 0.2 | 4.1 | 0.3 | 5.5 | 0.0 | 2.8 | 0.9 |
| Medicaid payer source | 72.3 | 1.9 | 9.1 | 0.0 | --- | --- | --- | --- | --- | --- | 62.0 | 0.2 | 18.1 | 2.3 |
| | Percent | | | | | | | | | | | | | |
| Diagnosis[4] | | | | | | | | | | | | | | |
| Alzheimer disease or other dementias | 27.8 | 1.8 | 35.5 | 0.2 | 46.3 | 0.3 | 35.6 | 0.4 | 45.5 | 0.7 | 49.1 | 0.0 | 33.7 | 2.8 |
| Arthritis | 18.5 | 1.6 | 61.7 | 0.2 | 29.6 | 0.2 | 62.8 | 0.3 | 52.6 | 0.6 | 27.6 | 0.0 | 20.5 | 2.1 |
| Asthma | 5.6 | 0.9 | 11.8 | 0.1 | 3.7 | 0.0 | 12.0 | 0.1 | 13.9 | 0.2 | --- | --- | 2.0 | 0.5 |
| Chronic kidney disease | 5.7 | 0.9 | 54.7 | 0.1 | 39.2 | 0.2 | 61.2 | 0.3 | 81.4 | 0.5 | --- | --- | 6.5 | 1.1 |
| Chronic obstructive pulmonary disease | 6.8 | 0.9 | 32.0 | 0.2 | 20.1 | 0.2 | 33.1 | 0.3 | 55.4 | 0.8 | --- | --- | 10.6 | 1.9 |
| Depression | 21.8 | 1.7 | 40.5 | 0.1 | 23.7 | 0.2 | 49.2 | 0.4 | 51.8 | 0.5 | 48.8 | 0.0 | 27.5 | 2.5 |
| Diabetes | 29.7 | 1.7 | 45.2 | 0.2 | 26.6 | 0.2 | 48.2 | 0.3 | 64.2 | 0.6 | 34.8 | 0.0 | 20.4 | 2.3 |
| Heart disease[5] | 13.3 | 1.4 | 54.4 | 0.2 | 37.9 | 0.3 | 59.8 | 0.4 | 68.3 | 0.6 | 20.1 | 0.0 | 17.3 | 1.9 |
| High blood pressure or hypertension | 51.1 | 2.0 | 89.2 | 0.1 | 50.3 | 0.3 | 93.6 | 0.1 | 93.5 | 0.3 | 76.9 | 0.0 | 55.2 | 2.7 |
| Osteoporosis | 12.7 | 1.6 | 15.0 | 0.1 | 6.4 | 0.1 | 17.4 | 0.2 | 10.5 | 0.2 | 11.4 | 0.0 | 12.0 | 1.5 |
| Need assistance in physical functioning | | | | | | | | | | | | | | |
| Bathing | 74.8 | 1.9 | 96.3 | 0.0 | --- | --- | 99.7 | 0.0 | --- | --- | 96.5 | 0.1 | 77.3 | 2.2 |
| Dressing | 64.2 | 2.0 | 95.6 | 0.0 | --- | --- | 99.9 | 0.0 | --- | --- | 92.7 | 0.1 | 61.7 | 2.5 |
| Toileting | 52.7 | 2.1 | 90.2 | 0.0 | --- | --- | 99.4 | 0.0 | --- | --- | 89.8 | 0.1 | 48.7 | 2.9 |
| Walking or locomotion | 57.7 | 2.0 | 97.2 | 0.0 | --- | --- | 99.8 | 0.0 | --- | --- | 92.4 | 0.1 | 69.0 | 2.6 |
| Transferring in and out of a chair or bed | 53.6 | 2.1 | 95.4 | 0.0 | --- | --- | 99.9 | 0.0 | --- | --- | 87.3 | 0.1 | 51.0 | 2.8 |
| Eating | 41.4 | 2.0 | 66.8 | 0.0 | --- | --- | 83.9 | 0.1 | --- | --- | 60.2 | 0.3 | 26.3 | 2.5 |

See footnotes at end of table.



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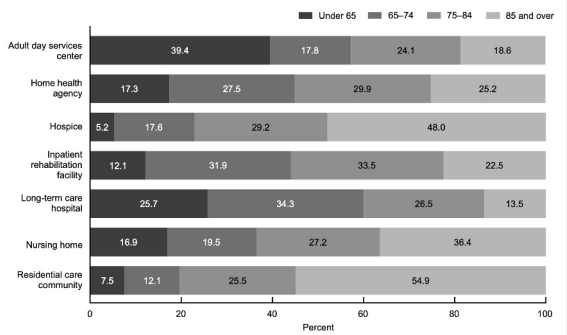
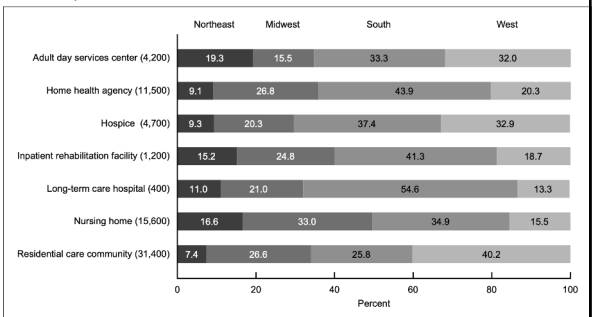
**Figure 20. Percent distribution of post-acute and long-term care services users, by sector and age group: United States, 2017 and 2018**




NOTES: Percentages for adult day services centers, nursing homes, and residential care communities were based on the number of users on a given day in 2018. Percentages for home health agencies, hospices, inpatient rehabilitation facilities, and long-term care hospitals were based on the number of patients who received care at any time in 2017. See Appendix I in this report for more information on data sources used for each sector. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding. Access data for this figure in Table XII of Appendix III.
SOURCES: National Center for Health Statistics, National Study of Long-Term Care Providers, 2018, and Centers for Medicare and Medicaid Services data files, 2017–2018.

20

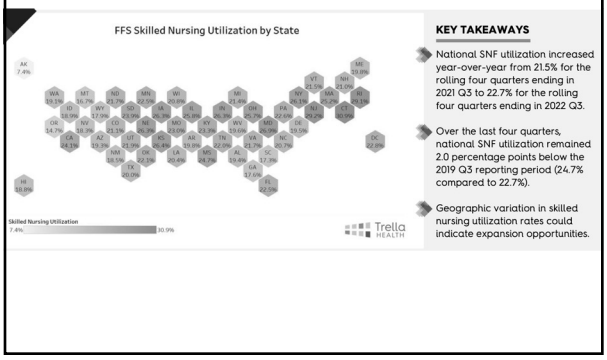
**Figure 1. Percent distribution of post-acute and long-term care services providers, by sector and region: United States, 2018**




NOTES: Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding. Access data for this figure in Table IX of Appendix III in this report.
SOURCES: National Center for Health Statistics, National Study of Long-Term Care Providers, 2018, and Centers for Medicare and Medicaid Services data files, 2018.



21

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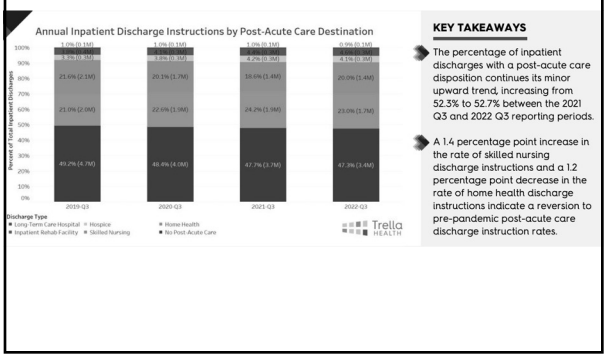


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# Home & Community Based Services

24

## What % of FL's LTSS budget is spent on HCBCS?

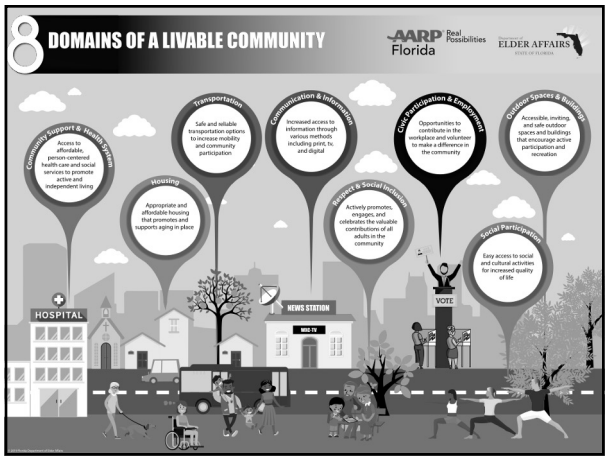
A) 17%

B) 27%

C) 37%

D) 47%

25

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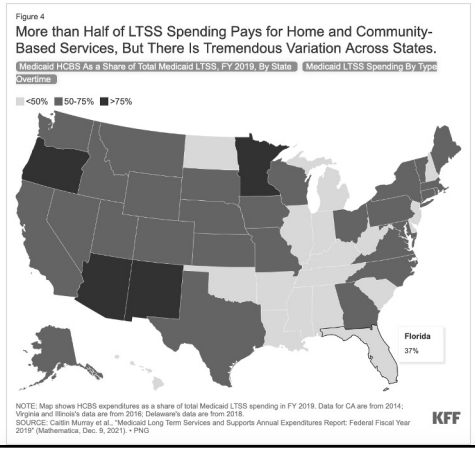


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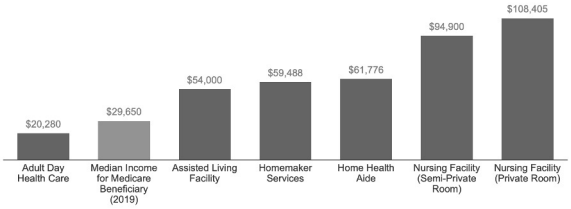
Figure 2

## LTSS Are Extremely Expensive and Generally Not Covered By Medicare.

Nursing facility costs are higher than those of other services but many people living outside of nursing facilities use multiple services simultaneously. Medicare only covers home health and skilled nursing facility care on a time-limited basis.




NOTE: Dollar amounts are annual costs for each type of care in 2021.
SOURCE: KFF analysis of Genworth 2021 Cost of Care Survey; KFF, Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic, Urban Institute / KFF analysis of DYNASIM data, 2019. • PNG

KFF

28

## STATEWIDE MEDICAID MANAGED CARE
## LONG-TERM CARE PROGRAM

Providing Long-Term Care (LTC) services to Florida's most vulnerable citizens is a multi-agency effort. The Agency for Health Care Administration (AHCA) administers the Statewide Medicaid Managed Care (SMMC) Long-Term Care program, sets coverage policy, and gets those eligible for services enrolled in a LTC plan. The Department of Children and Families (DCF) is responsible for determining financial eligibility for services. The Department of Elder Affairs (DOEA) is responsible for determining medical eligibility and level of care needed.

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29

AMERICA'S HEALTH RANKINGS

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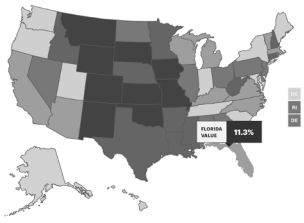
### Low-Care Nursing Home Residents

Percentage of nursing home residents who did not require physical assistance for bed mobility, transferring, using the toilet or eating




| Top States | Rank | Value |
|---|---|---|
| Hawaii | 1 | 3.7% |
| Maine | 2 | 4.4% |
| South Carolina | 3 | 7.9% |
| Tennessee | 4 | 8.6% |
| Maryland | 5 | 8.8% |

| Bottom States | Rank | Value |
|---|---|---|
| Montana | 45 | 24.8% |
| Colorado | 46 | 25.0% |
| Kansas | 47 | 26.0% |
| Oklahoma | 48 | 28.3% |
| Missouri | 49 | 31.3% |

View All States >

Data from Brown University, Shaping Long-Term Care in America Project, 2020

<= 10.5% | 10.6% - 12.9% | 13.0% - 16.2% | 16.3% - 18.4% | >= 18.5% | No Data

30


31

# PALTC Workforce

32

**The site of LTC that experienced the greatest impact on workforce following the pandemic is?**

**A) Nursing Homes**

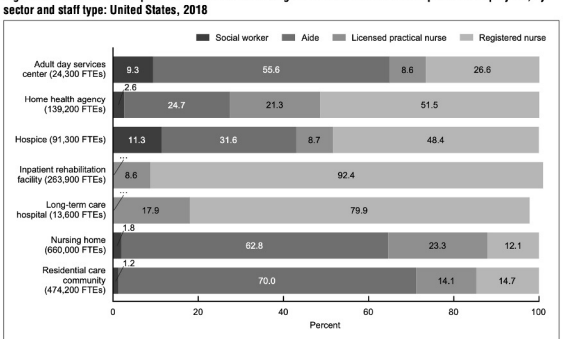
**B) Home Health**

**C) Outpatient Offices**

**D) Hospitals**

33

**Figure 9. Total number and percent distribution of nursing and social work full-time equivalent employees, by sector and staff type: United States, 2018**



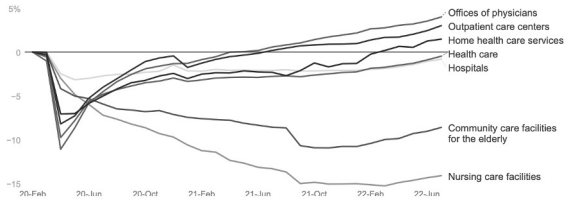

... Category not applicable.
NOTES: FTE is full-time equivalent. Only employees are included for all staff types; contract staff are not included. For adult day services centers and residential care communities, aide refers to certified nursing assistants, home health aides, home care aides, personal care aides, personal care assistants, and medication technicians or medication aides. For home health agencies and hospices, aide refers to home health aides. For nursing homes, aide refers to certified nurse aides, medication aides, and medication technicians. Social workers include licensed social workers or persons with a bachelor's or master's degree in social work in adult day services centers and residential care communities; medical social workers in home health agencies and hospices; and qualified social workers in nursing homes. See Appendix I in this report for information on how outliers were identified and coded. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding. Access data for this figure in Table X of Appendix III.
SOURCES: National Center for Health Statistics, National Study of Long-Term Care Providers, 2018, and Centers for Medicare and Medicaid Services data files, 2018.

34

Figure 9

## The Pandemic Exacerbated LTSS Existing Workforce Shortages.

Pandemic employment losses in health care were greatest for nursing care and community care facilities.
*Figure shows cumulative % change in health sector employment by setting.*




SOURCE: Peterson-KFF Health System Tracker • Get the data • PNG

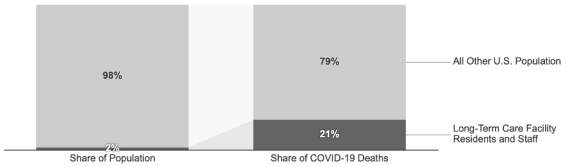
Peterson-KFF Health System Tracker

35

Figure 1

## Over One-Fifth Of All U.S. COVID-19 Deaths Were Among Long-Term Care Facility Residents and Staff.

At least 209,000 LTCF residents and staff have died as of 6/12/2022.




NOTE: Deaths in long-term care facilities (LTCFs) are undercounted because they count exclude deaths in non-nursing home settings after June 30, 2021 and reflect incomplete state reporting prior to that date. Some of the "All Other COVID-19 Deaths in the US" count likely reflect LTCF deaths that have not been categorized as such.
SOURCE: LTCF death counts are from KFF analysis of CMS COVID-19 Nursing Home Data, available state reports, press releases, and official state data through news reports. Total COVID-19 death count is from CDC. All data sources are as of June 12th, 2022. • PNG

KFF

36


37


38

# LTC Facilities: Staffing Ratios

39

## The projected annual cost of recently proposed minimum staffing ratios is?

A) $3.8B

B) $4.8B

C) $5.8B

D) $6.8B

40

This document is scheduled to be published in the Federal Register on 09/06/2023 and available online at **https://federalregister.gov/d/2023-18781**, and on **https://govinfo.gov** [Billing Code: 4120-01-P]

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 438, 442, and 483**

**[CMS-3442-P]**

**RIN 0938-AV25**

**Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would establish minimum staffing standards for long-term care facilities, as part of the Biden-Harris Administration's Nursing Home Reform initiative to ensure safe and quality care in long-term care facilities. In addition, this rule proposes to require States to report the percent of Medicaid payments for certain Medicaid-covered institutional services that are spent on compensation for direct care workers and support staff.

41

Florida Health Care Association

**Contact:** Kristen Knapp, APR
850-701-3530
kknapp@fhca.org

**FOR IMMEDIATE RELEASE**
October 10, 2023

**Proposed Federal Nursing Home Mandates Undermine Progress in Florida, Exacerbate Workforce Shortage According to New Study**
*Unfunded federal mandates will cost Florida an additional $188 million, despite existing state staffing requirements.*

**Tallahassee, Fla. –** A new analysis reveals the harmful and costly impacts the Biden administration's recently announced federal staffing mandates will have on Florida nursing centers and their residents. According to the study by professional services firm CLA (CliftonLarsonAllen, LLP), the federal Centers for Medicare and Medicaid Services (CMS) proposed staffing mandate will cost Florida nursing centers **an additional $188 million,** despite Florida already having comprehensive staffing standards. In many categories, Florida standards already exceed what is required by the federal mandate.

Florida's staffing standards recognize the different needs of each resident and provide flexibility for centers to staff according to those unique needs. Along with required nursing hours, Florida's standards also recognize the important role of social workers, activity staff, and therapists in delivering quality care. The CMS proposed rule would require 2.45 nurse aide hours per resident per day (HPRD) and 0.55 registered nurse (RN) HPRD compared to Florida's current requirement of 2.0 certified nursing assistant (CNA) hours, an additional .6 hour of direct care provided by specialty staff (may include a CNA) and 1 hour of licensed nursing services that are provided by a combined use of RNs and Licensed Practical Nurses (LPN). Under the CMS proposal, Florida centers would need to hire an **additional 3,487 full time employees to meet the mandate.**

"Florida is a proud leader when it comes to high-quality long-term care. We recognize the importance of minimum staffing requirements, which is why Florida nursing centers already abide by a stringent set of standards to ensure residents receive the highest quality of care," said Emmett Reed, CEO of the Florida Health Care Association (FHCA). "At a time when Florida's long-term care profession is facing workforce shortage challenges, these arbitrary and unfunded mandates will make it harder to recruit, train and retain long-term care workers."

The federal staffing mandate undermines the Florida staffing standards already in place, in particular the licensed nursing services that Florida residents receive. Moreover, the CMS proposal offers no place for Licensed Practical Nurses (LPNs) to be counted in the care for residents. LPNs, which is the next stage in the career ladder for certified nursing assistants, currently make up over 61% of the workforce that is helping to meet the licensed nursing requirement in Florida nursing centers.

"Out-of-touch federal mandates undercut the progress we are making in Florida and eliminate a career path for many of our frontline caregivers," said Deborah Franklin, FHCA Senior Director of Quality Improvement. "More of our nursing center residents are living with complex chronic conditions and need skilled nursing care. With an aging population that is seeking more specialized and person-centered services, what we need are common sense solutions to help attract, advance, and retain caregivers who can meet the needs of our residents, not more red tape."

42

## Summary of Findings and Conclusions

The following table summarizes the potential impact of the proposed staffing mandate on the skilled nursing facility industry.

| | Nurse Aide (2.45 HPRD) | RN 24/7 Coverage | RN (0.55 HPRD) | All/Total |
|---|---|---|---|---|
| ***Facilities that met criteria*** | 4,079 (28%) | 2,970 (20%) | 7,642 (52%) | 896 (6%) |
| ***Facilities that did NOT meet criteria*** | 10,532 (72%) | 11,729 (80%) | 7,057 (48%) | 13,803 (94%) |
| ***Estimated Annual Cost ($ in Millions)*** | $ 4,794 | $ 610 | $ 1,455 | $ 6,860 |
| ***Estimated FTEs to Meet Criteria*** | 80,077 | 6,897 | 15,180 | 102,154 |
| ***Potential Census Impacted*** | 186,920 (16%) | 96,528 (8%) | 147,167 (12%) | 287,524 (24%) |

The additional cost and FTEs for 24/7 RN coverage does allow some facilities to meet the RN HPRD requirement. The RN HPRD estimated annual cost and additional FTEs to meet the 0.55 HPRD is in excess of the RN 24/7 coverage.

The estimated $6.8 billion annual cost exceeds the CMS estimated annual cost of $4 billion dollars primarily due to the fiscal year cost reports utilized in the calculation. CLA utilized the most currently available reports, including some FYE 2022 reports, which represent higher compensation costs than FY 2021.



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## POSITION ON STAFFING STANDARDS IN LONG TERM CARE

**Date: 2022-08-10 12:00:00**

**This updates HOD Resolution of 2000 and AMDA Staffing Statement of 2002**

*Abbreviations: Centers for Medicare and Medicaid (CMS), Practitioners, Certified Nursing Assistant (CNA), Licensed Practical Nurse (LPN), Allied Health Professionals, Nurse Practitioner (NP), Physician's Assistant (PA), Physician*

**Summary**

The primary focus of this statement is to:

- Expand upon AMDA's 2000 position on minimum staffing standards in nursing homes (AMDA House of Delegates Resolution A00) and AMDA's 2002 position on direct care staffing in nursing homes (Statement H02)
- Encourage a systems approach to establishing appropriate staffing standards
- Encourage ongoing active engagement with both medical directors and adjunct provider teams in establishing appropriate staffing recommendations

**Background**

Despite intense interest over several decades from clinical professionals, resident advocates, and state and federal regulators, a systematic, evidence-based approach to determine the appropriate level of staffing to meet the needs of residents remains frustratingly elusive.

Skilled nursing facilities (SNFs) and long-term care (LTC) facilities (also referred to as nursing homes or

44

# PALTC Financing

45

## The primary payer of PALTC in the USA is?

A) Medicare

B) Medicaid

C) Out-of-Pocket

D) Private Insurance

46

FORBES › MONEY › PERSONAL FINANCE

### The U.S. Predicts Big Increases In Skilled Nursing And Long-Term Care Costs

**Howard Gleckman** Senior Contributor
*I cover tax, budget and retirement policy from Washington*

Follow

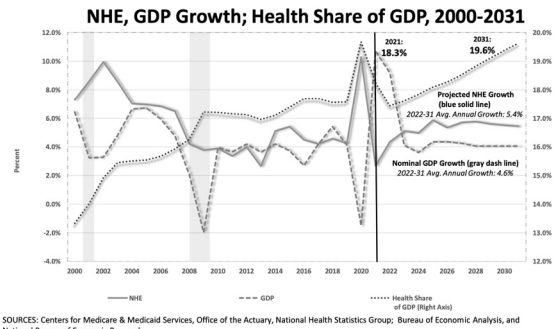
0 Apr 4, 2023, 09:59am EDT

Listen to article 6 minutes

Adriana Parada, is a certified nurse assistant providing care to Maria Antunez, 91. (Photo by Cliff ... [+] MEDIANEWS GROUP VIA GETTY IMAGES

New government projections estimate significant increases in both overall and out-of-pocket costs for home care, nursing facilities, and continuing care communities (CCRCs) through this decade. The projected steep rise in costs will lead to tough decisions for both consumers and government.

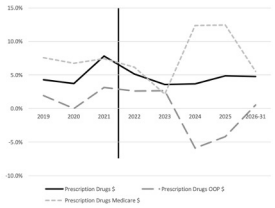
47




SOURCES: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group; Bureau of Economic Analysis, and National Bureau of Economic Research.
NOTES: Shaded areas represent recession periods.
** During 2020 there was a short economic recession in March and April.

48

## Inflation Reduction Act Impacts: Average Annual Growth in Prescription Drug Spending: Total, OOP, and Medicare, By Time Period




Notable Trends Impacted by IRA:

- 2023+:
  - The IRA's inflation rebates take effect.
- 2024:
  - IRA eliminates Part D's 5-percent beneficiary coinsurance in the catastrophic portion of the benefit resulting in negative growth in OOP spending for drugs and higher Medicare drug spending growth.
- 2025:
  - Reflects the introduction of a $2,000 cap on OOP spending on drugs by Part D enrollees leading to continued negative OOP growth.
- 2026-31:
  - Reflects Part D's lower negotiated prices for certain high-cost drugs, and their accompanying lower OOP payments, which acts to slow growth in Medicare prescription drug spending.

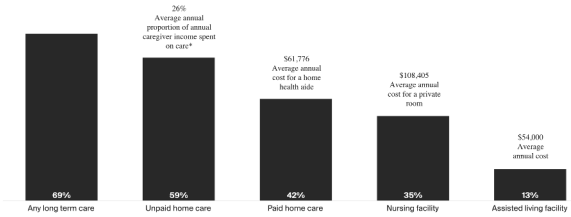
NOTE: Average annual growth rates are from previous year shown.
SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

49

EXHIBIT 1

## More than one-third of U.S. adults will use long-term care nursing facilities, which can cost more than $100,000 a year.

*Percentage of adults who ever use different forms of long-term care as they age, and the median cost of care in 2021*




Download data

* 26% does not account for the indirect costs of care, including lost wages and productivity, as well as the increased physical and mental burden on caregivers.

Data: Administration for Community Living, "How Much Care Will You Need?," LongTermCare.gov, last updated Feb. 18, 2020; AARP, *Caregiving Out-of-Pocket Costs Study* (AARP, June 2021); and Genworth, "Costs of Care Trends and Insights," Feb. 7, 2022.

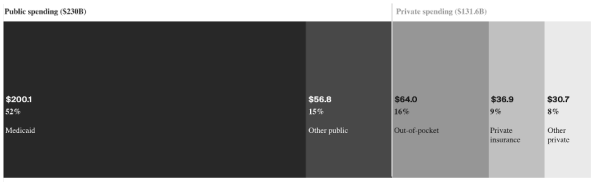
Source: Celli Horstman, Evan D. Gumas, and Gretchen Jacobson, *U.S. and Global Approaches to Financing Long-Term Care: Understanding the Patchwork* (Commonwealth Fund, Feb. 2023). https://doi.org/10.26099/2m36-vt53

50

EXHIBIT 2

## In 2020, most long-term care in the United States was publicly funded.

*Amount spent ($ billions)*



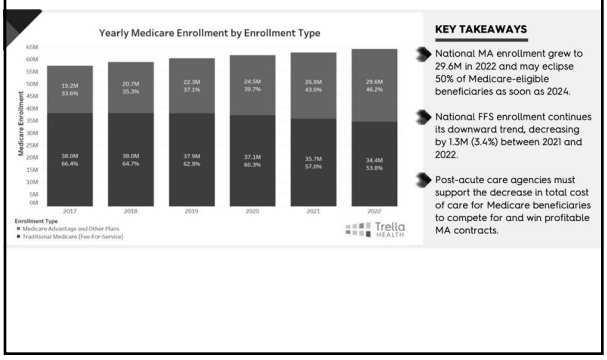

Download data

Notes: "Other public" refers to funding sources other than Medicare or Medicaid, including sources like Federal COVID-19 Pandemic Assistance, the Veterans Health Administration (VHA), and Children's Health Insurance Program (CHIP). "Other private" refers to sources like philanthropic fundraising organizations and support obtained from foundations and corporations. Percentages do not include Medicare, though Medicare spending for long-term services and supports was $86.6B in 2020.

