Our CMDA Community is Stronger Than Ever

Sing Palat MD CMD
April 28, 2023

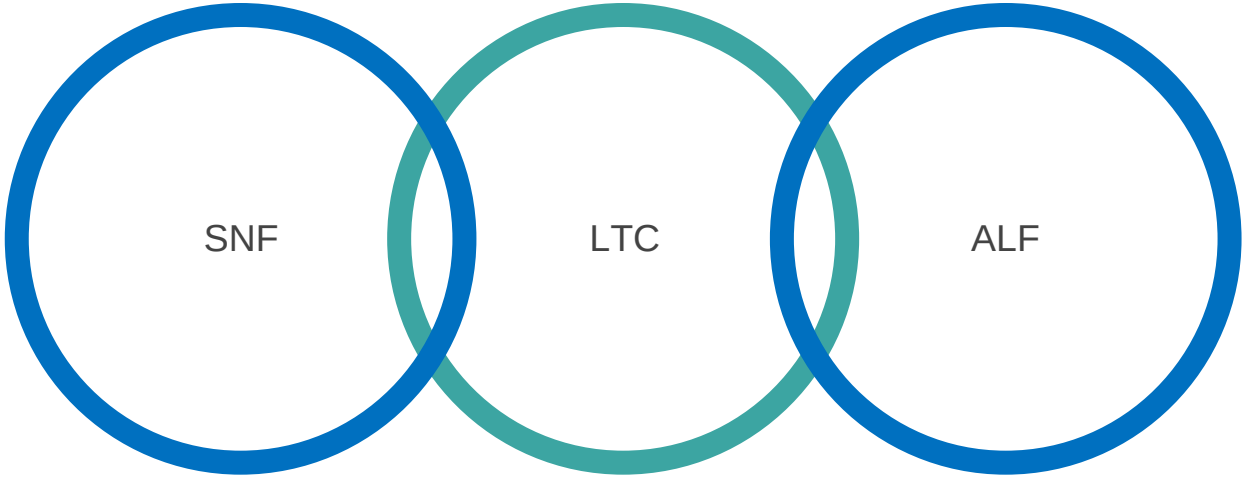
Not the title of this conference…

- *Nursing Homes are Cool*
- *Come Get your CME*
- *At Least Parking is Free*
- *Why can't the conference be in Hawaii for once?*

CMDA's 28th Annual Conference

PALTC 2023: Stronger Than Ever!

PALTC Medicine: Post -Acute and Long-Term Care



Strong Skills

Strong Purpose

Strong Connections

Go to
https://apex.paltc.org/course/view.php?id=1506

to collect CME, CMD, MOC, contact and pharmacology hours

Jointly provided by AMDA

Available through May 2

CMDA Programming

Monthly Meeting

Education, Updates

First Tuesdays each month by Zoom

Website

Presentations

Podcasts

Community Meetings

Ethics

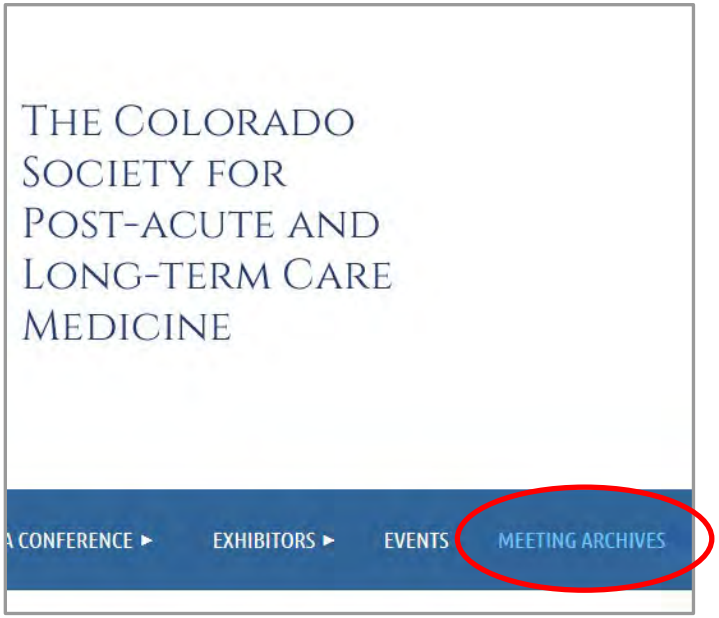
hcarwile@vivagebeecan.com

Journal Club

gahmmd@aol.com

Geriatric Grand Rounds
Jessica.m.martinez@cuanschutz.edu

www.CMDA.us



2022 Dec 6 CMDA Monthly Meeting Recordings, Slides

Sing Palat (Administrator) | 6 Dec 2022 9:35 PM

Agenda

Tuesday, Dec 6, 12 - 1 pm

Video - Audio - Slides below

Updates

- CDPHE: Chad Fear, Nursing Facilities Section Manager
- CHCA: Jenny Albertson NHA, Director of Quality and Regulatory Affairs

Hyperthyroidism

- Michael McDermott, MD, Director, Endocrinology and Diabetes Practice, University of Colorado Hospital
- President-Elect, American Thyroid Association

Hypodermoclysis

- Lesley Williams-Anderson, FNP-C, OptumCare

Exhibitors

Acadia Pharmaceuticals

Colavria Hospitality

Colorado Department of Public Health and Environment, Project Frontline

COPIC

Forte Health and Wellness

Lilly USA

Longevity Health Plan

Molnlycke Health Care

Optum

PharmcareUSA

Precision Clinical Laboratory

ProHealth One

Restore Wound Care

SinguLab

SK Life Science Inc.

Summit Medical Consultants

The Denver Hospice

The Foundation for Post-Acute and Long-Term Care Medicine

Urovant

Vivage Senior Living

Thanks to the CMDA Board – Newest Members

Rebecca Jackson
DO CMD

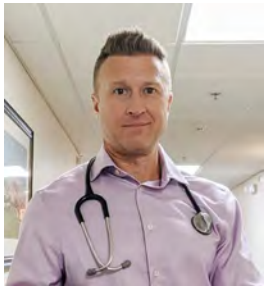
Raj Rai
MD

Alicia Smith
PA-C

Thanks to the CMDA Board Officers

Galin Hartsuiker
PA-C
Education Coordinator

Chris Horton
MD CMD
Community Liaison



Travis Neill
PA-C
Treasurer

Thanks to the CMDA Board & Conference Chairs

Allison Villegas
PA-C

Vice-President
Conference Co-chair

Leslie Eber
MD CMD

Immediate Past -President
Conference Co-chair

Enjoy the Conference

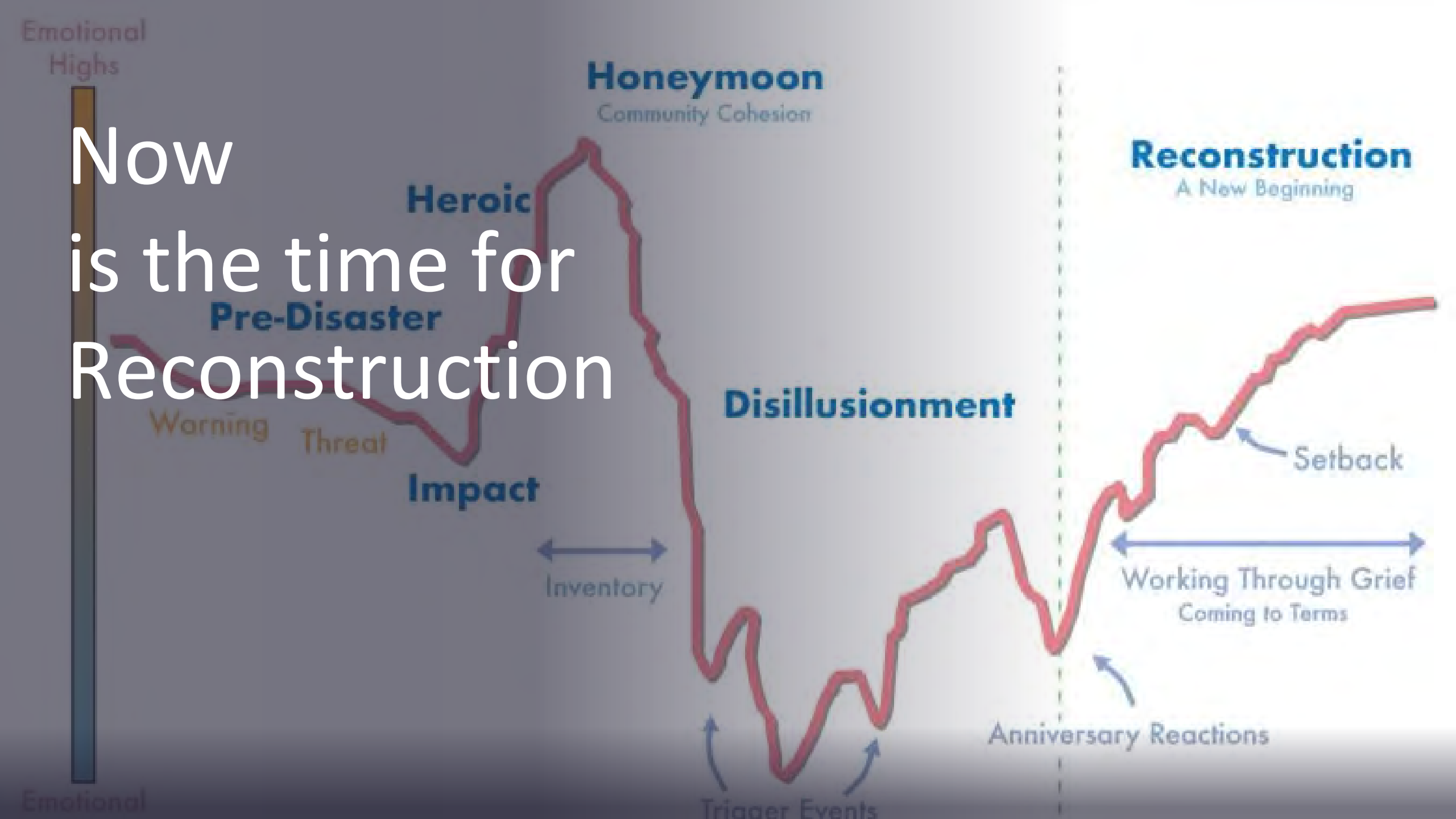
Follow us

#CMDA23

Update from your Association partner

Jenny Albertson, NHA, QCP, Director of Quality and Regulatory Affairs

We are still standing and still improving.


Now
is the time for
Reconstruction
Emotional Highs
Honeymoon
Community Cohesion
Heroic
Reconstruction
A New Beginning
Pre-Disaster
Warning
Threat
Impact
Disillusionment
Setback
Inventory
Working Through Grief
Coming to Terms
Anniversary Reactions
Trigger Events
Emotional

Post-Acute and Long-Term Care is adapting

WORKFORCE

IMPROVED COMPENSATION

MORE RESPONSIVE MANAGEMENT

BUILDING BUMPERS AROUND AGENCY

INVEST IN THE PERSON: CAREER LADDERS, PERSONALIZED SCHEDULING

OPERATIONS

- Refocus on care
- Get out of fight/flight cycle
- Springboard from the new compliance requirements
- Begin to plan for a future again

Pressures in play

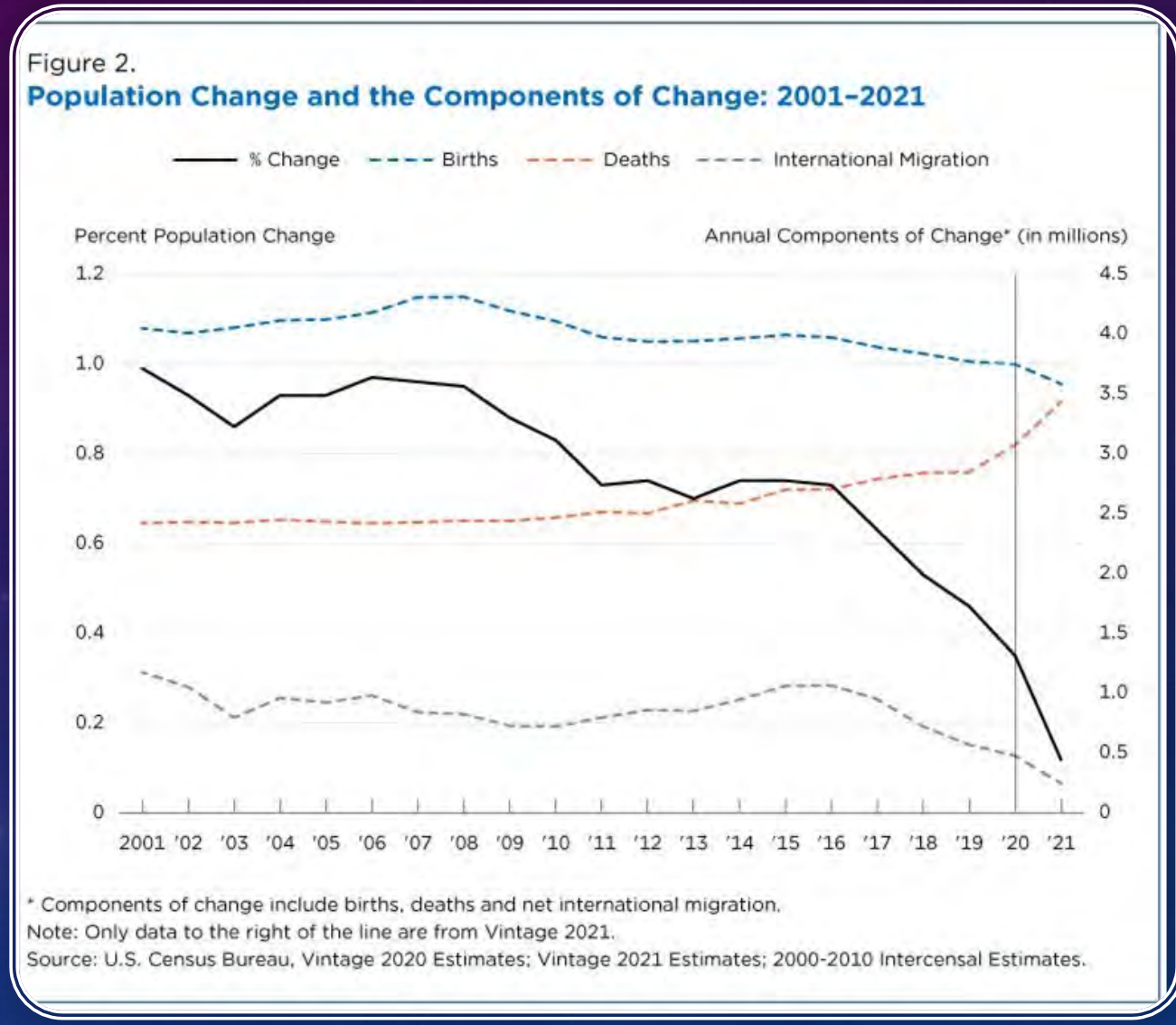
Compression of the Workforce

Just look at the numbers

Where are the people?

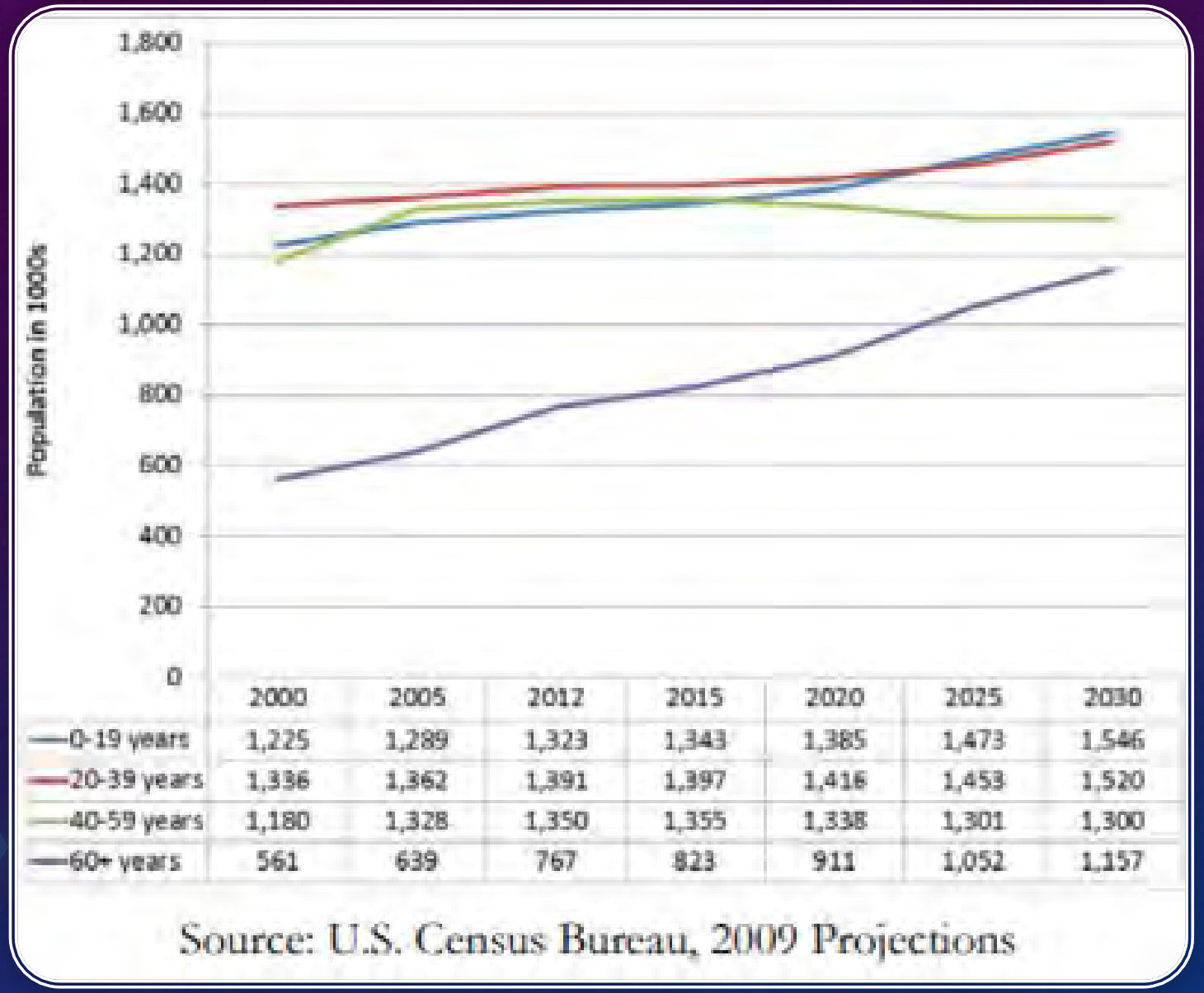
- The year 2021 is the first time since 1937 that the U.S. population grew by fewer than one million people, featuring the lowest numeric growth since at least 1900, when the Census Bureau began annual population estimates.

- In 2020, 27,337 people moved to Colorado, and in 2021, data shows that number dropped even further to 14,731. That's compared to 68,844 people who moved here in 2015.



https://www.census.gov/library/stories/2021/12/us-population-grew-in-2021-slowest-rate-since-founding-of-the-nation.html

https://www.9news.com/article/news/local/fewer-people-moving-to-colorado/73-3e1bf311-d6c8-49ec-8125-bbbd31d83016



	2000	2005	2012	2015	2020	2025	2030
0-19 years	1,225	1,289	1,323	1,343	1,385	1,473	1,546
20-39 years	1,336	1,362	1,391	1,397	1,416	1,453	1,520
40-59 years	1,180	1,328	1,350	1,355	1,338	1,301	1,300
60+ years	561	639	767	823	911	1,052	1,157

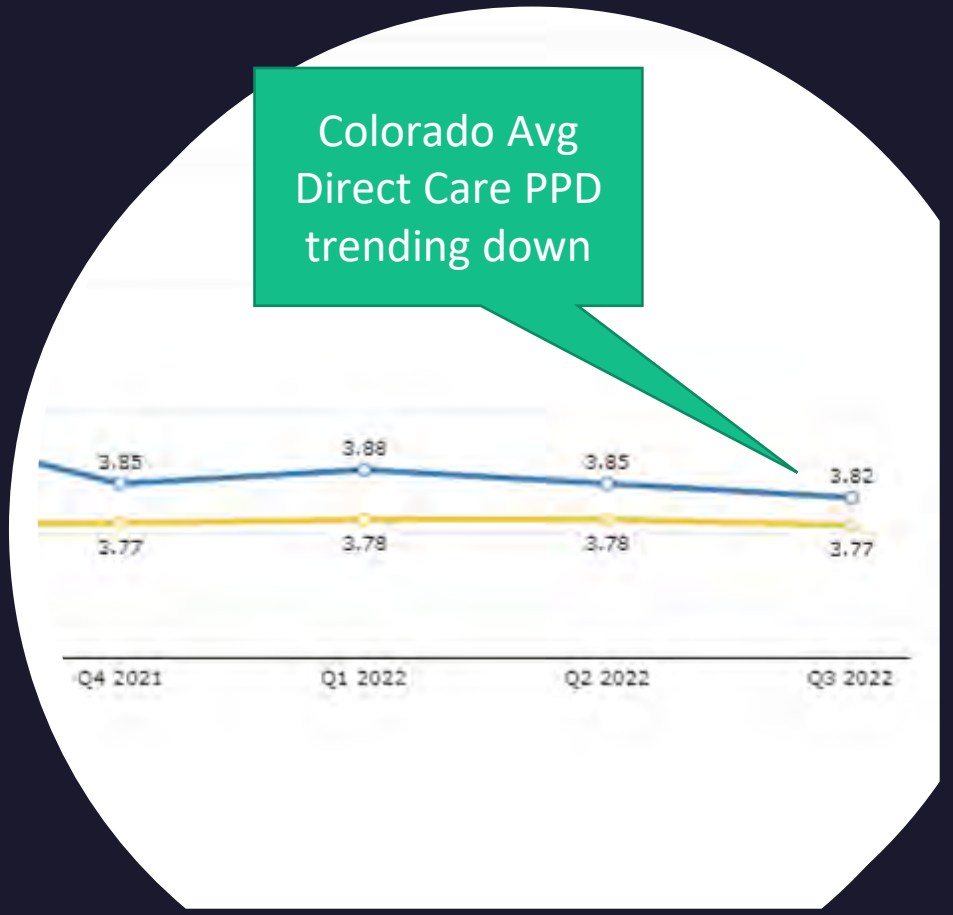
Source: U.S. Census Bureau, 2009 Projections

Colorado is aging

The proportion of Colorado's population that is over 60 is growing while the proportion that is under 60 is shrinking. The U.S. Census Bureau estimates that **21 percent of Colorado's population will be over age 60 by the year 2030**, an increase of 32% percent from 2012.

CMS Staffing mandate

- Expect it to be announced any day now – “by end of spring”
- 4.1 PPD anticipated to be the standard for direct care nursing



What's the big idea?

Aging in place

Funding and Cultural Shift to prefer home health care – "SNF at home"

ARPA funds used in CO to fund models development to transition people OUT of our settings

The average 65+ year old person thinks he/she is prepared to age in place at home.

Cost saving: HCPF pressuring to consolidate use of funds to fewer communities.

Post-acute and Long-term Care is still a vital part of the care continuum

- Home-based care for those we would normally serve requires more workers than we have
- Clinical acuity will continue to exceed home health services.
- Many are unfriended, and families cannot care for their loved ones while still conducting their lives.