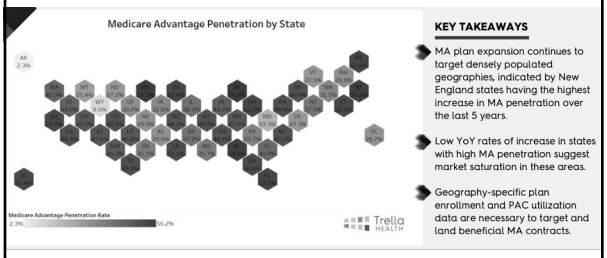
Data: Congressional Research Service, *Who Pays for Long-Term Services and Supports?*, In Focus 10343, vers. 9 (CRS, last updated June 15, 2022).

Source: Celli Horstman, Evan D. Gumas, and Gretchen Jacobson, *U.S. and Global Approaches to Financing Long-Term Care: Understanding the Patchwork* (Commonwealth Fund, Feb. 2023). https://doi.org/10.26099/2m36-vt53

51




52




53

# NH Quality

54

## Which US State reports the highest % of 4 & 5 Star NH's?

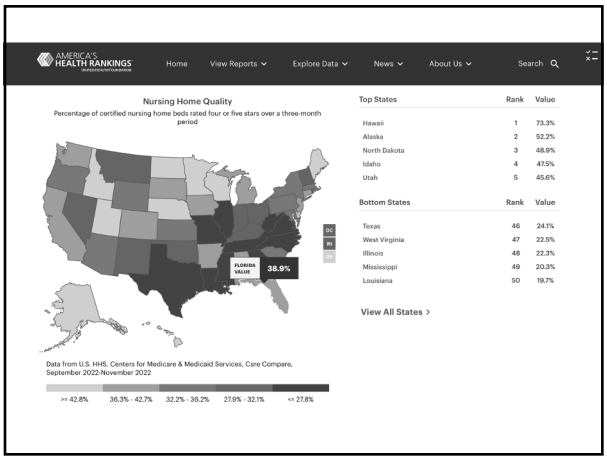
**A) Alaska**

**B) Florida**

**C) Hawaii**

**C) North Dakota**

55




56


57

# Disparities in PALTC

58

**Which PALTC setting in the USA has the higher utilization by men (vs women)?**

**A) Home Health**

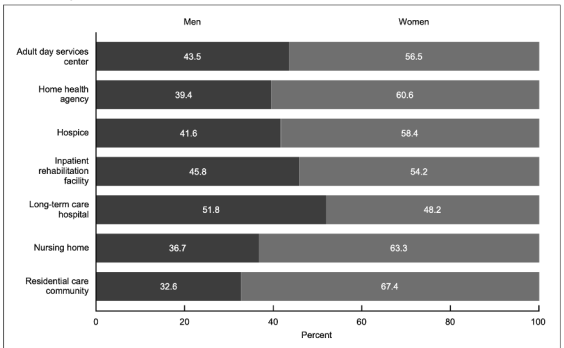
**B) Hospice**

**C) Long-Term Hospital**

**D) Nursing Home**

59

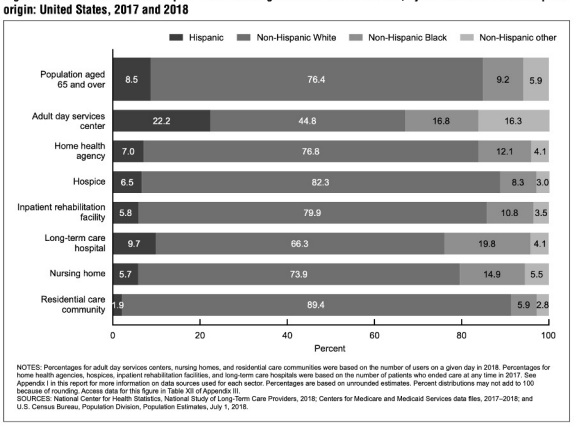
**Figure 21. Percent distribution of post-acute and long-term care services users, by sector and sex: United States, 2017 and 2018**




NOTES: Percentages for adult day services centers, nursing homes, and residential care communities were based on the number of users on a given day in 2018. Percentages for home health agencies, hospices, inpatient rehabilitation facilities, and long-term care hospitals were based on the number of patients who ended care at any time in 2017. See Appendix I in this report for more information on data sources used for each sector. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding. Access data for this figure in Table XII of Appendix III.
SOURCES: National Center for Health Statistics, National Study of Long-Term Care Providers, 2018, and Centers for Medicare and Medicaid Services data files, 2017–2018.

60

**Figure 22. Percent distribution of post-acute and long-term care services users, by sector and race and Hispanic origin: United States, 2017 and 2018**




NOTES: Percentages for adult day services centers, nursing homes, and residential care communities were based on the number of users on a given day in 2018. Percentages for home health agencies, hospices, inpatient rehabilitation facilities, and long-term care hospitals were based on the number of patients who ended care at any time in 2017. See Appendix I in this report for more information on data sources used for each sector. Percentages are based on unrounded estimates. Percent distributions may not add to 100 because of rounding. Access data for this figure in Table XII of Appendix III.
SOURCES: National Center for Health Statistics, National Study of Long-Term Care Providers, 2018; Centers for Medicare and Medicaid Services data files, 2017–2018; and U.S. Census Bureau, Population Division, Population Estimates, July 1, 2018.

61


62


63

# The Future is Now! Technology in PALTC

64

**Are you using Telehealth in your PALTC setting?**

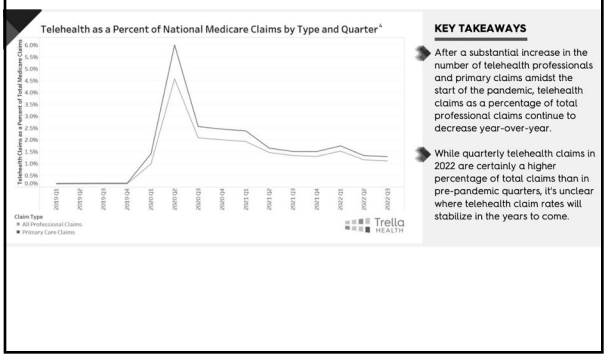
**A) Yes**

**B) No**

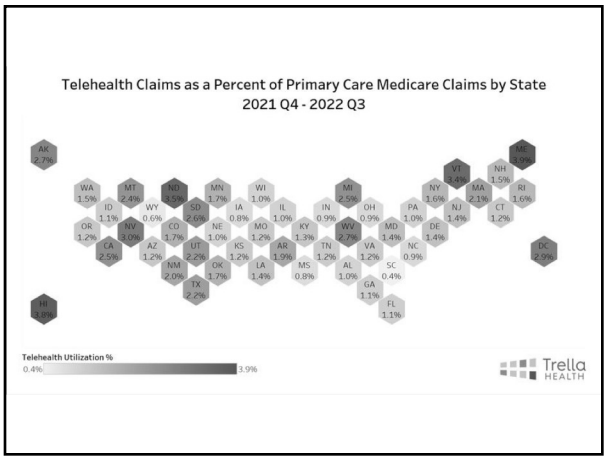
65


66

67


Telehealth as a Percent of National Medicare Claims by Type and Quarter[A]
Telehealth Claims as a Percent of Total Medicare Claims
6.0%
5.5%
5.0%
4.5%
4.0%
3.5%
3.0%
2.5%
2.0%
1.5%
1.0%
0.5%
0.0%
2019 Q1
2019 Q2
2019 Q3
2019 Q4
2020 Q1
2020 Q2
2020 Q3
2020 Q4
2021 Q1
2021 Q2
2021 Q3
2021 Q4
2022 Q1
2022 Q2
2022 Q3
Claim Type
All Professional Claims
Primary Care Claims
Trella HEALTH
KEY TAKEAWAYS
After a substantial increase in the number of telehealth professionals and primary claims amidst the start of the pandemic, telehealth claims as a percentage of total professional claims continue to decrease year-over-year.
While quarterly telehealth claims in 2022 are certainly a higher percentage of total claims than in pre-pandemic quarters, it's unclear where telehealth claim rates will stabilize in the years to come.

68


Telehealth Claims as a Percent of Primary Care Medicare Claims by State
2021 Q4 - 2022 Q3
AK 2.7%
ME 3.9%
VT 3.4%
NH 1.5%
WA 1.5%
MT 2.4%
ND 3.5%
MN 1.7%
WI 1.0%
MI 2.5%
NY 1.6%
MA 2.1%
RI 1.6%
ID 1.1%
WY 0.6%
SD 2.6%
IA 0.8%
IL 1.0%
IN 0.9%
OH 0.9%
PA 1.0%
NJ 1.4%
CT 1.2%
OR 1.2%
NV 3.0%
CO 1.7%
NE 1.0%
MO 1.2%
KY 1.3%
WV 2.7%
MD 1.4%
DE 1.4%
CA 2.5%
AZ 1.2%
UT 2.2%
KS 1.2%
AR 1.9%
TN 1.2%
VA 1.2%
NC 0.9%
DC 2.9%
NM 2.0%
OK 1.7%
LA 1.4%
MS 0.8%
AL 1.0%
SC 0.4%
TX 2.2%
GA 1.1%
FL 1.1%
HI 3.9%
Telehealth Utilization %
0.4%
3.9%
Trella HEALTH

69

70

@RhondaLRandallDO

71

# The Latest in PALTC

FMDA Annual Meeting
October 21 , 2023

Alex Bardakh, MPP, CAE – Senior Director, Advocacy and Strategic Partnerships

1

## Disclosure

- The speaker has no relevant disclosures

2

## 2023 Public Policy & Advocacy Priorities

**AMDA-Specific Issues**

- Telemedicine in PALTC
- CMS Medical Director Database
- Quality Measurement
- Reform of Requirements for Long-Term Care Facilities
- MACRA Implementation and new models of payment (i.e. Merit- Based Incentive Payment System (MIPS) and Alternative Payment Models (APM))
- Post-Acute and Long-Term Care as a Specialty
- Clinical Technologies in PALTC (HIT)
  - » Interoperability of EHRs
  - » Use of Data
- Strengthen and Add Value to Role of Medical Director

**Issues to Monitor**

- General Practice Issues
- General Physician Issues

**Coalition-Building Issues**

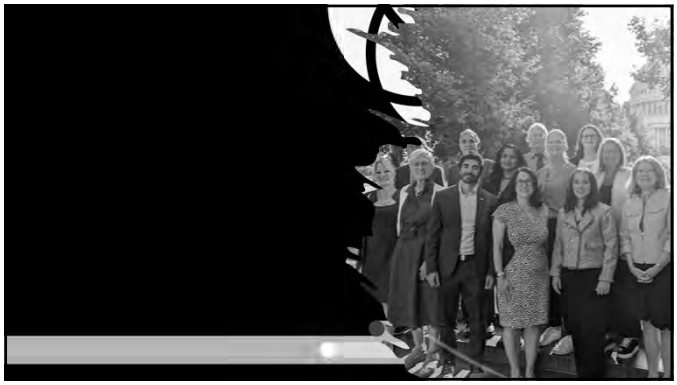
- PDPM Transition
- Payment/RUC
  - » Annual Physician Fee Schedule
  - » E/M Rework
- Improving Dementia Care in Nursing Homes
- Assisted Living (work with NCAL and ALFA)
- Minimum PALTC Staffing Requirements
- Appropriate Management of Pain
  - » Recognize nurse as agent
  - » Define emergency in the PALTC setting
- Infection control (HAIs)
- Geriatric workforce issues
- Medicare observation status/3 day stay
- Hospice/End of Life
  - » Physician Choice
  - » Relatedness to Terminal Prognosis
- Transitions of Care
- Medical liability
- Clinical Issues
  - » Marijuana Use in PALTC Setting
- Infection Control (HAIs)
- Antibiotic Stewardship

3

## AMDA Policy Development Structure

- Board of Directors – Milta Little, DO, CMD - President
- Public Policy Steering Committee – Chair, Vicki Walker, MD, CMD, Tim Holahan, MD, CMD Vice-Chair
  - Clinical Issues Subcommittee – Tom Lehner, MD CMD – Chair
  - Telehealth Subcommittee – Dallas Nelson, MD, CMD, Chair
  - State-Based Advocacy Subcommittee – Christian Bergman, MD, CMD – Chair; David Polakoff, MD, CMD – Vice Chair
- Society House of Delegates – Wayne Saltsman, MD, CMD - Chair
- RUC/CPT Representatives – Chuck Crecelius, MD, CMD; Bob Zorowitz, MD, CMD; Dallas Nelson, MD, CMD
- AMA House of Delegates – Karl Steinberg, MD, CMD; Leslie Eber, MD, CMD
- Practice Group Network – Tom Haithcoat – Chair

4



5

## Congress "in"Action or (Total Pandamonium)

- Government Shutdown? Have until Sept 30 to pass a continuing resolution
- Series of spending bills to fund various parts of the Federal government
- Must pass legislation – likely one big package at the end of the year

6

## HR177 – Nursing Home Transparency Act (It's a Marathon)

- Co-sponsored by Reps. Mike Levin (D-CA) and Brian Fitzpatrick (R-PA)
- Require nursing facilities to report medical director information and CMS to post on Care Compare website
- Public and policymakers need to have access to this information

7

## The Nursing Home Disclosure Act

Scan Below to Email Your Congressional Representative Asking Them to Support H.R. 177

SCAN ME

8

## Admin Plan NH Reform

- Establish a Minimum Nursing Home Staffing Requirement
- Single occupancy rooms
- Strengthen SNF Value-Based Purchasing Program
- Safeguards Against Unnecessary Medication and Treatments
- More funding for NH oversight
- Beef up scrutiny on Special Focus Facilities
- Expand Financial Penalties and Other Enforcement Sanctions
- Provide Technical Assistance to NHs
- Improve transparency around NH Ownership and role of private equity
- Improve workforce
- Strengthen requirements for infection preventionist

9

## CMS Issues Staffing Rule – Hit it out of the Park?

- Reactions have been mixed — but mainly negative. Long-term care facilities say that they can neither find nor afford more workers. On the other hand, some lawmakers argue the proposed rule doesn't do enough to protect care quality for patients. As for labor unions, they seem generally happy with the rule – first result in Google search

10

## Staffing Proposed Rule Details

- 3.0 hours per patient day of direct care
  - .55 hours by RN
  - 2.45 by nurse aide
- 24/7 RN
- Non-rural nursing homes – 3 years to comply
- Rural nursing homes – 5 years to comply
- Request for Information on "alternative approaches"
- Potential exemptions
- 60 Day Comment Period


11

## Society Reaction

- AMDA - The Society for Post-Acute and Long-Term Care Medicine, while applauding the effort by CMS to support staffing in nursing homes, is concerned about a "one size fits all" approach of mandating a specific minimum number for all nursing facilities to meet - https://paltc.org/amda-urges-prioritization-adequate-staffing-over-minimum-staffing-response-new-staffing-rule

Society's position statement https://paltc.org/?q=amda-white-papers-and-resolution-position-statements/position-staffing-standards-long-term-care (as of August 10, 2022)

Society statements:

- Staffing and trained workforce are key to quality care
- Benefits/career ladders and training all factors for direct care workforce
- Continued support Geriatric Workforce Enhancement Program (GWEP) and Geriatric Academic Career Awards (GACA)

12

12


## National Academies Of Sciences Report

- The way in which the United States finances, delivers, and regulates care in nursing home settings is ineffective, inefficient, fragmented, and unsustainable.
- Minimum staffing standards
- Must improve minimum education and competencies if interdisciplinary staff
- Transparency around medical director role!
- Improve financing mechanisms including value-based medicine!
- Adopt Health Information Technology in all nursing homes

- Full report https://www.nationalacademies.org/our-work/the-quality-of-care-in-nursing-homes

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## Moving Forward Action Plans Released

- Addressing Residents' Goals, Preferences, and Priorities
- Strengthening Residents Councils
- Improving Certified Nursing Assistant Wages and Support
- Expanding Certified Nursing Assistant Career Pathways
- Enhancing Surveyor Training on Person-Centered Care
- Designing a Targeted Nursing Home Recertification Survey
- Increasing Transparency and Accountability of Ownership Data
- Developing a Nursing Home Health Information Technology Readiness Guide
- Financing Household Models and Physical Plant Improvements

Click here to access the full action plan.

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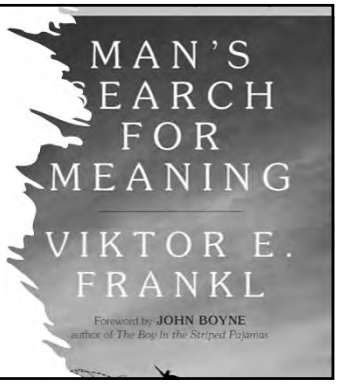
- "But today's society is characterized by achievement orientation, and consequently it adores people who are successful and happy and, in particular, it adores the young. It virtually ignores the value of all those who are otherwise, and in so doing blurs the decisive difference between being valuable in the sense of dignity and being valuable in the sense of usefulness. If one is not cognizant of this difference and holds that an individual's value stems only from his present usefulness, then, believe me, one owes it only to personal inconsistency not to plead for euthanasia along the lines of Hitler's program, that is to say, 'mercy' killing of all those who have lost their social usefulness, be it because of old age, incurable illness, mental deterioration, or whatever handicap they may suffer. Confounding the dignity of man with mere usefulness arises from conceptual confusion that in turn may be traced back to the contemporary nihilism transmitted on many an academic campus and many an analytical couch."
— **Viktor E. Frankl, Man's Search for Meaning**




15

## Highlights From Physician Fee Schedule Proposed Rule

- 3.3% pay cut
- AMDA Supports

Legislation to fix Medicare Payment

(Strengthening Medicare for Patients and Providers Act HR 2474)

| Code | Total 2024 | 2024 Payment Rate | Total 2023 | 2032 Payment Rate | Percentage Change |
|---|---|---|---|---|---|
| 99304 | 2.39 | $78.27 | 2.38 | $80.64 | -2.94% |
| 99305 | 3.97 | $130.01 | 3.94 | $133.50 | -2.61% |
| 99306 | 5.42 | $177.49 | 5.38 | $182.29 | -2.63% |
| 99307 | 1.2 | $39.30 | 1.17 | $39.64 | -0.87% |
| 99308 | 2.22 | $72.70 | 2.2 | $74.54 | -2.47% |
| 99309 | 3.21 | $105.12 | 3.15 | $106.73 | -2% |
| 99310 | 4.58 | $149.98 | 4.53 | $153.49 | -2.28% |
| 99315 | 2.43 | $79.58 | 2.41 | $81.66 | -2.55% |
| 99316 | 3.9 | $127.72 | 3.88 | $131.46 | -2.85% |
| G0317 | 0.9 | $29.47 | 0.9 | $30.49 | -3.35% |

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## Telehealth

- All physician mandated visits MUST BE DONE IN-PERSON
- Medically Necessary Visits Can Be Done Via Telehealth with no restrictions (until end of 2023 at least)
- Nursing homes can bill per encounter as an originating site using code Q3014
- Home Visits Can Be Done Via Telehealth
- Advance Care Plan Can be Done Via Telehealth (including Audio Only)
- Proposed rule extends these rules until Dec 31, 2024

17

## MACRA/MIPS

- MIPS Penalties for non or poor performance are back!
- Proposal for 4 new Measure Value Pathways (MVPs)
- Establishing the Medicare Clinical Quality Measures (CQMs) for Accountable Care Organizations (ACOs) participating in the Shared Savings Program (Medicare CQMs) as a new collection type for Shared Savings Program ACOs under the APP.
- Requiring all MIPS-eligible clinicians, Qualifying APM participants (QPs), and Partial QPs participating in a Shared Savings Program ACO (regardless of track) to report the measures and requirements under the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM Entity level.

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## Looking Ahead

- Public Health Emergency Expired May 11, 20
  - Expiration of 3-day stay waver
  - Expiration of waiver around CNA training
  - Payment for COVID-19 testing and treatments
- Administration Implementation of Nursing Home Reform
  - Proposed rule on Disclosure of Nursing Home Ownership
  - Staffing study leading to minimum staffing mandates (expected soon)
  - Antipsychotic use and inappropriate diagnosis of schizophrenia
- Moving Forward Coalition
- More permanent flexibilities around telehealth (already extended until Dec. 2023)
- Medicare fee schedule pay and Quality Payment Program (MACRA) reform
- Experience with new coding guidelines

paltc 23 19

19


20

## FINDING YOUR VALUE IN EVOLVING PAYMENT MODELS

VIRTUAL FORUM NOVEMBER 17 10AM-3PM ET

**Topics Covered**

- Defining Value-Based Reimbursement Models
- Evolution and Trends of "Traditional" CPT Coding
- Impact of Diagnosis Coding/Documentation on PDPM and Value-Based Models – ICD-10/HCC Scorin
- Value-Based Medicine Reimbursement Perspective - The Ground View
- Ask the Experts: Where are Your Opportunities in Value-Based Reimbursement

**REGISTER NOW: paltc.org**

21

THE FOUNDATION FOR POST-ACUTE AND LONG-TERM CARE MEDICINE

## Donations to the National Foundation for PALTC Medicine Support

- Research – (Recent Awards $75k)
- Clinical Resources – (More of a Good Thing & Drive to Deprescribe)
- Education
- Workforce Development (Futures Program)
- Unrestricted donations support any or all of the above as needs are identified

TOGETHER WE ARE MAKING A BETTER PALC!

22

22


Date
Time

### 2024 Excellence Awards – Nominations Due 9/30

- William Dodd Founder's Award for Distinguished Service
- James Pattee Award for Excellence in Education
- Medical Director of the Year
- Clinician of the Year

### Futures Program 2024 Campaign

$1,500 donation supports 1 scholarship

$3,000 donation supports 2 scholarships

All donations gratefully received

23

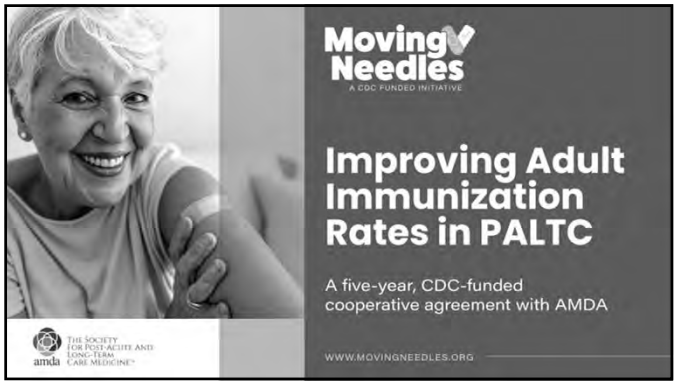
**"Stars & Stripes Campaign Raffle"**
**Benefitting the PALTC Foundation**

-$100 per ticket / Only 200 tickets to be sold
-$2,400 Value for Winning Ticket
-Share with your membership for Fun & to support the 2024 Futures Program!

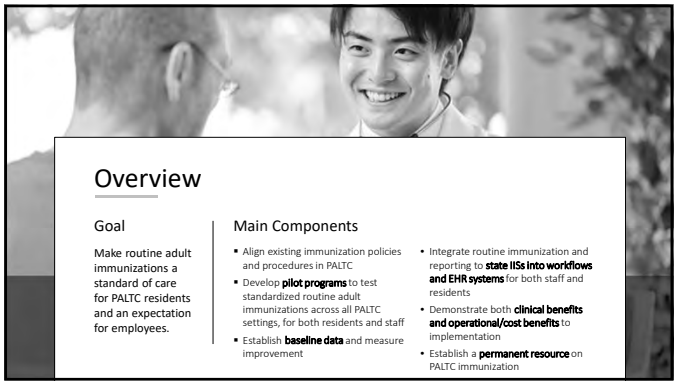
**Buy Your Ticket By 9/30 to Win!**

**paltcfoundation.org**


24


Moving Needles
A CDC FUNDED INITIATIVE
Improving Adult Immunization Rates in PALTC
A five-year, CDC-funded cooperative agreement with AMDA
WWW.MOVINGNEEDLES.ORG
amda
THE SOCIETY FOR POST-ACUTE AND LONG-TERM CARE MEDICINE

25


Overview
Goal
Make routine adult immunizations a standard of care for PALTC residents and an expectation for employees.
Main Components
Align existing immunization policies and procedures in PALTC
Develop pilot programs to test standardized routine adult immunizations across all PALTC settings, for both residents and staff
Establish baseline data and measure improvement
Integrate routine immunization and reporting to state IISs into workflows and EHR systems for both staff and residents
Demonstrate both clinical benefits and operational/cost benefits to implementation
Establish a permanent resource on PALTC immunization

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SAN ANTONIO • TEXAS
paltc 24
ANNUAL CONFERENCE
NEW DATES:
SATURDAY, MARCH 9 -
TUESDAY, MARCH 12, 2024
Registration opens November 1, 2023
paltc.org/annual-conference

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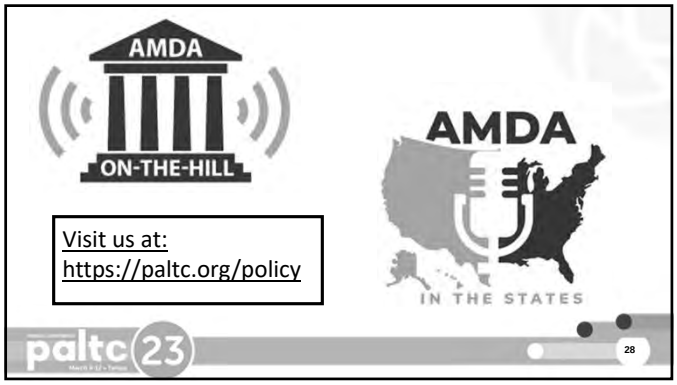



28

"From this one may see that there is no reason to pity old people. Instead, young people should envy them. It is true that the old have no opportunities, no possibilities in the future. But they have more than that. Instead of possibilities in the future, they have realities in the past - the potentialities they have actualized, the meanings they have fulfilled, the values they have realized - and nothing and nobody can ever remove these assets from the past."

— **Viktor E. Frankl, Man's Search for Meaning**

29


# Regulatory Update

Kimberly Smoak
Deputy Secretary/State Survey Agency Director
Division of Health Care Policy and Oversight

1

## Objectives

- Identify the topmost commonly cited deficiencies and ways to improve to avoid these areas of noncompliance. And how the medical director can assist with oversight to improve in these areas of noncompliance.
- Discuss the proposed federal NH staffing requirements and provide an overview of the Florida minimum standards.