We have allies

- Funding for increased Medicaid Reimbursement has been secured
- Pay for Performance doubled
- Takes funds **away** from total Medicaid fund so we have to earn the increase to reach full funding, BUT it promotes change in delivery of care

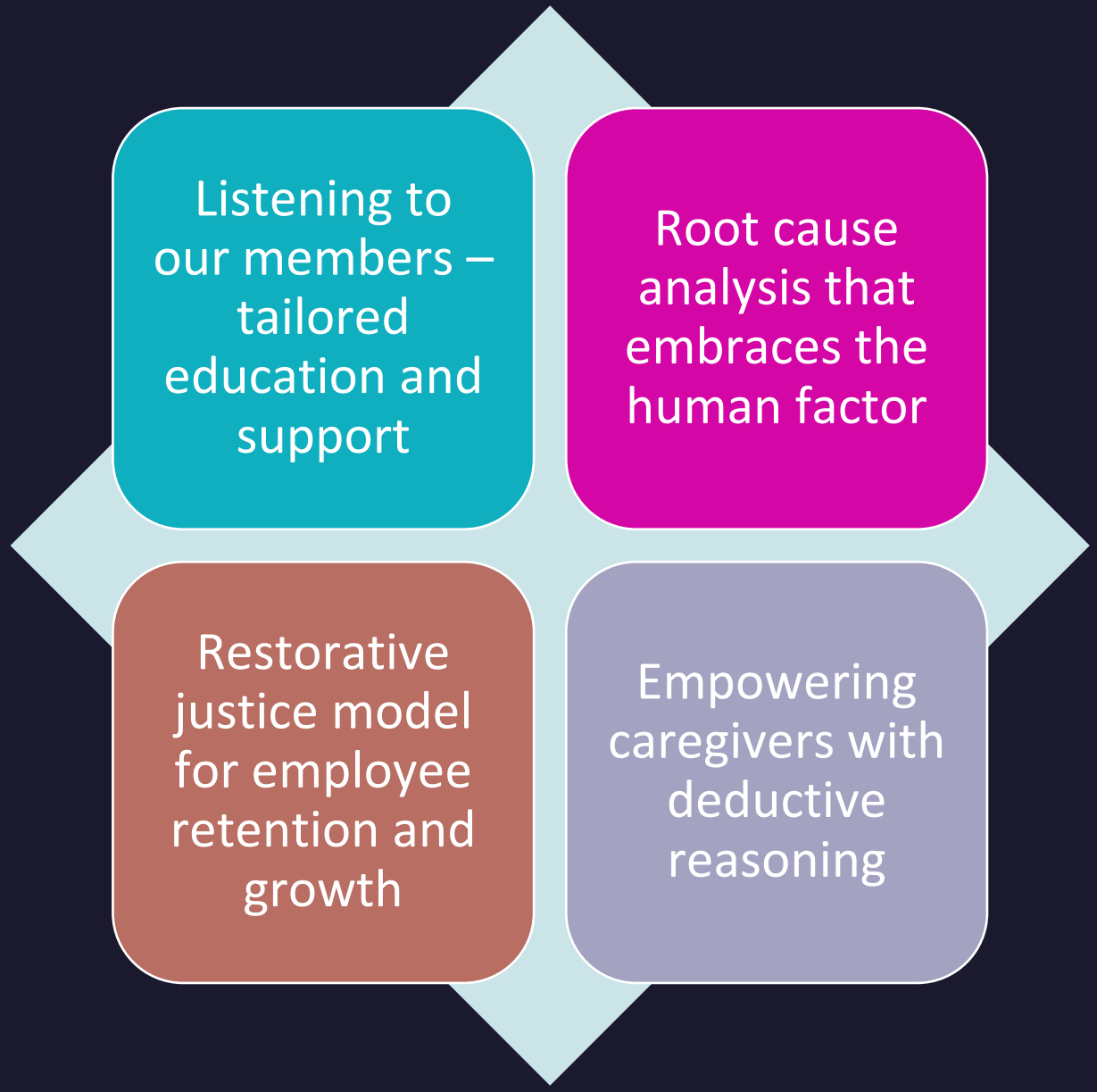
Other legislative positives

Dementia Care Training upon hire (4 hours) and annually (2 hours)

Agency bill moving forward – will prevent required buy-outs of employees

Guardianship bill introduced

What is making us better



We are in this together

Our Partnerships are strong and getting stronger

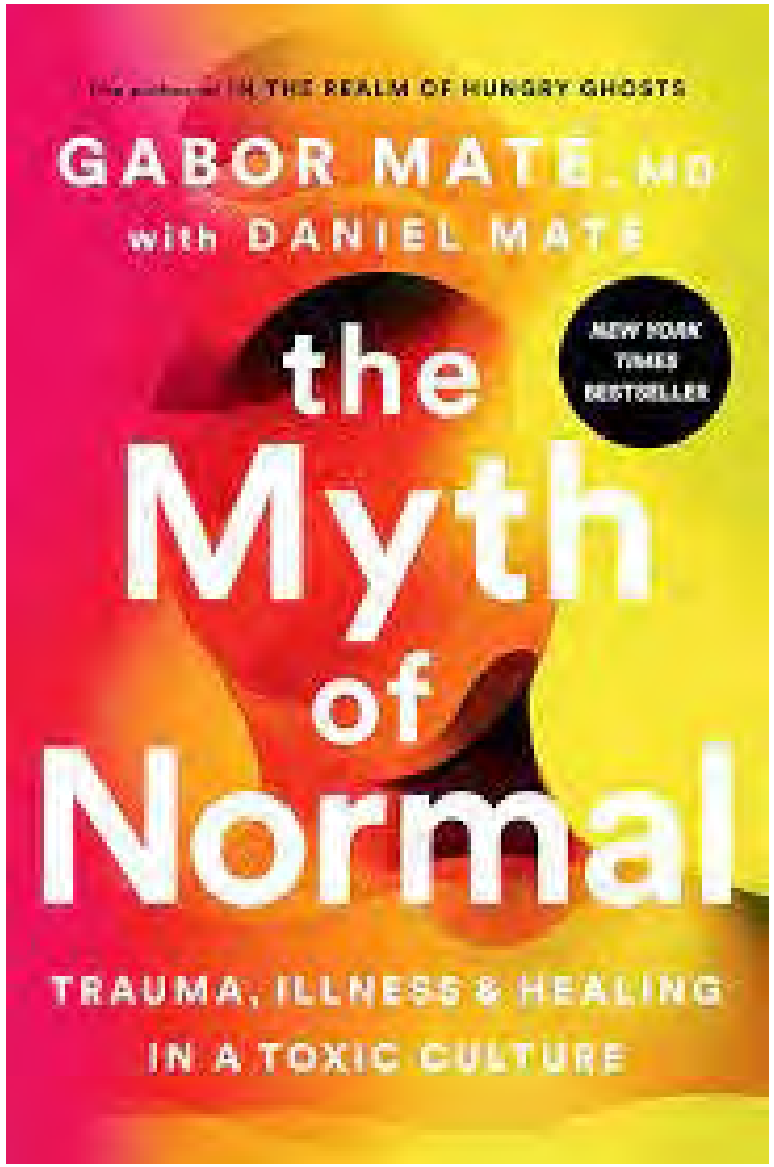
Trauma-Informed Care is a Culture that Helps Us All

Lea C. Watson, MD, MPH
Visiting Professor of Psychiatry and Geriatrics
University of Colorado School of Medicine


everyone you meet
is fighting a battle
you know nothing about

"Trauma pervades our culture, from personal functioning through social relationships, parenting, education, popular culture, economics, and politics. In fact, someone *without* the marks of trauma would be an outlier in our society."

~Dr. Gabor Mate in The Myth of Normal


IN THE REALM OF HUNGRY GHOSTS
GABOR MATÉ, MD
with DANIEL MATÉ
NEW YORK TIMES BESTSELLER
the Myth of Normal
TRAUMA, ILLNESS & HEALING
IN A TOXIC CULTURE

Creating a Sustainable Trauma-Informed Care Culture for Residents and Staff Post Pandemic

SHOUT OUT!

This talk includes content from a 3-hour workshop presented at the AMDA Annual Conference
March 2023
Tampa, FL

"The health care system is populated by trauma survivors, both those providing and receiving care."

(Fleishman, 2019)

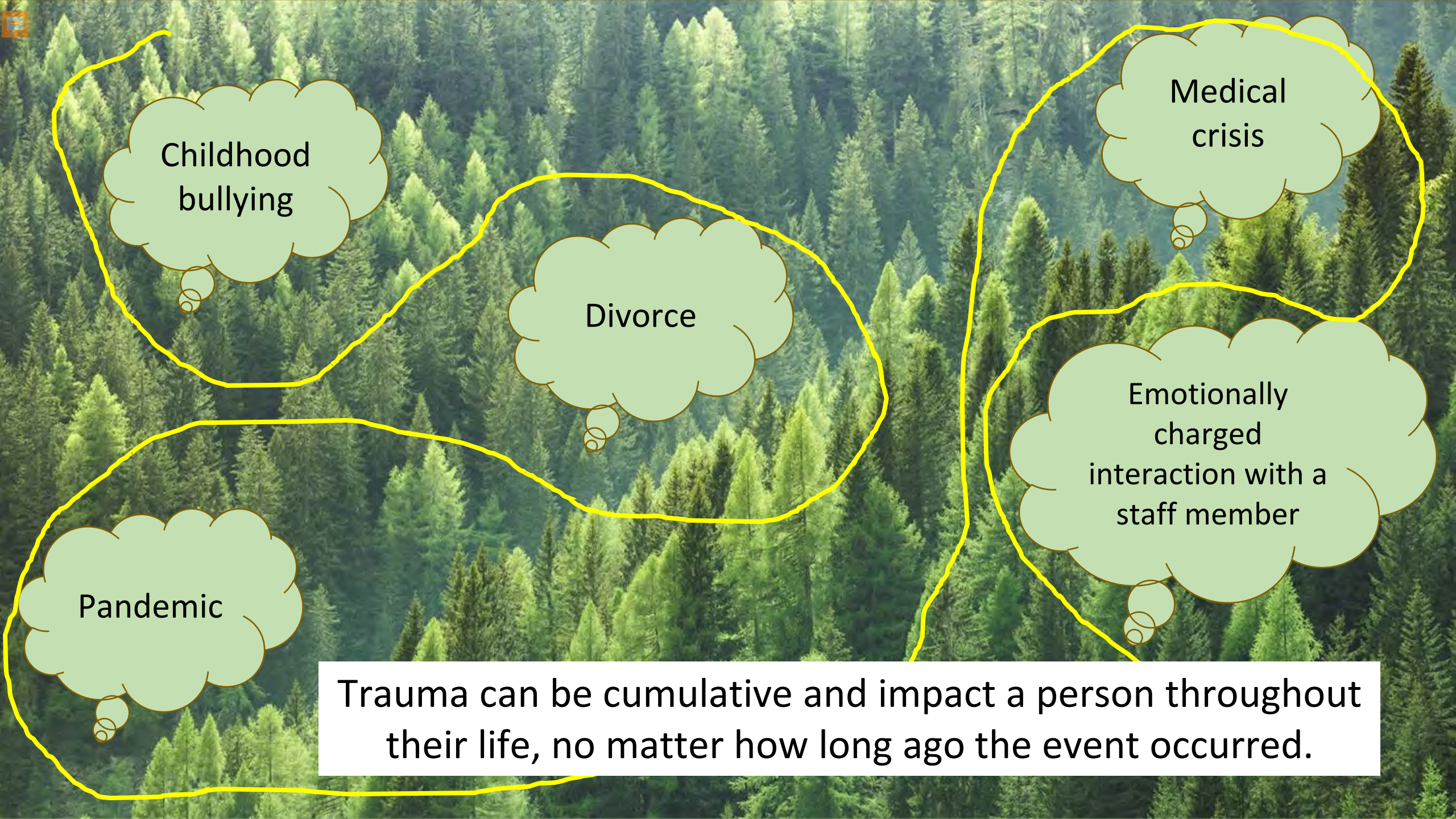
Paige Hector, LMSW, Lea Watson, MD
Lisa Lind, PhD, Allison Villegas, PA-C

Emotional and Psychological Trauma

"Result of **extraordinarily stressful events** that shatter your sense of security, making you feel **helpless** in a dangerous world. Often involve a threat to life or safety, but any situation that leaves you **feeling overwhelmed** and **isolated** can result in trauma, even if it doesn't involve physical harm. The more **frightened and helpless** you feel, the more likely you are to be traumatized."

(emphasis added)

Emotional and Psychological Trauma
https://www.helpguide.org/articles/ptsd-trauma/coping-with-emotional-and-psychological-trauma.htm



Trauma can be cumulative and impact a person throughout their life, no matter how long ago the event occurred.

Emotional Exhaustion Among Health Care Workers (HCWs)

- 40% of nurses and 23.8% of physicians plan to exit their practice in the next 2 years
- Comparison of post 9/11 combat veterans to HCWs during the pandemic shows equivalent rates of moral injury in both groups
  - Emotional exhaustion rates among HCWs were already considered alarmingly high before the pandemic

"**Emotional exhaustion** is a chronic state of physical and emotional depletion that results from excessive job demands and continuous hassles." (Psychology Wiki)

JAMA Network Open. 2022;5(9):e2232748. doi:10.1001/jamanetworkopen.2022.32748

Losses Related to Aging and Illness

- Independence – living space, driving
- Daily living skills (ADLs and IADLs)
- Finances
- Death of partner or spouse
- Loss of meaningful roles
- Health and cognition
- Nursing home “placement”

Sources of Medical Trauma

- Interactions with ‘the system’
- Communication that is too technical, too vague, too infrequent or too frequent
- Medication side effects
- Illness-related symptoms (e.g., pain, shortness of breath, racing heartbeat, GI distress, physical weakness, difficulty swallowing/choking)
- Loud noises, falls, nightmares
- IV placement, limited movement, restraints
- Exposure to sounds, lights, odors
- Private areas being seen/touched by multiple people
- Exposure to needles, blood, temperature changes
- Feeling isolated, powerless, vulnerable, depressed
- Fearing for one’s wellbeing and life
- Being in the dark
- Being treated or talked to “like a child”

Hospitalization can cause trauma

- Especially in those living with dementia
- Waiting can trigger feelings associated with neglect, abandonment
- Fragmented care
- Propensity for over-testing
- Transfer and transitions = uncertainty, discomfort, overwhelm, fear, anxiety
- Goals of care interrupted

Trauma-informed care is the adoption of principles and practices that promote a culture of safety, empowerment, and healing.

Substance Abuse and Mental Health Services Administration (SAMHSA), https://www.integration.samhsa.gov/clinical-practice/trauma

TIC is

- TIC is person-centered care
- TIC is a fundamental perspective
- TIC is an integrative framework
- TIC is a relational posture towards everyone who is involved
- TIC is a workplace culture

TIC is 'NOT'

- TIC is NOT a training on PTSD
- TIC is NOT based solely on the medical model
- TIC is NOT just a prescribed protocol or set of skills
- TIC is NOT just for residents
- TIC is NOT just for people who have PTSD

Ashley Swinson, MSW, LCSW

Fight

Flight

Freeze

Our Nervous System Reacts

We lose our access to choice and we react instead of respond

“Trauma is a psychic injury,
lodged in our nervous system,
mind, and body, lasting long past
the originating incident(s),
triggerable at any moment.”

~Dr. Gabor Mate

"Thinking about Thinking"

Higher Reasoning

Executive Function

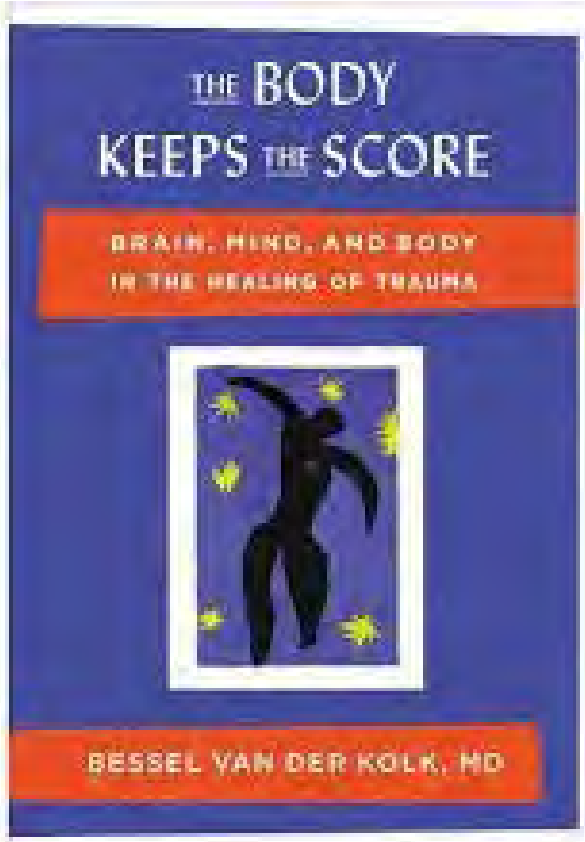
Prefrontal Cortex

9 Functions of the Prefrontal Cortex

1. Empathy
2. Insight
3. Response Flexibility
4. Emotion Regulation
5. Body Regulation
6. Morality
7. Intuition
8. Attuned Communication
9. Fear Modulation

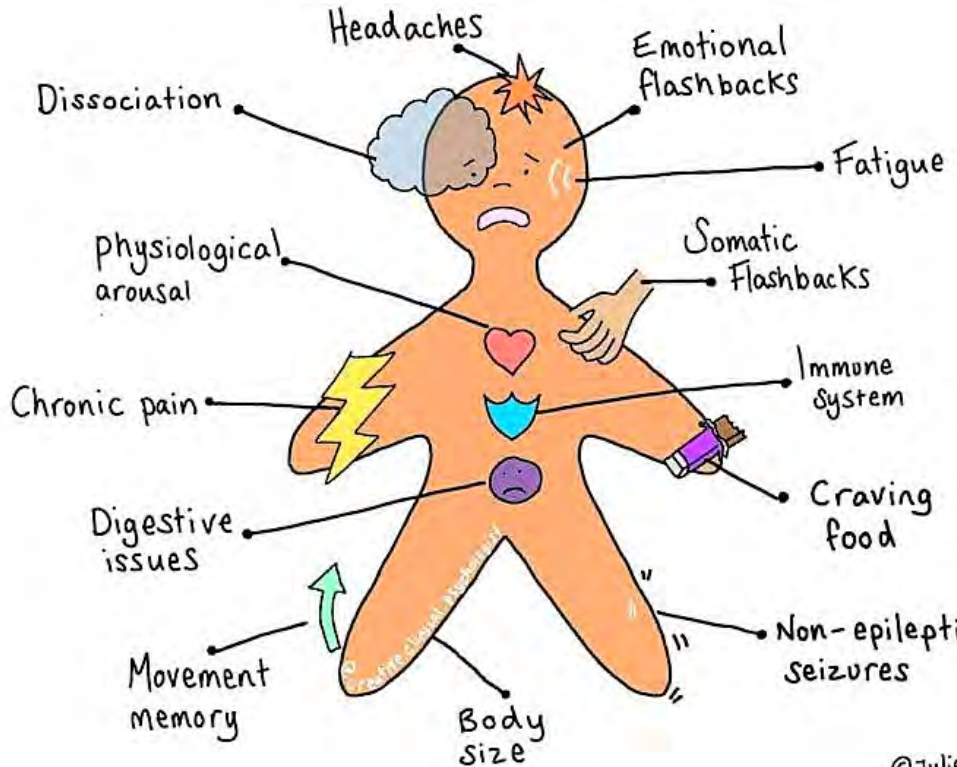
Limbic Brain

1. Fight, flight, freeze stress response
2. Thinks, "Am I safe? Do people want me?"
3. Emotions live here


THE BODY
KEEPS THE SCORE
BRAIN, MIND, AND BODY
IN THE HEALING OF TRAUMA
BESSEL VAN DER KOLK, MD

How Does the Body Keep the Score?

Sometimes when overwhelming traumatic events happen, the physiological energy can be pushed down into the body. This 'trapped trauma' energy can show in different ways...



Healthcare seeking

- Can be a proxy for getting emotional needs met
- Creates significant risk for iatrogenic harm
- Is often confounded by complex medical history
- Places high burden on the clinician

What are Triggers?

- Triggers are reminders of dangerous or frightening things (or people) that happened in the past* and the person experiences the event all over again (even if the current environment is “safe”)
- Triggers come without warning and can be ANYTHING
  - Triggers can be puzzling or disturbing for others, especially when the person associates us or something we are doing with trauma
- The person may not even associate the trigger with the event or know it’s happening
  - Watch for stiffening, combativeness, crying out, withdrawal, sudden silence, etc.

*The past can be moments ago or many years ago.

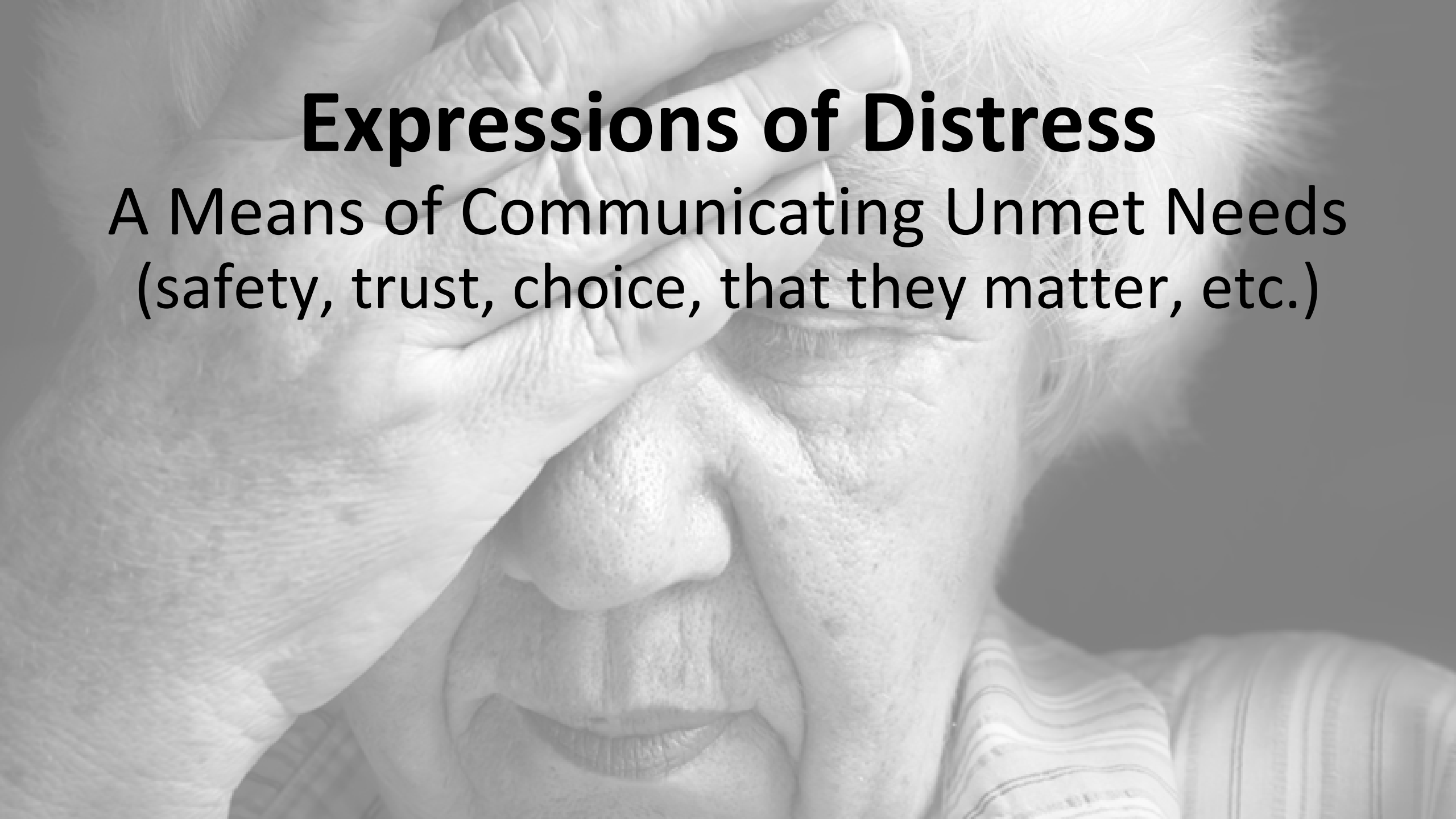
Triggers (*trauma reminders*) can be interpreted as…

“I’m not safe.”

“I can’t protect myself.”

“I’m going to die.”

Janssen S. Assessing for PTSD in Terminally Ill Patients. *The New Social Worker*. Accessed April 29, 2019



Expressions of Distress

A Means of Communicating Unmet Needs
(safety, trust, choice, that they matter, etc.)

Behavioral Expressions

- Yelling
- Arguing
- OCD and other anxiety disorders
- Isolation, withdrawal
- Protective gestures
- Aggression (verbal and physical)
- Resistance to care
- Declining care
- Self injurious coping mechanisms – drugs, alcohol, prostitution
- Unwelcome sexual expression

These may be COPING MECHANISMS that made perfect sense at the time of a traumatic experience although they may no longer suit the current circumstance.

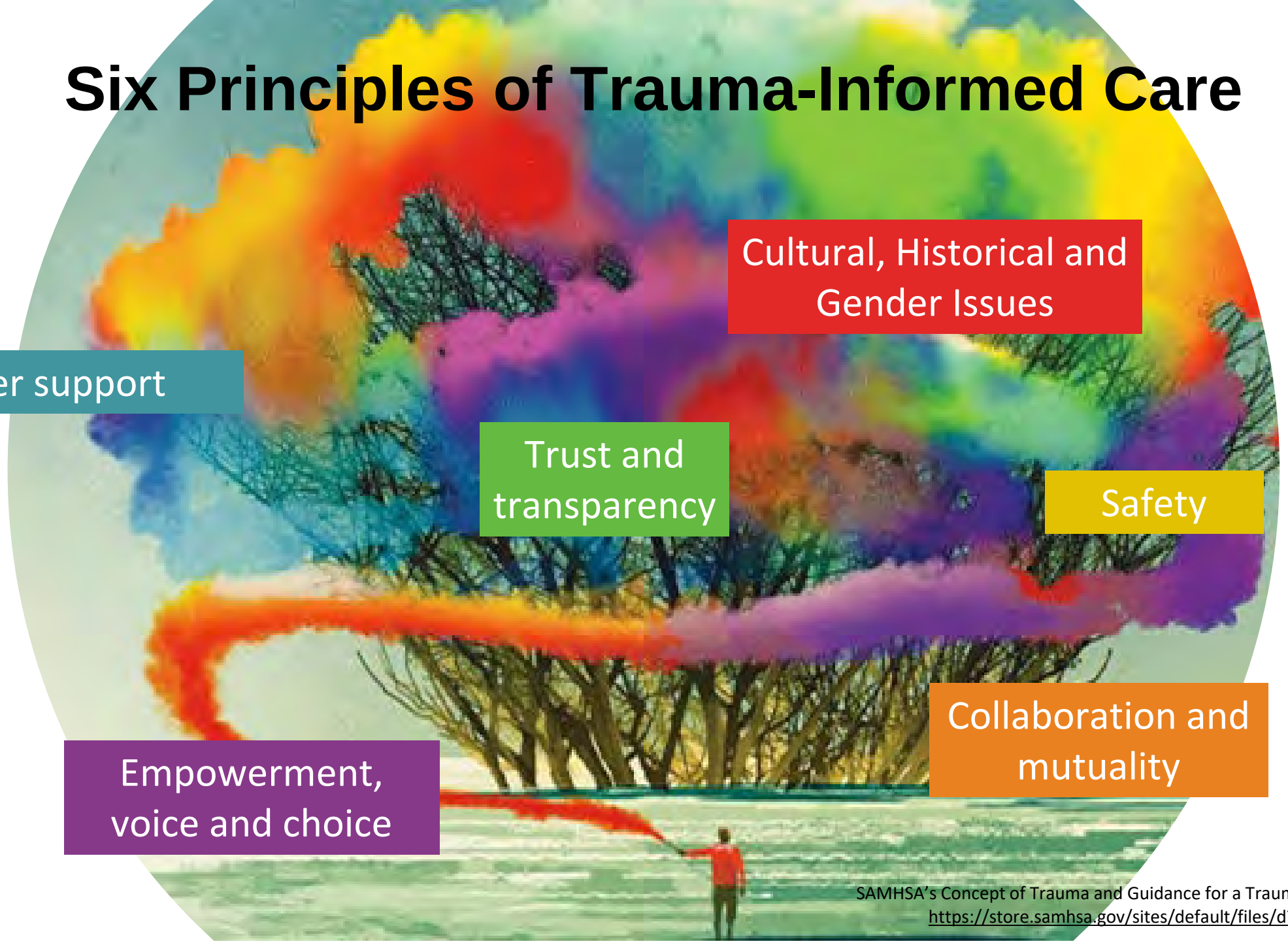
"Nor are they character faults; though they may cause us difficulty now, they began as modes of survival." (Dr. Mate)

Two Key Questions

1. How could this behavior make sense as a reaction to past trauma?
2. What might this person need to avoid reliving their trauma in the future?

(Crisis and Trauma Resource Institute)

Six Principles of Trauma-Informed Care



SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach, https://store.samhsa.gov/sites/default/files/d7/priv/sma14-4884.pdf

Safety

- **Physical safety** includes the physical plant, security measures, disaster planning, policies and procedures.

- **Social safety** refers to the ability to be a part of a group, to listen and to be heard, to be able to play a role in conflict resolution, to use one's intelligence and creativity to serve a group process without engaging in behavior or activities that destroy the integrity of the self or the group.

- **Moral safety** reflects an environment that actively defines and redefines a moral universe of integrity, responsibility, honesty, tolerance, compassion, peace, nonviolence, justice, and an abiding concern for human rights.

The Sanctuary Model: Through the Lens of Moral Safety by Sandra Bloom, https://sandrabloom.com/wp-content/uploads/2017-BLOOM-THE-SANCTUARY-MODEL-THROUGH-THE-LENS-OF-MORAL-SAFETY.pdf

Trust and Transparency

Trust – being vulnerable and sharing personal information can feel risky

- Gentle, low-key approach, no 'agenda'
- Confidentiality and privacy are key

Transparency - organizational operations and decisions are transparent

- Predictability with processes and daily activities
- Emphasis is not on "getting it right all the time" but rather how situations are handled when circumstances provoke feelings of being vulnerable or unsafe

Kezelman C, Stavropoulos P. *Talking About Trauma, Guide to Conversations and Screening for Health and Other Service Providers.* Blue Knot Foundation; 2018.

SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach, https://store.samhsa.gov/system/files/sma14-4884.pdf

Creating a trauma-informed organization is a fluid, ongoing process; it has no completion date.

(SAMHSA, 2014)

F699 Trauma-Informed Care
(Guidance issued in 2022)

“The facility must ensure that residents who are trauma survivors receive culturally competent, trauma-informed care in accordance with professional standards of practice and accounting for residents’ experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.”

F699 Trauma-Informed Care
(topics included in the Guidance to Surveyors)

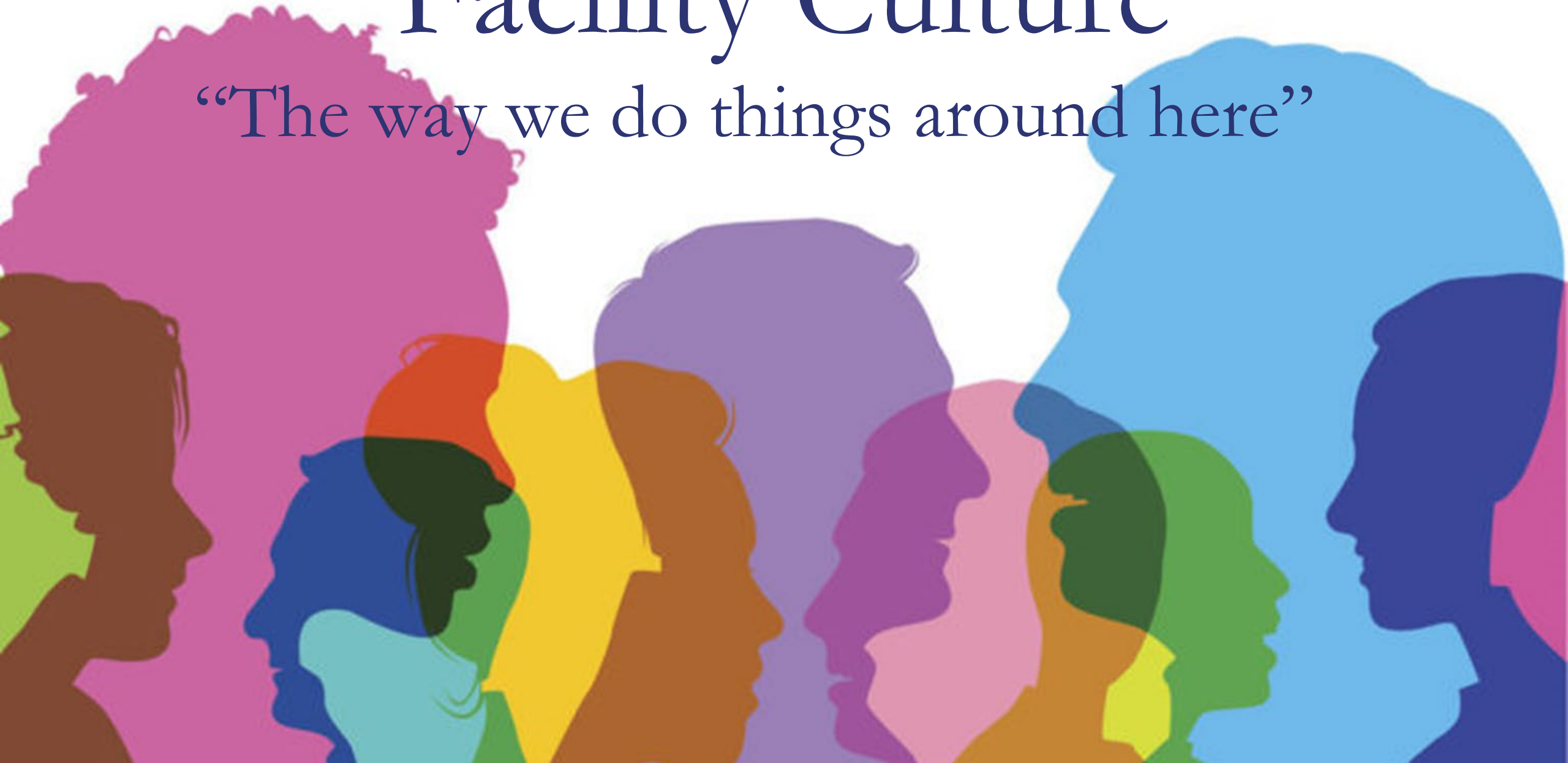
- 6 principles of trauma
- “Assessment” – CMS advises a multi-pronged approach to identifying a resident’s history of trauma
- Triggers and retraumatization
- Cultural “competency” defined by CMS
  - A “set of behaviors and attitudes held by clinicians that allows them to communicate effectively with individuals of various cultural backgrounds and to plan for and provide care that is appropriate to the culture and to the individual.”

F699 Trauma-Informed Care, cont.
(topics included in the Guidance to Surveyors)

- Care planning to minimize or eliminate the effect of the trigger on the resident
- Care planning to address cultural preferences
  - Language – verbal and written communication (e.g., forms)
  - Food preparation and choices
  - Clothing
  - Physical contact or provision of care by a member of the opposite sex
  - Cultural etiquette, e.g., eye contact
  - Activities that are culturally relevant
  - Religious or spiritual preferences throughout stay and at the end of life
- Monitoring delivery of care and services
  - Do the interventions mitigate or reduce the impact of identified triggers

Facility Culture

“The way we do things around here”



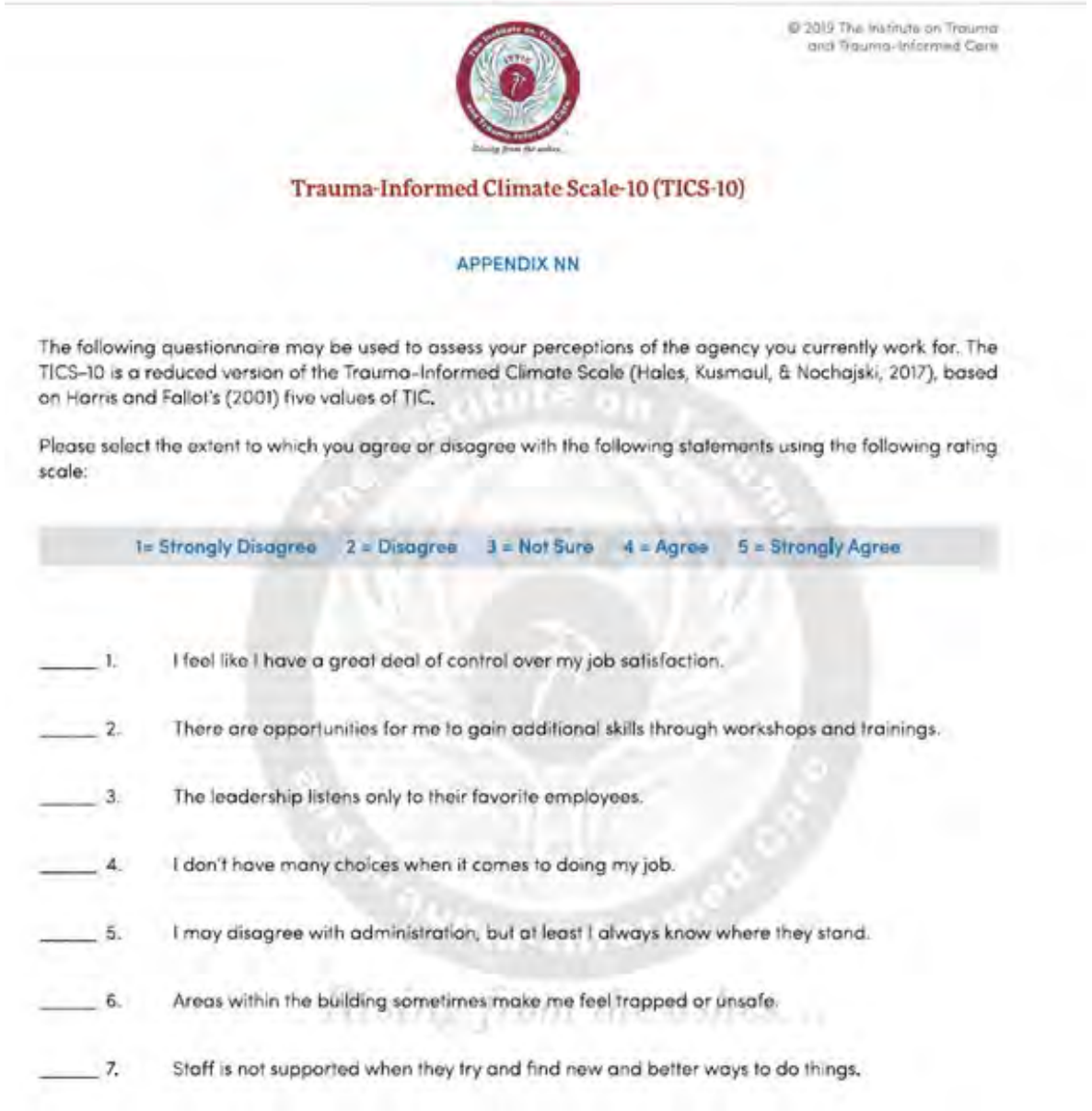
Trauma-Informed Climate Scale – 10

Assessing perceptions

Measures the extent to which employee rights, freedoms, and contributions are valued within the agency

Be clear about the intention with requesting staff to complete this questionnaire:

- How can you create a sense of safety?
- How will you uphold trust and transparency?



Trauma-Informed Climate Scale-10 (TICS-10)

APPENDIX NN

The following questionnaire may be used to assess your perceptions of the agency you currently work for. The TICS–10 is a reduced version of the Trauma-Informed Climate Scale (Hales, Kusmaul, & Nochajski, 2017), based on Harris and Fallot's (2001) five values of TIC.

Please select the extent to which you agree or disagree with the following statements using the following rating scale:

1= Strongly Disagree 2 = Disagree 3 = Not Sure 4 = Agree 5 = Strongly Agree

_____ 1. I feel like I have a great deal of control over my job satisfaction.

_____ 2. There are opportunities for me to gain additional skills through workshops and trainings.

_____ 3. The leadership listens only to their favorite employees.

_____ 4. I don't have many choices when it comes to doing my job.

_____ 5. I may disagree with administration, but at least I always know where they stand.

_____ 6. Areas within the building sometimes make me feel trapped or unsafe.

_____ 7. Staff is not supported when they try and find new and better ways to do things.

Trauma-Informed Organization Change Manual, http://socialwork.buffalo.edu/social-research/institutes-centers/institute-on-trauma-and-trauma-informed-care/Trauma-Informed-Organizational-Change-Manual0.html

SAMHSA 's Concept of Trauma and Guidance for a Trauma-Informed Approach

GOAL: Stimulate change-focused discussion

https://store.samhsa.gov/system/files/sma14-4884.pdf

SAMPLE QUESTIONS TO CONSIDER WHEN IMPLEMENTING A TRAUMA-INFORMED APPROACH

KEY PRINCIPLES					
Safety	**Trustworthiness and Transparency**	**Peer Support**	**Collaboration and Mutuality**	**Empowerment, Voice, and Choice**	**Cultural, Historical, and Gender Issues**

10 IMPLEMENTATION DOMAINS	
Governance and Leadership	• How does agency leadership communicate its support and guidance for implementing a trauma-informed approach? • How do the agency's mission statement and/or written policies and procedures include a commitment to providing trauma-informed services and supports? • How do leadership and governance structures demonstrate support for the voice and participation of people using their services who have trauma histories?
Policy	• How do the agency's written policies and procedures include a focus on trauma and issues of safety and confidentiality? • How do the agency's written policies and procedures recognize the pervasiveness of trauma in the lives of people using services, and express a commitment to reducing re-traumatization and promoting well-being and recovery? • How do the agency's staffing policies demonstrate a commitment to staff training on providing services and supports that are culturally relevant and trauma-informed as part of staff orientation and in-service training? • How do human resources policies attend to the impact of working with people who have experienced trauma? • What policies and procedures are in place for including trauma survivors/people receiving services and peer supports in meaningful and significant roles in agency planning, governance, policy-making, services, and evaluation?

If a resident discloses a traumatic event…

- **DO** respond with validating language. For example, *"I'm really glad you told me – this will help us take the best possible care of you."*
- **DON'T** try to investigate or ask for details right away – allow them to talk.
  - If they are getting upset or going into disturbing material, gently close the conversation and follow up with a clinical referral right away
- **DO** document any reported traumas and inform the clinical team. Include all known or suspected trauma triggers associated with the disclosed experience. This helps the team avoid those triggers.
- **DO** let the resident know that you will need to let a few key staff members know about "what happened" so that staff can avoid doing things that trigger difficult memories.
- **Do** refer to the disclosed experience in general terms. Avoid naming "what happened" unless the resident defines it in a given way.
- **DO** let the resident know that they won't need to talk about "what happened" if they don't want to -- but they may find that they do want to talk about it as time goes on. Let the resident know someone can be available for them to talk to if and when they are ready, including right away. **Follow up.**
- **DO** uphold the resident's privacy, even if the information is unusual.
- **DO** assess current safety. Was it a recent event or far in the past?

Barbara L. Ganzel PhD, LMSW
Director of Community Program Development
Clinical Associates/Pathways

Primary Care PTSD Screen for DSM-5 (PC-PTSD-5)

In the past month, have you …

1. had nightmares about the event(s) or thought about the event(s) when you did not want to?	YES	NO
2. tried hard not to think about the event(s) or went out of your way to avoid situations that reminded you of the event(s)?	YES	NO
3. been constantly on guard, watchful, or easily startled?	YES	NO
4. felt numb or detached from people, activities, or your surroundings?	YES	NO
5. felt guilty or unable to stop blaming yourself of others for the event(s) or any problems the events may have caused?	YES	NO
Total score is sum of "YES" responses in items 1-5.	**TOTAL SCORE**	

https://www.ptsd.va.gov/professional/assessment/documents/pc-ptsd5-screen.pdf

Indirect Screening

- We can always be engaged in indirect screening.
  - Especially for residents with cognitive impairment and for residents who do not wish to engage in direct screening
- During intake and day-to-day care, pay attention to comments/actions that could indicate symptoms of traumatic stress.
- After sufficient trust has been established, ask permission to discuss observations.
- If discussion indicates presence of symptoms of traumatic stress, ask if they want to speak to someone. If so, make a referral.
- In the plan of care, identify all potential trauma symptoms and triggers, as well as interventions.

Barbara L. Ganzel PhD, LMSW
Director of Community Program Development
Clinical Associates/Pathways

Universal Precautions Model

Gloving and handwashing no matter the hazard level

Assume all individuals have a history of trauma and glove up metaphorically to reduce possibility of triggering or re-traumatizing others.

Trauma-Informed Organization Change Manual, http://socialwork.buffalo.edu/social-research/institutes-centers/institute-on-trauma-and-trauma-informed-care/Trauma-Informed-Organizational-Change-

Pause.

Listen.

Mind your tone and body language.

Don’t react, *respond*.

Trauma-Informed

CARE

cmda

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

Heart Failure in Post-Acute Care Patients: A Practical Approach

Nicole Orr, MD, FACC
President, Post-Acute Cardiology Care
Assistant Professor of Medicine,
Division of Cardiology
Tufts Medical Center

Tufts Medical Center

PACC
Post-Acute Cardiology Care

Objectives

- Overview of heart failure in PAC patients
- Discuss the differential and assessment of dyspnea among patients in post acute or long-term care.
- Highlight select recent relevant updates to the management of HFrEF and HFpEF as they relate to patients in PAC
- Introduce practical strategies for treating medically complex heart failure patients

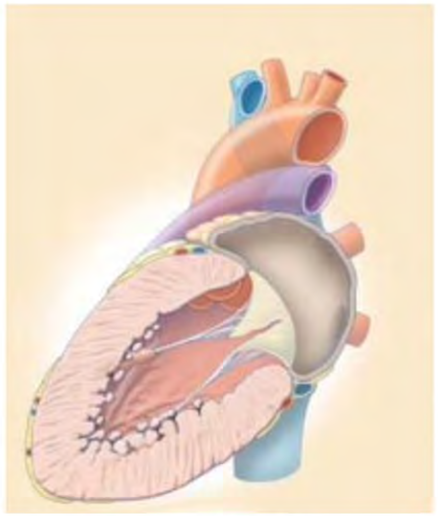
PACC - Background

- Independent cardiac consulting practice for SNFs with expressed focus on improving care for high risk cardiac patients and developing CHF programs
- Source of referrals: MDs, APRNs, rehabilitation staff, unit supervisors, DON, admissions, discharging hospitalists, hospital case management/social work
- Weekly bedside medical rounds
- Program development, In-servicing staff
- Facility Level and Corporate consultation, Hospital SNF network

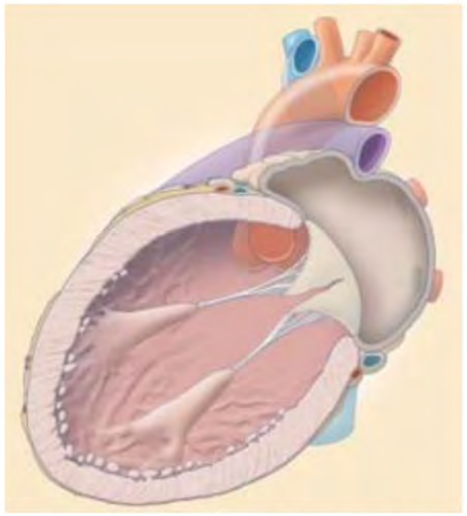
PACC
Post-Acute Cardiology Care
LLC

Defining of Heart Failure

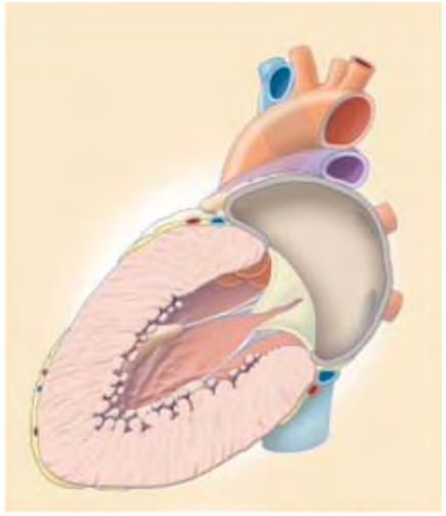
A clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood



Normal Heart



HF with Reduced Ejection Fraction (HF*r*EF)



HF with Preserved Ejection Fraction (HF*p*EF)

Jesus M, Brozena SA. New Engl J Med. 2003; 348:2007-2018
2013 ACCF/AHA Guideline for the Management of Heart Failure. Yancy CW, et al. Circulation. 2013;128:e240 e327.