2

## Objectives, cont.

- Provide brief overview of Senate Bill 558- Qualification Medication Aides.
- Discuss key revisions to Quality Assurance and Performance Improvement (QAPI).
- Summarize the 2022 to 2023 immediate jeopardy findings for nursing homes and discuss how the role of the medical director, nurse leaders and pharmacist can help the nursing homes identify areas for improvement to avoid immediate jeopardy findings.

3

## Highlights of Top 10 Florida Nursing Home Federal Tags

- The 10 top tags are the same for 2021 and 2022, but different ranking
- Top ranking tag for 2022 is the same as 2021
- Three of the top 10 tags relate to Quality of Care
- Two of the top 10 tags relate to Quality of Life
- F880 citations have decreased in 2021 and 2022

4

## Top Ten Florida Nursing Home Federal Tags

January 1, 2022
December 31, 2022

| Rank | Tag | Tag Title |
|---|---|---|
| 1 | F812 | Food Safety Requirements |
| 2 | F761 | Label/Store Drugs & Biologicals |
| 3 | F684 | Quality of Care |
| 4 | F689 | Free of Accident Hazards/Supervision/Devices |
| 5 | F695 | Respiratory/Tracheostomy Care and Suctioning |
| 6 | F584 | Safe/Clean/Comfortable/Homelike Environment |
| 7 | F656 | Develop/Implement Comprehensive Care Plan |
| 8 | F677 | ADL Care Provided for Dependent Residents |
| 9 | F842 | Resident Records - Identifiable Information |
| 10 | F880 | Infection Prevention & Control |

5

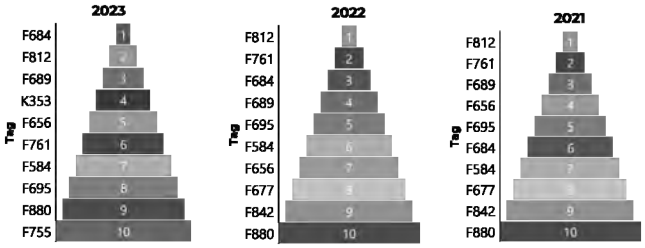
## Top Ten Florida Nursing Home Federal Tags

January 1, 2023
September 15, 2023

| Rank | Tag | Tag Title |
|---|---|---|
| 1 | F684 | Quality of Care |
| 2 | F812 | Food Safety Requirements |
| 3 | F689 | Free of Accident Hazards/Supervision/Devices |
| 4 | K0353 | Sprinkler System - Maintenance and Testing |
| 5 | F656 | Develop/Implement Comprehensive Care Plan |
| 6 | F761 | Label/Store Drugs & Biologicals |
| 7 | F584 | Safe/Clean/Comfortable/Homelike Environment |
| 8 | F695 | Respiratory/Tracheostomy Care and Suctioning |
| 9 | F880 | Infection Prevention & Control |
| 10 | F755 | Pharmacy Services/Procedures/Pharmacist/ Records |

6

## Top 10 FL Federal NH Tag Ranking Comparison

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# 2023 Legislative Update

8

## Senate Bill 558 - Qualified Medication Aides

- Authorizes nursing homes (NH) to allow Registered Nurses (RN) to delegate some medication tasks to certified nursing assistants (CNA).
- The Department of Health (board), in consultation with AHCA shall establish by rule standards and procedures that a CNA must follow when administering medication to a resident of a nursing home. (This must be done before implementation.)

9

## Training Requirements

- CNAs must take a six-hour medication course with an additional 34 hours of training approved by the Board of Nursing.
- *(Six hours is the initial delegation course already in FS 464.2035 which was passed in 2021.)*

10

## Medications QMAs Allowed To Administer:

- Oral
- Transdermal
- Ophthalmic
- Otic
- Inhaled
- Topical

11

## The 34 Hour Training Will Include:

- Medication administration and associated tasks, including, but not limited to, blood glucose level checks, dialing oxygen flow meters to prescribed settings, and assisting with continuous positive airway pressure devices.

12

## Competency

- QMAs must demonstrate clinical competency by successfully completing a supervised clinical practice in medication administration and associated tasks conducted in the facility.

13

## Criteria for Staff

- CNAs must hold a clear, active certification from the Florida Department of Health for at least a year prior to delegation.
- QMAs must complete annual validation and two hours of inservice in medication administration and medication error prevention.

14

## SB 558 - Qualified Medication Aides

- Medication administration can be delegated to a QMA by a **Registered Nurse**.
- Medication administration is under the direct supervision of a **Licensed Nurse**.
- Medication administration must be included in the performance improvement activities.

15

## SB 558 - Qualified Medication Aides

- CNAs performing the duties of QMA may not be included in computing hours for CNAs or licensed nurses.

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# Nursing Home Staffing

# Federal and State

17

## Proposed Medicare and Medicaid Programs: Minimum Staffing Standards (CMS-3442-P)

- On September 1, 2023, the Centers for Medicare & Medicaid Services (CMS) issued the Minimum Staffing Standards for Long-Term Care.
- The rule also proposes to enforce the new standards solely through the survey and enforcement system.
- Comments are due to CMS no later than November 6, 2023.

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## Staffing Standards

- CMS **proposes** staffing ratios for two categories of nurses:
  - RN's 0.55 hours per resident per day (HPRD)
  - Nurse aides 2.45 HPRD
- Requirement to have a RN onsite 24 hours a day, seven days a week
- Enhanced facility assessment requirements.
- CMS does not propose a staffing standard for licensed practical nurses (LPN's)

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## Enhanced Facility Assessment Requirements

- Clarify nursing homes must use evidence-based methods when care planning for their residents.
- Require facilities use of the facility assessment to assess the specific needs of each resident in the facility and to adjust as necessary based on any significant changes in resident population.
- Input from facility staff, including, leadership, management, direct care staff, other staff.
- Develop a staffing plan to maximize recruitment and retention of staff.

20

## Regulatory Flexibility

- CMS proposes to allow for a hardship exemption in limited circumstances.
  - workforce unavailability based on location;
  - good faith efforts to hire and retain staff; and
  - financial commitment to staffing by documenting the total annual amount spent on direct care staff.
- Prior to being considered, the NH must have a survey to assess the health and safety of residents.

21

## Regulatory Flexibility, cont.

- Facilities would not be eligible for an exemption if:
  - Failed to submit their data to Payroll based journal system;
  - Identified as a specific focus facility (SFF);
  - Identified within the preceding 12 months as having widespread insufficient staffing with resultant resident actual harm or a pattern of insufficient staffing resultant resident actual harm or have been cited at the IJ level of severity with respect to insufficient staffing.

22

## Staggering Implementation

- CMS proposes that implantation of the final requirements will occur in three phases over a 3-year period for all **non-rural** facilities.
  - Phase 1 facilities in urban areas to comply with facility assessment requirements 60-days after publication date of final rule;
  - Phase 2 facilities in urban areas to comply with the requirement for RN onsite 24/7 days a week two years after the publication of the final rule; and
  - Phase 3 facilities in urban areas to comply with minimum staffing requirements of 0.55 and 2.45 HPRD, three years after the publication of the final rule.

23

## Staggering Implementation, cont.

- CMS proposes that implantation of the final requirements will occur in three phases over a 3-year period for **rural** facilities.
  - Phase 1 facilities to comply with facility assessment requirements 60-days after publication date of final rule;
  - Phase 2 facilities in urban areas to comply with the requirement for RN onsite 24/7 days a week three years after the publication of the final rule; and
  - Phase 3 facilities in urban areas to comply with minimum staffing requirements of 0.55 and 2.45 HPRD, five years after the publication of the final rule.

24

## State Staffing Requirements- Current Law

- In 2022 HB 1239 revised Florida state staffing requirements.
- Definition of Direct Care Staff
  - Persons who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being, including, but not limited to, disciplines and professions that must be reported in accordance with 42 C.F.R. s. 483.70(q) in the categories of direct care services of nursing, dietary, therapeutic, and mental health.

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## Direct Care Staff

- **Does not include** a person whose primary duty is maintaining the physical environment of the facility, including, but not limited to, food preparation, laundry, and housekeeping.
- **Does not include** time spent on nursing administration, activities program administration, staff development, staffing coordination, and the administrative portion of the MDS and care plan coordination for Medicaid.
- Determined by each facility based on the facility assessment and the individual needs of a resident based on the resident's care plan.

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## Minimum Requirements

- Weekly (Sunday through Saturday) average of 3.6 hours of care by direct care staff per resident per day
- **2.0** hours of direct care by a CNA per resident per day
- May not staff below one CNA per 20 residents
- 1.0 hour of direct care by a licensed nurse per resident per day
- May not staff below one licensed nurse per 40 residents

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## Failure To Comply

- Facility that has failed to comply with state minimum-staffing requirements for 48 consecutive hours is prohibited from accepting new admissions until the facility has achieved the minimum-staffing requirements for 6 consecutive days.

28

## CMS QSO-23-21-NH (September 20, 2023)

- CMS makes several changes to *Care Compare;*
  - revises staffing domain,
  - replaces some quality measures, and
  - updates CMS forms.
- Revisions to staffing methodology so that providers who "*fail to submit staffing data or submit erroneous data receive the lowest score possible for corresponding staffing turnover measures*"

29

## Adjusting Staffing and Quality Measures

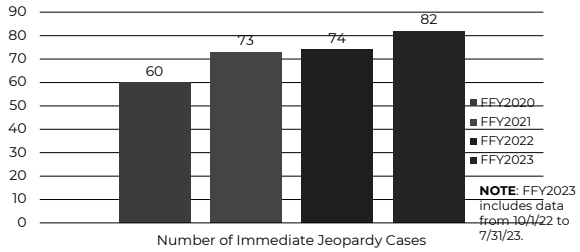
- October 2023, items in the MDS (Section G) will be eliminated and replaced by new (Section GG) items.
- Beginning April 2024, CMS will freeze the staffing measures for three months
- In July 2024 CMS will post nursing home staffing measures based on the Patient Driven Payment Model (PDPM)

30

# Immediate Jeopardy Discussions


31

## Number of Yearly Nursing Home Immediate Jeopardy Cases, FFY2020 to Present

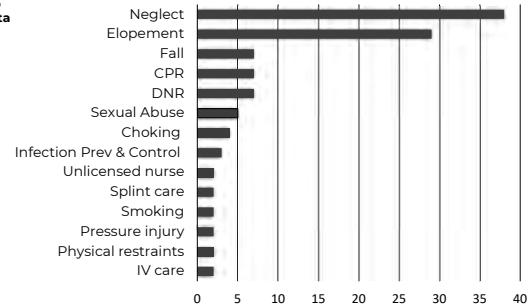



**NOTE**: FFY2023 includes data from 10/1/22 to 7/31/23.

32

## 2023 Top Categories for IJ Noncompliance

**10/1/2022 to 7/31/2023 Data**

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## Florida Nursing Home IJ Data Trends
October 1, 2022 – July 31, 2023

- Majority of Immediate Jeopardy cases were removed, but *ongoing* IJ is on the rise.
- Complaint surveys generated the most Immediate Jeopardies.
- Many IJs came from self-reported incidents.
- Majority of Immediate Jeopardy cases resulted in *likely* serious harm, followed by actual serious harm and death, with *actual harm on the rise.*

34

## Quality Assurance and Performance Improvement (QAPI)

35

## Key Revisions to Quality Assurance and Performance Improvement (QAPI)

- New guidance in F865 for the QAPI plan and program
- Requirements in F866 have been moved to F867
- New requirements for the QAPI program, feedback, data collection, analysis and monitoring, and improvement activities
- Expansion of required Quality Assessment and Assurance (QAA) required committee members
  - Infection Preventionist
- New QAPI training requirements

36

## Survey Process for QAPI & QAA Review

- Before conducting this task, surveyors will ask for and review the QAPI Plan and policies and procedures
- This task has 2 parts
  - Review of the QAPI Policies & Procedures
  - Interview with the QAPI contact person, as well as other QAA Committee members

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## Survey Process for QAPI & QAA Review, cont.

- Prior to interviewing the facility staff about the QAA program
  - Review the Facility Rates for MDS Indicators, prior survey history, FRIs, and complaints, present concerns and repeat deficiencies
- For each area of non-compliance identified by the survey team, prior to initiating the QAPI/QAA Review, interview the QAA contact person and review evidence to determine if the QAA committee is aware of the issue; and if so, took corrective action; monitored the corrective action; analyzed the corrective action results; revised their corrective actions based on result; and tracked performance

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## Interview with QAPI Contact/QAA Committee Members

- Surveyors will ask about:
  - QAA Committee knowledge of a deviation from expected performance or a negative trend.
  - Mechanism for staff to report quality concerns to the QAA Committee.
  - Facility decision-making on which issues to work on.
  - Facility awareness of implementation, effectiveness and improvement of corrective actions.

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## QAPI & QAA Review Reminders

- Disclosure of documents generated by the QAA committee may be requested by surveyors only to determine compliance with QAPI regulations.
- Surveyors **must not use documentation** provided by the facility during the QAPI/QAA review **to identify additional concerns not previously identified by the survey team** during the current survey

40

## QAPI/QAA Surveyor Review

- Request and review the documentation for the QAPI program and QAA Committee activities to determine:
  - Actions aimed at improving performance, establishing priorities for improvement activities.
  - Tracking and analyzing adverse events and medical errors and implementing preventative actions.
  - Facility's full range of facility care, and services is reflected in the collection, use and monitoring of data for QAPI program.
  - Use of feedback from residents, resident representative and facility staff.

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## QAPI/QAA Surveyor Review, cont.

- QAA Committee develops and implement plans of action to correct quality deficiencies or potential problems.
- How facility measures success and tracks performance after implementing action plans to improve performance?
- Facility conducts at least **1 performance improvement project (PIP) annually** that focuses on f high-risk or problem-prone areas.
- QAA committee regularly reviews and analyzes data collected under the QAPI program, including **drug regimen reviews** and acts to make improvements.

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## Committee

- Surveyor will review of QAA records, determine:
  - **The QAA committee includes the required members**
    - Director of Nursing Services
    - **Medical Director or his/her designee**
    - Nursing home administrator, owner, board member, or other individual in a leadership role
    - Infection Preventionist (IP)
    - Two other staff members
  - The committee meets as frequently as needed, but **not less than quarterly.**
  - The QAA committee report its activities to the facility's **governing body.**
  - The **IP participates on the QAA committee** and report on the Infection Prevention and Control Program (IPCP) on a regular basis.

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## QAPI Program, Plan, Disclosure, and Governance and Leadership

- Surveyor will consider all of the information obtained through interviews and record review, and determine:
  - Has the facility developed, implemented, and maintained an effective QAPI program which:
    - Addresses the full range of care and services, including unique care and services, the facility provides;
    - Is comprehensive, data-driven and ongoing; and
    - Focuses on indicators of outcomes of care, quality of life, and resident choice.

44

## QAPI Program, Plan, Disclosure, and Governance and Leadership, cont.

- The facility must provide its QAPI plan to the surveyors during recertification survey or upon request.
- The facility maintains documentation and is able to present evidence of its ongoing QAPI program implementation and activities to demonstrate compliance with requirements.
- The facility's governing body and/or executive leadership maintains oversight of the QAPI program and activities per §483.75(f)(1)-6)

45

## CMS Survey & Certification's Quality, Certification and Oversight Reports (QCOR)

- QCOR is available for providers – https://qcor.cms.gov
  - This website had nursing home reports, including citation frequency
  - QCOR can be a useful QAPI tool

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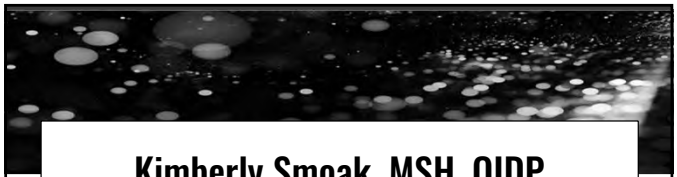

## Kimberly Smoak, MSH, QIDP

Deputy Secretary
State Survey Agency Director
Agency for Health Care Administration
Phone # 850-559-8273 or 850-412-4516
Kimberly.Smoak@ahca.myflorida.com

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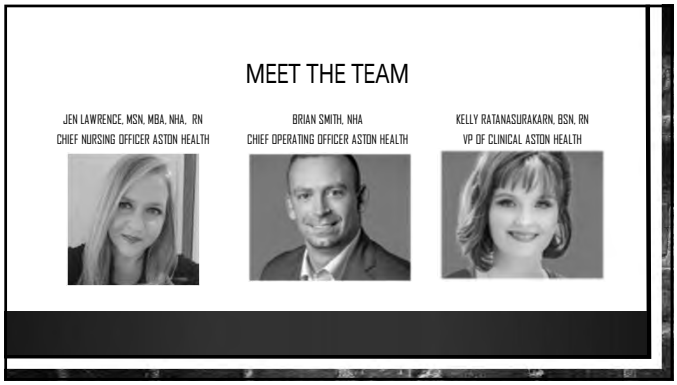
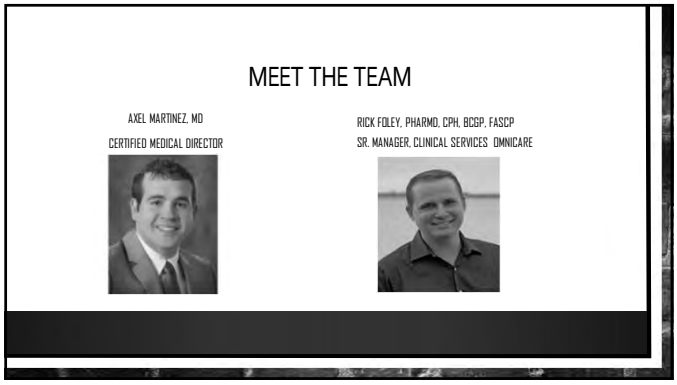
QA&A AND QAPI: DRIVING THE CALL TO ACTION

1


MEET THE TEAM
JEN LAWRENCE, MSN, MBA, NHA, RN
CHIEF NURSING OFFICER ASTON HEALTH
BRIAN SMITH, NHA
CHIEF OPERATING OFFICER ASTON HEALTH
KELLY RATANASURAKARN, BSN, RN
VP OF CLINICAL ASTON HEALTH

2


MEET THE TEAM
AXEL MARTINEZ, MD
CERTIFIED MEDICAL DIRECTOR
RICK FOLEY, PHARMD, CPH, BCGP, FASCP
SR. MANAGER, CLINICAL SERVICES OMNICARE

3

## ROADMAP

- *"IF YOU DON'T KNOW WHERE YOU ARE GOING, YOU'LL END UP SOMEPLACE ELSE"*

  *(YOGI BERRA)*

4

## OBJECTIVES

- DESCRIBE THE QA COMMITTEE
- DEFINE THE RELATIONSHIP BETWEEN QA AND QAPI
- RECOGNIZE HOW AN AGENDA DEFINES THE MEETING PROCESS
- IDENTIFY COMPONENTS OF A SUCCESSFUL QAPI AGENDA
- OUTLINE CATEGORIES OF A PIP AND REPORTING ON PIPS
- DESIGN A QAPI MEETING TOOL

5

## CALL TO ACTION – QA/QAPI MEETING

- THE CALL TO ACTION INVOLVES A TWO PART PROCESS
- REGULATORY GUIDANCE DEFINES QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT AS A MERGER OF TWO COMPLEMENTARY APPROACHES TO QUALITY MANAGEMENT.
- QUALITY MANAGEMENT BEGINS WITH THE QA MEETING AND INVOLVES THE QAPI PROCESS

6

# ACCOUNTABILITY

NAVIGATING YOUR QA/QAPI MEETING

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## QA MEETING SCENARIO #1 - ACCOUNTABILITY

- WELCOME TO VALLEY NURSING AND REHAB FACILITY. IT IS THE 3RD THURSDAY OF THE MONTH AND IT IS TIME FOR THEIR MONTHLY QA/QAPI MEETING. THE DON, ADMINISTRATOR, INFECTION PREVENTIONIST AND THE MEDICAL DIRECTOR ARE ALL PRESENT. IT IS THE BEGINNING OF THE MEETING AND THE MEDICAL DIRECTOR JUST ANNOUNCED THAT HE DOESN'T HAVE MUCH TIME.

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## WHO MAKES UP THE QA COMMITTEE


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## QUALITY ASSURANCE

- QA COMMITTEE WORKS TO ENSURE THE FACILITY'S COMPLIANCE WITH STATE AND FEDERAL REGULATIONS
- 3 STEP PROCESS:
  - EXAMINE WHY THE FACILITY FAILED TO MEET A CERTAIN STANDARD
  - DEVELOP A FIX FOR THE PROBLEM
  - MONITOR THE FIX


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## WHAT IS PERFORMANCE IMPROVEMENT

- PERFORMANCE IMPROVEMENT = ACTION ORIENTED = PROACTIVE APPROACH TO QUALITY
- CONTINUOUS STUDY OF PROCESSES = OPERATIONAL SYSTEMS = RESULTS YOU EXPECT
- GROUP EFFORT IDENTIFYING ROOT CAUSE AND WORKING TOWARDS A SOLUTION


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## KEY ELEMENTS

### MEETING REQUIREMENTS

- MEETINGS ARE REQUIRED AT LEAST QUARTERLY
- DIRECTOR OF NURSING, ADMINISTRATOR, MEDICAL DIRECTOR, INFECTION PREVENTIONIST AND 3 OTHER TEAM MEMBERS
- SHOULD OCCUR IN PERSON
- AGENDA OF MEETING
- MINUTES/RECORD KEEPING/REPORTS

### AGENDA

- DATE/TIME = CONSISTENT
- ROLL CALL/ATTENDANCE = SIGNATURE OF PARTICIPATION
- INTRODUCTION OF GUESTS AND NEW TEAM MEMBERS
- GUEST PRESENTATIONS (PRODUCT REVIEWS, NEW SERVICES OR PROVIDERS, ETC.)
- SUMMARY OVERVIEW QAPI MEETING - DISCUSSION: NEW POLICIES/PROTOCOLS/CARE PRACTICES/TRAININGS/EDUCATIONAL SEMINARS, ETC.)

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## KEY ELEMENTS

**RISK MANAGEMENT**

- EVENT REPORTS
- TRENDS
- MEDICATION ERRORS
- REPORTABLES
  - ABUSE/NEGLECT/EXPLOITATION/MISAPPROPRIATION/INJURY OF UNKNOWN SOURCE – ANALYSIS/SUMMARY

**BENCHMARKS OF CARE**

- PRESSURE ULCERS
- FALLS
- AVOIDABLE WEIGHT LOSS
- RETURN TO HOSPITAL
- RESTRAINTS
- ELOPEMENTS
- AMA DISCHARGE
- BAKER ACT
- PSYCHOTROPIC MEDICATION

**INFECTION CONTROL**

- INFECTIONS
  - IN HOUSE ACQUIRED RATE/COMMUNITY ACQUIRED RATE
- ANTIBIOTIC STEWARDSHIP
- VACCINATIONS

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## KEY ELEMENTS

**RESIDENT/FAMILY COUNCIL**

- RESIDENT COUNCIL MEETINGS
- FAMILY COUNCIL MEETINGS
- FOOD COMMITTEE
- CALL LIGHT AUDITS
- GUARDIAN ANGEL ROUNDS
- MEET & GREET
- EVENTS/ACTIVITIES

**GRIEVANCES/COMPLAINTS**

- GRIEVANCES
- UNRESOLVED GRIEVANCES/ISSUES
- TRENDS
- COMPLIANCE CALLS
- OMBUDSMAN VISITS
- REVIEWS/CUSTOMER SATISFACTION SCORES

**STAFF RETENTION**

- OPEN POSITIONS/NEW HIRES
- EMPLOYEE TURNOVER
- WORK RELATED INJURIES – TRENDS/LIGHT DUTY/OSHA
- EMPLOYEE OF MONTH/APPRECIATION
- EMPLOYEE RETENTION PLANS

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## QA & QAPI RELATIONSHIP


- BLENDING OF THE OLD AND THE NEW
- MOVE FOCUS OF MEETINGS FROM QUALITY ASSURANCE TO PERFORMANCE IMPROVEMENT
- PROVIDE STRUCTURE TO PLAN AN EFFICIENT AND EFFECTIVE MEETING
- HELP MEET QAPI REGULATION

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QA + PI = QAPI

RE-HOSPITALIZATION

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QA MEETING SCENARIO #2 – RE-HOSPITALIZATION

- WELCOME TO VALLEY NURSING AND REHAB FACILITY. IT IS THE 3RD THURSDAY OF THE MONTH AND IT IS TIME FOR THEIR MONTHLY QA/QAPI MEETING. THE DON, ADMINISTRATOR, INFECTION PREVENTIONIST AND THE MEDICAL DIRECTOR ARE ALL PRESENT. EVERYONE IS ON TIME AND THE MEETING BEGINS WITH ROLL CALL, ATTENDANCE, REVIEW OF LAST MONTH'S MINUTES AND RISK MANAGEMENT REPORT. THE DON BEGINS BY TALKING ABOUT BENCHMARKS AND RETURN TO HOSPITAL.

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RE-HOSPITALIZATION - QAPI FOCUS

- HIGH REHOSPITALIZATION RATE
  - YOU KNOW IT'S THERE
  - YOU KNOW IT'S A PROBLEM
- ADDRESSING THE PROBLEM REQUIRES FOCUS
- STRUCTURE AND A SYSTEMS APPROACH THAT IS DATA-DRIVEN


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## DRILL DOWN

- DO YOU KNOW YOUR RE-HOSPITALIZATION RATE
- WHAT ARE THE MOST COMMON DIAGNOSES FOR RE-HOSPITALIZATION
- ARE THERE ANY PATTERNS SUCH AS DAY OF THE WEEK, TIME OF DAY, ETC.
- WHAT IS THE TREND IN CUMULATIVE RE-HOSPITALIZATION RATE? IS IT BETWEEN 10-20 DAYS OF RESIDENT'S STAY?

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## ROOT CAUSE ANALYSIS

- ASSEMBLE THE TEAM: ADMINISTRATOR, DON, UNIT MANAGERS, MEDICAL DIRECTOR, THERAPY, PHARMACY, PCP, NP, DISCHARGE PLANNERS, ETC.
- ANALYZE HIGH REHOSPITALIZATION RATE WITHIN 30 DAYS OF ADMISSION: WHY?
- ASSESS INTERNAL DISCHARGE PLANNING PROCESS AND SYSTEMS TO IDENTIFY AND ACT ON EARLY CHANGE IN CONDITION – HOW INVOLVED ARE PCPS? – WHAT IS THE RELATIONSHIP WITH ACUTE CARE FACILITY? – TARGET PROBLEM DIAGNOSES TO START WITH
- ASSESS STAFFING (RNS, LPNS) – STAFF COMPETENCIES
- ASSESSMENT SKILLS: RESPIRATORY/CARDIAC, FUNCTIONAL
- TECHNICAL SKILLS: IV/OTHER PARENTERAL ADMINISTRATION
- CNA SKILLS: VITAL SIGNS, WEIGHTS, INTAKE/OUTPUT
- OTHER RESOURCES: PHARMACY, RADIOLOGY, ETC.
- PHYSICIANS, PHYSICIAN EXTENDERS, NPS: AVAILABILITY AND RELIABILITY RESPONSE TO STAFF
- FAMILIES • UNDERSTANDING OF DISEASE PROCESSES • COMMUNICATION ABOUT WHEN TO HOSPITALIZE

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## POSSIBLE CONTRIBUTORY FACTORS

- SYSTEMIC ISSUES: – NEW ADMISSION PROTOCOLS DROPPED OFF AFTER FIRST WEEK
- CONTRACTED SERVICES • STAT X-RAYS, STAT MED ORDERS NOT AVAILABLE
- INTERNAL STAFFING • LACK OF RN COVERAGE NIGHTS/WEEKEND

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## PROCESS TOOLS, RESOURCES, EDUCATION

### PROCESS TOOLS & RESOURCES

- INTERNAL TOOLS: ADMISSION DATA, SHIFT COMMUNICATION/CHANGE OF CONDITION FORMS
- EARLY WARNING TOOL, "STOP AND WATCH" SBAR COMMUNICATION TOOL AND PROGRESS NOTE
- QUALITY IMPROVEMENT TOOL FOR REVIEW OF ACUTE CARE TRANSFERS
- ADVANCE CARE PLANNING TOOLS

### EDUCATION

- STAFF EDUCATION – ELEMENTS FOR ALL STAFF LEVELS COMPETENCIES UPDATED AND REVIEWED, CLINICAL SKILL SETS "
- BRING CONSULTANTS AND MEDICAL SERVICES ON BOARD WITH THE QUALITY FOCUS
- RESIDENT AND FAMILY EDUCATION – ENSURE RESIDENT AND FAMILIES HAVE OPPORTUNITY TO CONTRIBUTE
- MATERIALS SPECIFIC TO RESIDENT AND FAMILIES
- END OF LIFE , ADVANCE DIRECTIVES ETC., DISEASE CONDITIONS
- COMMUNITY COLLABORATION

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## PLAN, DO, STUDY, ACT


- PLAN - IDENTIFY AND TARGET ROOT CAUSES OF PROBLEMS ▪ DEVELOP ACTION PLAN
- DO - PILOT THE PLANNED SOLUTION ▪ IMPLEMENT ACTIVITY
- STUDY - MEASURE ▪ AUDIT ▪ EVALUATE OUTCOMES
- ACT - DETERMINE IF IMPROVEMENTS HAVE BEEN MET ▪ REFINE AND EXPAND SOLUTIONS ▪ MONITOR PROGRESS

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## PERFORMANCE IMPROVEMENT PROJECTS

- REVIEW PIPS FOR: PROBLEM/ISSUE, INTERVENTIONS, PROGRESS EVALUATION, TEAM, GOAL, MEASURE DATE.
- FROM TEAM REVIEW OF CURRENT MEETING IDENTIFY NEW AREAS OF CONCERN FOR PIP IMPLEMENTATION
- PIPS CAN BE IDENTIFIED AT ANY TIME AND CAN BE A SINGLE OCCURRENCE OR AN IDENTIFIED TREND
- PIPS REQUIRE: PLAN/DO/STUDY/ACT - ROOT CAUSE ANALYSIS OF THE CONCERN

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## QA/QAPI - PIT STOPS

ADDITIONAL AGENDA TOPICS

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## QA/QAPI ADDITIONAL TOPICS

### ANNUAL REVIEWS

- ANNUAL REVIEWS AS NECESSARY: EDUCATION CALENDAR/TRAININGS, FACILITY POLICIES AND PROCEDURES, PHARMACY POLICY AND PROCEDURES, FACILITY ASSESSMENT, COUNTY EMERGENCY MANAGEMENT PLANS, SECURITY PLAN, EMERGENCY PREPAREDNESS PLAN

### REGULATORY VISITS

- LAST ANNUAL SURVEY – RESULTS – CITATIONS (STATE/FEDERAL/LIFE SAFETY) – OPEN WINDOW, PREPARATION (MOCK SURVEY)
- COMPLAINT SURVEY ACTIVITY – RESULTS – CITATIONS (STATE/FEDERAL/LIFE SAFETY)
- DCF VISIT – ACTIVITY/OUTCOME
- OMBUDSMAN – ACTIVITY/OUTCOME
- PHARMACY SURVEY – ACTIVITY/OUTCOME
- DOH VISIT – ACTIVITY/OUTCOME
- FIRE MARSHALL VISIT – ACTIVITY/OUTCOME
- TJC VISIT – ACTIVITY/OUTCOME

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## QUALITY INDICATOR/QUALITY MEASURE REVIEW

- MOST RECENT 5 STAR RATINGS: OVERALL/HEALTH INSPECTION/QUALITY MEASURES/STAFFING/RN STAFFING
- REVIEW QM THAT TRIGGER GREATER THAN 75 PERCENTILE
- SUMMARY OF CASPER REPORT - ANALYSIS USING CASPER REPORT FOR QUALITY FOCUS

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## THERAPY

- CASELOAD – SUMMARY
- LENGTH OF STAY – MTD/YTD
- RESTORATIVE

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## TEAM REVIEW

- ACTIVITIES
- ADMINISTRATION
- ADMISSIONS/MARKETING
- BUSINESS OFFICE
- FOOD AND NUTRITION SERVICES
- HOUSEKEEPING
- HR/PAYROLL
- LAB/DIAGNOSTICS
- MEDICAL DIRECTOR
- MEDICAL RECORDS
- MDS
- NURSING
- PHARMACY
- PLANT OPS
- SOCIAL SERVICES
- THERAPY

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## AD HOC QA

- AD HOC QA MEETINGS ARE USED TO ADDRESS UNFORESEEN PROBLEMS, CHALLENGES, OR CHANGES THAT ARISE IN THE FACILITY. MAY BE SCHEDULED WHEN IT'S ESSENTIAL FOR EMPLOYEES AND OTHER STAKEHOLDERS TO MAKE URGENT DECISIONS REGARDING EMERGENCIES THAT STRONGLY IMPACT RESIDENT CARE.
- AN IMPROMPTU MEETING MAY NOT HAVE A FORMALIZED AGENDA BUT REQUIRES A SPECIFIC FORMAT: ATTENDEES/IDENTIFICATION OF PROBLEM/GOAL/ACTION ITEMS/FOLLOW UP/MEETING TOOLS/TIME MANAGEMENT.
- AD HOC MEETINGS ARE NOT REQUIRED TO BE IN PERSON: MEDICAL DIRECTOR MAY ATTEND VIA ZOOM CONFERENCE, TELEPHONE, ETC.

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## TO PIP OR NOT TO PIP


- PROCESS OF TRANSLATING DATA INTO ACTION
- PRIORITIZE OPPORTUNITIES FOR MORE INTENSIVE IMPROVEMENT WORK
- CONSIDER HIGH RISK, HIGH FREQUENCY AND/OR PROBLEM PRONE
- ALL IDENTIFIED PROBLEMS NEED ATTENTION BUT NOT ALL REQUIRE PIPS
- ESTABLISH A CHARTER PIP TEAM – RESPONSIBLE FOR REVIEWING AND EXPLORING THE PROBLEM

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## OUTCOME/SUSTAINABILITY

- OUTCOME: HAVE THE REVISIONS OR CHANGES IN THE PROCESS MADE A POSITIVE IMPACT ON RESIDENT OUTCOMES? HAVE THE RESIDENTS' QUALITY OF LIFE IMPROVED?
- SUSTAINABILITY: PERFORMANCE IMPROVEMENT IS AN ONGOING CYCLE OF MEASURING RESIDENT OUTCOMES. MONITORING RESULTS IS ESSENTIAL. PARTICIPANTS SHOULD CONTINUALLY LOOK FOR NEW WAYS OF IMPROVING THE PROCESS.
- EDUCATION/TRAINING: ONGOING EDUCATION WITH TEAM INCLUDING RESIDENTS/FAMILIES; STAFF COMPETENCY

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## DESTINATION

- WHAT HAVE WE TALKED ABOUT TODAY THAT WILL MAKE THE LIVES OF OUR RESIDENTS AND/OR STAFF BETTER BY THE NEXT TIME WE MEET?
- REVIEW OF QAPI PLAN
- DATE OF LAST REVIEW
- ANY CHANGES NEEDED TO QAPI PLAN? FACILITY ASSESSMENT?
- MEETING TOOL

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## QUESTIONS

THANK YOU FOR YOUR PARTICIPATION! WE WELCOME ANY QUESTIONS OR COMMENTS.

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## RESOURCES/REFERENCES

- CMS QAPI AT A GLANCE HTTPS://CMS.GOV/MEDICARE/PROVIDER-ENROLLMENT-AND-CERTIFICATION/QAPI/DOWNLOADS/QAPIATAGLANCE.PDF
- QAPI HEALTH SERVICES ADVISORY GROUPS HSAG QUALITY IMPROVEMENT ORGANIZATIONS CMS HTTPS://WWW.HSAG.COM/QAPI
- CMS QAPI DESCRIPTION AND BACKGROUND HTTPS://CMS.GOVWWW.CMS.GOV/MEDICARE/PROVIDER-ENROLLMENT-AND-CERTIFICATION/QAPI/QAPIDEFINITION
- U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES GUIDANCE PORTAL QAPI RESOURCES HTTPS://WWW.HHS.GOV/GUIDANCE/DOCUMENT/QAPI-RESOURCES

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# Medicare Billing & Coding Update

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Dr Crecelius has no conflicts of interest or disclosures

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## Learning Objectives

- Identify the best code for individual patients and circumstances
- Compare advantages and disadvantages of medical decision making versus time-based billing
- Discuss the appropriateness of ancillary codes such as advance care planning and annual wellness visit exams
- Review common billing patterns seen in our field

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## Tip for Accurate Coding: Know Your Codes and Reimbursement!


Medicare Physician Fee Schedule Lookup:
https://www.cms.gov/medicare/physician-fee-schedule/search



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## E/M Guideline Changes

- Over several years guidelines for all cognitive E/M families of codes have been revised with the following principles:
  - Decrease administrative burden and audit needs
  - Decrease documentation burden in the medical record not needed for patient care
  - Ensure payment is resource based with no goal of redistributing payment across specialties

**Select the appropriate level of E/M services based on the following:**

The level of the MDM as defined for each service ◄ OR ► The total time for E/M services performed on the date of the encounter.

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## De-Emphasis of History and Physical Examination

- Must be performed and documented as clinically appropriate
- No longer an element in the selection of the level of E&M service codes
- No need to document gratuitous reviews of systems for the purpose of claims unless performed or reviewed as clinically appropriate
- Remain important activities clinically and to support medical necessity of the service

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## Time

- Total time on the date of the encounter, NOT "Typical time"
- The indicated total time must be met or exceeded
- Includes both face-to-face time *with the patient* and/or family/caregiver and non-face-to-face time (must include a face-to-face encounter) on a given date
- Includes time regardless of location
- Since only a single E&M service may be reported per day, total time = cumulative time of all encounters that day
- Do not count time spent on:
  - Travel
  - General teaching not limited to specific patient management
  - Other services that are reported separately

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## Medical Decision Making 2023

| Level of MDM (Based on 2 out of 3 Elements of MDM) | Number and Complexity of Problems Addressed at the Encounter | Amount and/or Complexity of Data to be Reviewed and Analyzed | Risk of Complications and/or Morbidity or Mortality of Patient Management |
|---|---|---|---|
| **Straightforward** | Minimal | Minimal or None | Minimal |
| **Low** | Low | Limited | Low |
| **Moderate** | Moderate | Moderate | Moderate |
| **High** | High | Extensive | High |

- Level of Medical Decision-Making is determined by the highest level in 2 of the three elements
- The details and examples of Medical Decision-Making are described entirely in the 2023 CPT Manual



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## Why learn MDM when I can use time?

| HCPCS Code | Short Description | Total Time in Min. | Medical Decision-Making Level | Price (2023) |
|---|---|---|---|---|
| 99304 | 1st nf care sf/low mdm | 25 | Straightforward or Low | $80.65 |
| 99305 | 1st nf care moderate mdm | 35 | Moderate | $133.52 |
| 99306 | 1st nf care high mdm | 45 | High | $182.31 |
| 99307 | Sbsq nf care sf mdm | 10 | Straightforward | $39.65 |
| 99308 | Sbsq nf care low mdm | 15 | Low | $74.55 |
| 99309 | Sbsq nf care moderate mdm | 30 | Moderate | $106.75 |
| 99310 | Sbsq nf care high mdm | 45 | High | $153.51 |

*NOTE TIME CHANGES 2024: 99306: 50 minutes; 99308 20 minutes



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| ►Elements of Medical Decision Making | | | |
|---|---|---|---|
| **Level of MDM** (Based on 2 out of 3 Elements of MDM) | **Number and Complexity of Problems Addressed at the Encounter** | **Amount and/or Complexity of Data to Be Reviewed and Analyzed** ****Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below.*** | **Risk of Complications and/or Morbidity or Mortality of Patient Management** |
| **Straightforward** | **Minimal**<br>■ **1** self-limited or minor problem | **Minimal or none** | **Minimal risk of morbidity from additional diagnostic testing or treatment** |
| **Low** | **Low**<br>■ **2** or more self-limited or minor problems;<br>**or**<br>■ **1** stable, chronic illness;<br>**or**<br>■ **1** acute, uncomplicated illness or injury;<br>**or**<br>■ **1** stable, acute illness;<br>**or**<br>■ **1** acute, uncomplicated illness or injury requiring hospital inpatient or observation level of care | **Limited**<br>*(Must meet the requirements of at least 1 out of 2 categories)*<br>**Category 1: Tests and documents**<br>■ **Any combination of 2 from the following:**<br>• Review of prior external note(s) from each unique source*;<br>• Review of the result(s) of each unique test*;<br>• Ordering of each unique test*<br>**or**<br>**Category 2: Assessment requiring an independent historian(s)**<br>*(For the categories of independent interpretation of tests and discussion of management or test interpretation, see moderate or high)* | **Low risk of morbidity from additional diagnostic testing or treatment** |

Could be family member, caregiver, CNA or other staff members



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| ►Elements of Medical Decision Making | | | |
|---|---|---|---|
| **Level of MDM** (Based on 2 out of 3 Elements of MDM) | **Number and Complexity of Problems Addressed at the Encounter** | **Amount and/or Complexity of Data to Be Reviewed and Analyzed** ****Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below.*** | **Risk of Complications and/or Morbidity or Mortality of Patient Management** |
| **Moderate** | **Moderate**<br>■ **1** or more chronic illnesses with exacerbation, progression, or side effects of treatment;<br>**or**<br>■ **2** or more stable, chronic illnesses;<br>**or**<br>■ **1** undiagnosed new problem with uncertain prognosis;<br>**or**<br>■ **1** acute illness with systemic symptoms;<br>**or**<br>■ **1** acute, complicated injury | **Moderate**<br>*(Must meet the requirements of at least 1 out of 3 categories)*<br>**Category 1: Tests, documents, or independent historian(s)**<br>■ **Any combination of 3 from the following:**<br>• Review of prior external note(s) from each unique source*;<br>• Review of the result(s) of each unique test*;<br>• Ordering of each unique test*;<br>• Assessment requiring an independent historian(s)<br>**or**<br>**Category 2: Independent interpretation of tests**<br>■ Independent interpretation of a test performed by another physician/other qualified health care professional (not separately reported);<br>**or**<br>**Category 3: Discussion of management or test interpretation**<br>■ Discussion of management or test interpretation with external physician/other qualified health care professional/appropriate source (not separately reported) | **Moderate risk of morbidity from additional diagnostic testing or treatment**<br>Examples only:<br>■ Prescription drug management<br>■ Decision regarding minor surgery with identified patient or procedure risk factors<br>■ Decision regarding elective major surgery without identified patient or procedure risk factors<br>■ Diagnosis or treatment significantly limited by social determinants of health |

What is Prescription Drug Management ?



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## What is Prescription Drug Management?

A) Initiating or increasing a prescription drug that may have significant adverse effects

B) Continuing a prescription medication; documenting the decision-making involved & risk if any

C) Listing medications and writing to be continued

D) A & B

E) A,B & C

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| ►Elements of Medical Decision Making | | | |
|---|---|---|---|
| **Level of MDM** (Based on 2 out of 3 Elements of MDM) | **Number and Complexity of Problems Addressed at the Encounter** | **Amount and/or Complexity of Data to Be Reviewed and Analyzed** ****Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below.*** | **Risk of Complications and/or Morbidity or Mortality of Patient Management** |
| **High** | **High**<br>■ **1** or more chronic illnesses with severe exacerbation, progression, or side effects of treatment;<br>**or**<br>■ **1** acute or chronic illness or injury that poses a threat to life or bodily function | **Extensive**<br>*(Must meet the requirements of at least 2 out of 3 categories)*<br>**Category 1: Tests, documents or independent historian(s)**<br>■ **Any combination of 3 from the following:**<br>• Review of prior external note(s) from each unique source*;<br>• Review of the result(s) of each unique test*;<br>• Ordering of each unique test*;<br>• Assessment requiring an independent historian(s)<br>**or**<br>**Category 2: Independent interpretation of tests**<br>■ Independent interpretation of a test performed by another physician/other qualified health care professional (not separately reported);<br>**or**<br>**Category 3: Discussion of management or test interpretation**<br>■ Discussion of management or test interpretation with external physician/other qualified health care professional/appropriate source (not separately reported) | **High risk of morbidity from additional diagnostic testing or treatment**<br>*Examples only:*<br>■ Drug therapy requiring intensive monitoring for toxicity<br>■ Decision regarding elective major surgery with identified patient or procedure risk factors<br>■ Decision regarding emergency major surgery<br>■ Decision regarding hospitalization or escalation of hospital-level care<br>■ Decision not to resuscitate or to de-escalate care because of poor prognosis<br>■ Parenteral controlled substances◄ |



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## Additional HIGH MDM for Nursing Facility 2023

"When selecting a level of medical decision making (MDM) for nursing facility services, the number and complexity of problems addressed at the encounter is considered. For this determination, a **high-level MDM type specific to initial nursing facility care** by the ***principal**** physician or other qualified health care professional is recognized. This type is:

"**Multiple morbidities requiring intensive management**: A set of conditions, syndromes, or functional impairments that are likely to require frequent medication changes or other treatment changes and/or re-evaluations. The patient is at significant risk of worsening medical (including behavioral) status and risk for (re)admission to a hospital.

"The definitions and requirements related to the amount and/or complexity of data to be reviewed and analyzed and the risk of complications and/or morbidity or mortality of patient management are unchanged."



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## Nursing Facility Care Services 2023

**Initial Nursing Facility Care**

| **Patient:** New or Established | | | |
|---|---|---|---|
| **Code** | 99304 | 99305 | 99306 |
| **REQUIRED ELEMENTS** | | | |
| **Medically Appropriate History and/or Examination** | X | X | X |
| **Medical Decision Making Level** | | | |
| Straightforward or Low | X | | |
| Moderate | | X | |
| High | | | X |
| **OR** | | | |
| **Total Time (On Date of the Encounter)** | | | |
| Minutes | 25 | 35 | 45 |

**Subsequent Nursing Facility Care**

| **Patient:** New or Established | | | | |
|---|---|---|---|---|
| **Code** | 99307 | 99308 | 99309 | 99310 |
| **REQUIRED ELEMENTS** | | | | |
| **Medically Appropriate History and/or Examination** | X | X | X | X |
| **Medical Decision Making Level** | | | | |
| Straightforward | X | | | |
| Low | | X | | |
| Moderate | | | X | |
| High | | | | X |
| **OR** | | | | |
| **Total Time (On Date of the Encounter)** | | | | |
| Minutes | 10 | 15 | 30 | 45 |



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## Example of New MDM and a NH Subsequent Visit #1

- CC: CHF Exacerbation
- HPI: 3 days worsening SOB, orthopnea, edema, sats low 90's w/ O2@ 3liter -f/s/c, productive cough, wheeze.
- PE: T98, BP 105/60, P 102, RR20. Bilateral bibasilar crackles, 6 cm JVD. RRR S1S2+S3 no murmur; abd: benign 2+ edema to knees
- AP: CHF acute on chronic systolic - ECHO, BMP. Daily weights, VS tid. Lasix 40. 02.



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## So what do you bill via MDM?

A) 99307
B) 99308
C) 99309
D) 99310

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## Example of New MDM and a NH Subsequent Visit #1

- CC: CHF Exacerbation
- HPI: 3 days worsening SOB, orthopnea, edema, sats low 90's w/ O2@ 3liter -f/s/c, productive cough, wheeze.
- PE: T98, BP 105/60, P 102, RR20. Bilateral bibasilar crackles, 6 cm JVD. RRR S1S2+S3 no murmur; abd: benign 2+ edema to knees
- AP: CHF acute on chronic systolic - ECHO, BMP. Daily weights, VS tid. Lasix 40. 02.

*Number and complexity of problems: MODERATE 1 or more chronic illnesses with exacerbation or side effects of treatment*

*Data: LOW: 2 unique tests ordered*

*Risk: MODERATE: Prescription drug management*



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## Example of New MDM and a NH Subsequent Visit #2

- CC: CHF Exacerbation
- HPI: 3 day worsening SOB, orthopnea, edema, *declining* sats w/ O2@ 3l *(prev. RA) last 24 hours.* -f/s/c, prod cough, wheeze*. Eating more salty snacks, now more anorexic*
- PE: T98, BP 105/60, P 102, RR20, Sat 90% 3l. New bilat bibasilar crackles, 6 cm JVD. RRR S1S2+S3 no M abd: benign 2+ edema *to knees, previously trace*
- AP: CHF acute on chronic systolic - *repeat* ECHO, *last 6 month old. Check* CXR, *r/o infiltrate, effusion*. Check BMP, last Creat 1.5 *three month ago, concern for history hypokalemia with poor intake and diuretic*. Increase weights to daily *and* VS to tid *given current tenuous values -until seen in 4 days. Double Lasix to 40 pending results. Titrate 02, notify provider if needs >5 liters or RR>24. Educate family /patient on low Na diet. High risk of hospitalization if not improved next 24 hours, phone check with nurse tomorrow am.*



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## So What Do You Bill Via MDM Now?

A) 99307
B) 99308
C) 99309
D) 99310

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## Example of New MDM and a NH Subsequent Visit #2

- CC: CHF Exacerbation
- HPI: 3 day worsening SOB, orthopnea, edema, declining sats w/ O2@ 3l (prev. RA) last 24 hours. -f/s/c, prod cough, wheeze. Eating more salty snacks, now more anorexic
- PE: T98, BP 105/60, P 102, RR20, Sat 90% 3l. New bilat bibasilar crackles, 6 cm JVD. RRR S1S2+S3 no M abd: benign 2+ edema to knees, previously trace
- AP: CHF acute on chronic systolic - repeat ECHO, last 2 year old. Check CXR, r/o infiltrate. Check BMP, last Creat 1.5 three month ago, concern for history hypokalemia with poor intake and diuretic. Increase weights to daily and VS to tid given current tenuous values -until seen in 4 days. Double Lasix to 40 pending results. Titrate 02, notify provider if needs >5 liters or RR>24. Educate family /patient on low Na diet. High risk of hospitalization if not improved next 24 hours, phone check with nurse tomorrow am.

- Number and complexity of problems: HIGH 1 or more chronic illnesses with severe exacerbation or side effects of treatment
- Data: MODERATE: 3 unique tests ordered
- Risk: HIGH: Drug management requiring intensive monitoring for toxicity, impending decision to escalate care



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## Example of New MDM and Initial Visit

- CC: New admit admitted from XWZ Hospital with Acute on Chronic Syst CHF, Acute /Chronic Kidney Disease, T2 Diabetes poorly controlled, and COPD w/ exacerbation
- HPI: 86 yo admitted 7 d ago with cough, green phlegm, wheezing, fever and SOB x 2 d, found have COPD exacerbation with acute CHF, worsening renal function, hyperglycemia. Steroids, IV ATB, diuresis, SSI and now off O2, respiratory sx resolved, CHF compensated, bs back to usual low 100's, Creat back baseline. 3rd hosp admit 6 month. Feels weak, gait unsteady, still has mild DOE with any exertion
- PMHx: NKDA. Rx: Lisinopril 10 qd, Lasix 40 qd, Saxagliptin 2.5 mg qd, Trelegy qd, albuterol 2p q4 hr PMedSurgHX: Chronic CHF (EF 25%), COPD, DM T2 with Chronic Kidney Disease stage 3a
- F/S Hx: +DM, CAD. Widow, former nurse, 2 child out town, lives by self, no ETOH, 40 pk-yr but quit 3 yr ago. SDOH: finances, lack social support



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## MDM—Initial Visit Continued

- PE: T98 BP 115/70 P72 RR16 O2Sat 93 RA Skin no lesions, ENT-, Lungs mild decrease bs all fields, Cor RRR no S3, JVD, murmur, Abd benign, trace ankle edema, neuro NF
- A/P 1) Syst. CHF compensated: no change lasix/lisinopril, BMP in 2 days ordered, monitor VS esp w/ therapy, I/O

  2) COPD: compensated with Rx. Monitor sats QID, prn albuterol ordered

  3) DM T2: bs good, no change Rx, decreased bs to bid, no SSI

  4) Chronic Kidney Disease stage3a: diabetes related, last Creat @ baseline, monitor intake, ordered BMP

  5) Debility: due recent illness, PT/OT, supplements

  6) Code status: Goal of Care and Advance Directives reviewed – code status changed from full to limited



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## So What Do You Bill via MDM

A) 99304
B) 99305
C) 99306

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## MDM—Initial Visit Continued

- PE: T98 BP 115/70 P72 RR16 O2Sat 93 RA Skin no lesions, ENT-, Lungs mild decrease bs all fields, Cor RRR no S3, JVD, murmur, Abd benign, trace ankle edema, neuro NF
- A/P 1) Syst. CHF compensated: no change lasix/lisinopril, BMP in 2 days ordered, monitor VS esp w/ therapy, I/O

  2) COPD: compensated with Rx. Monitor sats QID, prn albuterol ordered

  3) DM T2: bs good, no change Rx, decreased bs to bid, no SSI

  4) Chronic Kidney Disease stage3a: diabetes related, last Create @ baseline, monitor intake, ordered BMP

  5) Debility: due recent illness, PT/OT, supplements

  6) Code status: Goal of Care and Advance Directives reviewed – code status changed from full to limited
- Number and complexity of problems: HIGH – multiple comorbidities requiring intensive management
- Data: MODERATE: 3 unique tests ordered
- Risk: HIGH: Drug management requiring intensive monitoring for toxicity, impending decision to descalate care, code status change



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## Nursing Home Codes and Telehealth Time

| Code | Short Descriptor | Status |
|---|---|---|
| 99304 | Nursing facility care init comp | Unavailable due to Regulatory Requirement |
| 99305 | Nursing facility care init comp | Unavailable due to Regulatory Requirement |
| 99306 | Nursing facility care init comp | Unavailable due to Regulatory Requirement |
| 99307 | Nursing fac care subseq | Permanent – q 14 day limit |
| 99308 | Nursing fac care subseq | Permanent – q 14 day limit |
| 99309 | Nursing fac care subseq | Permanent – q 14 day limit |
| 99310 | Nursing fac care subseq | Permanent – q 14 day limit |
| 99315 | Nursing fac discharge day | Available up Through Dec. 31, 2024 |
| 99316 | Nursing fac discharge day | Available up Through Dec. 31, 2024 |

https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes



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## What do I bill when I assume the care of a patient from another provider?