Latest of Many……

JOURNAL OF CARDIAC FAILURE

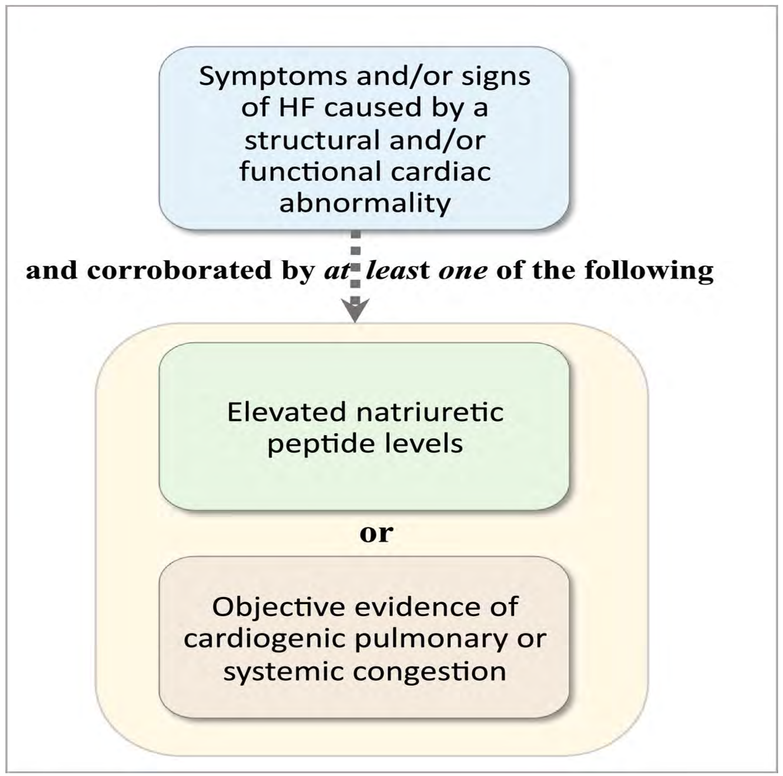
CONSENSUS STATEMENT | ARTICLES IN PRESS

Universal Definition and Classification of Heart Failure

A Report of the Heart Failure Society of America, Heart Failure Association of the European Society of Cardiology, Japanese Heart Failure Society and Writing Committee of the Universal Definition of Heart Failure

Biykem Bozkurt, MD, PhD, Chair • Andrew JS Coats, DM, DSC • Hiroyuki Tsutsui, MD, Co-Chair • ...
Clyde Yancy, MD, MSc • Jian Zhang, MD, PhD • Shelley Zieroth, MD • Show all authors

Published: March 01, 2021 • DOI: https://doi.org/10.1016/j.cardfail.2021.01.022



HF with reduced EF (HFrEF):

- HF with LVEF ≤ 40%

HF with mildly reduced EF (HFmrEF):

- HF with LVEF 41-49%

HF with preserved EF (HFpEF):

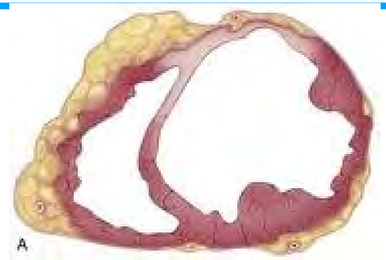
- HF with LVEF ≥ 50%

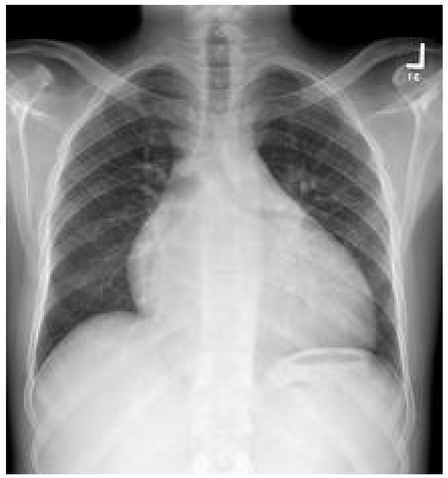
HF with improved EF (HFimpEF):

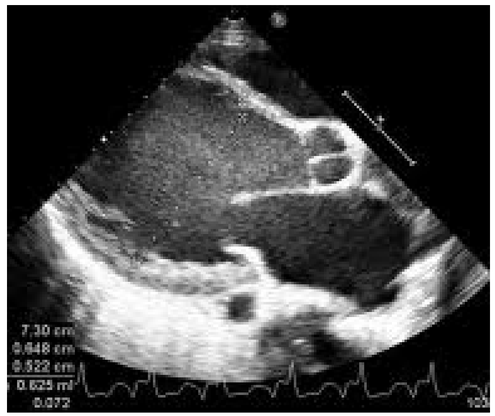
- HF with a baseline LVEF ≤ 40%, a ≥ 10 point increase increase from baseline LVEF, and a second measurement of LVEF > 40%

HF - A Clinical Syndrome of Insufficient Cardiac Output

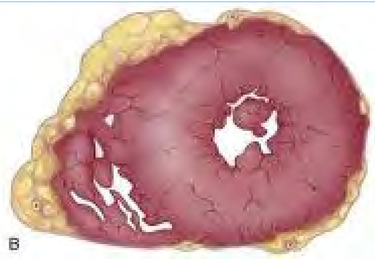
- 60 YO male with long-standing HF
- 3 weeks of worsening SOB
- BP 95/40

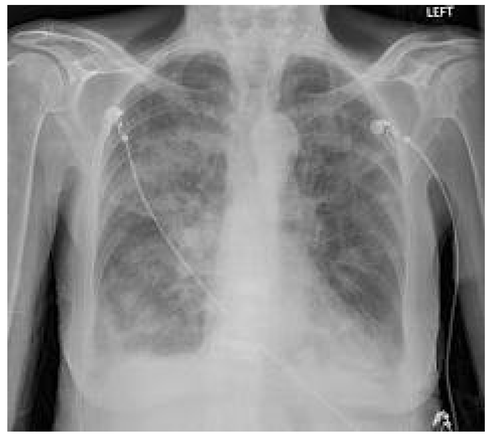


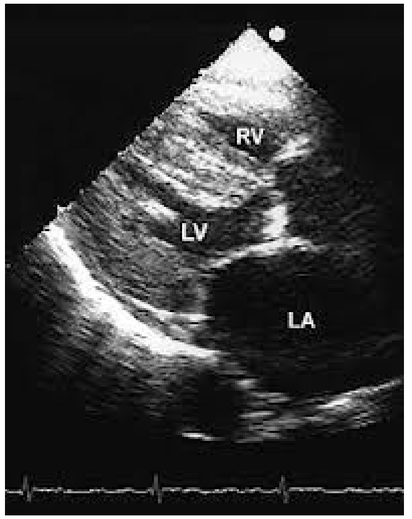




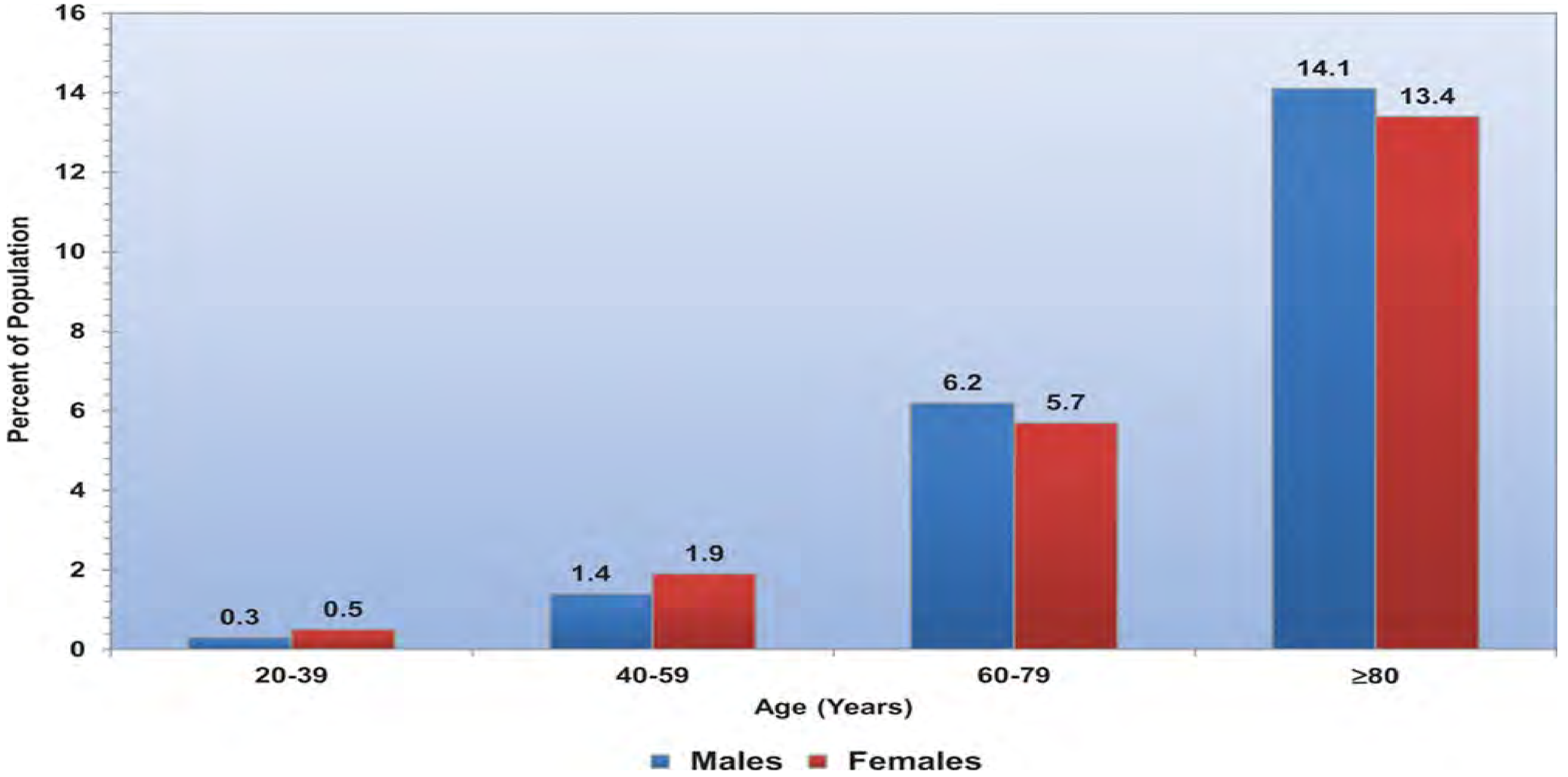
- 80 yo female with long-standing hypertension
- 1 hours of sudden onset of SOB
- BP 185/120







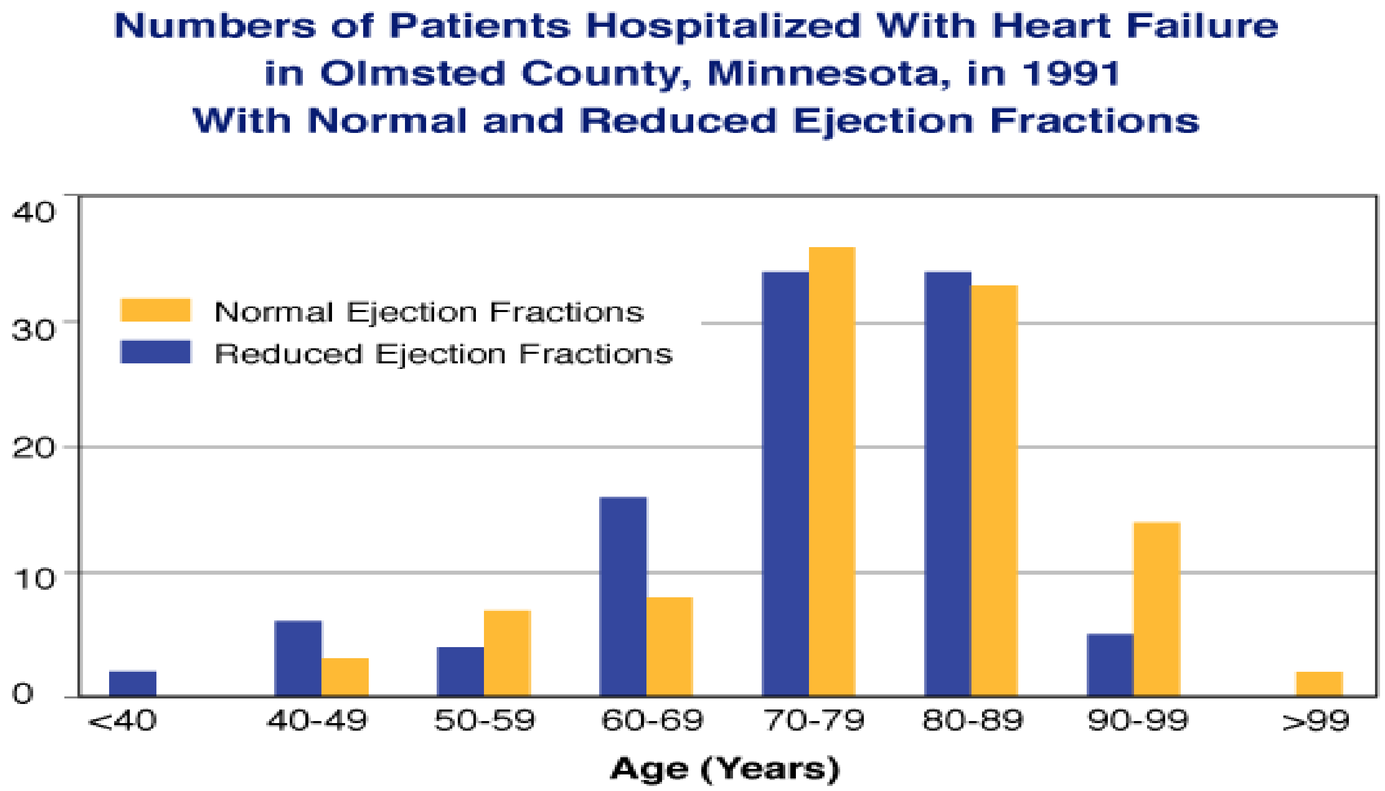
Increasing Prevalence of HF with Aging

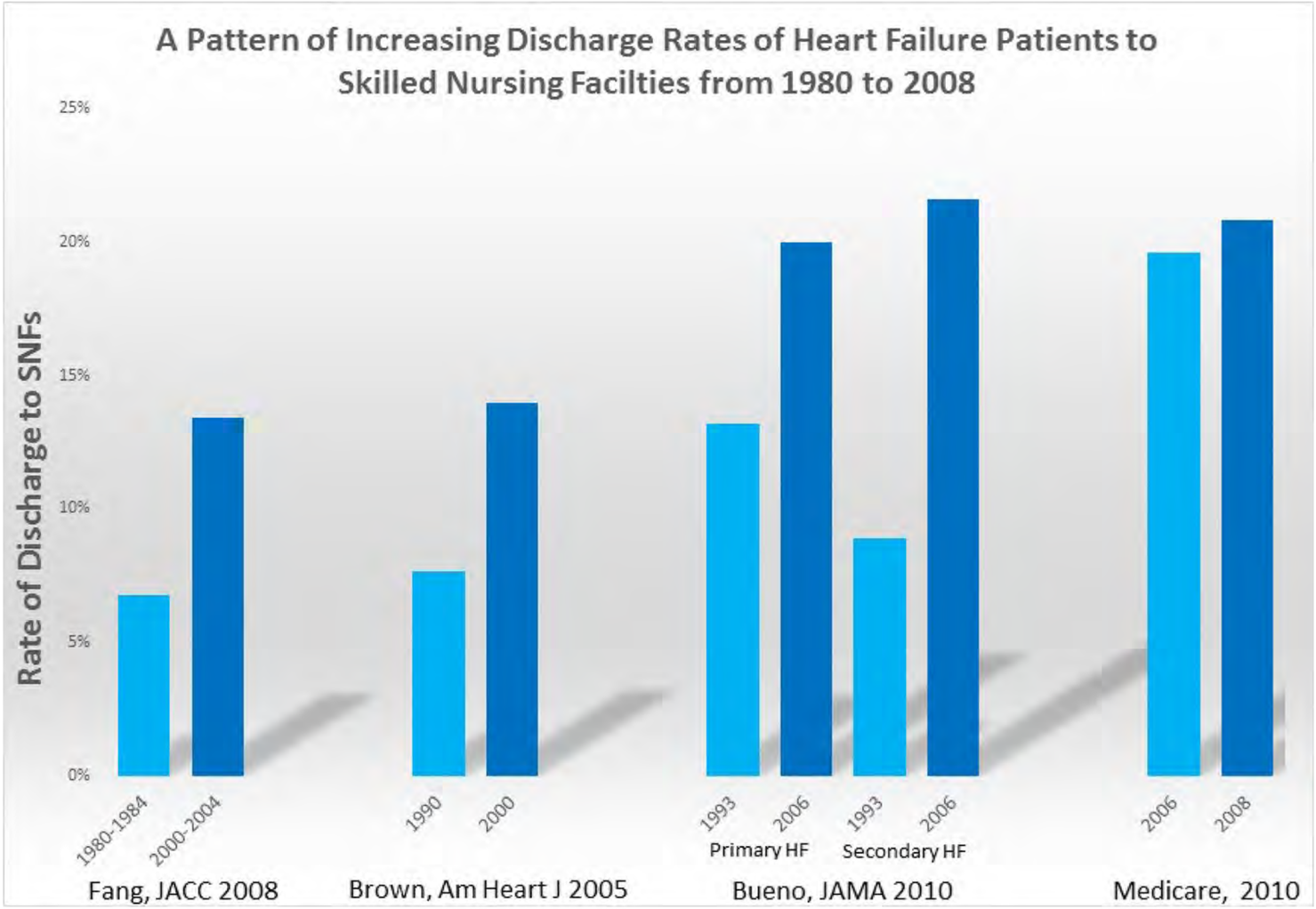


Heart Disease and Stroke Statistics—2018 Update: A Report From the American Heart Association, Volume: 137, Issue: 12, Pages: e67-e492, DOI: (10.1161/CIR.0000000000000558)

Heart Failure and Aging

Older patients show a particular propensity for developing HF with preserved LV systolic function (HFNEF) and the proportion with HFNEF increases with advancing age.





Orr, Forman, DeMatteis, Gambassi. Current Geriatrics Report 2015

Variable Rate of Discharge to SNFs Among US Hospitals; Higher Rates Not Associated with Lower Readmission

Figure 5.3 Distribution of Rate of Discharge to SNFs, 2008

Medicare FFS beneficiaries aged ≥65 years

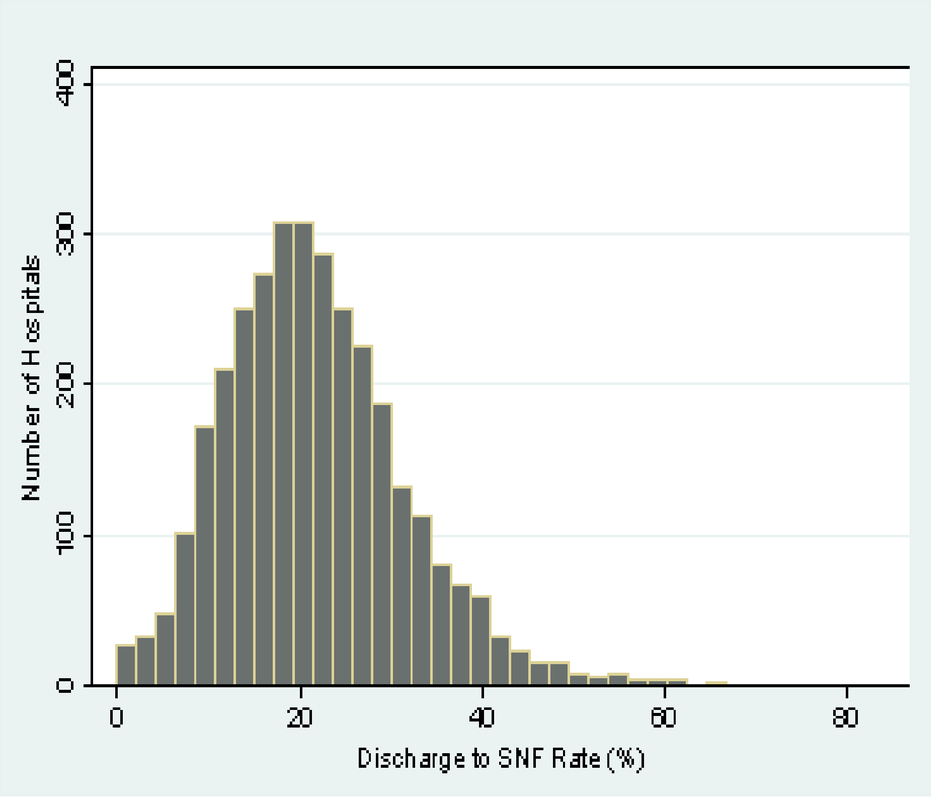
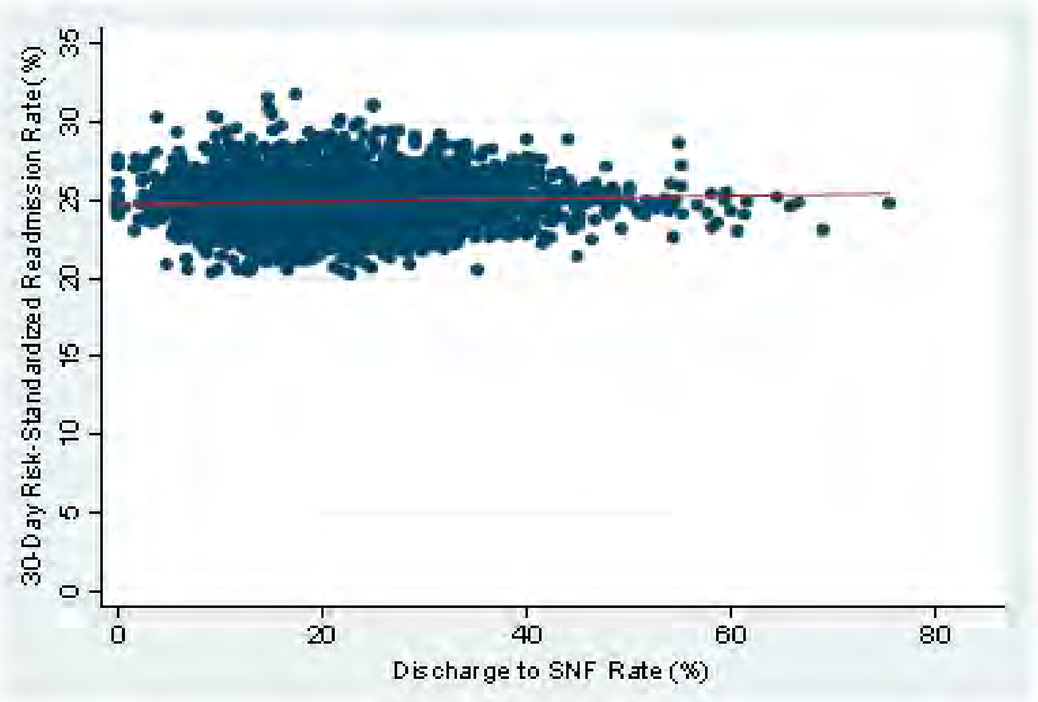


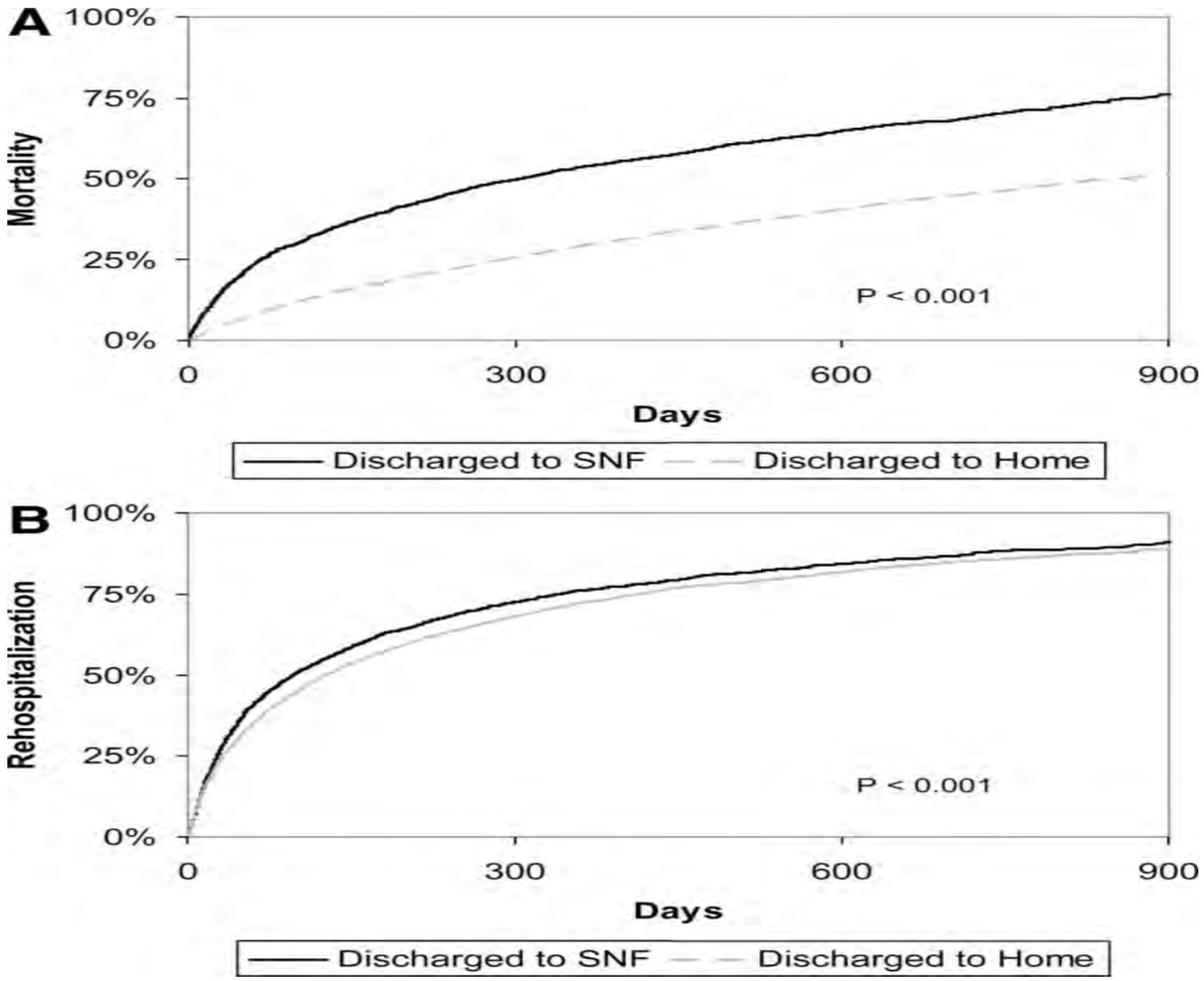
Figure 5.5 Scatterplot of Hospital RSRRs by Rate of Discharge to SNFs