- Bill an Initial Nursing Facility Care code if assuming care from non-related provider (different practice)
- Clarified in the 2023 CPT manual
  - "Initial nursing facility care codes 99304, 99305, 99306 may be used once per admission, **per physician** or other qualified health care professional, regardless of length of stay".
  - "An initial service may be reported when the patient has not received any face-to-face professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice *during the stay*".
  - "An initial service may also be reported if the patient is a new patient as defined in the Evaluation and Management Guidelines".



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## What do I bill upon readmission from a hospitalization?

Somewhat unclear, BUT…

- Under §483.20(b) Comprehensive Assessments, "For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or therapeutic leave."
- From CPT 2023: "Regulations pertaining to the care of nursing facility residents govern the nature and minimum frequency of assessments and visits. These regulations also govern who may perform the initial comprehensive visit."
- And in the CPT 2023 language to the Initial Nursing Facility Care codes:
"Initial nursing facility care codes 99304, 99305, 99306 may be used once per admission, per physician or other qualified health care professional regardless of length of stay. They may be used for the initial comprehensive visit performed by the principal physician or other qualified health care professional."
- And according to the 2023 Physician Fee Schedule Final Rule:
  - "The initial comprehensive assessment required under 42 CFR 483.30(c)(4) will be billed as an initial NF visit (CPT code 99304–99306)."

https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf



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## Nursing Home Codes wRVU Revalued

- AMA RUC review of nursing home codes done in 2021
  - New values effective 1/1/23
  - Compelling evidence to review codes based off flawed methodology in 2009 and increased acuity, multiple EMRs
  - RUC accepted survey results, many thanks to those that completed the survey to derive values. Had stellar data to present
  - CMS in 2023 Final Rule accepted RUC values but felt time and values may not be accurate, request CPT & RUC to reconsider or will revalue time and wRVU themselves in 2024. Has not been done yet via Proposed Rule
  - Given Conversion Factor, practice expense etc should see about 8% increase overall



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## Revalued wRVU for 2023 (minus CF and Sequester)

| | Frequency | 2022 wRVU | 2023 wRVU | 2020 Total wRVU | 2023 Total wRVU |
|---|---|---|---|---|---|
| **99304** | 336,776 | **1.64** | **1.5** | 552,312 | 505,164 |
| **99305** | 1,054,727 | **2.35** | **2.5** | 2,478,608 | 2,636,818 |
| **99306** | 1,389,990 | **3.06** | **3.5** | 4,253,369 | 4,864,965 |
| **99307** | 2,372,760 | **0.76** | **0.7** | 1,803,297 | 1,660,932 |
| **99308** | 11,302,104 | **1.16** | **1.3** | 13,110,440 | 14,692,735 |
| **99309** | 10,009,767 | **1.55** | **1.92** | 15,515,139 | 19,218,763 |
| **99310** | 1,671,664 | **2.35** | **2.8** | 3,928,410 | 3,928,410 |
| **99315** | 185,707 | **1.28** | **1.5** | 237,705 | 278,560 |
| **99316** | 337,140 | **1.9** | **2.5** | 640,566 | 842,140 |
| | 28,660,635 | | | 42,519,846 | 48,628,487 |
| | | | | Increase wRVU | 6,108,641 |
| | | | | **% Increase** | **14.37** |



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## What About CPT G2211?

- G2211 Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)
- G2211 is an add-on code to office and other outpatient services, 99202–99215
- CMS plans reimbursement 2024 after a 4 year delay. Estimated to be used with 90% of PCP office visits, which may lower the CF by about 5%
- At the present time CANNOT be used with NH facility code set. There may be a possibility of using with POS-32 after future negotiations with CMS / others



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## What about coding in Assisted Living Facilities?

### Domiciliary, Rest Home (eg, Boarding Home), or Custodial Care Services

**New Patient**

►(99324, 99325, 99326, 99327, 99328 have been deleted. For domiciliary, rest home [eg, boarding home], or custodial care services, new patient, see home or residence services codes 99341, 99342, 99344, 99345)◄

**Established Patient**

►(99334, 99335, 99336, 99337 have been deleted. For domiciliary, rest home [eg, boarding home], or custodial care services, established patient, see home or residence services codes 99347, 99348, 99349, 99350)◄



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## Home *and* Assisted Living Facility Care 2023

(Place of service codes have not changed)

"The following codes are used to report evaluation and management services provided in a home or residence. Home may be defined as a private residence, temporary lodging, or short-term accommodation (eg, hotel, campground, hostel, or cruise ship).

"**These codes are also used when the residence is an assisted living facility**, group home (that is not licensed as an intermediate care facility for individuals with intellectual disabilities), custodial care facility, or residential substance abuse treatment facility."

**Home or Residence Services**

| Patient: New | | | | |
|---|---|---|---|---|
| Code | 99341 | 99342 | 99344 | 99345 |
| REQUIRED ELEMENTS | | | | |
| Medically Appropriate History and/or Examination | X | X | X | X |
| Medical Decision Making Level | | | | |
| Straightforward | X | | | |
| Low | | X | | |
| Moderate | | | X | |
| High | | | | X |
| OR | | | | |
| Total Time (On Date of the Encounter) | | | | |
| Minutes | 15 | 30 | 60 | 75 |

**Home or Residence Services**

| Patient: Established | | | | |
|---|---|---|---|---|
| Code | 99347 | 99348 | 99349 | 99350 |
| REQUIRED ELEMENTS | | | | |
| Medically Appropriate History and/or Examination | X | X | X | X |
| Medical Decision Making Level | | | | |
| Straightforward | X | | | |
| Low | | X | | |
| Moderate | | | X | |
| High | | | | X |
| OR | | | | |
| Total Time (On Date of the Encounter) | | | | |
| Minutes | 20 | 30 | 40 | 60 |



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## Home Care, Assisted Living, Residential Care Codes Now Combined into a Single Code Set

| Code | MDM | 2022 AL | 2022 HC | 2023 | 2023 Time |
|---|---|---|---|---|---|
| **99341** | SF new | **1.01** | **1.01** | **1** | 15 |
| **99342** | Low new | **1.52** | **1.52** | **1.65** | 30 |
| **99344** | Mod new | **2.53, 3.88** | **2.63** | **2.87** | 60 |
| **99345** | High new | **4.09** | **3.46, 4.09** | **3.88** | 75 |
| | | | | | |
| **99347** | SF est | **1** | **1** | **0.9** | 20 |
| **99348** | Low est | **1.56** | **1.22** | **1.5** | 30 |
| **99349** | Mod est | **2.33** | **2.46** | **2.44** | 40 |
| **99350** | High est | **3.28** | **3.58** | **3.6** | 60 |



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## Prolonged Services

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## Prolonged Services:

- CMS rejected all CPT Prolonged Service codes in 2023 including non- face to face mainly on basis of base code service times
- Three "G" codes for prolonged services now in place
  - G0316 Prolonged Hospital or Observation Services
  - G0317 Prolonged Nursing Home Services
  - G0318 Prolonged Home or Residence Services
- Clarified the time horizon for nursing home prolonged service codes

https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf



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## G0317

- ***G0317*** *Prolonged* ***nursing facility*** *evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service);*
- *each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact*
  - *(list separately in addition to CPT codes 99306, 99310 for nursing facility evaluation and management services).*
  - *(Do not report G0317 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 99418).*
  - *(Do not report G0317 for any time unit less than 15 minutes)*



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## CMS' Logic for Prolonged Service Changes

- All code set families (e.g office, NH) include pre-, intra- and post-service times.
- Previously only intra-service time was considered for prolonged service codes.
- Nursing Facility codes include pre- (the day before), intra-service (the day of) and post-service (3 days after the date of service) times
- CMS concluded that reporting 99358-99359 on any of those days would essentially be duplicative reporting as these codes only include intra-service time
- Thus, CMS converted other CPT prolonged service codes to "I" status*:
  - 99358-99359 Prolonged E/M service before and/or after direct patient care
  - 99418 Prolonged inpatient or observation E/M service(s) time with or without direct patient contact
- In addition, taking into consideration surveyed pre-service and post-service time embedded in the reimbursement, threshold times for reporting were revised (previously only intraservice time was considered

*I="ineligible" or "no longer recognized by CMS"



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## Time Thresholds for Prolonged Services

Nursing home pre & post times=35 min initial, 25 min subsequent
Home/Residence pre & post times=50 min new, 35 min subsequent

| Primary E/M Service | Prolonged Code* | Service Time (as per code descriptor) | Time Threshold to Report Prolonged | Count Physician/NPP time spent within this time period (surveyed timeframe) |
|---|---|---|---|---|
| Initial NF Visit (99306) | G0317 | 45 minutes | 95 minutes | 1 day before visit + date of visit + 3 days after |
| Subsequent NF Visit (99310) | G0317 | 45 minutes | 85 minutes | 1 day before visit + date of visit + 3 days after |
| NF Discharge Day Management | n/a | n/a | n/a | n/a |
| Home/Residence Visit New Pt (99345) | G0318 | 75 minutes | 140 minutes | 3 days before visit + date of visit + 7 days after |
| Home/Residence Visit Estab. Pt (99350) | G0318 | 60 minutes | 110 minutes | 3 days before visit + date of visit + 7 days after |

* Time must be used to select visit level. Prolonged service time can be reported when furnished on any date within the primary visit's surveyed timeframe and includes time with or without direct patient contact by the physician or NPP. Consistent with CPT's approach, we do not assign a frequency limitation.

https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf



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## How to Use G0317

- May only be used if reporting the following nursing facility codes, using ***time***:
  - 99306 Initial nursing facility care, per day, 45 minutes must be met or exceeded, *but threshold is 95 minutes to report G0317 X 1*
  - 99310 Subsequent nursing facility care, per day, 45 minutes must be met or exceeded, *but threshold is 85 minutes to report G0317 X 1*
- May be reported for prolonged time within the surveyed time frame:
  - One day before the E&M service
  - On the day of the E&M service
  - Up to 3 days after the E&M service
- May be reported only when the prolonged time equals or exceeds 15 minutes beyond the maximum time specified by the codes
- May be reported for each 15-minute increment beyond the maximum time specified in the codes; ***there is no frequency limitation***
- Includes both face-to-face and non-face-to-face time; may be discontinuous



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When provider care relative to an initial nursing facility service (99306) and/or prolonged time for those services (G0317) covers a timespan of several days, what are the appropriate DOS for those services?

A) Bill 99306 using the date of patient encounter. Bill G0317 at the end of 5 day period.

B) Bill 99306 using the date of patient encounter. Bill G0317 whenever the 15 minute threshold is met

C) Bill 99306 using the date of patient encounter. Bill G0317 as appropriate using the same service date as 99306

D) Bill 99306 using the date the 95 minute threshold for prolonged services is met. Bill G0317 at the end of the 5 day period

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## Prolonged Services: RVUs

| HCPCS | Descriptor | CY 2022 Work RVU | Final CY 2023 Work RVU |
|---|---|---|---|
| G3016 | Prolonged hospital inpatient or observation care | NEW | 0.61 |
| G0317 | Prolonged nursing facility evaluation and management service(s) | NEW | 0.61 |
| G0318 | Prolonged home or residence evaluation and management service(s) | NEW | 0.61 |

https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf
(see page 211 of the PDF document or page 69614 of the Federal Register, Vol 87, No. 222)



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## So Is It Worth the Effort to Bill Prolonged Services?

- If using prolonged service, reviewing admit materials in depth is better done the day of actual patient visit to maximize time toward a 99306 (as opposed to the day prior). Same for family communication and post time
- Prolonged service codes are used for managing the same initial problems as addressed on admission. If new problems / complications occur, a subsequent visit is more appropriate

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## Split or Shared Visits

***30.6.18 - Split (or Shared) Visits***
***(Rev. 11288; Issued: 03-04-22; Effective: 01-01-22; Implementation: 02-15-22)***
***A. Definition of Split (or Shared) Visit***
*A split (or shared) visit is an evaluation and management (E/M) visit in the facility setting that is performed in part by both a physician and a nonphysician practitioner (NPP) who are in the same group, in accordance with applicable law and regulations such that the service could be billed by either the physician or NPP if furnished independently by only one of them. Payment is made to the practitioner who performs the substantive portion of the visit.*
*Facility setting means an institutional setting in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited under our regulations.*

--*Medicare Claims Processing Manual, Chapter 12*



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## Split Visits

| E/M Visit Code Family | 2022-2024 Definition of Substantive Portion | 2025 Definition of Substantive Portion |
|---|---|---|
| SNF, Inpatient/Observation Hospital, ER, other outpatient (NOT office) | History, or exam, or MDM, or more than half the total time | More than half the total time |
| Office | Cannot use ( office has incident to instead) | Cannot use (office has incident to instead) |
| Critical Care | More than half the total time | More than half the total time |



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## Chronic Care Management (CCM) Available but Difficult to Use

- Two or more "significant chronic conditions" -NF only (no use in SNF)
- Non face-to-face work
  - Clinical Staff: 20 minutes (99490)
  - Physician or Other Qualified Healthcare Professional (QHP): 30 minutes (99491)
- Billed no more frequently than once per calendar month per qualified patient
- Services covered include
  - Regular development and revision of an electronic plan of care using certified EHR
  - Communication with other treating health professionals Medication management
  - 24/7 access to address a patient's acute chronic care needs
- May be billed concurrently with Transitional Care Management Services when medically necessary and reasonable



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## Chronic Care Management Additional Time: Physician

99437 Each additional 30 minutes by a *physician or other qualified health care professional* per calendar month (List separately in addition to code for primary procedure)

- Applies only to 99491; cannot be applied to 99490
- Maximum 2 units per month

| Total Duration of Physician Care Management Services | Chronic Care Management |
|---|---|
| Less than 30 minutes | Not reported separately |
| 30-59 minutes | 99491 X 1 |
| 60-89 minutes | 99491 X1 AND 99437 X 1 |
| 90 minutes or more | 99491 X 1 AND 99437 X 2 as appropriate |



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## Chronic Care Management Additional Time: Staff

99439 Each additional 20 minutes of *clinical staff time* directed by a physician or other qualified health care professional, per calendar month

- Applies only to 99490; cannot be applied to 99491
- Maximum 2 units per month

| Total Duration of Staff Care Management Services | Chronic Care Management |
|---|---|
| Less than 20 minutes | Not reported separately |
| 20-39 minutes | 99490 X 1 |
| 40-59 minutes | 99490 X1 AND 99439 X 1 |
| 60 minutes or more | 99490 X 1 AND 99439 X 2 (see also 99487; service of this duration may indicate Complex Chronic Care Management) |



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## Chronic Care Management (CCM)

- Services covered include
  - Continuity of care with a designated practitioner or member of the care team with whom the patient is able to get successive routine appointments.
  - Care management for chronic conditions including systematic assessment and development of a patient centered plan of care.
  - Management of care transitions within health care.
  - Coordination with home and community based clinical service providers.
  - Enhanced opportunities for a patient to communicate with the provider through telephone and secure messaging, internet or other asynchronous non face-to-face consultation methods.

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## Chronic Care Management (CCM)

- Electronic Care Plan - components
  - establish, implement, revise, or monitor and manage an electronic care plan that addresses the physical, mental, cognitive, psychosocial, functional and environmental needs of the patient
  - maintain an inventory of resources and supports that the patient needs
  - The practice must use a certified EHR to bill CCM codes.
  - The care plan must be available to anyone providing CCM services in a timely fashion
  - A copy of the electronic care plan must be provided to the patient

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## Chronic Care Management (CCM)

- Billing
  - The practice must have the patient's consent (verbal OK)
  - Only one clinician can be paid for CCM services in a calendar month
  - Billed at the end of the month
  - CMS originally did not pay in PA/LTC, but now allows if all requirements met. Can be difficult to do as requires use of physician and not facility staff



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## Possible Example of Chronic Care Management in PA/LTC

82 year old man with moderate dementia, behavioral disturbances and heart failure who's had 2 episodes of decompensated heart failure treated in the facility in the last year. *Physician's clinical staff* coordinates visits by cardiologist and psychiatrist, providing prior history and goals of care. Care planning includes 3X week weights with parameters for extra diuretic and physician notification, regular lab test monitoring, restorative therapy, regular assessment of cardiopulmonary status and parameters for reporting changes. A care plan for behavioral symptoms is instituted as well. These elements are included in the facility care plan and shared with the authorized decision-maker. EHR is utilized for all electronic and telephonic encounters of physician and clinical staff clearly documented. Cumulative time for all encounters by clinical staff amounts to 25 minutes for that calendar month and is clearly documented

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## Possible example of complex chronic care management in PA/LTC

83-year-old male with moderate dementia with paranoid / depressive features, CHF, DM & peripheral neuropathy, recurrent falls due to combined physical and mental incapacities with minor to moderate associated injuries to date. Care planning includes frequent monitoring of multiple aspects including: medications used to treat his medical and psychiatric status; non-pharmacologic behavioral interventions; fall interventions with the interdisciplinary team; vital signs, physical and psychosocial status with pertinent call parameters for his medical diagnosis; and regular communication with a consulting psychiatrist. These elements are included in the facility care plan. EHR is utilized with all electronic and telephonic encounters of physician and the *physician's clinical staff* clearly documented and time elements summed to more than 60 minutes per month

NOTE: Complex Chronic Care Management Services 99487-99489 requires medical decision making of moderate-to-high complexity during the calendar month in which services are provided



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## More Examples of Physician Employed Staff Activities that Would Lend Themselves to CCM

- **Physician employed staff** reviews latest Oscar report for all physician patients who trigger late-loss life ADL, falls, antipsychotic use, hypnotic use, UTI, depressive behaviors and pain, collates report and identifies high risk patients who trigger 3 or more who would benefit from an intensive physician review
- **Physician employed staff** reviews all physician patient's advance directives, hospitalizations in the last year, functional status, runs prognostic scale (e.g. Porock or Flacker), reviews last facility care plans and runs report for physician to identify patients needing family discussion / education on advance directives, referral to palliative care services

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## Chronic Care Management: National Rates 2021

| Code | Brief Description | wRVU | 2022 NF MPFS National Rate | 2022 F MPFS National Rate |
|---|---|---|---|---|
| 99487 | Cplx chrnc care 1st 60 min[2] | 1.45 | $83.40 | $75.44 |
| 99489 | Cplx chrnc care ea addl 30[2] | 1.00 | $60.22 | $52.60 |
| 99490 | Chrnc care mgmt staff 1st 20[2] | 1.00 | $63.33 | $50.53 |
| 99491 | Chrnc care mgmt phys 1st 30[1] | 0.71 | $48.45 | $35.64 |
| 99437 | Chrnc care mgmt phys ea addl 30 min[1] | 0.70 | $61.25 | $52.26 |
| 99439 | Chrnc care mgmt staff ea addl 20 min[2] | 0.70 | $48.45 | $36.34 |

[1] Counts staff time
[2] Counts physician/qualified healthcare provider time
MPFS=Medicare Physician Fee Schedule; NF=Non-facility; F=Facility



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## Now that 99318 Annual Nursing Home Visit has been deleted, how can I report an annual comprehensive exam?

- May use subsequent nursing facility visit codes 99307-99310, selecting the level by either total time of the visit or medical decision-making
- Alternately, consider incorporating the Medicare Wellness Visit into your practice
- Note: Components of Wellness Exams may not be goal-concordant with frail, elderly nursing home residents; may need to customize components of wellness visits to appropriately meet the needs of nursing home residents



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## What is Included in the Initial Annual Wellness Visit ?

1. Perform Health Risk Assessment (HRA)
2. Establish patient's medical and family history
3. Establish list of current providers and suppliers
4. Measure/Exam
5. Detect any cognitive impairment patients may have
6. Review patient's potential depression risk factors, including current or past experiences with depression or other mood disorders
7. Review patient's functional ability and level of safety
8. Establish an appropriate written screening schedule for patients, such as a checklist for the next 5-10 years
9. Establish list of patient risk factors and conditions where primary, secondary or tertiary interventions are recommended or underway

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html

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## What is Included in the Initial Annual Wellness Visit (AWV)?

10. Provide patient's personalized health advice and appropriate referrals to health education or preventive counseling services or programs
11. Review current opioid prescriptions
12. Screen for potential Substance Use Disorders (SUDs)

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html

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## What is included in the Subsequent Annual Wellness Visit (AWV)?

1. Review and Update ~~Perform~~ Health Risk Assessment (HRA)
2. Update ~~Establish~~ patient's medical and family history
3. Update ~~Establish~~ list of current providers and suppliers
4. Measure/Exam
5. Detect any cognitive impairment patients may have
6. ~~Review patient's potential depression risk factors, including current or past experiences with depression or other mood disorders~~
7. ~~Review patient's functional ability and level of safety~~
8. Update patient's ~~Establish an appropriate~~ written screening schedule ~~for patients, such as a checklist for the next 5-10 years~~
9. Update ~~Establish~~ list of patient risk factors and conditions where primary, secondary or tertiary interventions are recommended or underway

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html

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## What is included in the Subsequent Annual Wellness Visit (AWV)?

10. As necessary, provide and update patient's Personalized Prevention Plan Services (PPPS), which includes ~~Provide patient's~~ personalized health advice and appropriate referrals to health education or preventive counseling services or programs when needed
11. Provide Advance Care Planning (ACP) services at patient's discretion
12. Review current opioid prescriptions
13. Screen for potential Substance Use Disorders (SUDs)

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html

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## Pearls

- Notes should concentrate on MDM and thought process. Time should not be the predominant means of billing for experienced practitioners
  - Consider using a laminated MDM cards for a few weeks to really learn MDM
  - Time elements for 99306 & 99308 will go up in 2024 to 50 & 20 minutes respectively
- Prolonged service code usage is limited, but many if not most times a subsequent code is appropriate given changing patient condition
- You should bill an initial visit code when assuming care of other provider's patients, and when patients return from a hospital stay
- Split visits between a physician and NP/PA are permitted, but not incident to
- Assisted Living is now billed via Home & Residence code set
- Chronic care management can be billed in LTC (not SNF) but requirements are difficult to meet as CCM/CCCM are designed for the office setting
- 99318 Annual Exam has been deleted. Similar work can be done through 99307-10 and the Annual Wellness Exam (which has requirements designed for outpatient use)

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## Questions?

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**APPENDIX**
**Fun Facts To Know and Tell!**

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## Advance Care Planning

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## Advance Care Planning Services

**99497** Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate

**+ 99498** each additional 30 minutes (List separately in addition to code for primary procedure)

- *CPT Changes: An Insider's View* 2015
- *CPT Assistant* Dec 14:11

(Use 99498 in conjunction with 99497)



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## When will CMS Cover ACP?

- "When the described service is reasonable and necessary for the diagnosis or treatment of illness or injury"
- At present, there is no controlling national coverage policy
- No specific diagnoses required



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## Are there minimum amounts of time to bill the code

- In the absence of rules otherwise, CMS defers to CPT descriptor language
- According to CPT coding convention, the threshold for minimum time is reached after the midpoint
- For 99497, "first 30 minutes" is reached at 16 minutes
- For 99498, additional 30 minutes is reached at 30 + 16 minutes=46 minutes



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## How often can ACP be billed?

- Per CPT language, there is no limit
- CMS has declined to establish frequency limits at this time
- BUT—if billed multiple times, CMS would expect to see "a documented change in the beneficiary's health status and/or wishes regarding his or her end-of-life care."

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## Are there rules governing who may actually perform the service?

- Besides the CPT descriptor, there is no introductory language nor are there explanatory notes governing the performance of the service
- According to the final rule (80 Fed. Reg. 70956), "99497 and 99498 are appropriately provided by physicians or using a team-based approach provided by physicians, NPPs and other staff under the order and medical management of the beneficiary's treating physician."
- CMS expects the billing physician or NPP to "meaningfully contribute to the provision of the services in addition to providing a minimum of direct supervision."
- "Incident to" service rules apply
- All applicable state law and scope of practice requirements must be met

(NPP=Non-Physician Practitioner, usually referring to Nurse Practitioners, Physician Assistants and Clinical Nurse Specialists, subject to state laws)



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## Must the beneficiary be present?

- According to the code descriptor, the service is "face-to-face with the patient, family member(s) and/or surrogate*
- Cannot be reported if performed by phone*;
- Subject to CMS Telehealth service payment requirements (see: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/TelehealthSrvcsfctsht.pdf)
- According to CMS, if beneficiary is not present, must document that the beneficiary is impaired and unable to participate effectively
- Must still be face-to-face with family member(s) and/or surrogate*

*BUT MAY BE PERFORMED VIA TELEHEALTH THROUGH 2024

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## What must be documented?

- No requirements in the CPT code descriptor
- Consent is necessary, but does not require documentation
- Medicare Administrative Contractors (MACs) have so far not issued guidance
- Recommendations from CMS; document:
  - That participation is voluntary
  - An account of the discussion
  - Who was present
  - Explanation of advance directives, including any completed forms
  - Time spent in the encounter



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## Can ACP be reported in addition to other services?

- YES, May be reported in addition to E/M codes
  - But need to keep time separate
- May be reported during same service period as Transitional Care Management or Chronic Care Management
- May be reported during global surgical periods
- May use well exam diagnosis when ACP furnished as part of the Medicare Annual Wellness Visit (AWV)
  - Append modifier -33
- May not be reported on same date as certain critical care services



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## Do deductibles and copays apply?

- YES, except when reported as element of the AWV; use modifier -33
- YES, when reported in addition to Introductory Preventive Physical Examination ("Welcome to Medicare Exam")
- Recommend that practitioners let beneficiaries know



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## Advance Care Planning: National Rates 2022

| Code | Short Description/ CMS Posted Typical Time(s) | 2021 NF MPFS National Rate | 2021 F MPFS National Rate |
|---|---|---|---|
| 99497 | Advance care plan 30 min | $85.48 | $77.86 |
| 99498 | Advance care plan addl 30 min | $74.06 | $73.36 |

MPFS=Medicare Physician Fee Schedule; F=Facility; NF=Non-facility

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/FAQ-Advance-Care-Planning.pdf



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## What is medically necessity?