Medicare FFS beneficiaries aged ≥65 years



CMS: Medicare Hospital Quality Chart Book, 2010

Discharge to a Skilled Nursing Facility and Subsequent Clinical Outcomes Among Older Patients Hospitalized for Heart Failure



30-day mortality 14.4% vs. 4.1%;
1-year mortality 53.5% vs. 29.1%,

30- day rehospitalization: 27% vs. 23.5%, P<0.0001

Allen, et al, Circ Heart Fail. 2011

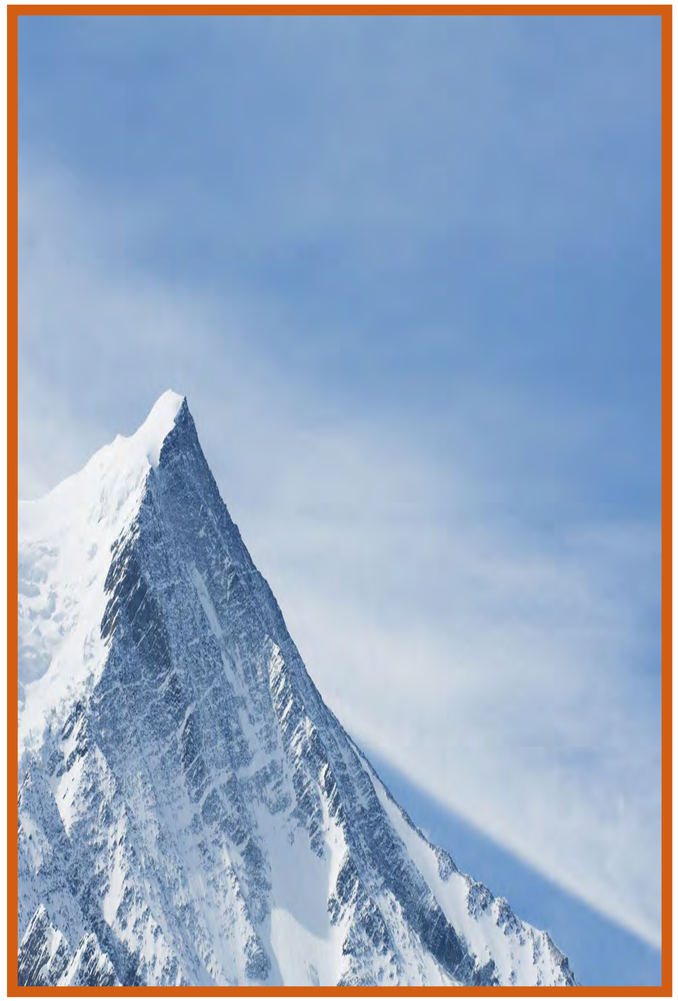
Heart Failure in Post-Acute Care - Management Framework

GOALS:

- Improve or maintain medical stability
- Optimize function
- Prepare for community D/C if possible
- Prevent hospital readmission

Diagnosis often made pre-SNF admission

- Extensive diagnostic work up not necessary



Patient-Centered Heart Failure Care

Tufts Medical Center

Consider the type of SNF HF patient and their goals of care

“Rehabilitation Group”

“Uncertain Prognosis Group”

“Long Term Care Residents”

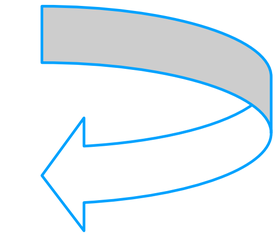
Jurgens et al, Circ Heart Fail. 2015;8:655–687

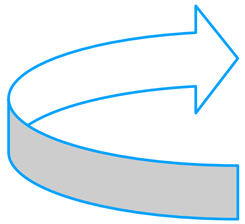
PACC
Post-Acute Cardiology Care

Recognizing Heart Failure Symptoms in the Elderly

Tufts Medical Center

- Fatigue
- Exercise intolerance
- Dyspnea
- Nocturnal cough
- Altered mental status/worsening cognition
- Lethargy
- Restlessness
- Worsening appetite
- Edema





Anorexia: polypharmacy, depression, palatability, dietary, restrictions

Fatigue: depression, frailty, aging, reduction in activities to avoid symptoms, anemia, hypothyroidism

Exercise intolerance: chronotropic incompetence, PVD, deconditioning

Dyspnea: chronic pulm disease, PNA, pulmonary HTN, changes in vascular tone, lung capacity, HTN

Altered mental status: psychosocial stressors, medications, infections

Edema: venous tone, decreased skin turgor, prolonged sedentary states, idiopathic, medications, renal or hepatic disease

*ESC 2016: "*Signs *and symptoms of HF are often non-specific and do not discriminate well between HF and other clinical conditions"*

Ponikowski P, et al. Eur J Heart Fail. 2016;18:891-975.

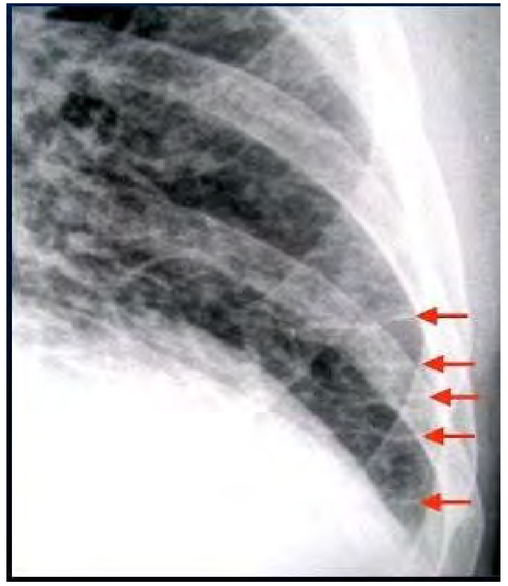
PACC Post-Acute Cardiology Care

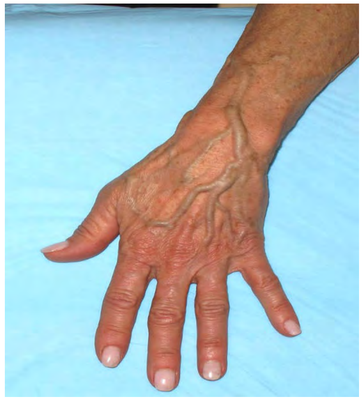
HF Evaluation - Evidence of Volume Overload

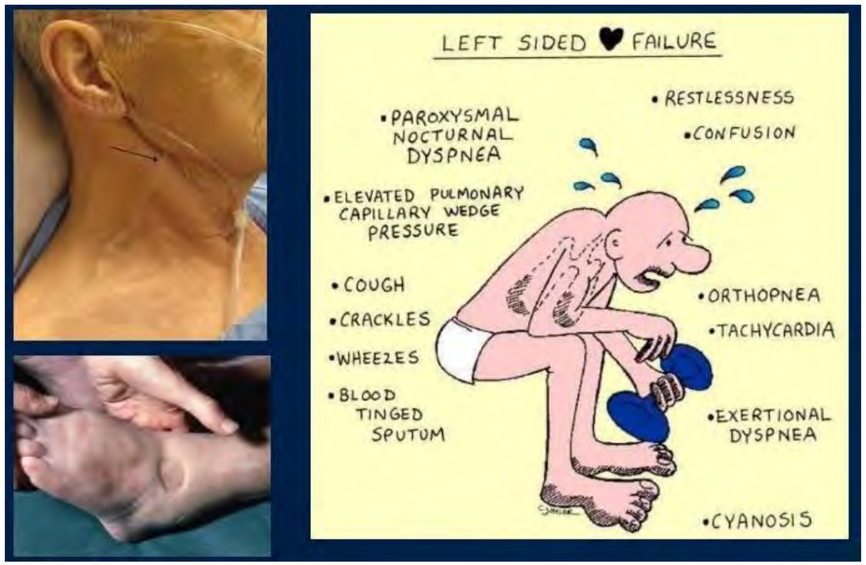
Framingham Diagnostic Criteria for Heart Failure*

Major criteria	Minor criteria
Acute pulmonary edema	Ankle edema
Cardiomegaly	Dyspnea on exertion
Hepatojugular reflex	Hepatomegaly
Neck vein distension	Nocturnal cough
Paroxysmal nocturnal dyspnea or orthopnea	Pleural effusion
Rales	Tachycardia (> 120 beats per minute)
Third heart sound gallop	

*—Heart failure is diagnosed when two major criteria or one major and two minor criteria are met.







Bendopnea

Weight Gain

Management Overview

1. Is the patient stable?
2. Cardinal signs of heart failure?

YES!

1. Reduce Congestion
2. WHY?
3. Obtain/Determine LVEF
4. Patient-centered GDMT

- ➢ Improve exertional tolerance/function
- ➢ Return to desired place of dwelling
- ➢ Avoid hospital admission
- ➢ Prolong survival

NO!

- History of HF
- WHAT'S HAPPENING IN REHAB?
- Risk factors for HF (HFpEF Score)?
- Comorbidities?
- Treatment strategy aligned with GOC

Evaluation - Criteria for Hospitalization (if not DNH)

Tufts Medical Center

HEMODYNAMICALLY UNSTABLE

- Tachycardia, >120 bpm
- Hypotension, SBP<80mmHg
- Tachypnea/hypoxia
- Cardiogenic shock
- Altered mentation

MANAGEMENT FAILURE

- Persistent dyspnea
- Edema or weight gain
- Worsening CKD

Reduce Congestion

- Initial IV dose = 2.5 x or more maintenance
  e.g., 40 mg oral Furosemide = IV bolus of 40-100 mg
- Urine output should be 3-5 liters per day

If not responding:

- Double daily dose
- Triple daily dose
- BID dosing
- Switch to an alternative loop diuretic
- *Furosemide –variable bioavailability
- Add potentiating diuretic
- Reduce exogenous sodium
- Address symptoms according to GOC

Helpful Diuretic References

Conversion:
Furosemide 40mg = Furosemide 20mg IV
= Torsemide 20mg
= Bumetanide 1 mg

Distal tubule:
Metolazone 2.5-5 mg daily
Chlorothiazide 500-1000 mg daily
Hydrochlorothiazide 25-50 mg daily

Know the Risk Factors for Readmission

Tufts Medical Center

Chronic Kidney Disease/ Worsening Renal Function*

Hypotension*

Diabetes

Polypharmacy (≥7 Medications)

Multiple Co-morbidities

Multiple Prior Admissions

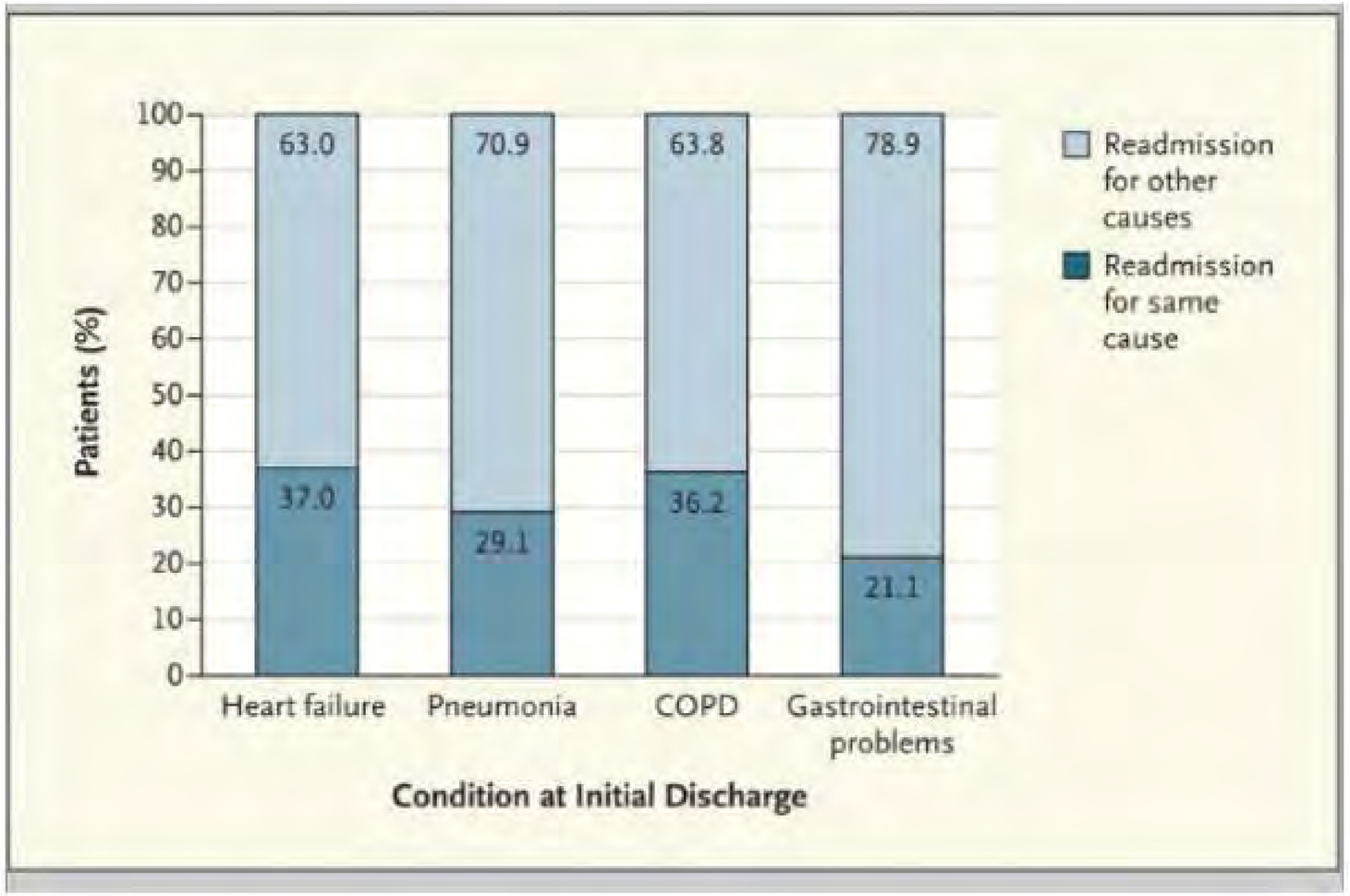
COPD

Persistent NYHA III/IV Symptoms

** Increased mortality risk*

PACC
Post-Acute Cardiology Care

Readmission Diagnosis Often Differs from Index Admission Diagnosis



Krumholz NEJM 2013
Post-Hospital Syndrome — An Acquired, Transient Condition of Generalized Risk

General Management Algorithm

1. Is the patient stable?
2. Cardinal signs of heart failure?

YES!

NO!

1. Reduce Congestion
2. CAUSE OF DECOMPENSATION
3. Obtain/Determine LVEF
4. Patient-centered GDMT for HFrEF

- ➢ Improve exertional tolerance/function
- ➢ Return to desired place of dwelling
- ➢ Avoid hospital admission
- ➢ Prolong survival

- History of HF
- WHAT'S HAPPENING IN REHAB?
- Risk factors for HF (HFpEF Score)?
- Comorbidities?
- Treatment strategy aligned with GOC

Post-Acute Cardiology Care experience 2014-present

Discern the Cause of Decompensation - New Admissions and Decompensation

- Noncompliance
- Inadequate pre-treatment
  *before/during hospital admission
- Hypertension
- Iatrogenic volume overload
- NSAIDS
- Arrythmia

- Infection
- Addition or increase of negative inotropes (beta blockade/CCB)
- Ischemia
- Thyroid dysfunction
- Anemia

General Management Algorithm

1. Is the patient stable?
2. Cardinal signs of heart failure?

YES!

1. Reduce Congestion
2. WHY?
3. Obtain/Determine LVEF
4. Patient-centered GDMT for HFrEF

- ➢ Improve exertional tolerance/function
- ➢ Return to desired place of dwelling
- ➢ Avoid hospital admission
- ➢ Prolong survival

NO!

- History of HF
- WHAT'S HAPPENING IN REHAB?
- Risk factors for HF (HFpEF Score)?
- Comorbidities?
- Treatment strategy aligned with GOC

Match SNF Based Pharmacologic Therapy to HF Phenotype

- When appropriate, patients should be treated with guideline directed medical therapies, if tolerated and aligned with GOC

- Focused updates include Class I indications for newer agents (ARNIs and SGLT2 inhibitors)

- Know the indications, pharmacology, and side effects on these newer agents as they apply to the geriatric patient admitted post initiation of SNF level care

Match SNF Based Pharmacologic Therapy to HF Phenotype

Recommendations for treatment of patients with heart failure with preserved ejection fraction and heart failure with mid-range ejection fraction

Recommendations	Class[a]	Level[b]	Ref[c]
It is recommended to screen patients with HFpEF or HFmrEF for both cardiovascular and non-cardiovascular comorbidities, which, if present, should be treated provided safe and effective interventions exist to improve symptoms, well-being and/or prognosis.	I	C	
Diuretics are recommended in congested patients with HFpEF or HFmrEF in order to alleviate symptoms and signs.	I	B	178, 179

HFmrEF = heart failure with mid-range ejection fraction; HFpEF = heart failure with preserved ejection fraction.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting recommendations.

AT RISK FOR HEART FAILURE

HEART FAILURE

STAGE A
At high risk for HF but without structural heart disease or symptoms of HF

e.g., Patients with:
- HTN
- Atherosclerotic disease
- DM
- Obesity
- Metabolic syndrome

OR

Patients
- Using cardiotoxins
- With family history of cardiomyopathy

THERAPY

Goals
- Heart healthy lifestyle
- Prevent vascular, coronary disease
- Prevent LV structural abnormalities

Drugs
- ACEI or ARB in appropriate patients for vascular disease or DM
- Statins as appropriate

Structural heart disease

STAGE B
Structural heart disease but without signs or symptoms of HF

e.g., Patients with:
- Previous MI
- LV remodeling including LV Hand low EF
- Asymptomatic valvular disease

Development of symptoms of HF

THERAPY

Goals
- Prevent HF symptoms
- Prevent further cardiac remodeling

Drugs
- ACEI or ARB as appropriate
- Beta blockers as appropriate

In selected patients
- ICD
- Revascularization or valvular surgery as appropriate

STAGE C
Structural heart disease with prior or current symptoms of HF

e.g., Patients with:
- Known structural heart disease and
- HF signs and symptoms

HF*p*EF

THERAPY

Goals
- Control symptoms
- Improve HRQOL
- Patient education
- Prevent hospitalization
- Prevent mortality

Strategies
- Identification of comorbidities

Treatment
- Diuresis to relieve symptoms of congestion
- Follow guideline driven indications for comorbidities, e.g., HTN, AF, CAD, DM
- Revascularization or valvular surgery as appropriate

HF*r*EF

THERAPY

Goals
- Control symptoms
- Improve HRQOL
- Patient education
- Prevent hospitalization
- Prevent mortality

Drugs for routine use
- Diuretics for fluid retention
- ACEI or ARB
- ARNI
- Beta blockers
- Aldosterone antagonists

Drugs for use in selected patients
- Hydralazine/isosorbide dinitrate
- ACEI and ARB
- Ivabradine
- Digoxin

Inselected patients
- CRT
- ICD
- Revascularization or valvular surgery as appropriate

Refractory symptoms of HF at rest, despite GDMT

STAGE D
Refractory HF

e.g., Patients with:
- Marked HF symptoms at rest
- Recurrent hospitalizations despite GDMT

THERAPY

Goals
- Control symptoms
- Improve HRQOL
- Reduce hospital readmissions
- Establish patient's end-of-life goals

Options
- Advanced care measures
- Heart transplant
- Chronic inotropes
- Temporary or permanent MCS
- Experimental surgery or drugs
- Palliative care and hospice
- ICD deactivation

Stages in the development of HF and recommended therapy by stage. ACEI indicates angiotensin-converting enzyme inhibitor; AF, atrial fibrillation; ARB, angiotensin-receptor blocker; CAD, coronary artery disease; CRT, cardiac resynchronization therapy; DM, diabetes mellitus; EF, ejection fraction; GDMT, guideline-directed medical therapy; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; HRQOL, health-related quality of life; HTN, hypertension; ICD, implantable cardioverter-defibrillator; LV, left ventricular; LVH, left ventricular hypertrophy; MCS, mechanical circulatory support; and MI, myocardial infarction. Adapted from Hunt et al.[3]

Yancy CW et al., ACCF/AHA Guideline for the Management of Heart Failure, *Circulation*, 10/15/13.
Yancy CW et al., 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure, Circulation, 08/08/2017.

Sacubitril/Valsartan

Combination of a neprilysin inhibitor and an angiotensin II receptor blocker

Increases effects of endogenous compensatory peptides
↑Vasodilation
↑ Natriuretic and diuretic effects
↓Proliferation
↓Hypertrophy
↓ SNS outflow/sympathetic tone
↓ Aldosterone secretion
↓ Detrimental effects of vascular remodelling

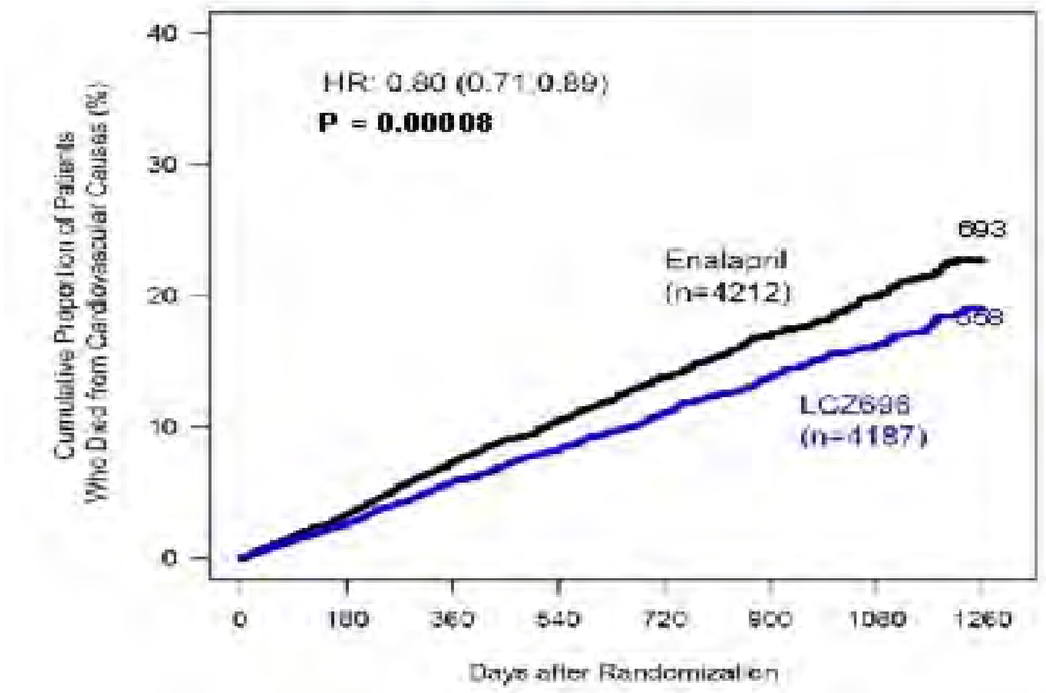
Suppresses RAAS-mediated effects
↓ Vasoconstriction
↓ Sodium and water retention
↓ Ventricular hypertrophy/remodeling
↓ Aldosterone secretion
↓ Cardiac fibrosis
↓ Sympathetic tone
↓ Systemic vascular resistance

1. Levin ER et al. N Engl J Med. 1998;339(5):321-328; 2. Nathisuwan S, Talbert RL. Pharmacotherapy. 2002;22(1):27-42; 3. Schrier RW, Abraham WT. N Engl J Med. 2009;341(8):577-585; 4. Langenickel TH, Dole WP. Drug Discov Today: Ther Strateg. 2012;9(4):e131-139.