- E/M visits for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member are payable under the physician fee schedule under Medicare Part B[1]
- Services or supplies that: are proper and needed for the diagnosis or treatment of your medical condition, are provided for the diagnosis, direct care, and treatment of your medical condition, meet the standards of good medical practice in the local area, and aren't mainly for the convenience of you or your doctor[2]
- The overarching criterion for payment in addition to the individual requirements of a CPT code. It would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which a specific level of service is billed. Documentation should support the level of service reported

[1]Medicare Claims Processing Manual, Chapter 12, Physicians/Non-physician Practitioners
[2]www.cms.gov/apps/glossary/search.asp?Term=medically+necessary&Language=English&SubmitTermSrch=Search



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## Summarizing:

The visit must be medically necessary AND

The level of service reported must be medically necessary (supported by H&P, MDM etc.)

THEREFORE: **Documentation must support both the medical necessity of the visit itself AND the level of service being reported**

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## Mandated regulatory physician visits: Frequency

**F712**
**(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)**
**§483.30(c) Frequency of physician visits**

- **§483.30(c)(1) The residents must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 thereafter.**
- **§483.30(c)(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.**
- **§483.30(c)(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.**
- **§483.30(c)(4) At the option of the physician, required visits in SNFs, after the initial visit, may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner or clinical nurse specialist in accordance with paragraph (e) of this section.**



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## Mandated regulatory physician visits: Content

**DEFINITIONS §483.30(c) Must be seen,** for purposes of the visits required by §483.30(c)(1), means that the physician or NPP must make actual face-to-face contact with the resident, and at the same physical location, not via a telehealth arrangement. There is no requirement for this type of contact at the time of admission, since the decision to admit an individual to a nursing facility (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission. (SOM/Appendix PP, p 445)

**IMPLICATIONS**

- Though payment policy allows nursing home visits to be performed via Telehealth (payment policy), this does not apply to regulatory visits (federal regulations)
- Regulatory visits must be face-to-face
- Other visits may be performed via Telehealth, subject to the q14 day limitation



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## Mandated regulatory physician visits: Content

**F711**
**(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)**

**§483.30(b) Physician Visits**
**The physician must—**

- **§483.30(b)(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;**
- **§483.30(b)(2) Write, sign, and date progress notes at each visit; and**
- **§483.30(b)(3) Sign and date all orders with the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.**



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## Authority for Non-Physician Practitioners to Perform Visits, Sign Orders and Sign Medicare Part A Certifications/Recertifications When Permitted by the State

| | Initial Comprehensive Visit /Orders | Other Required Visits^ | Other Medically Necessary Visits & Orders+ | Certification/ Recertification ± |
|---|---|---|---|---|
| **SNFs** | | | | |
| PA, NP & CNS employed by the facility | May not perform/ May not sign | May perform alternate visits | May perform and sign | May not sign |
| PA, NP & CNS not a facility employee | May not perform/ May not sign | May perform alternate visits | May perform and sign | May sign subject to State Requirements |
| **NFs** | | | | |
| PA, NP, & CNS employed by the facility | May not perform/ May not sign | May not perform | May perform and sign | Not applicable |
| PA, NP, & CNS not a facility employee | May perform/ May sign* | May perform | May perform and sign | Not applicable |

*At the option of the state, NPP may perform admission H&P. Physician must leave order to admit

^ 30/60 regulatory visits

+Medically necessary visits are independent of required visits and may be performed prior to the initial comprehensive visit.

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## Physician/NP Visits Relative to Admission

**Medicare Claims Processing Manual, Chapter 12, Sect. 30.6.13:**

- "Beginning January 1, 2006, the new CPT codes, Initial Nursing Facility Care, per day, (99304 - 99306) shall be used to report the initial federally mandated visit. Only a physician may report these codes for an initial federally mandated visit performed in a SNF or NF (with the exception of the qualified NPP in the NF setting who is not employed by the facility and when State law permits, as explained above)." (*with AI modifier)

**2023 AMA CPT Manual**:

- "The principal physician or other qualified health care professional may work with others (who may not always be in the same group) but are overseeing the overall medical care of the patient, in order to provide timely care to the patient. Medically necessary assessments conducted by these professionals prior to the initial comprehensive visit are reported using subsequent care codes (99307, 99308, 99309, 99310)."



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**Are Counseling and Coordination of Care visits without a patient exam still allowed in the in-patient and Nursing Home and Assisted Living settings? If so, I assume it must be a time-based service and how should the service be documented?**

Counseling and Coordination of Care remain important clinical services

They are no longer separate components for the purposes of selecting a level of service

Counseling and Coordination of Care may be included in the total time of the encounter, if using time to select the level of care, or medical-decision making



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BILLING PATTERNS

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## General Patterns

- Total visits decreased in 2020 but are close to baseline 2021
  - 26,443,733 encounters in 2021
- Percent SNF vs. NF increased in 2021
  - Historically 60-40 split SNF-NF
  - 2021: 67.3% SNF
  - ?Effect COVID
- NP/PA continue to increase presence in 2021
  Percent of all visits made:
  - NP: 41.4% PA: 6.3% NP/PA: 47.7%
  - IM: 21.7% FP: 12.1% PMR: 5%



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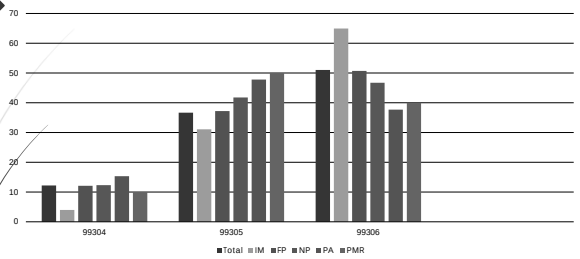
## Initial Nursing Home Code Distribution




Caveat: Your distribution may be different based off medical necessity



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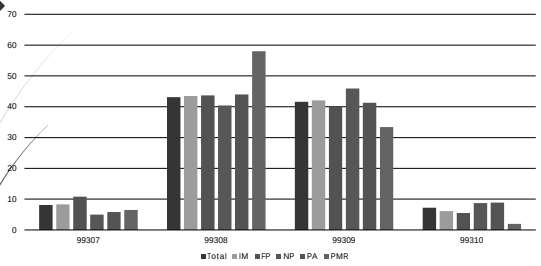
## Subsequent Nursing Home Code Distribution




Caveat: Your distribution may be different based off medical necessity



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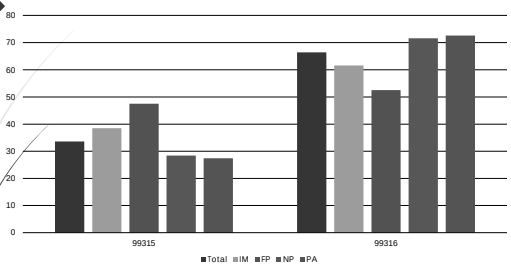
## Discharge Nursing Home Code Distribution




Caveat: Your distribution may be different based off medical necessity



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## Time Thresholds for Prolonged E&M Services: 2023

| Primary E/M Service | Prolonged Code* | Service Time (as per code descriptor) | Time Threshold to Report Prolonged | Count Physician/NPP time spent within this time period (surveyed timeframe) |
|---|---|---|---|---|
| Initial IP/Obs. Visit (99223) | G0316 | 75 minutes | 105 minutes | Date of visit |
| Subsequent IP/Obs. Visit (99233) | G0316 | 50 minutes | 80 minutes | Date of visit |
| IP/Obs. Same-Day Admission/Discharge (99236) | G0316 | 85 minutes | 125 minutes | Date of visit to 3 days after |
| IP/Obs. Discharge Day Management (99238-9) | n/a | n/a | n/a | |
| Initial NF Visit (99306) | G0317 | 45 minutes | 95 minutes | 1 day before visit + date of visit + 3 days after |
| Subsequent NF Visit (99310) | G0317 | 45 minutes | 85 minutes | 1 day before visit + date of visit + 3 days after |
| NF Discharge Day Management | n/a | n/a | n/a | n/a |
| Home/Residence Visit New Pt (99345) | G0318 | 75 minutes | 140 minutes | 3 days before visit + date of visit + 7 days after |
| Home/Residence Visit Estab. Pt (99350) | G0318 | 60 minutes | 110 minutes | 3 days before visit + date of visit + 7 days after |
| Consults | n/a | n/a | n/a | |
| Cognitive Assessment and Care Planning (99483) | G2212 | 60 minutes (typical) | 100 minutes | 3 days before visit + date of visit + 7 days after |

* Time must be used to select visit level. Prolonged service time can be reported when furnished on any date within the primary visit's surveyed timeframe and includes time with or without direct patient contact by the physician or NPP. As with CPT's approach, we do not assign a frequency limitation.

https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf



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| Name of Service | |
|---|---|
| AMA Link to 2023 Evaluation and Management CPT Code Revisions | https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjTy7DP3NP6AhW4IIkEHSZ-CTsQFnoECBAQAQ&url=https%3A%2F%2Fwww.ama-assn.org%2Fsystem%2Ffiles%2F2023-e-m-descriptors-guidelines.pdf&usg=AOvVaw3602CDkjKKTlCu7RZECisq |
| CMS Website on COVID-19 Waivers | https://www.cms.gov/coronavirus-waivers |
| Appendix PP: State Operations Manual—Guidance to Surveyors (All the F-tags and federal regs for nursing facilities) | https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf |
| Medicare Claims Processing Manual, Chapter 12 (Physician/Non-physician Practitioners) | https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf |
| CMS List of Covered Telehealth Services during the COVID-19 Pandemic | https://www.cms.gov/Medicare/Medicare-General-information/Telehealth/Telehealth-Codes |
| Health and Human Services Telehealth Info | https://www.telehealth.hhs.gov/ |
| CMS COVID-19 Waivers | https://www.cms.gov/coronavirus-waivers |



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| Name of Service | Where to find the information |
|---|---|
| Chronic Care Management Services | https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf |
| Cognitive Assessment and Care Services | https://www.alz.org/careplanning/downloads/cms-consensus.pdf |
| Advance Care Planning Services | https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AdvanceCarePlanning.pdf |
| 2023 Medicare Physician Fee Schedule Final Rule (Source for CMS Prolonged Service 'G' Codes) | https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf |
| Care Management Services in Rural Areas | https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FQHCPPS/Downloads/FQHC-RHC-FAQs.pdf |



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| Name of Service | Where to find the information |
|---|---|
| The Initial Preventive Physical Exam ("Welcome to Medicare Visit") | https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html |
| Annual Wellness Exam (AWV) | https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html |
| Incorporating the AWV into the Nursing Facility (This is one example of how to incorporate part of the AWV into nursing home practice) | Little MO, Sanford AM, Malmstrom TK, Traber C, Morley JE. Incorporation of Medicare Annual Wellness Visits into the Routine Clinical Care of Nursing Home Residents. J Am Geriatr Soc. 2020 Dec 18. doi: 10.1111/jgs.16984. Epub ahead of print. PMID: 33339071. https://agsjournals.onlinelibrary.wiley.com/doi/epdf/10.1111/jgs.16984 |
| Transitional Care Management Services | https://www.aafp.org/family-physician/practice-and-career/getting-paid/coding/transitional-care-management/faq.html (May require membership, password or fee) https://www.aafp.org/family-physician/practice-and-career/getting-paid/coding/transitional-care-management.html (May require membership, password or fee) |
| Behavioral Health Integration Services | https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/BehavioralHealthIntegration.pdf |
| | https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Behavioral-Health-Integration-FAQs.pdf |
| Medicare Physician Fee Schedule Lookup | https://www.cms.gov/medicare/physician-fee-schedule/search |



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## Other resources for Telehealth Services during the COVID-19 Pandemic

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- Special coding advice during COVID-19 public health emergency

https://www.ama-assn.org/system/files/2020-03/covid-19-coding-advice.pdf

- AMA quick guide to telemedicine in practice

https://www.ama-assn.org/practice-management/digital/ama-quick-guide-telemedicine-practice

- Medicare Telemedicine Provider Fact Sheet

https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet

**NOTE:** Because of rapidly changing rules and directives during the COVID-19 Public Health Emergency, please check the dates on internet resources to be assured the information is accurate and current



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## Other resources for Telehealth Services during the COVID-19 Pandemic

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- Long-Term Care Nursing Homes Telehealth and Telemedicine Tool Kit (note: dates from 2020, so much of the information is dated)

https://www.cms.gov/files/document/covid-19-nursing-home-telehealth-toolkit.pdf

- AMA quick guide to telemedicine in practice

https://www.ama-assn.org/practice-management/digital/ama-quick-guide-telemedicine-practice

- Rural Crosswalk: CMS Flexibilities to Fight COVID-19

https://www.cms.gov/files/document/omh-rural-crosswalk-5-21-21.pdf

- Telehealth Services (Medicare Learning Network)

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/TelehealthSrvcsfctsht.pdf

**NOTE:** Because of rapidly changing rules and directives during the COVID-19 Public Health Emergency, please check the dates on internet resources to be assured the information is accurate and current



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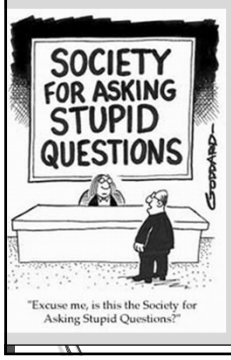

"Excuse me, is this the Society for Asking Stupid Questions?"

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# Cardiovascular Health and Cognitive Resilience

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**Disclosure of conflict of interest: None**

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## Objectives

- **To identify that the top risk factor of cognitive decline is impaired cardiovascular function;**
- **To describe ways to maintain and improve vascular and cardiac health;**
- **To review the importance of reducing cardiac & vascular risk factors (e.g., HTN, dyslipidemias, CHF & arrhythmias), on preserving the brain.**

2

## Case Presentation #1

**81 yo woman with HTN, MCI, hearing loss, macular degeneration, depression.**

**Caregivers statement: "During the past month she has become suddenly "demented". Gets "lost" in middle of a sentence & "conversation does not make any sense. Also has nausea all the time, no appetite, and she is much fatigued."**

**Prior functional status: Good. Prior cognitive status, MCI.**

**Meds: Donepezil 5mg, Omeprazole 20mg, amlodipine 10mg, citalopram 10mg**

**PE: Vitals wnl; Reduced respiratory excursion and reduced breath sounds; Syst M 3/5 LLSB; Pedal edema 3+ bilat; Hearing loss, too weak for cognitive test;**

| Laboratory data | |
|---|---|
| H&H | 13.6 / 42.5 |
| BMP | WNL |
| TSH | WNL |
| LFTs | WNL |
| eGFR | 52 |
| UA | normal |

Local PCP had diagnosed her as having side-effects of donepezil because of nausea, loss of appetite and had reduced donepezil dose;

Caregivers were concerned about dementia and wanted the donepezil to be increased again.

3

## Case #1, con'd Treatment & Outcome

**Labs:** Unremarkable, except BNP = 2749

2D-Echo: LVEF 10%; diffuse hypokinesis; MR; TR; PR; dilated RA and dilated LA;

**Dx:** **Delirium**, due to acute heart failure, with poor brain perfusion, hypoxemia; Predisposing factors: age, MCI, hearing loss, visual impairment, depression.

**Outcome:** With gradual diuresis, LVEF gradually improved to >20%, and cognition progressively returned to pt's baseline of MCI.

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## Case # 2

92 yo woman, PMH: GERD, osteoporosis, Vit D deficiency.
No h/o smoking or alcohol, father died, age 68, heart attack

One evening, started having heartburn after eating at a restaurant. Took 2 aspirins. Called the PCP, was advised to go to ER.
She was alone at home - heartburn continued. Called PCP again, ambulance called.

Meds: aspirin 81 mg, Vit D 50,000 IU/mo, B12 1mg injection/mo

PE: BP 109/80mmHg, pulse 85/min, weight 103 lbs, BMI 19.5
Cardiac S1 and S2 normal, no murmur or gallop. Pulses 2+
Mental status – judgment and insight intact

In ER, EKG: ST elevation, anteriolat leads
CK 470, troponin 31.5, BNP 1760
Lipids 168, TG 39, HDL 53, LDL 107

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## Case # 2, con'd Treatment & Outcome

**Work-up:**

- Cardiac Cath: LMCA patent; LAD, 100% occlusion at ostium; Left circumflex normal; RCA 100% occlusion in proximal part and fills via collaterals from the distal portion; LVEDP 22mmHg and filling defect at apex
- S/P PCI with Placement of BMS in LAD
- Echo with LVEF 25%, severe diffuse hypokinesis with only inferior wall moving well. RV pressure 50
- Outcome: Discharged home on Plavix, carvedilol and lasix

**Follow-up:**

- Currently still going strong, at age 104 years old!
- BP 150/64, Pulse 94, Temp 97.1 °F (36.2 °C), Resp 20, SpO2 99%, BMI 17 kg/m²
- Cognition – alert, oriented x3, conversation good. Has excellent insight
- Able to walk holding onto objects and using a cane (prefers no walker).

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## Case #3

## Beaten by an Old Heart

**This is the first time I've gotten old (I think) …**

**At night all night long love,**
**my heart babbles to me of gone loves,**
**racing with excitement and regret,**
**my heart is beating me to death.**

**On my stone, they'll write "Beaten by his heart,"**
**and the space between my thoughts**
**will be found in the closets**
**where they hang to dry all my tangled memories.**

*1955, The Estate of Leslie L. Seamans*

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## 2022-2023 Cardiology Advances

- **2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure:**
- **Prevention of HF;**
- **Management strategies in stage C HF, including: New treatment strategies in HF, including SGLT2i, GLP-1 and ARNi; Management of HF and atrial fibrillation (AF), including ablation of AF; Management of HF and AS and secondary MR, including TAVR and TMVR transcatheter repairs;**

**Specific management strategies, including: Cardiac amyloidosis; Cardio-oncology; Implantable devices. Left ventricular assist device (LVAD) use in stage D HF;**

**IV iron (ferric carboxymaltose or ferric derisomalotose) for HFrEF & HFmrEF and IDA**

JACC May 2022; JACC Aug 2023;,Circ 2023

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## CLINICAL PRACTICE GUIDELINE 2023: AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease (CCD):

- **Team-based, shared decision making;**
- **Non-Pharm therapies, including diet and exercise;**
- **Reduce sitting time, aerobic & resistance; cardiac rehab;**
- **Use SGLT2 I and GLP-1;**
- **BB or CCB, for shorter duration;**
- **Statin or adjunct agents (ezetimibe, PCSK9I, bempedoic acid);**
- **Antiplatelet RX for shorter duration if needed;**
- **No clear benefit of omega-3 or other supplements;**
- **No routine testing if no clinical/functional change; No e-cigs**
- **PCI = Med mgmt; PCI Radial ?= Femoral; BMS ?=DES**
- **TAVR = SAVR; TMVR ?=SMVR**

Circulation, Aug 2023; JACC Sept 2023

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## CVD and ADRD, Common Risk Factors

**Known**

- Family history
- Age
- Atherosclerosis
- Hypertension
- Dyslipidemia
- Head injury
- Arrhythmia
- LVH
- Diabetes
- Thyroid disorder

**Emerging**

- ApoEe4
- Metabolic syndrome
- Fibrinogen
- Hepatic Lipase
- Oxidative stress
- C-reactive protein
- Homocysteine
- Inflammation
- Hyperinsulinemia
- Other polymorphisms

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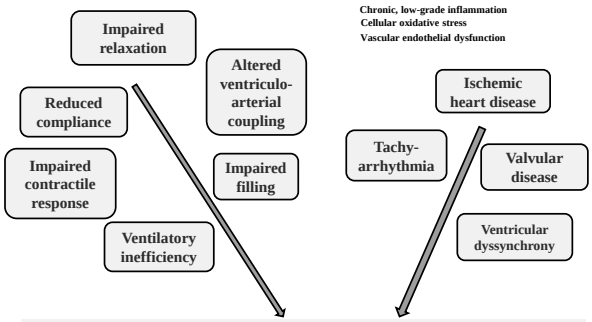
## Age-related continuum from HTN to HFpEF




Signs and symptoms of LVH, AMI, HF, TIA, CVA, AD/RD

Wei, '92, 2004; Abbate et al., 2015; Buford, 2016; Azhar et al., 2017; Kario, 2018; Huang et al., 2019; Wilson et al., 2020

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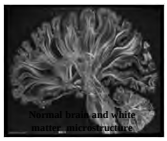
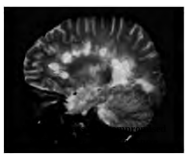
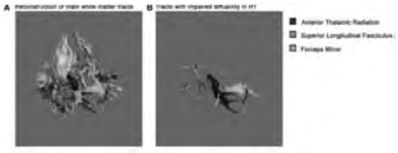
## HTN, LVH Linked to Early Brain Changes




Brain MRI fiber-tracking reveals white matter alterations in hypertensive patients without damage under conventional neuroimaging; HTN in middle-age (40's-50's) predicts cognitive decline in old age (70's-80's).

This approach could identify patients at initial stages of brain damage and could gain benefit of therapies aimed at limiting the transition to cognitive decline and neurodegeneration.





Moore et al., 2018; Carnevale et al., 2018, 2019; Wilson,, 2020; Zhao et al., 2023

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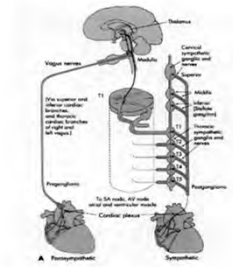
# Heart-Vasculature-Brain Connections

***The reins of the soul are the nerves in the thorax.*** *- T. Willis, 1664*



**Memory Loss is associated with:**

- **Hypertension & Hypotension**
- **Arrhythmias & HF**
- **Cerebral emboli & vascular insufficiency**
- **CAD, CABG, stents & valves**

Flacker et al, 2001; Azhar et al, 2017; Carnevale et al., 2018;

**Hypoxia-reoxygenation injury:**

- **More injury to the brain *vs* heart**
- **Earlier DNA fragmentation in brain *vs* heart**
- **More injury in old *vs* young adult heart, brain**

Mize et al., 2021

***In fixing the heart, the brain may sometimes pay the price*** Kennedy et al, 2013: Wang et al, 2019

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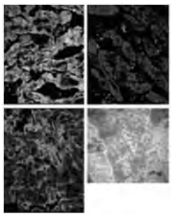
# Women at higher risk for HFpEF, Takotsubo & ADRD

**Table 2.** ADJUSTED ODD RATIOS (OR) FOR CHF WITH PRESERVED SYSTOLIC FUNCTION

| *Independent Risk Factor* | *Adjusted OR* | *95% CI* | *P Value* |
|---|---|---|---|
| Left ventricular hypertrophy | 2.6 | 1.8–3.8 | .001 |
| Gender (women) | 2.5 | 1.8–3.6 | .001 |
| Hypertension | 1.6 | 1.1–2.3 | .010 |
| Age (10 y)* | 1.2 | 1.1–1.4 | .003 |
| Diabetes | 0.6 | 0.4–0.9 | .024 |
| Mitral regurgitation | 0.4 | 0.3–0.5 | .001 |
| CAD | 0.3 | 0.2–0.5 | .001 |

*The odds ratio for age is determined for a 1 decade (10 year) increment in age, e.g., a 70-year-old is 20% more likely to have CHF with preserved systolic function compared with a 60-year-old after adjusting for other factors.



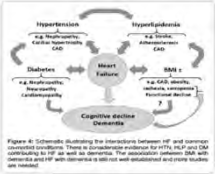



Figure 4: Schematic illustrating the interactions between HF and common comorbid conditions. There is considerable evidence for HTN, HLP and DM contributing to HF as well as dementia. The association between SMI with dementia and HF with dementia is still not well established and more studies are needed.

A high incidence of Takotsubo stress cardiomyopathy in postmenopausal women may be due to cardiovascular over-activation (induced by emotional stress) in the setting of low estrogen, with reduced estrogen-mediated cardioprotection, via indirect action on the CNS as well as direct actions on the heart.

**HTN and HF increase NADPH Oxidase ROS release;**
**HTN and HF are associated with cognitive decline;**
**Treatment of HTN and HF will improve cognition;**

Samuel et al., 1999; Akashi et al., 2009; Azhar et al, 2017; Ghazal et al, 2018; Wilson et al., 2020

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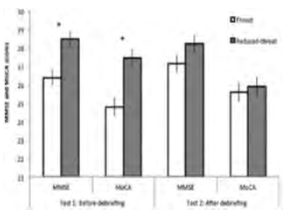
# Translational Research in Geriatrics:

**New CV Risk Factors:** ***Psychological & psychosocial*** *- Depression, Low self-esteem, social isolation* **- Higher post-MI morbidity & mortality regardless of EF**

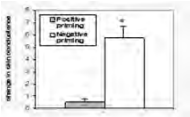
**Negative Aging Stereotypes Impair Performance on Brief Cognitive Tests Used to Screen for Predementia**



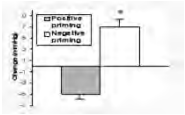

**Participants' scores on MMSE and MoCA tests before and after debriefing as a function of Threat condition. Bars represents standard errors of the mean. The asterisk indicates significantly different group means below .05.**

Haslam et al., 2012; Mazerolle et al., 2017

**Positive Age Stereotypes: Enhancing Functional Independence & cardiovascular health**




**Skin conductance & anxiety are lower with positive priming**




**SBP & HR are reduced with positive priming**

Hausdorff et al., 1999; Levy et al., 2000, 2008, 2016, 2022

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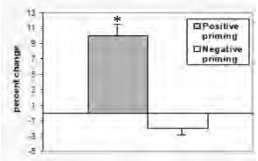
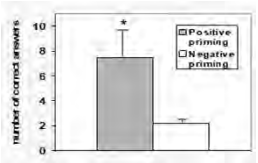
## Age Stereotypes: The Power of positive subliminal priming on physical and cognitive function




**Gait speed improved with positive priming, = to that achieved post 12 wks of exercise, x 30 min x 5 days/wk**




**Verbal & math performance & *self efficacy* improved with positive priming**

Hausdorff et al., 1999; Levy et al., 2000, 2008, 2016; Mazerolle et al., 2016

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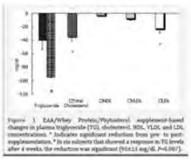
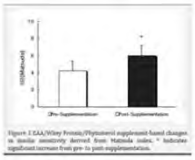
## Daily Consumption of Essential Amino Acid-Based Dietary Supplement reduces risk of metabolic syndrome, CVD, hypertri-glyceridemia & Improves Physical Performance in elderly





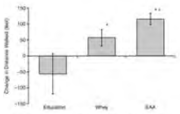


Table 2. Anthropometrics/Body Composition

| | Whey Protein (n = 32) | | EAA (n = 28) | | Education Only (n = 29) | |
|---|---|---|---|---|---|---|
| | Baseline | Final | Baseline | Final | Baseline | Final |
| | Mean ± SEM | Mean ± SEM | Mean ± SEM | Mean ± SEM | Mean ± SEM | Mean ± SEM |
| Body weight (kg) | 86.0 ± 2.64 | 85.2 ± 2.33* | 82.3 ± 3.43 | 81.3 ± 3.50** | 82.3 ± 4.36 | 82.8 ± 4.29* |
| BMI (kg/m²) | 31.7 ± 0.98 | 31.4 ± 0.94* | 30.2 ± 1.11 | 29.9 ± 1.15** | 32.7 ± 1.53 | 32.7 ± 1.47 |
| Lean body mass (kg) | 47.8 ± 1.60 | 48.3 ± 1.63* | 43.7 ± 2.14 | 43.9 ± 2.24 | 44.3 ± 1.43 | 45.3 ± 1.34 |
| % Body fat | 39.8 ± 1.48 | 39.0 ± 1.57* | 40.2 ± 1.21* | 39.7 ± 1.25* | 41.4 ± 1.81 | 41.7 ± 2.02** |
| Fat mass (kg) | 33.8 ± 1.80 | 32.9 ± 1.61* | 32.4 ± 1.75 | 31.6 ± 1.74** | 37.4 ± 2.69 | 38.8 ± 2.61 |

Note: BMI = body mass index; EAA = essential amino acid.
*n = 22 for the education-only group's weight and % body fat at baseline and final visits; n = 25 for the EAA group's % body fat at baseline and final visits.
*Statistically significant (p < .05) change from baseline at the final visit. **Statistically significant (p < .01).