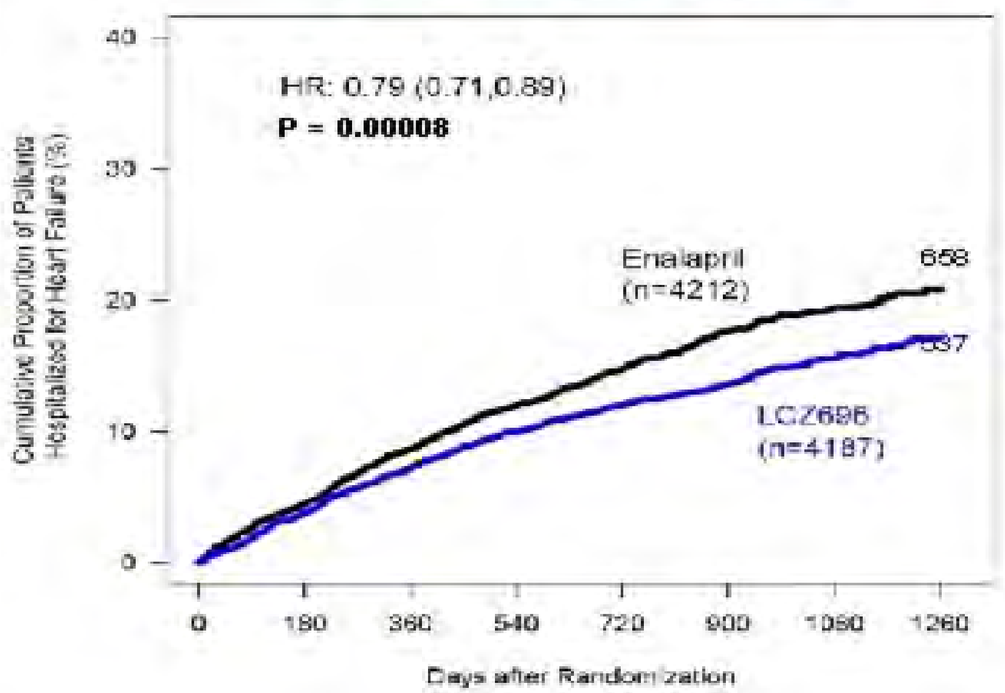
PARADIGM-HF: CV Death or HF Hospitalization

Primary composite outcome
HR: 0.80 (0.73, 0.87) p = 0.0000004

Death from CV causes
20% risk reduction



HF hospitalization
21% risk reduction

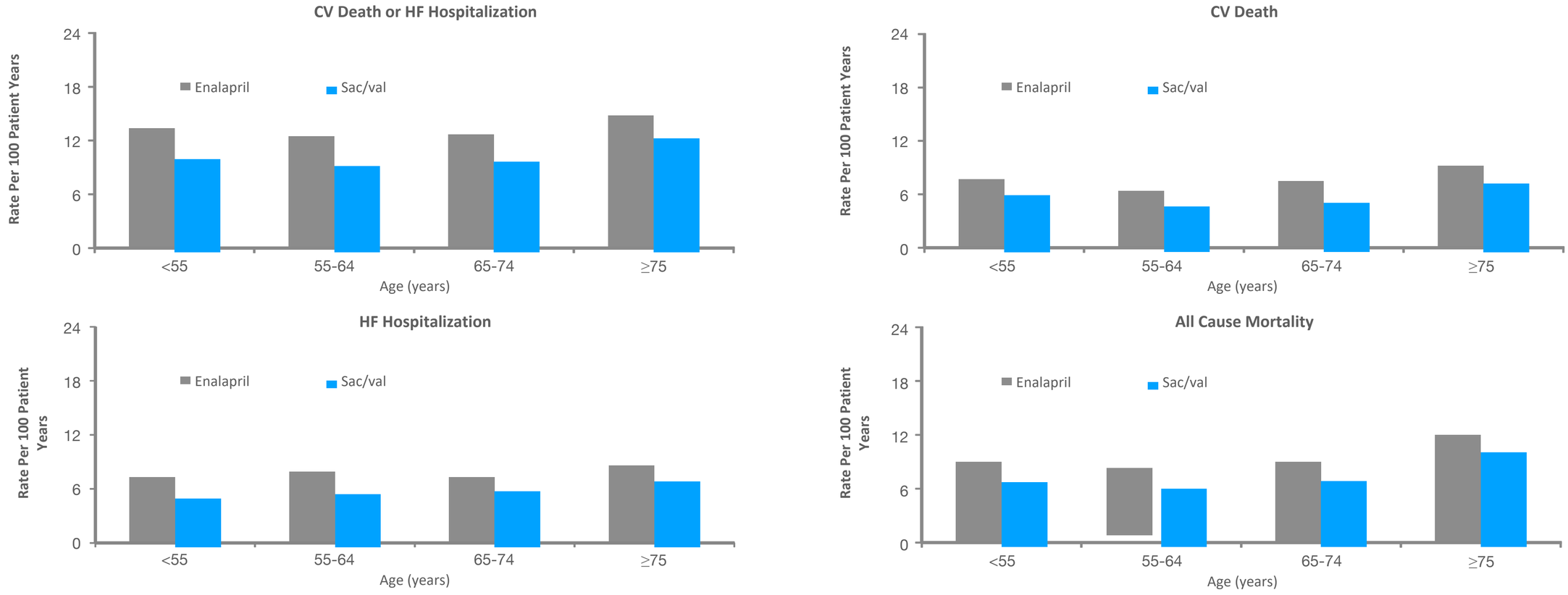


McMurray JJ et al. N Engl J Med. 2014;371:993 1004.

PARADIGM-HF: Effect According to Age

Results: Clinical Outcomes

Rate per 100 patient years of each outcome according to randomized treatment and age group



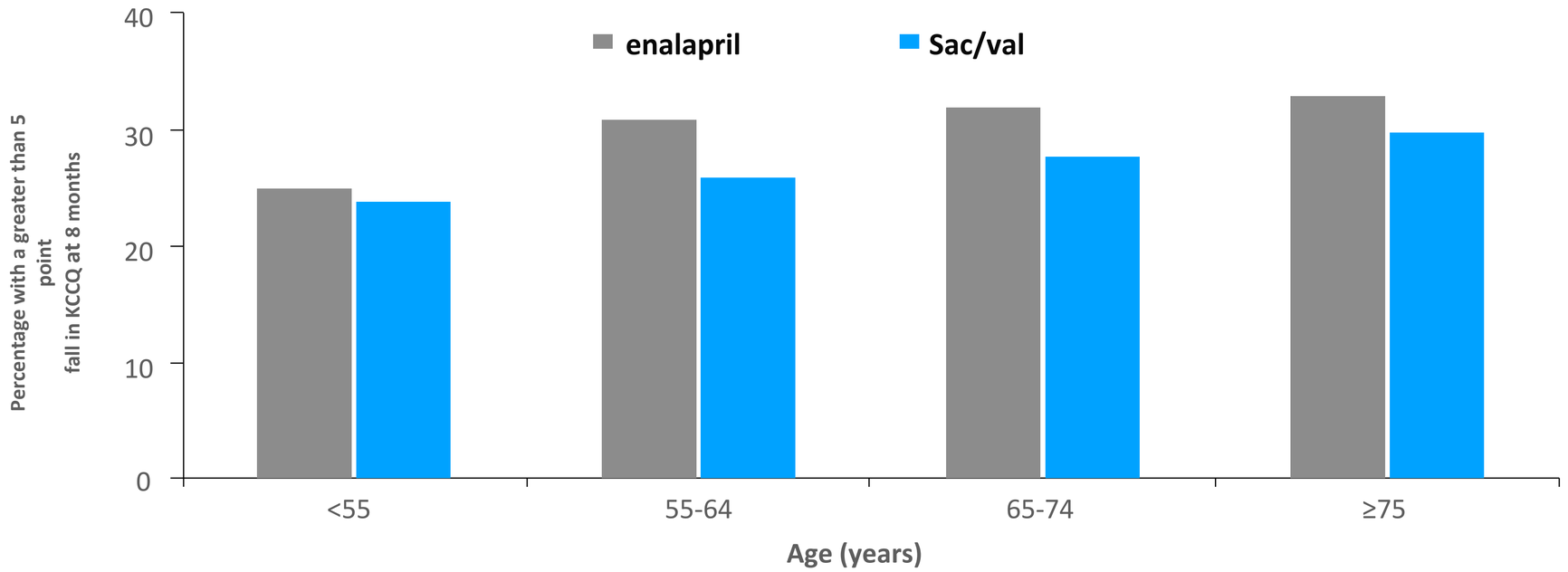
The rate of each outcome was lower in those treated with sacubitril/valsartan compared with enalapril

Jhund PS, et al. Eur Heart J. 2015;36(38):2576–2584.

PARADIGM-HF: Effect on QOL According to Age

The Kansas City Cardiomyopathy Questionnaire Scores

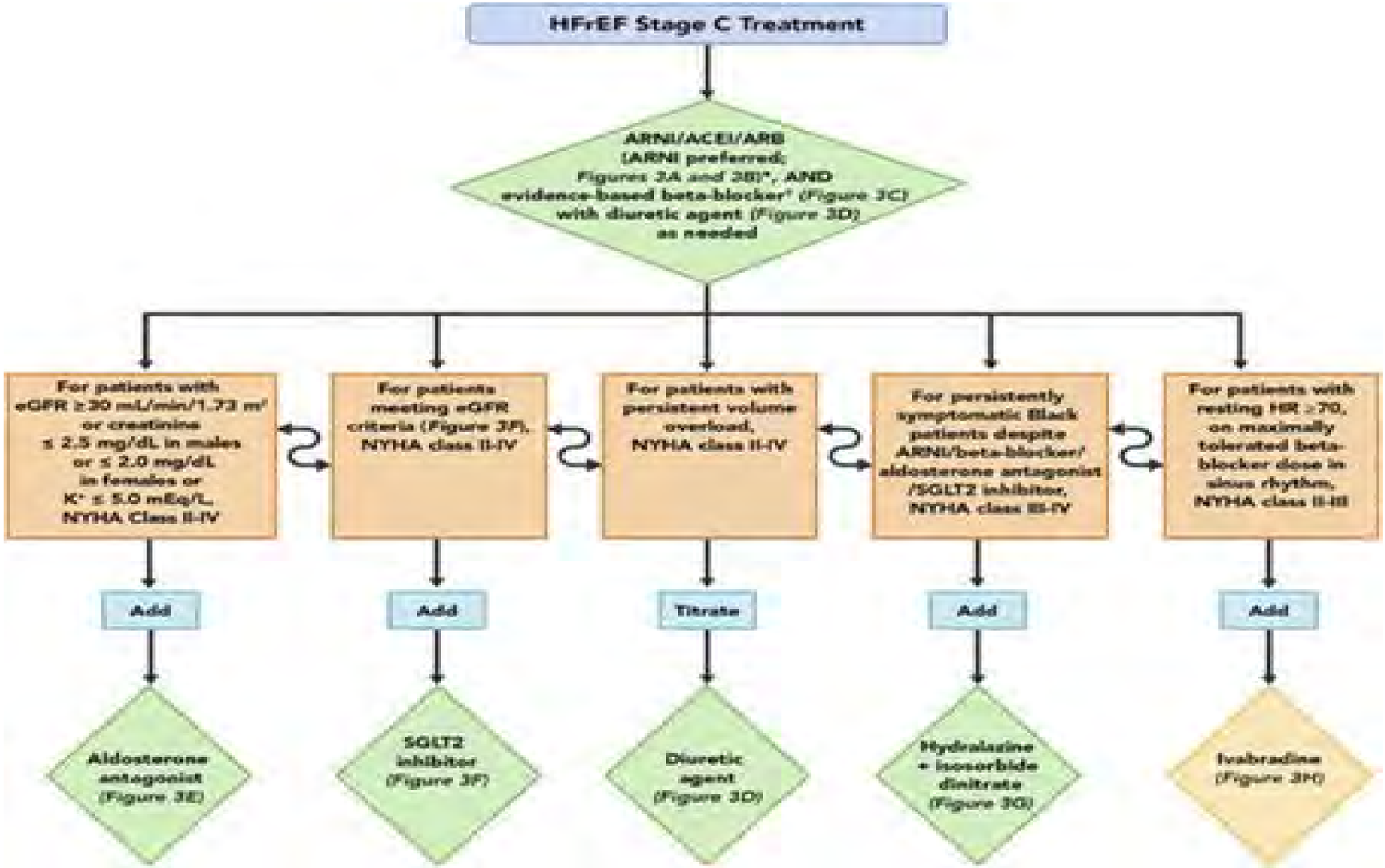
Proportion with a greater than 5 point fall in KCCQ score at 8 months by randomized treatment and age



The benefit of sacubitril/valsartan over enalapril in preventing worsening of KCCQ was consistent across the age groups (p for interaction=0.90)

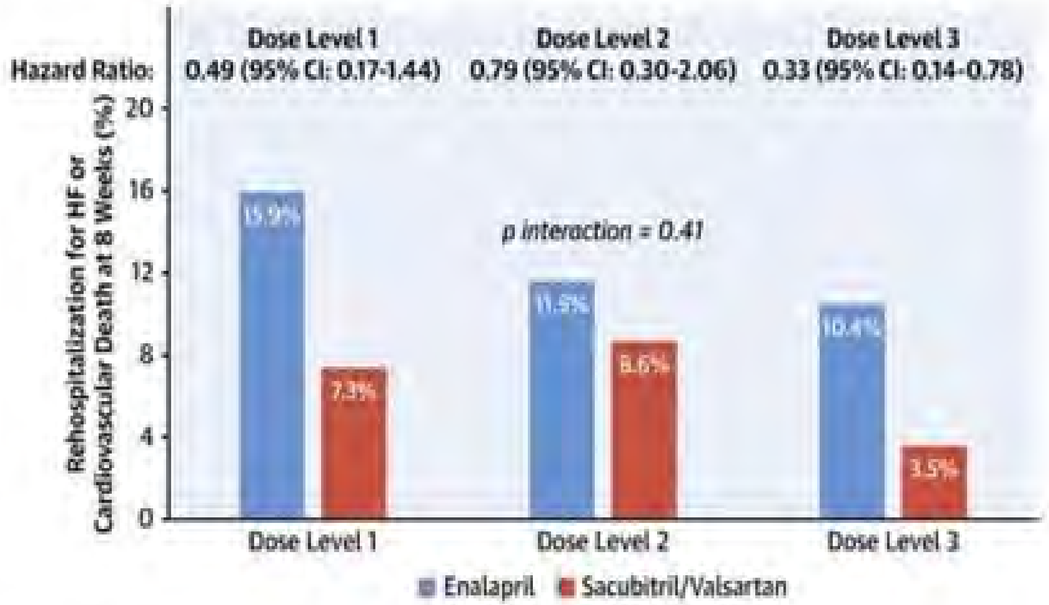
Jhund PS, et al. Eur Heart J. 2015;36(38):2576–2584.

2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee

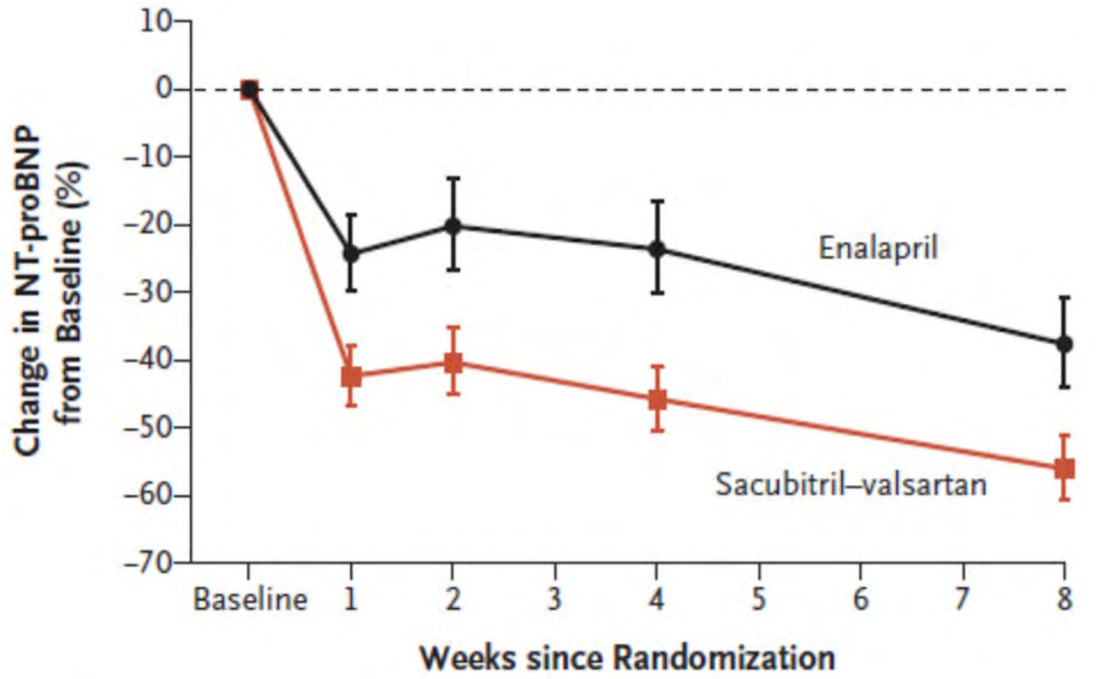


JACC 2021 Feb, 77 (6) 772–810

PIONEER-HF: Sacubitril-Valsartan Initiated in Hospitalized HF Patients



Berg, D.D. et al. J Am Coll Cardiol HF. 2020;8(10):834-43.

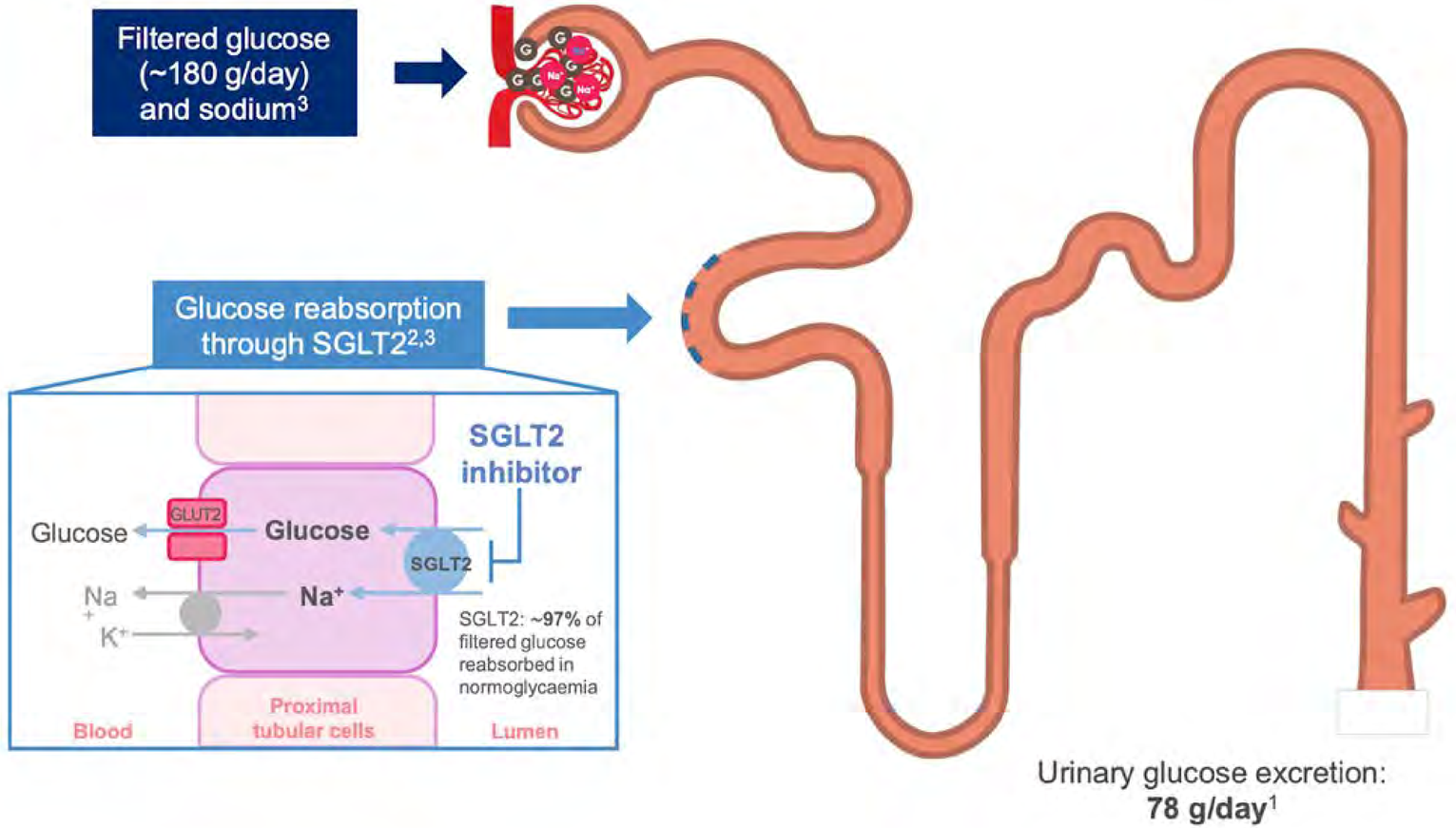


No. at Risk

Enalapril	394	359	351	350	348
Sacubitril–valsartan	397	355	363	365	349

Velasquez E et al. N Engl J Med. 2019

SGLT2 Inhibitors: Mechanism of Action - Facilitates Renal Excretion of Glucose



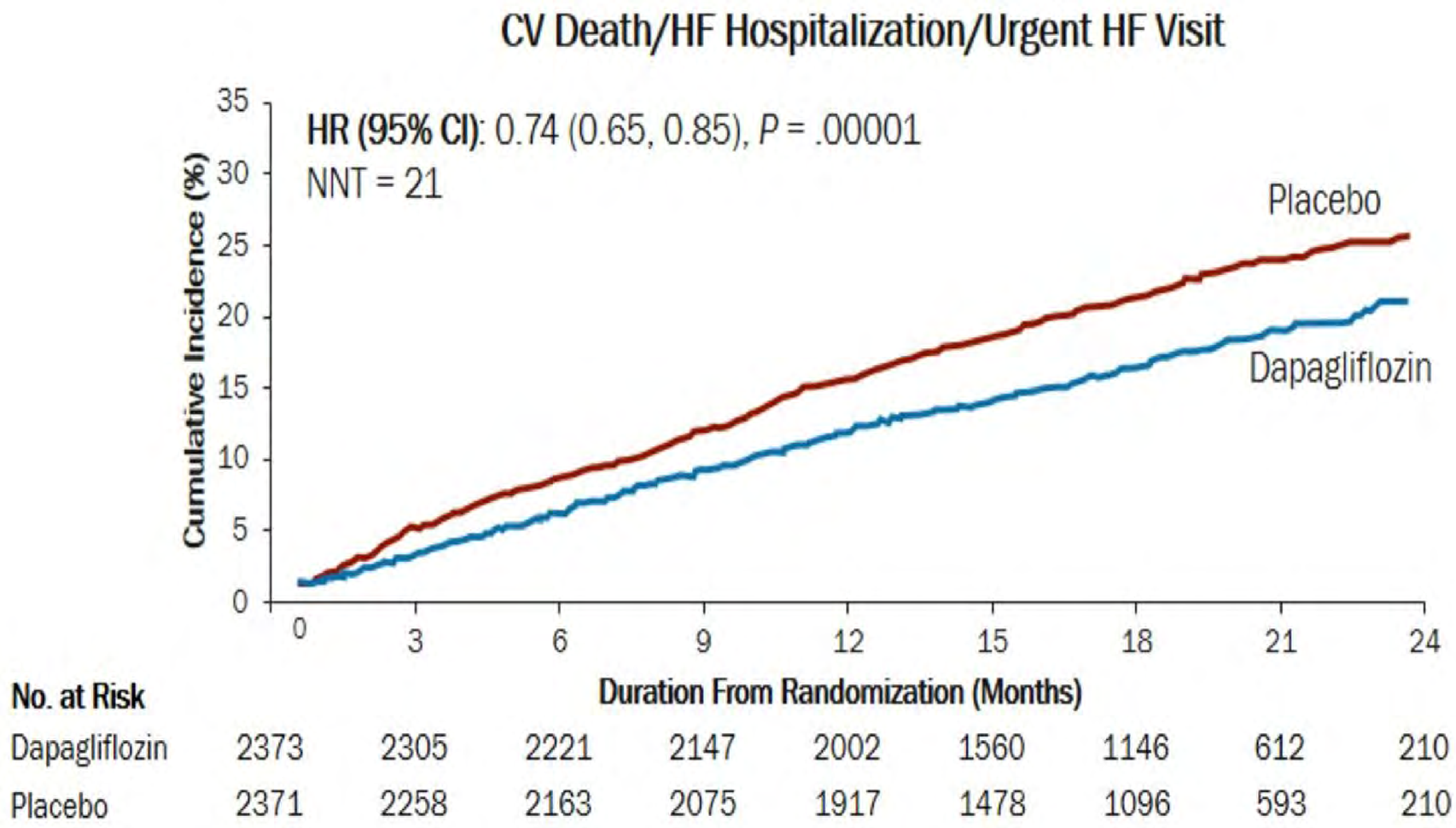
SGLT2 inhibition **reduces glucose and sodium reabsorption** in the proximal tubule[1] leading to:

- Diuresis[1]
- Glucose excretion[1,2]
- Natriuresis[1]

GLUT2, glucose-transporter-2; SGLT2, sodium-glucose co-transporter-2

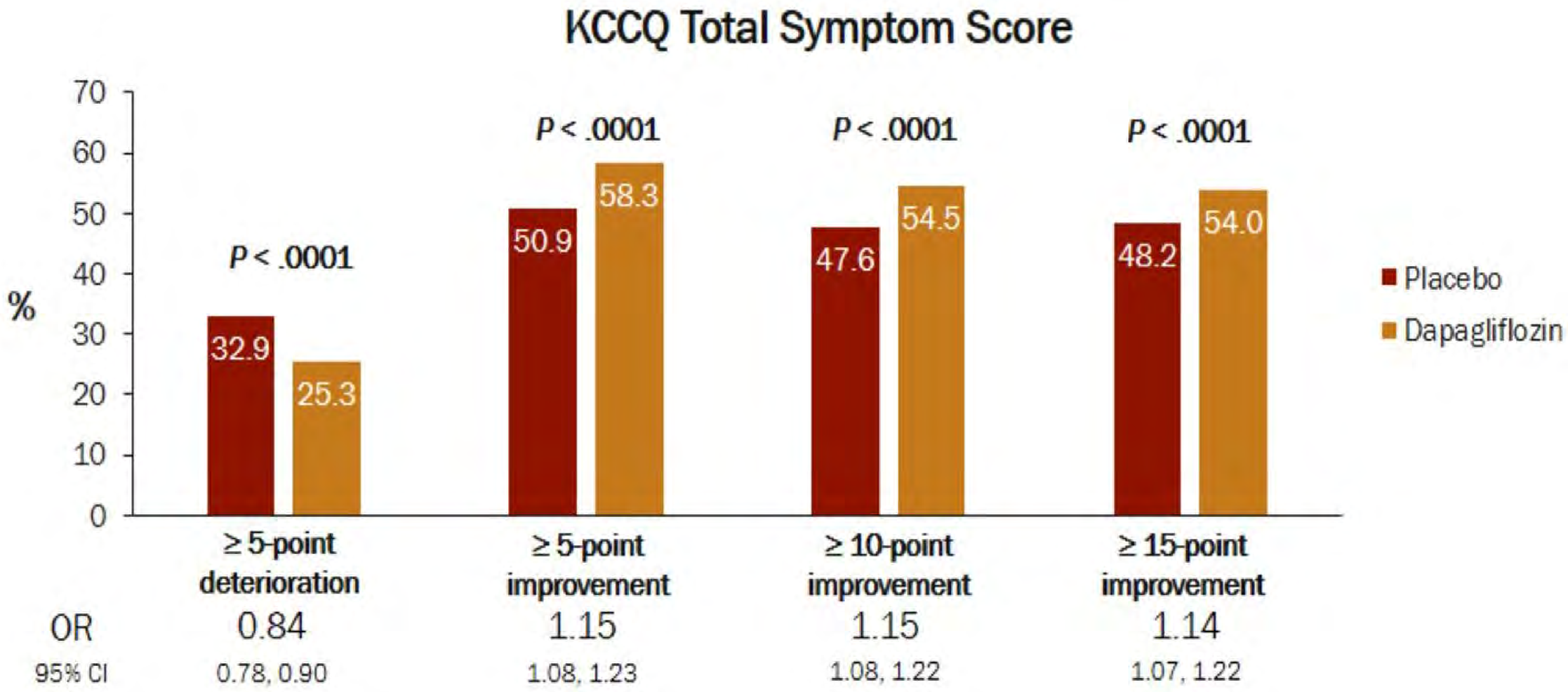
1. Heise T et al. Clin Ther 2016;38:2265. 2. Vallon V & Thomson SC. Diabetologia 2017;60:215. 3. Bakris GL *et al. Kidney Int* 2009;75:1272

DAPA - HF Study



McMurray JJ, et al. N Engl J Med. 2019;381:1995-2008.

SGLT2 Inhibitors - Effect on Quality of Life



Kosiborod MN, et al. Circulation. 2020;141:90-99.

Practical Tips for the Management of SNF HFrEF Patients Post Hospitalization

Tufts Medical Center

- Sacubitril/Valsartan and SGLT2 Inhibitors will be seen more frequently
  ** Diuretic properties, check volume status with hemodynamic alterations
- Diuretic requirements may decrease with positive remodeling
- ARBs – less vasodilatory, so may consider in setting of hypotension
- Carvedilol - more vasoactive, start if patient hypertensive.
- Furosemide – variable bioavailability, consider other loop agents: torsemide bumetanide
- Monitor magnesium
- Don’t start BB while patient is still volume overloaded
- Once euvolemic, resume or titrate GDMT according to patient preferences

What to Do with Chronic Maintenance Therapy in ADHF

- Continue ACE/ARB unless hypotensive, AKI, hyperkalemic
- Beta-blockers:
  - Mild HF - Continue
  - Moderate HF - Drop 50%
  - Severe HF (shock, inotrope needed) - Hold before transfer
- Don’t start BB while patient is still volume overloaded
- Avoid non-dihydropyridine CCB in HFrEF
- Once euvolemic, resume or titrate GDMT according to patient preferences

HFpEF - Evolving Understanding of the Pathophysiology

Hypertension

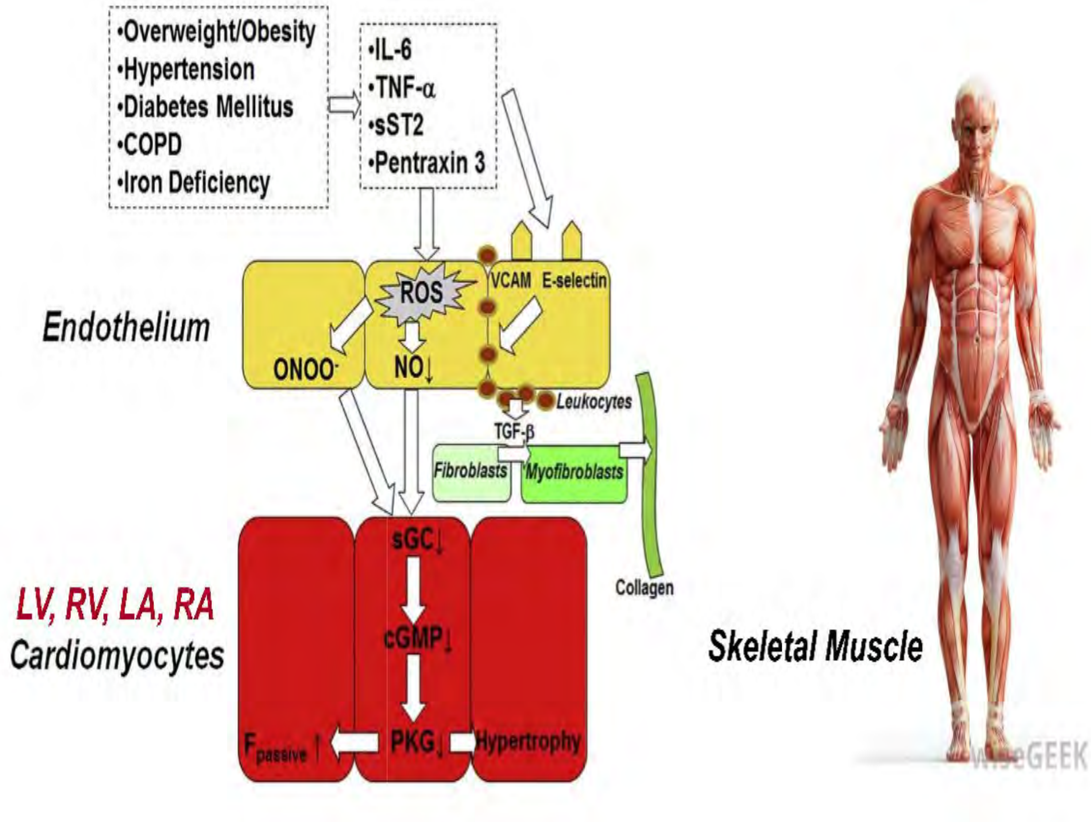
↓

Concentric LVH
Fibrosis

⋮

↓

Diastolic Dysfunction



Co-Morbidities - Mimics or Makers

Tufts Medical Center

Chronic Lung Disease

Diabetes

Age

Obesity

HTN

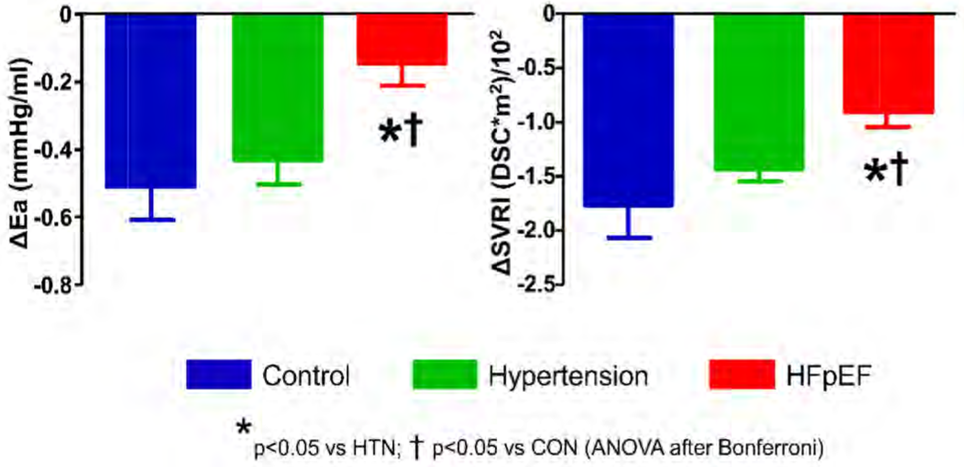
Renal dysfunction

Dyslipidemia

Anemia

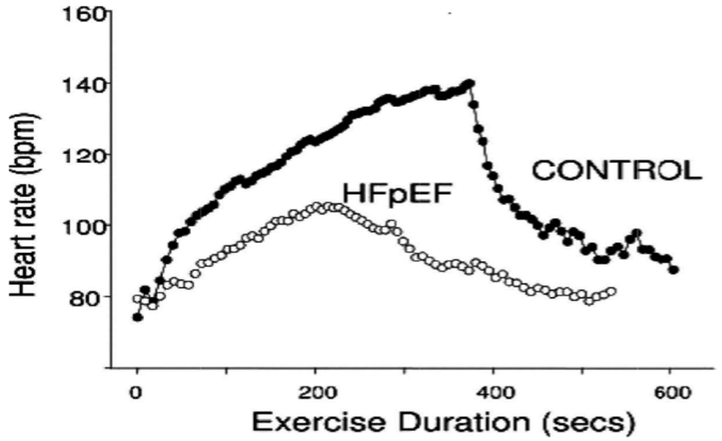
HFpEF - NOT Just the Left Ventricle

Impaired Peripheral Vascular Vasodilatory Reserve



Vasodilatation at matched low-level exercise

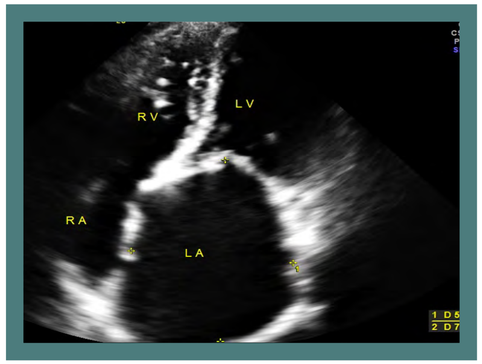
Chronotropic Incompetence



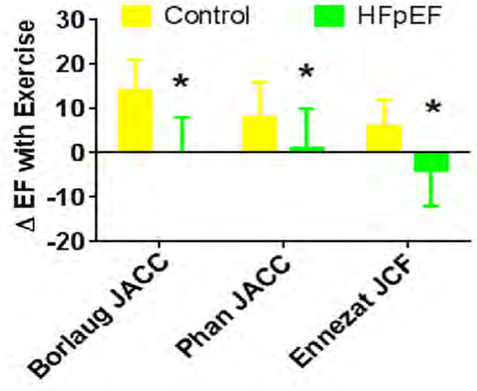
Pulmonary Hypertension

PA pressure > 40 mmHg

RV Enlargement and Dysfunction



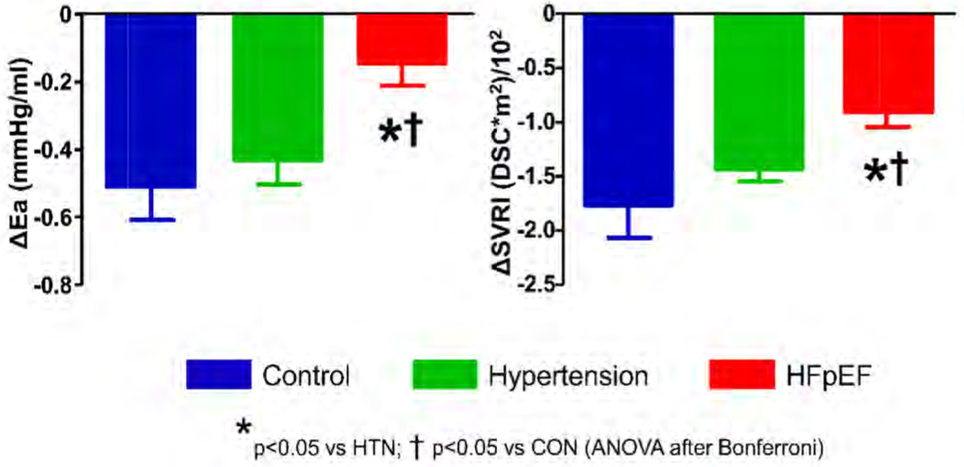
Decreased Systolic Reserve



Borlaug, Circ 2006, Brubaker, Circ 2011; Borlaug et al, JACC, 2010,

HFpEF - NOT Just the Left Ventricle

Impaired Peripheral Vascular Vasodilatory Reserve



Vasodilatation at matched low-level exercise

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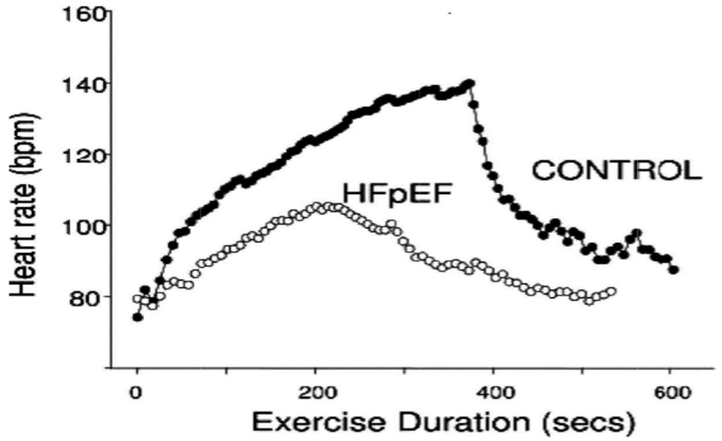
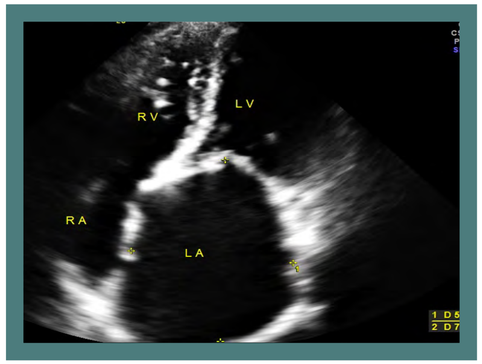


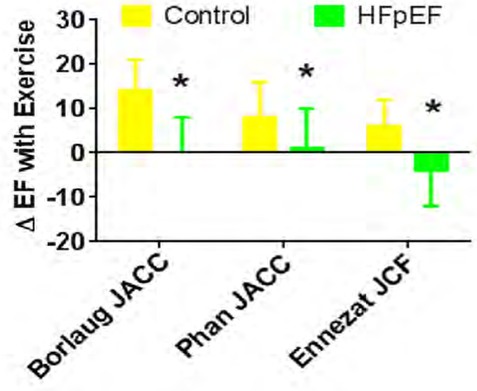
Pulmonary Hypertension

PA pressure > 40 mmHg

RV Enlargement and Dysfunction



Decreased Systolic Reserve



Borlaug, Circ 2006, Brubaker, Circ 2011; Borlaug et al, JACC, 2010,

HFpEF – Elevations in PCWP During Exercise

Exercise Hemodynamics Enhance Diagnosis of Early Heart Failure With Preserved Ejection Fraction

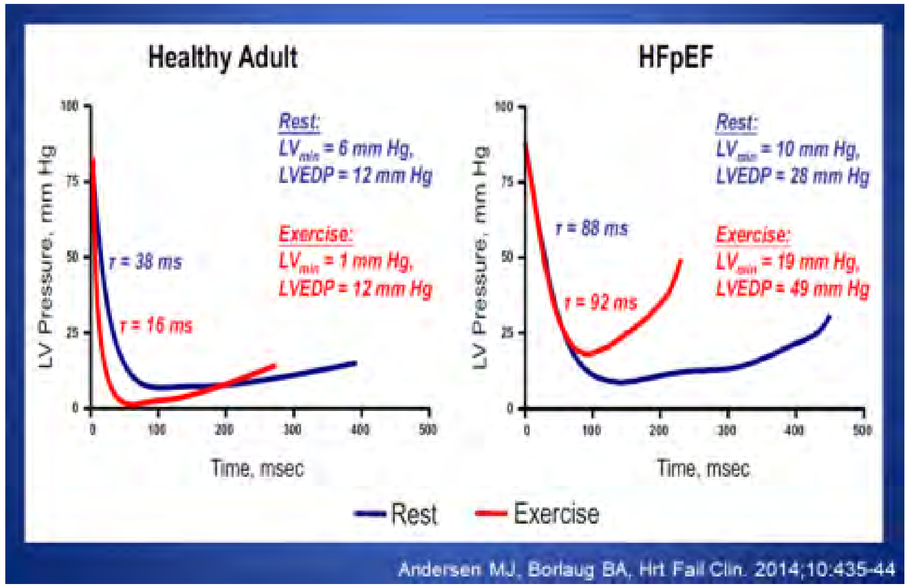
Barry A. Borlaug, MD; Rick A. Nishimura, MD; Paul Sorajja, MD;
Carolyn S.P. Lam, MBBS; Margaret M. Redfield, MD

Background—When advanced, heart failure with preserved ejection fraction (HFpEF) is readily apparent. However, diagnosis of earlier disease may be challenging because exertional dyspnea is not specific for heart failure, and biomarkers and hemodynamic indicators of volume overload may be absent at rest.

Methods and Results—Patients with exertional dyspnea and ejection fraction >50% were referred for hemodynamic catheterization. Those with no significant coronary disease, normal brain natriuretic peptide assay, and normal resting hemodynamics (mean pulmonary artery pressure <25 mm Hg and pulmonary capillary wedge pressure [PCWP] <15 mm Hg) (n=55) underwent exercise study. The exercise PCWP was used to classify patients as having HFpEF (PCWP ≥25 mm Hg) (n=32) or noncardiac dyspnea (PCWP <25 mm Hg) (n=23). At rest, patients with HFpEF had higher resting pulmonary artery pressure and PCWP, although all values fell within normal limits. Exercise-induced elevation in PCWP in HFpEF was confirmed by greater increases in left ventricular end-diastolic pressure and was associated with blunted increases in heart rate, systemic vasodilation, and cardiac output. Exercise-induced pulmonary hypertension was present in 88% of patients with HFpEF and was related principally to elevated PCWP, as pulmonary vascular resistances dropped similarly in both groups. Exercise PCWP and pulmonary artery systolic pressure were highly correlated. An exercise pulmonary artery systolic pressure ≥45 mm Hg identified HFpEF with 96% sensitivity and 95% specificity.