Cohen et al, 2015; Arhar et al. 2017; Picetti et al., 2017; Sugerit et al.,2017; Arhar et al. 2021

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## Cognitive Resilience:

**Definition**:

***Cognitive Resilience*** **describes the capacity to overcome the negative effects of setbacks and associated stress on cognitive function or performance.**

### Characteristics:

- Positive self-image;
- Problem-solving skills;
- Self-regulation; Adaptability;
- Faith/understanding the meaning and one's purpose;
- Positive outlook;
- Skills and talents that are valued by self and community;
- General acceptance by others.

### Other factors:

- Having good communication skills.
- Viewing setbacks as impermanent, opportunities for growth.

Bowles et al., 2019; Lancet Comm, 2020; Mize et al, 2021; Salinas et al, 2021

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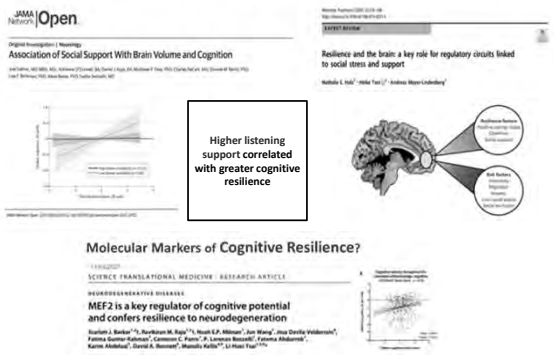
## Markers of Cognitive Resilience




microRNA signatures correlate with cognition and may be future targets against cognitive decline

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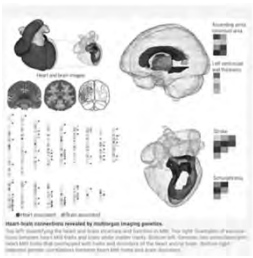
## Cardiovascular health interacts with Cognitive health in complex ways



- Multiorgan imaging data obtained from >40,000 subjects in the UK Biobank (UKB) study
- Genome-wide association analysis of heart MRI traits identified 80 associated genomic loci ($P < 6.09 \times 10^{-10}$), that shared genetic influences and colocalized with heart and brain diseases and complex traits.
- This suggests that adverse heart metrics may have implications for brain abnormalities and the risk of brain diseases.
- By understanding human health from a multiorgan perspective, we may be able to improve disease risk prediction and prevention and mitigate the negative effects of one organ disease on other organs that may be at risk.

Zhao , et al., Science, 380, 934 (2023)

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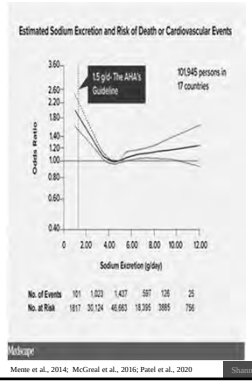
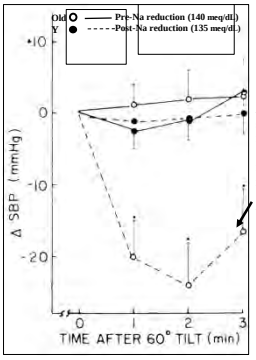
## Q: Is 99 the new 60? Prevention of HTN & HF;

**Also need Sufficient Sodium and Salt Intake**




After modest sodium reduction, SBP drops markedly in healthy Old following upright tilt.

Mente et al., 2014; McGreal et al., 2016; Patel et al., 2020

Shannon et al., 1986; Wei, 1992, 2004; Picetti, et al., 2017; Wilson et al., 2020; Azhar et al., 2021

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## Cognitive Resilience: Pearls

**Learning Opportunities:**
- **Being resilient is not a trait, but a dynamic learning process.**
- **Focus on Progress, not Goals**
- **Perceive Obstacles as Challenges Rather Than Hindrances.**
  ***Challenges are what make life interesting; overcoming them is what makes life meaningful.***

**Social Markers:**
- **Higher listening support from others gives greater cognitive resilience**
- **Feeling valued by others**
- **Listening to favorite music**

**Molecular Markers:**
- **Current:**
  **APOe4; Abeta 42/40; NfL; p-Tau 217 & 181; a-synuclein**
- **New:**
  **MEF2, SARE & TFs, microRNAs; BDNF; ADRD proteins**

Bowirrat et al., 2019; Lancet Comm, 2020; Islam et al. 2021; Solmaz et al. 2021; Barker et al., 2021; Zammit et al., 2022

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## CV health & Cognitive resilience: Pearls

**½ - 2/3 of Alzheimer's & related dementias are preventable:**

**Before 65: HTN, HF, vascular disease, dyslipidemia, T2DM, homocysteine, inactivity, sleep disruption, depression, heart disease, arrhythmias, hearing loss, head trauma, pollution, isolation.**

**Social interactions: need listening support, feeling valued**

**After 65: Exercise and strength training: boost memory, maintain health and enhance longevity**

**Diet: MIND, veggies & fruit (eat the rainbow); low-fat, salt low carb, antioxidants, vitamins, proteins**

**Naps & Sleep: Boosts memory and cognition**

**PPositive**

Levy et al., 2008; Coker et al., 2015; Larson-Prior, 2018; Kim et al., 2019; UC Berkley, 2019; Lancet, 2020; Wilson et al., 2020; Mize et al, 2021; Blach et al., , 2023

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# Cardiovascular Health and Cognitive Resilience

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**Little Rock, AR**

**Disclosure of conflict of interest: None**

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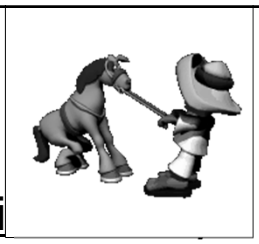
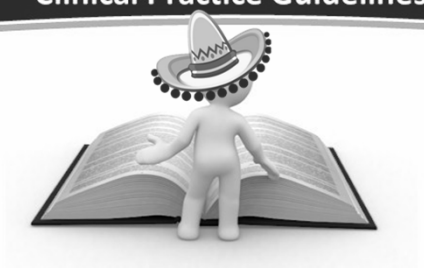
# C. di  ificil

Management of
Clostridioides difficile infection (CDI)
David LeVine, M.D.

1

## Clinical Practice Guidelines



The American College of Gastroenterology (ACG) and The Infectious Diseases Society of America (IDSA) in conjunction with the Society for Healthcare Epidemiology of America (SHEA) 2021
Up To Date 2023

2

## Case scenario

- Anita John is a pleasant 82 y.o. WF who resides at an ALF with mild dementia.
- You recently see her on Friday for routine visit, and she has no complaints or acute findings.
- The following day, Anita's family visits and notices that she is sleepy and more confused.
- The family demands a urine be checked to exclude UTI, and the on call doctor is called.
- The on call doctor orders CC UA which shows 5-10 WBC. Urine C & S is pending.

3

## Case scenario

- The on call doctor calls in ciprofloxacin 250mg PO b.i.d. x 1 week while awaiting urine C & S.
- Several days later Anita has voluminous diarrhea and abdominal cramps.
- She tests positive for C diff and is started on metronidazole for 14 days.
- She becomes anorexia and loses 10 lbs
- On Day 15, her diarrhea returns and she becomes more debilitated and dehydrated.
- Patient is sent to hospital and admitted to ICU with severe sepsis (AMS, low BP, elevated BUN, leukocytosis).

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## C. difficile is a Gram-positive, spore forming, and toxin-producing anaerobic rod bacterium that secretes: Toxin A – enterotoxin Toxin B- cytotoxin (10x more toxic than A)

Recently, researchers have discovered a "binary toxin" seen primarily in virulent strains (e.g. NAP1 strains) felt to contribute to severity of symptoms (often not tested for routinely by labs).

Binary Toxin Expression by Clostridioides difficile Is Associated With Worse Disease
Mary K Young, Jhansi L Leslie, Gregory R Madden, David M Lyerly, Robert J Carman, Matthew W Lyerly, David B Stewart, Mayuresh M Abhyankar, William A Petri, Jr.
Open Forum Infectious Diseases, Volume 9, Issue 3, March 2022, ofac001,
https://doi.org/10.1093/ofid/ofac001MDPI

A B

An Update on Clostridioides difficile Binary Toxin
by Adrián Martínez-Meléndez 1,Flora Cruz-López 1ORCID,Rayo Morfin-Otero 2,Héctor J. Maldonado-Garza 3 andElvira Garza-González 4,*ORCID

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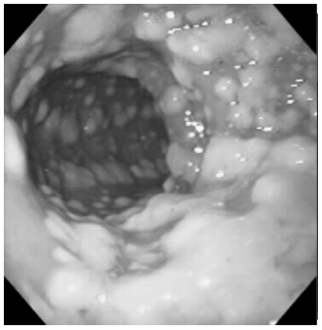

**Pseudomembranous colitis**

6

## Prevalence of *C. d*

- Common in infant colonic flora
- 2-3% of healthy adults
- 5-7% in LTC facilities
- 20-50% of hospitalized patients
- 20-30% of all antibiotic associated diarrhea
- 50-70% of all antibiotic associated colitis

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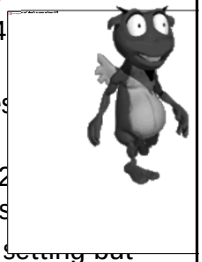
## *C. difficile infection (CDI)*

*CDC Data 2023*



- The incidence of CDI in the United States is approximately 1% of all hospitalized patients
- Increases length of stay by 55%
- Acute inpatient costs exceeds $4 annually
- Among highest readmission rates infection including sepsis
- Overall incidence rate of CDI in 2 121.2 cases per 100,000 persons
- Incidence plateauing in hospital setting but increasing in the community

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## Symptoms

- Diarrhea
- Cramps
- Abdominal pain
- Fever +/-
- Leukocytosis
- Abdominal distention (less common)
- Occasionally ileus or constipation (especially in patients who are post-op)

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10


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# POOPIE

## (clues that you are dealing with CDI)

- P- Pancolitis on CT with no SB involvement
- O- Odor of loose stool is foul
- O- Old aged patient (>=65y.o.)
- P- PPI use, Protein and albumin are low
- I- Increased WBC and procalcitonin
- E- Exposure to antibiotics (1-3 months)

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## Complications

- Anorexia/Malnutrition
- Dehydration
- Ileus
- Toxic megacolon
- Hypoalbuminemia
- Shock
- Renal failure
- Leukemoid reaction
- Death

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## Diarrhea & WBC

| WBC | 15-20K | 20-30K | >30K |
|---|---|---|---|
| | N=200 | N=147 | N=53 |
| Infection identified | 48% | 54% | 60% |
| CDI | 11% | 15% | 34% |

***Clin Infec Dis. 2002;34:1585-1592***

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## *C. Difficile can be a fatal disease*

*CDC data 2023*

- 1/2 million C difficile cases per year in US
  - 50% community acquired
  - 50% healthcare-associated (i.e. hospital)
- 30 day mortality is about 6.6-7.2% (especially >65y.o.)
- 29,000 die/year (usually within first month)
- 15,000 of these deaths could be directly attributed to C. difficile infection.

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## Risk factors

- Elderly age (especially >= 65 y.o.)
- Hospitalization
- Chronic care facility e.g. NH or ALF
- NSAIDs? (as well as H2 antagonists and methotrexate)
- Presence of existing gastrointestinal pathology:
  - Inflammatory bowel disease
  - Colon cancer
  - Intestinal obstruction
- Abdominal surgery
- Hip fracture
- Burns
- Immunosuppresion/Transplantation
- Nasogastric tubes
- End-stage renal disease
- Diabetes mellitus

**Antibiotics!!!**

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## CDAD causing antibiotics through the decades: 1970s


clindamycin (amoxicillin)

18

CDAD causing antibiotics through the decades: 1980s

2nd-3rdg cephalosporins(clindamycin)

19

CDAD causing antibiotics through the decades: 1990s

2nd-4thg cephalosporins (clindamycin)

20

CDAD causing antibiotics through the decades: 2000s

quinolones(2nd-4thg cephalosporins)

21

## CDAD causing antibiotics through the decades: 2010 to present

Broad spectrum penicillins (quinolones)

22

## Antibiotic risk and *C. difficile*

23

## Highest risk antibiotics

- **Broad spectrum penicillins** (e.g. piperacillin/tazobactam (Zosyn)*, ticarcillin/clavulanate, amoxicillin/clavulanate)
- **Fluoroquinolones** (e.g. ciprofloxacin, levofloxacin, moxifloxacin, gemifloxacin)
- **2nd, 3rd, 4th generation cephalosporins** (e.g. cefuroxime, ceftriaxone, cefotaxime, cefipime)
- **Clindamycin**
- **Carbipenems** (e.g. imipenem, meropenem, ertapenem, doripenem)

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## Medium risk antibiotics

- **Penicillins** (narrow spectrum e.g. amoxicillin)
- **1st generation cephalosporins** (e.g. cefazolin, cephalexin)
- **Macrolides** (e.g. azithromycin)
- **Trimethoprim-sulfamethoxazole**
- **Sulfonamides**

Use of 1 to 2 doses of 1st generation cephalosporin for surgical prophylaxis does not confer significant risk for C difficile infection

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## Minimal risk antibiotics

- Linezolid
- Tetracyclines (e.g. doxycycline, IV tigecycline)
- Metronidazole
- Rifaximin
- Vancomycin (IV)
- Aminoglycosides
- Nitrofurantoin
- Chloramphenicol
- Fosfomycin
- Methenamine*

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## Nap 1 Strain (NAP1/B1/027)

- Recognized in Quebec 2002 – now global
- 30-60% of all cases in the mid to late 2000s
- Causes more serious disease
  - toxic megacolon
  - leukemoid reaction
  - severe hypoalbuminemia
  - septic shock and death.
- Highest associated mortality (up to 17%)
- Releases more toxin(16-23x): A,B, and binary
- More refractory to treatment
- More likely to relapse
- Most often associated with fluoroquinolones
- Fidaxomicin or Vancomycin Rx should be considered 1st line if NAP1 identified (as cure rates with metronidazole are 50%).

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**C. difficile NAP1/B1/027 is most common among healthcare-associated CDI cases, while the type 078 is more commonly associated with community-acquired CDI**

NAP-1

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## Recommendations for stool testing

- Do not test asymptomatic patients
- Patients should have >=3 watery stools/day not due to laxatives
- Send only diarrheal stools (which take shape of container) unless ileus is present
- Send only one stool since duplicate samples do not increase yield (may be useful to repeat >1 week from last test)
- Tests are for diagnosis and do not measure response to treatment or resolution of disease.
- Understand what test is used by the laboratory for the right interpretation

29

## Testing for C difficile

**NAAT**-nucleic acid amplification testing is used in about 50% of labs in the USA. NAAT is sensitive for detecting the presence of toxigenic strains of C. difficile usually using PCR (polymerase chain reaction) method. A negative test will r/o C. diff but positive test cannot distinguish between colonization and active production of the toxin.

**GDH** - glutamate dehydrogenase is rapid test (less than one hour) very sensitive assay that detects C diff antigen GDH. Negative test will r/o C diff but positive test may detect non-toxic Clostridium. Therefore, usually done with EIA.

**EIA -** enzyme immunoassay used if NAAT or GDH are positive. EIA detects toxins faster than other tests but isn't sensitive enough to detect many infections and has a 20-30 % false (-) rate. If 2 tests are positive, then C diff diagnosed. Begin Rx if suspicion is high for C diff even if EIA negative and do further testing.

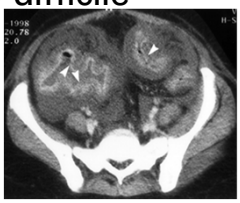
**GDH/EIA -** Uses a glutamate dehydrogenase (GDH) in conjunction with an EIA test. (C. DIFF QUIK CHEK COMPLETE ® test)

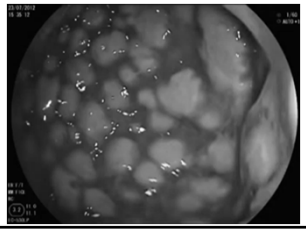
**Cell cytotoxicity assay -** looks for the effects of the C. difficile toxin on human cells grown in a culture. This type of test is sensitive, but it is less widely available, more cumbersome to do and requires 24 to 48 hours for test results. Some hospitals use both the EIA test and cell cytotoxicity assay to ensure accurate results.

30

# Testing for C difficile

- **Imaging tests -** an abdominal X-ray or a computerized tomography (CT) scan, can detect the presence of complications such as thickening of the colon wall, expanding of the bowel, or more rarely, a hole (perforation) in the lining of your colon.
- **Colon examination -** flexible sigmoidoscopy or colonoscopy can look for areas of inflammation and pseudomembranes.





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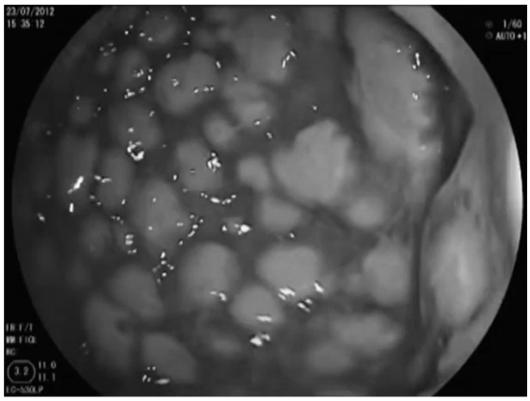

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*Clostridium difficile* toxin is very unstable. The toxin degrades at room temperature and may be undetectable within 2 hours after collection of a stool specimen. False-negative results occur when specimens are not promptly tested or kept refrigerated until testing can be done.

LAB→

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36

# Treatment of suspected CDI

- Stop implicated antibiotic (if not possible, try to avoid highest risk antibiotics)
- Correct fluid and electrolyte balance
- Regular,low residue diet (lactose-free not required)
- Avoid anti-diarrheal agents/narcotics
  - Unless difficulty keeping up with fluid losses
  - Providing there is no evidence of ileus or colonic distention
- Appropriate antibiotic treatment for C difficile if sxs persist

37

# Infection control

- Antibiotic stewardship
  - Appropriate antibiotic use based on evidence-based prescribing
  - 2021 study by CDC found that 56% of ABX use in US hospitals in 2015 was unsupported because patients didn't have signs or symptoms of a bacterial infection, the wrong antibiotic was prescribed, or the length of treatment was too long.
  - Avoid overuse
    - Simple UTIs can be treated with 1-3 days of antibiotics
    - Most hospital pneumonias can be treated with 5-7 days of antibiotics
    - 2016 data from BJM suggests 3 days adequate for mild to moderate outpt pneumonia
  - Do not treat asymptomatic bacturia
- Early detection and isolation
  - Single room/single toilet/try to avoid taking patient out of room for tests
  - Cohort cases. Routine cleaning of rooms prior to disinfection.
  - EPA-registered sporicidal disinfectants (at least 10% bleach)
  - Avoid rectal thermometers
- Contact precautions – gloves and gowns (mask unnecessary)
- Chlorhexidine patient baths (limited success).
- Appropriate hand hygiene.
  - EtoH gel hand sanitizers do not kill spores
  - Wash hands with soap and water for >=20 seconds


38

# Hand washing


*"Think it can last 20 seconds this time?"*

39

## UV Light Disinfection Significantly Reduces Clostridium difficile Incidence

**Oct 6,2016** *Infection Control & Hospital Epidemiology*

- Ultraviolet C light germicidal irradiation disinfection reduced C. *difficile* infections (CDI) in high-risk patients who later occupied those rooms
- The study was conducted in three hematology-oncology units at the Hospital of the University of Pennsylvania during a one-year period (February 2014-January 2015).
- Results showed that adding UV disinfection to typical disinfection protocols reduced the incidence of CDI by 25 percent among new patients in these units, compared to the prior year.
- At the same time, CDI rates increased 16 percent in the non-study units during this period. According to this study, room cleaning took only five minutes longer on average compared to non-study units.
- The no-touch device, used after patients with CDI were discharged from the hospital, also resulted in substantial healthcare savings, estimated between $350,000 and $1.5 million annually.

40

## C. difficile disease severity

- Nonsevere CDI
  - <= WBC 15K
  - Serum creatinine < 1.5 mg/dL
- Severe CDI
  - > WBC 15K
  - Serum creatinine >= 1.5 mg/dL
- Fulminant colitis (Previously referred to as severe, complicated CDI)
  - Hypotension, shock, ileus, or megacolon
  - Hospitalization required

41


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## 1ST Line Antibiotic Treatment

**2018**

- Metronidazole 500mg PO tid x 10-14 days if:
  - WBC<15,000
  - Cr <1.5x baseline
  - Cost $11-36
- Vancomycin 125mg PO qid x 10-14 days if:
  - WBC>15,000
  - Cr>1.5x baseline
  - Patient is severely ill or has NAP1 strain
  - Cost $75-1000

***IV metronidazole can be effective but IV vancomycin does not work***

43

## 1ST Line Antibiotic Treatment

**2021**

- Fidaxomicin 200mg PO bid x 10 days:
  - Cost $4,800-5,200
- Vancomycin 125mg PO qid x 10 days
  - Cost $1000 (GoodRX price $75-309)

For nonsevere CDI, metronidazole 500mg PO tid x 10-14 days is an alternative if other agents are not available. Avoid if frail, >65yo, or have inflammatory bowel disease.

44


45

## Recurrent C. difficile

- 1st episode – 25% chance of recurrent infection
- 2nd episode – 45% chance of recurrent infection
- 3 or more episodes – >60% chance of recurrent infection

46

## Relapse CDI

Fidaxomicin (Dificid) 200mg po bid x10 days is effective alternative and has a 15% relapse rate as compared to vancomycin with a 25% relapse rate

47

## Relapse CDI

- 1st relapse retreat like initial treatment
- 2nd or more relapses
  - Fidaxomicin 200mg bid x 10 days OR...
  - Fidaxomicin 200mg bid x 5 days then once every other day for 20 days
  - Vancomycin 125mg po qid x 10-14 days then...
    - add "rifaximin chaser" following initial vanco course using rifaximin 400mg po tid x 20 days OR...
    - taper to Vancomycin 125mg po bid x 7 days followed by 125mg po daily x 7 days then every 2-3 d x 2-8 weeks

Bezlotoxumab 10mg/kg IV once during antibiotic therapy especially if vanco used and there is no hx of significant CHF

48

## Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection

January 26, 2017
N Engl J Med 2017; 376:305-317
DOI: 10.1056/NEJMoa1602615

- MODIFY I and MODIFY II, two double-blind, randomized, placebo-controlled, phase 3 trials, involving 2655 adults receiving oral standard-of-care antibiotics for primary or recurrent C. difficile infection.
- Actoxumab and bezlotoxumab are human monoclonal antibodies against C. difficile toxins A and B, respectively
- Participants received an infusion of bezlotoxumab (10 mg per kg of body weight), actoxumab plus bezlotoxumab (10 mg/kg each), or placebo. (Actoxumab alone (10 mg/kg) ineffective)
- Among participants receiving antibiotic treatment for primary or recurrent C. difficile infection, bezlotoxumab was associated with a substantially lower rate of recurrent infection than placebo and had a safety profile similar to that of placebo. The addition of actoxumab did not improve efficacy.

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## 2021 Guideline Changes

- Fidaxomicin now first-line therapy for first and second C. difficile episodes (non-fulminant)
- The 2021 IDSA/SHEA guidelines suggest using bezlotoxumab as a co-intervention along with standard antibiotics in primary infection only if the patient is at high risk for recurrence and has severe CDI, whereas ESCMID suggests it is relevant for high-risk patients only if fidaxomicin is not available.

50

## Do probiotics work for C difficile?

- Hempel et al reported a 42% reduction in the risk of developing AAD with the use of probiotics (relative risk [RR] =0.58; 95% confidence interval [CI], 0.50–0.68; $P<0.001$).
- In a meta-analysis by Johnston et al, a 66% reduction in the risk of CDI with the use of probiotics (RR =0.34; 95% CI, 0.24–0.49; $P<0.001$) was observed.
- A Cochrane Review reported similar results with a 64% reduction in the risk of CDI.

51

**Probiotics are effective at preventing Clostridium difficile-associated diarrhea: a systematic review and meta-analysis**

Lau CS1, Chamberlain RS2.
Int J Gen Med. 2016 Feb 22;9:27-37.
doi: 10.2147/IJGM.S98280.
eCollection 2016.

52

## Int J Gen Med Feb 2016

- Twenty-six RCTs involving 7,957 patients were analyzed.
- Probiotic use significantly reduced the risk of developing CDI by 60.5% (relative risk [RR] =0.395; 95% confidence interval [CI], 0.294-0.531; P<0.001).
- Probiotics proved beneficial in both adults and children (59.5% and 65.9% reduction), especially among hospitalized patients.
- Lactobacillus, Saccharomyces, and a mixture of probiotics were all beneficial in reducing the risk of developing CDI (63.7%, 58.5%, and 58.2% reduction).

53

## Do probiotics work for C difficile?

Society for Healthcare Epidemiology of America. "Probiotics useful in the fight against Clostridium difficile infection: New research shows probiotics may be a prevention tool for Clostridium difficile infections."

ScienceDaily. ScienceDaily, 26 April 2018.

54

## 2021 CDI Guidelines re probiotics

- ACG (American College of Gastroenterology) advised against use of probiotics for primary prevention in patients receiving antibiotics or for secondary prevention of CDI recurrence
- AGA (American Gastroenterological Association) guidelines suggest that probiotics may be used in patients (especially high-risk patients) receiving antibiotics in order to prevent CDI using specific strains and combinations of strains:
  - Saccharomyces boulardia
  - Lactobacillus acidophilus CL1285 and Lactobacillus casei LBC80R
  - Lactobacillus acidophilus, Lactobacillus delbrueckii, Bifidobacterium bifidum with or without Streptococcus salivarius

55

## Are there adverse effects with probiotics?

- Although some case studies have reported fungemia, bacteremia, and sepsis associated with probiotic use, the incidences of these adverse events are inconsistent and not statistically significant across studies.
- Most studies showed no statistical significance between patients receiving probiotics and the control group with respect to nausea, abdominal cramping, constipation, and urticaria.
- Several studies even noted that probiotics were associated with decrease in length of stay, fever, and nausea/vomiting.

56

## Not all probiotics are the same: 3 probiotic products with the best data for primary prevention of CDAD

- A proprietary mixture of three Lactobacilli strains: Lactobacillus acidophilus CL1285®, Lactobacillus casei LBC80R® and Lactobacillus rhamnosus CLR2® ($P<0.001$)
- Mixture of L. acidophilus with B. bifidum ($P=0.002$)
- Saccharomyces boulardii ($P=0.003$)

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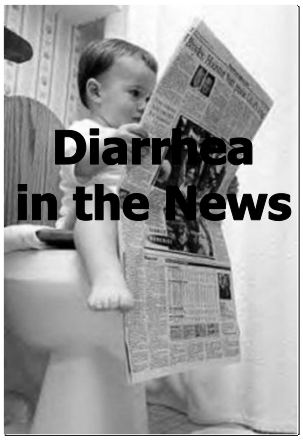


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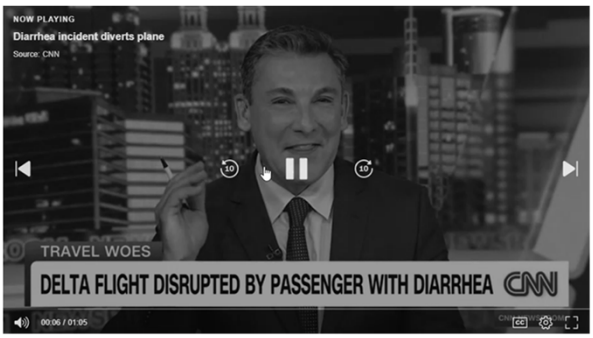
September 7, 2023

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# Microbiome-based therapeutics

fecal microbiota, live – jslm 11/30/2022

SER-109 04/26/2023



61

Fecal microbiota, live – jslm
AKA RBX2660 approved by FDA 2022

- RBX2660 is the first fecal microbiota transplantation product for the prevention of recurrence of Clostridioides difficile infection (CDI) in people >=18 years of age
- RBX2660 studied in largest clinical trial program in the field of microbiome-based therapeutics, including five clinical trials with more than 1,000 participants.
- It is administered rectally as a single dose and is prepared from stool donated by qualified individuals. The donors and the donated stool are tested for a panel of transmissible pathogens.
- Cost of the single dose 150 ml treatment is $9,000
- It is reimbursed by Medicare B with appropriate J code in patients >50y.o. with Medicare

62

Cost-Effectiveness Analysis of REBYOTA™ (Fecal Microbiota, Live-jslm [FMBL]) Versus Standard of Care for the Prevention of Recurrent Clostridioides difficile Infection in the USA

Published online Apr 24, 2023
Adv Ther. 2023; 40(6): 2784–2800

FMBL was found to be cost-effective compared to SOC for the prevention of recurrent CDI with more benefits among patients at first recurrence. Patients >60y.o. treated with FMBL experienced higher total quality-adjusted life year and reduced healthcare resource utilization, including reduced hospitalizations.

63

## SER-109 (Vowst) approved by FDA 2023

- SER-109 is the first FDA approved orally administered fecal microbiota therapy for prevention of recurrent C difficile./
- The safety of SER-109 was evaluated in a randomized, double-blind, placebo-controlled, clinical study and an open-label clinical study conducted in the U.S. and Canada. The participants had recurrent CDI, were 48 to 96 hours post-antibacterial treatment and their symptoms were controlled.
- Across both studies, 346 individuals 18 years of age and older with recurrent CDI received SER-109 .
- Among 90 SER-109 recipients, (compared to 92 placebo recipients), the most common side effects by SER-109 recipients were bloating, fatigue, constipation, chills and diarrhea.
- In the 8 week randomized, placebo-controlled clinical study (89 participants received SER-109 and 93 participants received placebo), CDI recurrence in SER-109-treated participants was lower compared to placebo-treated participants (12.4% compared to 39.8%).

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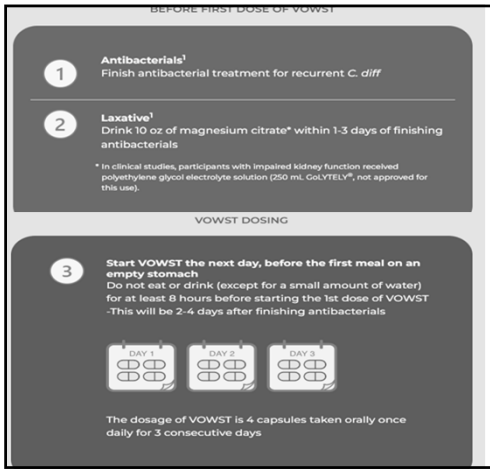


SER-19 available as of June 2023 for a cost of $17,500 per prescrption

65


66

## What if offending antibiotics cannot be stopped (e.g. osteomyelitis treatment)?

Try to switch to low risk antibiotic such as IV vancomycin, aminoglycoside, linezolid, or narrow spectrum beta-lactam

Consider continued Vancomycin 125mg daily and the possible addition of an appropriate probiotic and continue both for 5 days after completion of the offending antibiotic.

67

## What if CDAD treatment isn't working?

- Suspect noncompliance
- Consider other causes of diarrhea
- Escalate therapy
  - If on metronidazole, switch to fidaxomicin or vancomycin (especially if no benefit in 5-7 days)
  - If on fidaxomicin or vancomycin repeat course and consider tapering course of fidaxomicin for 20 days or vancomycin over 2 to 8weeks. If on Vancomycin, consider "Xifaxan chaser" (and/or add IV bezlotoxumab to prevent reoccurrence)

68

## What if EIA assay is negative but symptoms are suggestive?

Repeat EIA assay due to 20-30% false negative rate and begin empiric antibiotic treatment if patient is seriously ill

Alternate option is to order NAAT/PCR or GDH if available. A negative result rules out *C. difficile* and therapy could be discontinued

69

## What if CDI reoccurs after completion of an initial successful treatment?

1) Rechallenge with 10-14 day course of same antibiotic which was successful the first go around
2) If 2nd reoccurrence then continue for a longer course and taper gradually over 1-2 months
3) For any reoccurrence, consider IV Bezlotoxumab, rifaximin chaser during treatment - OR - after treatment consider new microbiome therapeutics with single dose enema or 3-day course of capsules

Studies using Bezlotoxumab with fidaxomicin are limited

70

## What if patient has severe ileus or is vomiting?

Fecal microbiota transplantation (FMT) vs. IV metronidazole 500mg q 8hours with rectal vancomycin 500mg qid by retention enema and surgical consult

IV metronidazole has been used with rectal vancomycin in combination in patients with ileus but with increased mortality

No current evidence to support fidaxomicin for fulminant CDI

71

## What if a 75 y.o. patient has been recently hospitalized for CDI and now requires antibiotics?

Updated ACG guidelines state that oral vancomycin prophylaxis to prevent recurrence may be considered in patients at high risk with a suggested dosage of vancomycin 125 mg once daily continued for 5 days after completion of antibiotic therapy

Addition of a probiotic such as Saccharomyces boulardii could be considered as well but is not part of the current ACG guidelines

72

What if your patient has multiple reoccurrences of CDI and not responding to oral antibiotics?

Fecal microbiota transplant!

Donor stool is screened (for risk of transferable pathogens) then stool is homogenized and filtered and inserted by NG tube or colonoscopy

73


74

Stool transplant

Fecal transplant ready to be delivered to a patient.

- Cammarota et al conducted an RCT involving 39 patients with recurrent CDI
- 20 patients receiving fecal transplantation and 19 patients receiving vancomycin
- Conclusion: significantly higher rates of resolution with the use of fecal transplantation (90% versus 26%, P<0.0001).

75

Q: How do you pick the stool transplant donor?

A: It's never the first person...
IT'S ALWAYS THE NUMBER 2 DONOR

76

The CDI guidelines now recommend Fecal Microbiota Transplantation (FMT) therapy for the treatment of multiple recurrences of CDI.

77


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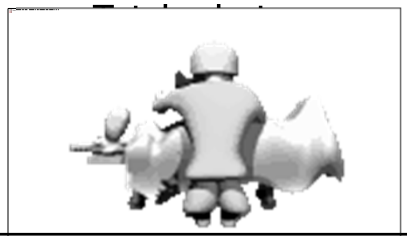
What if patient is seriously ill with ileus, sepsis, toxic megacolon, colonic wall thickening, WBC >20, serum lactic acid >5mmol/L, ARF, and not responding to other therapies (e.g. antibiotics, FMT?)



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## Loop ileostomy may be better alternative than total colectomy

- Loop Ileostomy Vs. Total Colectomy As Surgical Treatment For Clostridium Difficile Associated Disease: An Eastern Association for the Surgery of Trauma Multicenter Trial J Trauma Acute Care Surg. 2017 Jul; 83(1): 36–40.
- Conclu eostomy

80

## Pearls: True or False

Recent studies show increases in CDI with the use of alcohol-based hand rubs versus soap and water.

FALSE: No studies show increases in CDI with the use of alcohol-based hand rubs versus soap and water. Furthermore, several studies have found reductions in MRSA or VRE with the use of alcohol-based hand rubs compared with soap and water. Gloves remain the mainstay of hand hygiene with CDI.

81

## Pearls: True or False

- It is mandatory to retest stool for CDI after completion of antibiotic therapy before isolation can be discontinued to be certain that the patient is no longer infectious .

FALSE: Isolation can be discontinued once the patient has completed therapy and has formed stools. Retesting should not be performed.

82

## Pearls: True or False

New therapies including Bezlotoxumab, SER-109 and fecal microbiota, live – jslm are now FDA approved to treat CDI

FALSE: These therapies are FDA approved to prevent C diff reoccurrence (but not approved to treat CDI).

83

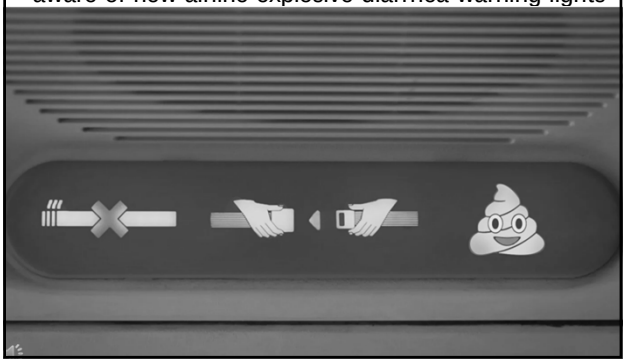
## Poop Pearls

- Fidaxomicin is now recommended 1st line medication for C dfficile although cost considerations will generally require us to use vancomycin
- Metronidazole is not recommended for most CDI episodes
- Treat for C diff if suspicion is high despite (-) toxin
- Use short courses of low-risk ABX when possible
- Do not send formed stools for C. diff testing
- Do not retest stool once infection is treated and symptoms resolve
- Fecal Microbiota Transplant has >90% cure rate

84

## Poop Pearls

- One last pearl… If you are flying Delta Airlines, be aware of new airline explosive diarrhea warning lights



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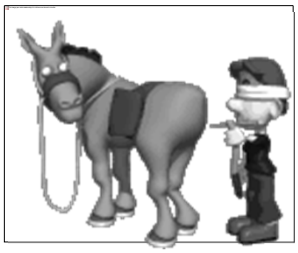
**What's more fun than riding around on motorized toilets?**

86

**Finishing this crappy lecture.**

THE END



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# Wound Care Topical Treatments

OMG.....What the heck do I put on that????

Shark Bird, MD, CMD
Janet S Mackenzie, MD, ABPS, CWSP

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## Wound Dressing Selection

- Based on the etiology, condition, and moisture content of the wound
- Application ease and dressing frequency play a secondary role
- Cost considerations optimize health care dollars
- It is assumed the underlying cause of the wound has been addressed
- Non/slow response warrants further consideration and/or investigation

3

## Wound Dressing Guidelines

- WHS and NPIAP guidelines 2015/2019
- Maintain moisture and select dressings that:
  - Manage exudate and odor
  - Minimize pain
  - Protect wound and peri-wound
  - Prevent tissue damage
  - Secure in place
  - Address bioburden
  - Provide wound needs
  - Is cost effective

4

## Treatment Categories - functional

| Moisture donating | Moisture absorbing | Cavity filling |
|---|---|---|
| ➢ Hydrogels<br>➢ Honeys<br>➢ Impregnated gauzes<br>➢ Combination gels | ➢ Alginates<br>➢ Hydrofiber<br>➢ Foams<br>➢ Superabsorbants<br>➢ Hydroductive | ➢ Packing strips<br>➢ Gauze<br>➢ Hypertonic gauze<br>➢ Antimicrobial gauze<br>➢ Impregnated gauze |

5

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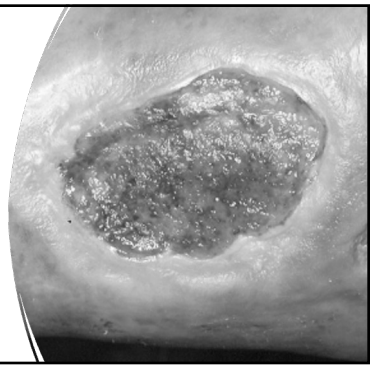
## Case 1

- 69 year old female with PMH of DM, Obesity, HTN, and Anxiety. While in wheelchair banged right arm 3 days ago. Now has a dry open wound 3 cm by 4 cm with a depth of 0.3 cm. No drainage and no sign of infection.



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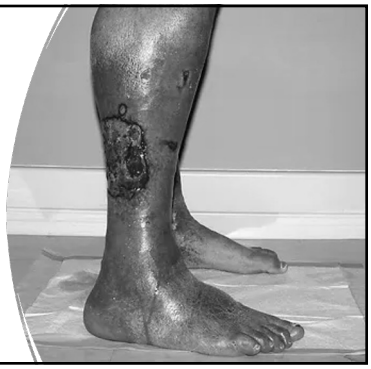
## Case 2

- 74 year old male with a history of CAD and chronic venous insufficiency. Has recurring wounds of the lower extremity along with increased swelling as the day progresses.



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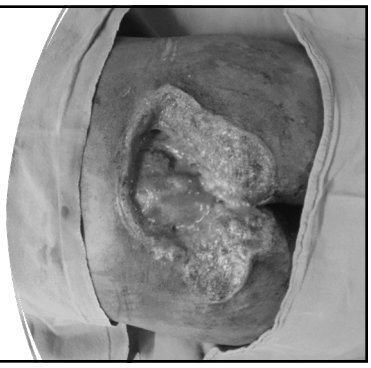
## Case 3

- 84 year old bedridden female with history of CVA and hemiparesis. Large sacral pressure injury with moderate exudate.



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## Treatment Categories - functional

**Antimicrobial**

- Topical antibiotics
  - Mupriocin
  - Gentamicin
  - Bacitracin/TAO
- Silvers
- Iodines
- Dyes – methylene blue, Gentian Violet
- Polyhexanide (PHMB)

**Enzymatic**

- Collagenase
- Trypsin

**Surfactants and Cleansing agents**

- Surfactant
  - P-188
  - Betaine
- Antiseptic solutions
  - Benzalkonium chloride
  - Chlorhexidine
- Acid solutions
  - Sodium Hypochlorite
  - Hypochlorus acid
  - Acetic Acid

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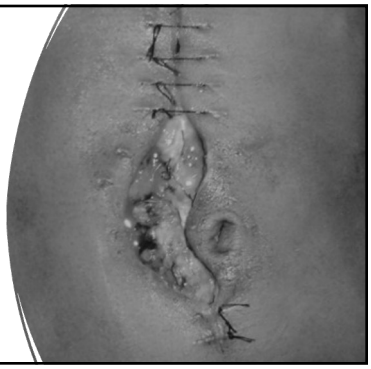
## Case 4

- 59 year old female MVA accident victim who received multiple lacerations and sutures about 2 weeks ago. Leg wound previously sutured has dehisced and has a yellow/green discharge.



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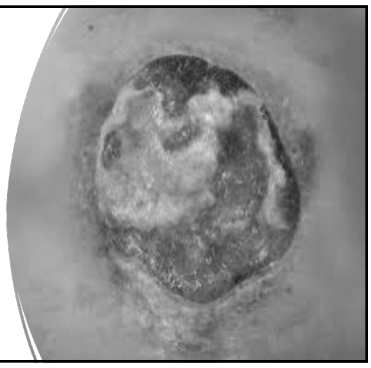
## Case 5

- 82 year old male with Right hip wound 6 that had been doing well until the past couple of weeks where you have noticed increased amounts of necrotic tissue. Patient refuses surgical debridement. Otherwise no signs of infection.



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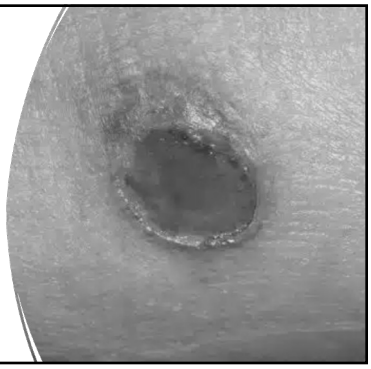
## Case 6

- 87 year old female with dementia, HTN, and high cholesterol has a left buttock pressure wound that has been doing well but progress has slowed over the past few weeks. Wound is now about 8 weeks old and you suspect biofilm. After debridement, you would like to decrease the reformation of biofilm



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## Treatment Categories - functional

**Contact Layers**

- Silicone
- Vaseline gauze
- Vaseline gauze with Bismuth
- Film
- Hydrocolloid

**Stimulatory**

- Growth factors
  - PDGF
- Osmotic gradients
  - Honey
  - Hypertonic
- Lipid-Colloid particles

**Negative Pressure**

- Traditional wound vac
- Single use wound vac
- Mechanically powered

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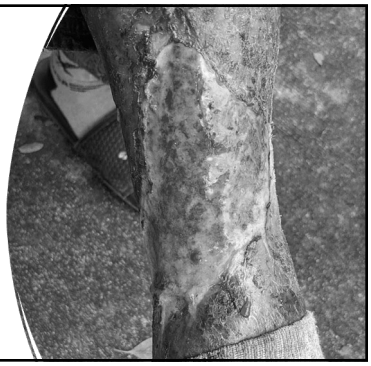
## Case 7

- Mr Jones is a 91 year old man with a history of lower extremity wounds. He complains of pain with dressing removal.
- What dressing might you use to reduce the bandages from adhering to the underlying tissue?



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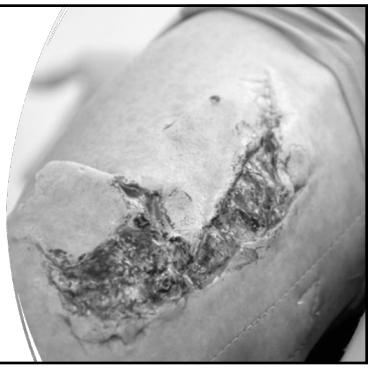
## Case 8

- 83 year old female with a wound on her left thigh. Her past medical history is unremarkable, but this long standing wound seems to be stalled. You have re-assessed your plan of care and everything seems to be correct. You decide to change to a dressing in hopes of kick starting further healing.



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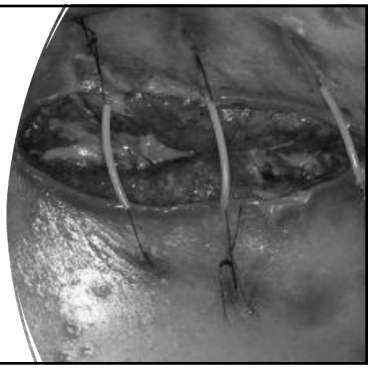
## Case 9

- 72 year old recently admitted from the hospital after receiving abdominal surgery. Initially suture line was healing well but the wound dehisced and now is back on a path to healing.
- What post surgical application might aid in closing of this wound?



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## Treatment Categories - functional

| Substrate Providing | Tissue membranes | Other |
|---|---|---|
| ➢ Collagens<br>➢ Oxidized regenerated cellulose<br>➢ ECM sheets | ➢ Tissue derived skin substitutes (a-cellular)<br>➢ Preserved tissue matrix (cellular) | ➢ Compression bandages<br>➢ Moisture barrier creams<br>➢ Maggots |

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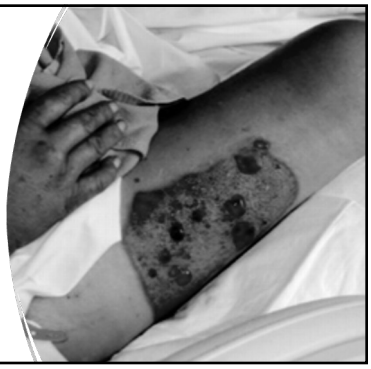
## Case 10

- You have been asked to see a 58 year old burn patient who recently received split-thickness skin grafts to wounds on their arms. The donor site was the patient's thigh. While the graft site is doing well, the donor site has been slow to heal and has basically stalled. The wound is free of necrosis with moderate exudate.



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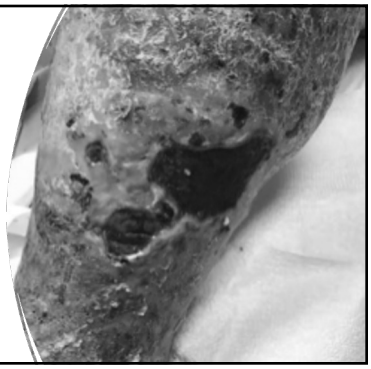
## Case 11

- This is a 69 year old with a history of chronic LE edema. Both LE have stasis dermatitis and the left leg has a recalcitrant 8 cm by 4 cm wound with moderate to large exudate. Wound has failed despite compression and elevation.



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## Skin Substitutes:Cellular and/or Tissue Based Products (CTPs)

- Human Skin Allografts
- Allogeneic Matrices
- Composite matrices
- Acellular matrices

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## CTPs most appropriate use

- DFU
- VLU
- Must first treat with standard treatments: 30 days
  - Edema control
  - Mechanical offloading
  - Mechanical compression
  - Limb elevation
  - Debridement
  - Manage comorbid conditions
  - Appropriate therapeutic dressings

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## Failed Response

- **Failed Response** is defined as an ulcer or skin deficit that has failed to respond to documented appropriate wound-care measures, has increased in size or depth, or has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).

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## Conditions to be met

- Presence of neuropathic ulcers and diabetic foot ulcer(s) having failed to respond to documented conservative wound-care measures of greater than four weeks, during which the patient is compliant with recommendations, and without evidence of underlying osteomyelitis or nidus of infection.
- Presence of a venous stasis ulcer for at least 3 months but unresponsive to appropriate wound care for at least 30 days with documented compliance.
- Presence of a full thickness skin loss ulcer that is the result of abscess, injury or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer.
  In all wound management the ulcer must be free of infection and underlying osteomyelitis with documentation of the conditions that have been treated and resolved prior to the institution of CTP therapy. For purposes of this LCD, appropriate therapy includes, but is not limited to:
  - ☐ Control of edema, venous hypertension or lymphedema
  - ☐ Control of any nidus of infection or colonization with bacterial or fungal elements
  - ☐ Elimination of underlying cellulitis, osteomyelitis, foreign body, or malignant process
  - ☐ Appropriate debridement of necrotic tissue or foreign body (exposed bone or tendon)
  - ☐ For diabetic foot ulcers, appropriate non-weight bearing or off-loading pressure
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- ☐ For venous stasis ulcers, compression therapy provided with documented diligent use of multilayer dressings, compression stockings of > 20mmHg pressure, or pneumatic compression
- ☐ Provision of wound environment to promote healing (protection from trauma and contaminants, elimination of inciting or aggravating processes)

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## Other Products:

- Compression bandage
- Biological (debridement)
- Moisture barrier creams
- Antifungals

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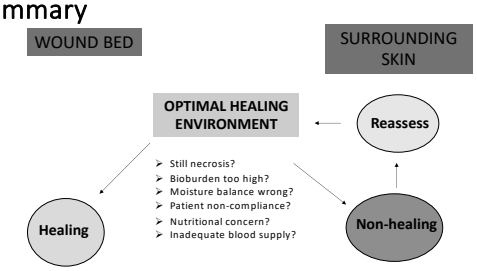
## Summary

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## Putting it All Together:
Patient scenarios

- Dressing selection:
  - Moisture donating, moisture absorbing, cavity filling
  - Contact layer
  - Antimicrobial
  - Debridement
  - Substrate-providing
  - Negative pressure, CTPs, growth factors, etc

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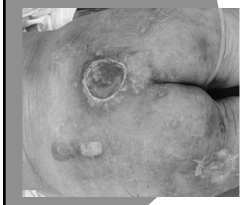
- Case #12
  Sacral Wound



- 78 year old woman with end-stage MS
- Hip DTIs, lower extremity contractures
- Wound 4 x 5 x 0.4cm. Heavy exudate
- What are the important factors in dressing selection for this wound?
  - Wet or Dry? — Wet
  - Cavity? — No cavity
  - Infected? — Not infected
  - Appropriate for CTPs? — Possibly

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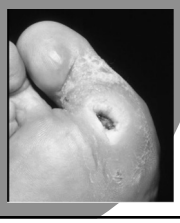
Case #13
Diabetic Foot Wound



- 68 year old man with NIDDM, neuropathy, and PAD.
- DFU 1.0 x 0.5 x 1.6cm; odor, increased exudate
- What are the important factors in dressing selection for this wound?
  - Wet or Dry? — Moderate exudate
  - Cavity? — Cavity/tunnel
  - Infected? — Possibly infected
  - Appropriate for CTPs? — No

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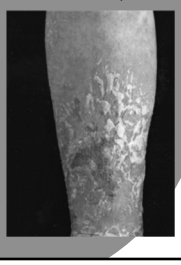
Case #14
Lower Extremity Wound



- 57 year old woman with chronic venous hypertension
- Bilateral stasis dermatitis, edema
- What are the important factors in dressing selection for this wound?
  - Wet or Dry? — Heavy exudate
  - Cavity? — None
  - Infected? — No
  - Appropriate for CTPs? — Possibly
  - Other considerations? — Compression

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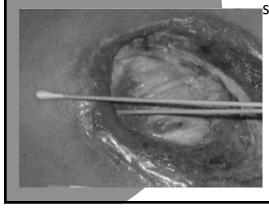
## Case #15
Sacral Wound

- 82 year old woman with stage 4 sacral wound
- Patient is less alert, afebrile. Odor and heavy purulent drainage.
- What are the important factors in dressing selection for this wound?



- Wet or Dry?
- Cavity?
- Infected?
- Appropriate for CTPs?
- Other considerations?

- Heavy exudate
- Yes, plus undermining
- Yes
- No
- Necrotic tissue

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