Conclusions—Euvolemic patients with exertional dyspnea, normal brain natriuretic peptide, and normal cardiac filling pressures at rest may have markedly abnormal hemodynamic responses during exercise, suggesting that chronic symptoms are related to heart failure. Earlier and more accurate diagnosis using exercise hemodynamics may allow better targeting of interventions to treat and prevent HFpEF progression. (***Circ Heart Fail.* 2010;3:588-595.**)

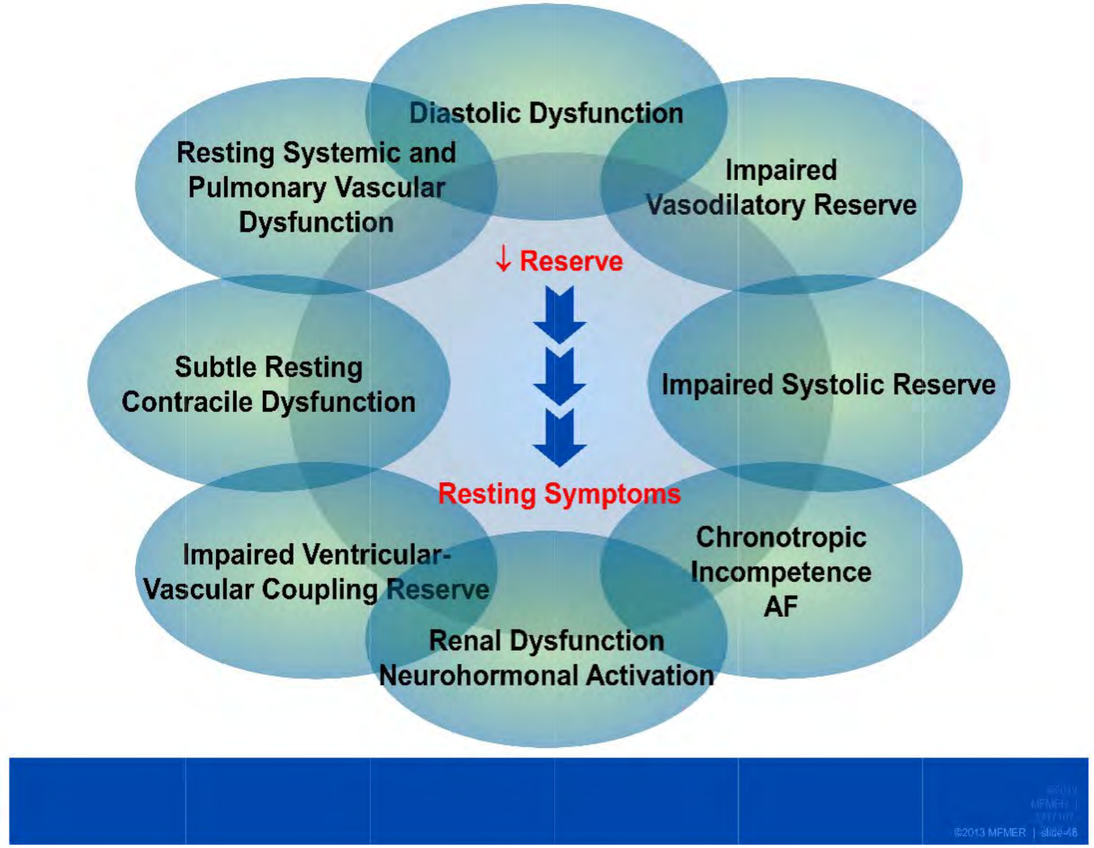
Key Words: heart failure ■ exercise ■ hemodynamics ■ diastole ■ diagnosis



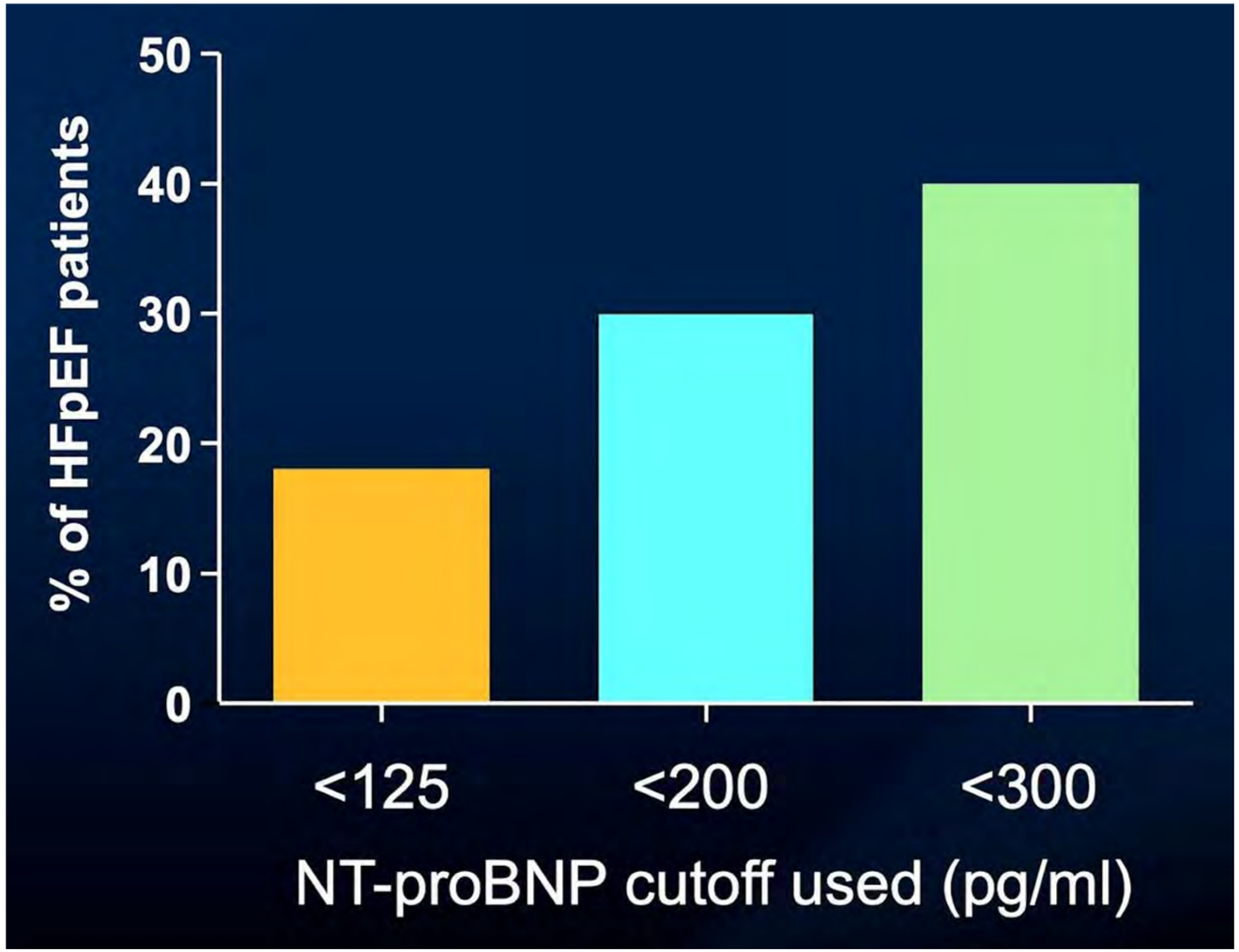
Borlaug et al, Circ Hear Fail 2010; Anderson et al, Hrt Fail Clin 2014

Mechanisms of Dyspnea in HFpEF – Not Just Volume Overload*

- Chronotropic incompetence
- Impaired vasodilation
- Increased left-sided filling pressures from either venoconstriction or diastolic dysfunction,
- Peripheral muscular changes
- Endothelial dysfunction



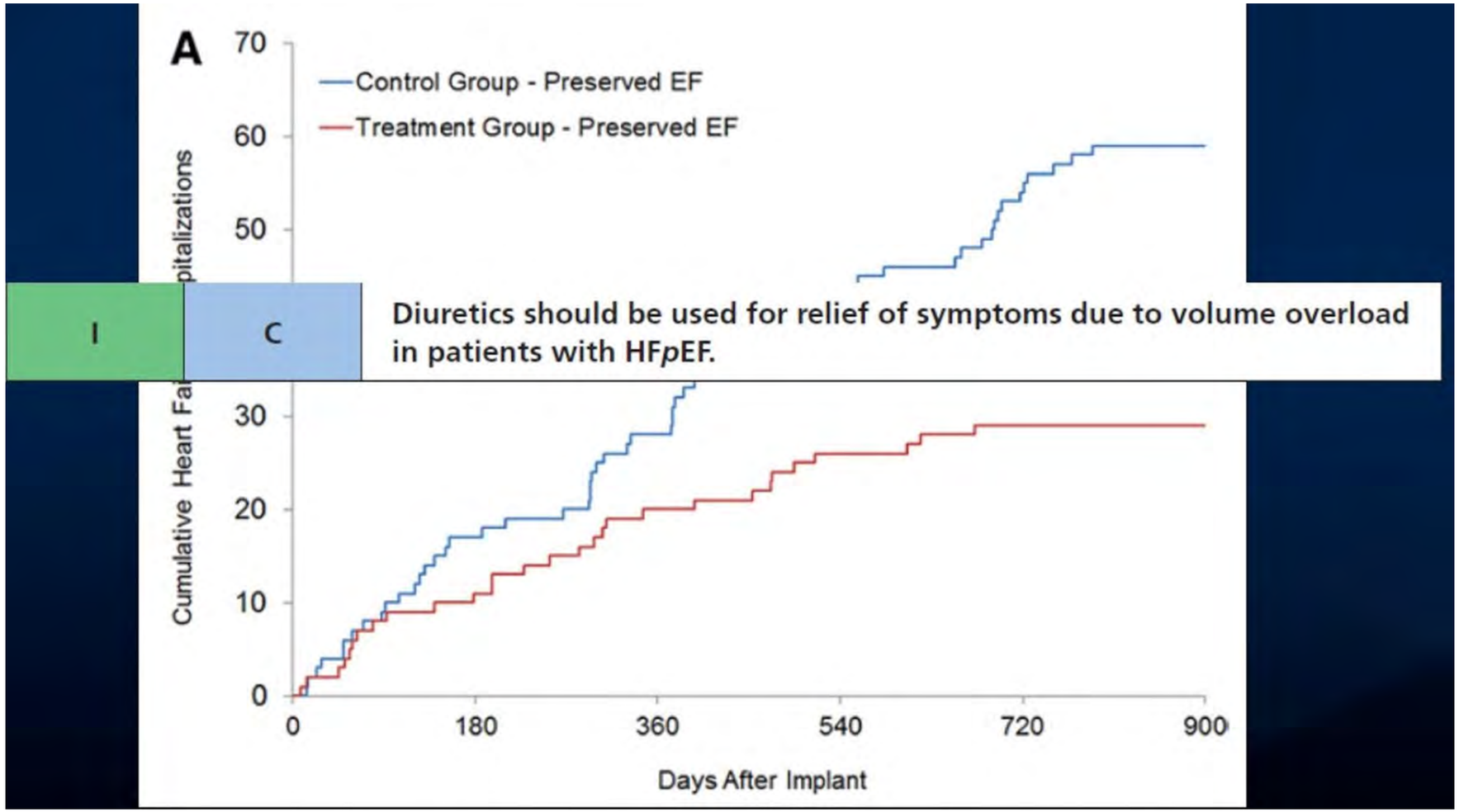
Normal NT-proBNP Does NOT Exclude HFpEF



30% of HFPEF patients have Normal BNP Levels

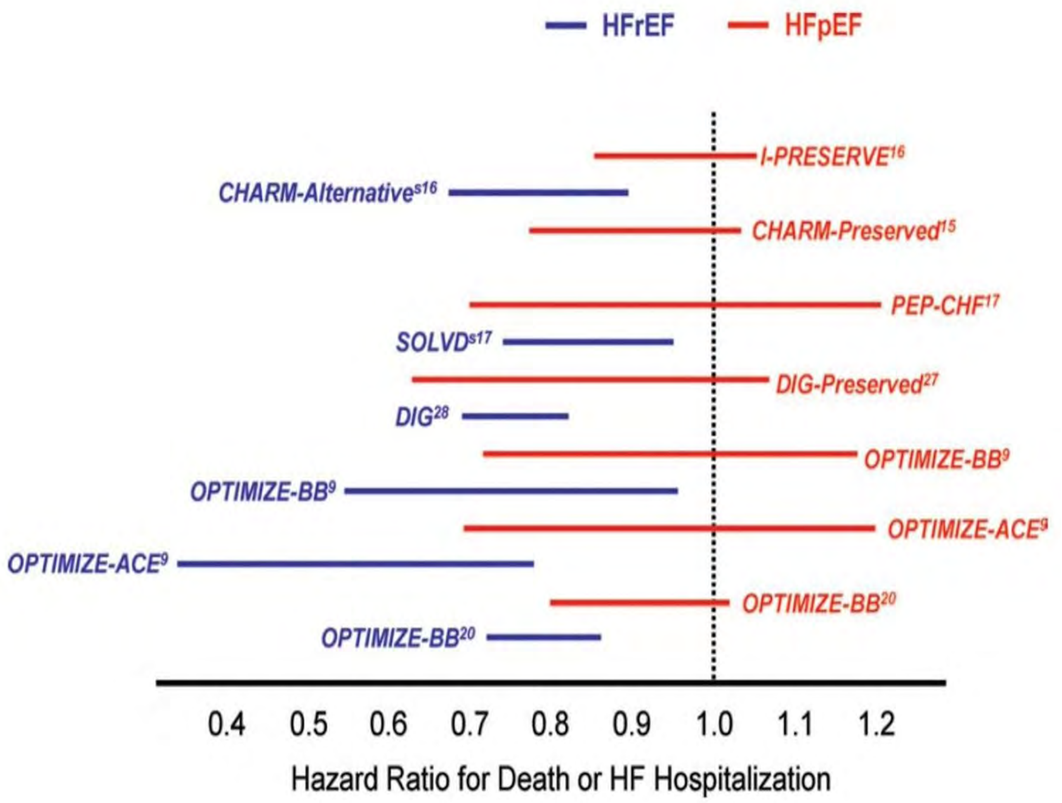
Obokata, Borlaug Circulation. 2017

HFpEF Management - #1 Diuretics Work



Adamson, Circ Heart Fail. 2014

HFpEF Management - #2 Neurohormonal Antagonists Don't Really Work Well

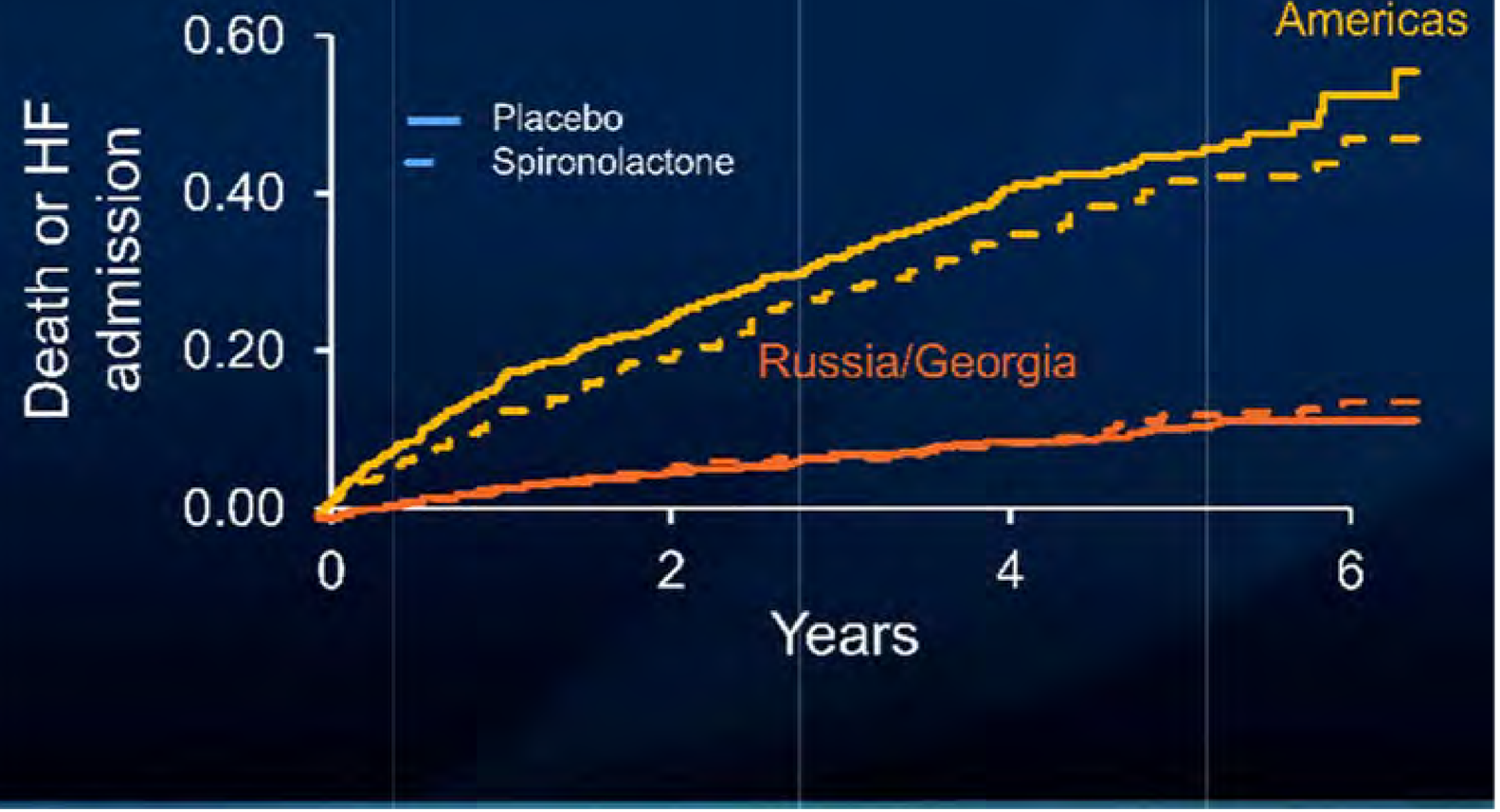


Acronym	Agent	N	Mortality
CHARM-PRE	candesartan	3023	No effect
I-PRESERVE	irbesartan	4128	No effect
PEP-CHF	perindopril	850	No effect
SENIORS	nebivolol	2128	No effect
TOPCAT	spironolactone	3445	No effect

Borlaug & Redfield Circulation. 2011

Negative Trials in HFpEF

- RELAX – sildenafil
- NEAT HF – Isosorbide mononitrate
- CHARM, I-PRESERVE – ACE / ARBs
- TOPCAT – spironolactone

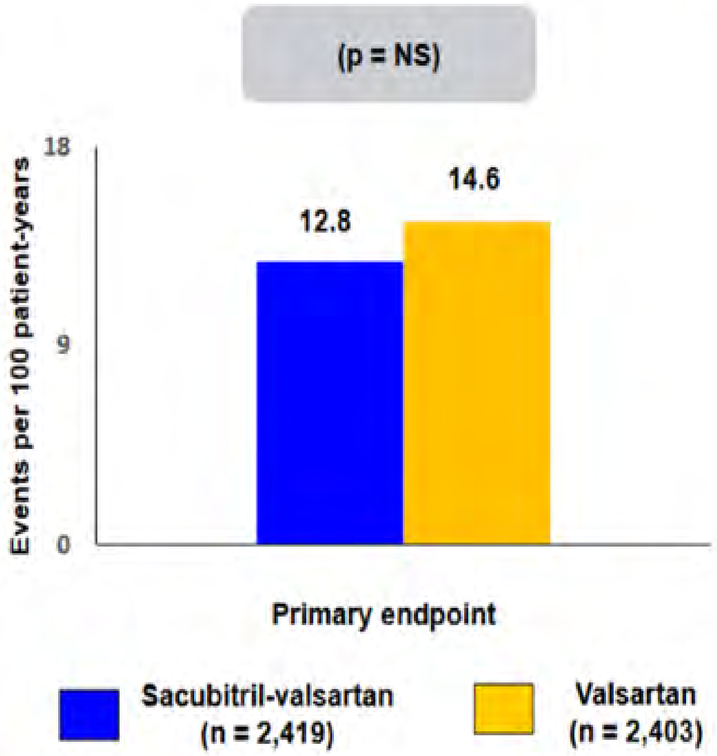


Pfeffer Circulation 2014

PARAGON – HF - Sacubitril/Valsartan Was Not Effective in HFpEF

Tufts Medical Center

Trial Description: Patients with heart failure with preserved ejection fraction were randomized to sacubitril-valsartan 97/103 mg twice daily versus valsartan 160 mg twice daily.



RESULTS

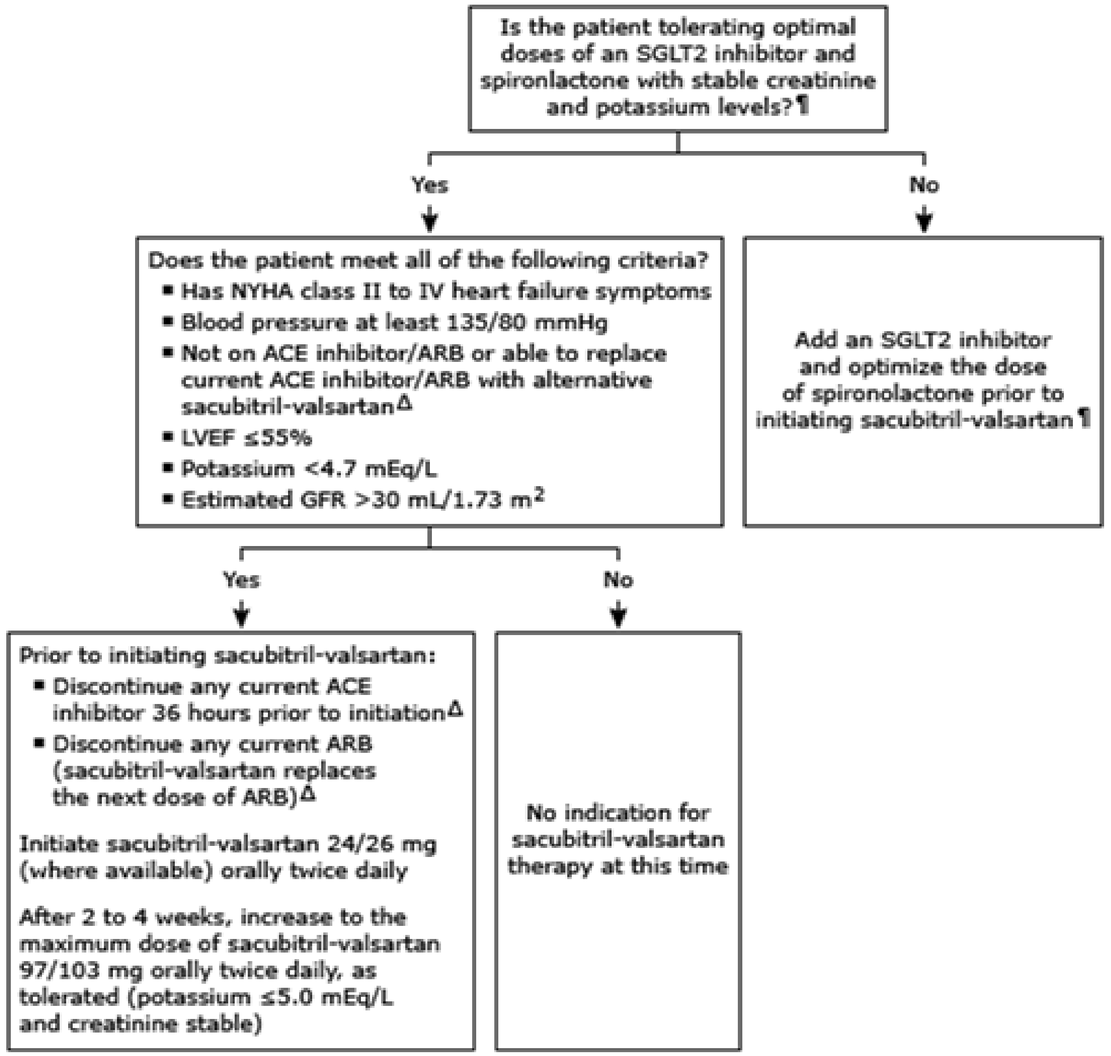
- Primary efficacy endpoint: rate of cardiovascular deaths or hospitalizations for heart failure was 12.8 events per 100 patient-years in the sacubitril-valsartan group vs. 14.6 events per 100 patient-years in the valsartan group (p = NS)
- NYHA class improvement: 15.0% in the sacubitril-valsartan group vs. 12.6% in the valsartan group ($p < 0.05$)

CONCLUSIONS

- Among patients with heart failure with preserved ejection fraction, sacubitril-valsartan was not effective at reducing the incidence of cardiovascular death or hospitalization for heart failure compared with valsartan

Solomon SD, et al. N Engl J Med 2019;Sep 1:[Epub]

Initiating Sacubitril-Valsartan in Adults with HF with Preserved Ejection Fraction*



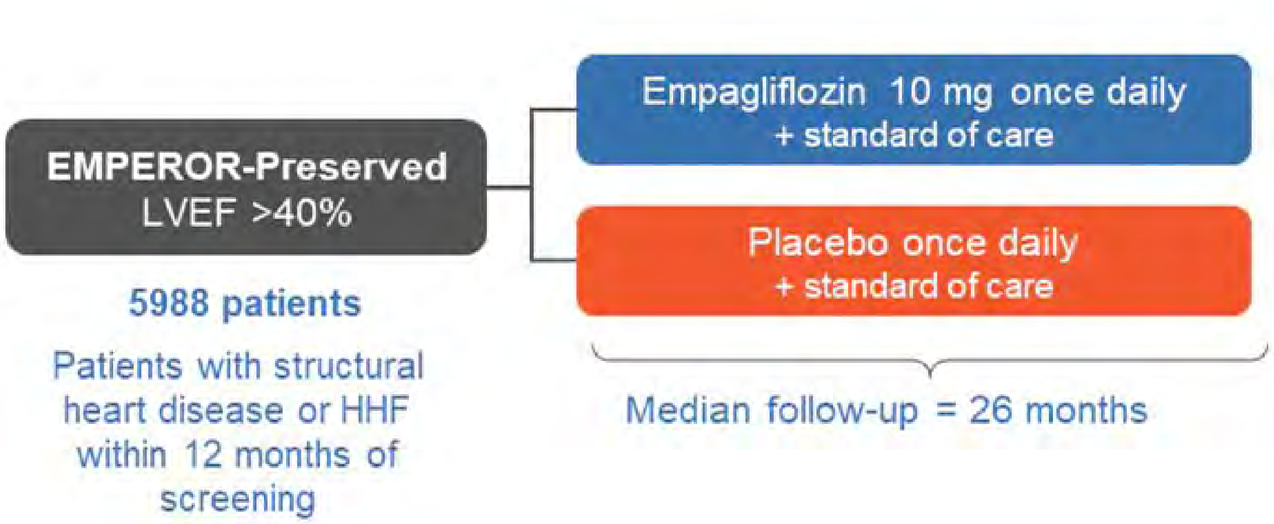
EMPEROR-Preserved - Study Design

Tufts Medical Center

Phase III randomised double-blind placebo-controlled trial

Aim: to evaluate efficacy and safety of empagliflozin versus placebo, on top of standard of care, in **patients with HFpEF** with or without diabetes

Population: T2DM & non-T2DM, aged ≥18 years, chronic HF (NYHA class II–IV), eGFR≥20



COMPOSITE PRIMARY ENDPOINT

Time to first event of adjudicated cardiovascular death or adjudicated HHF

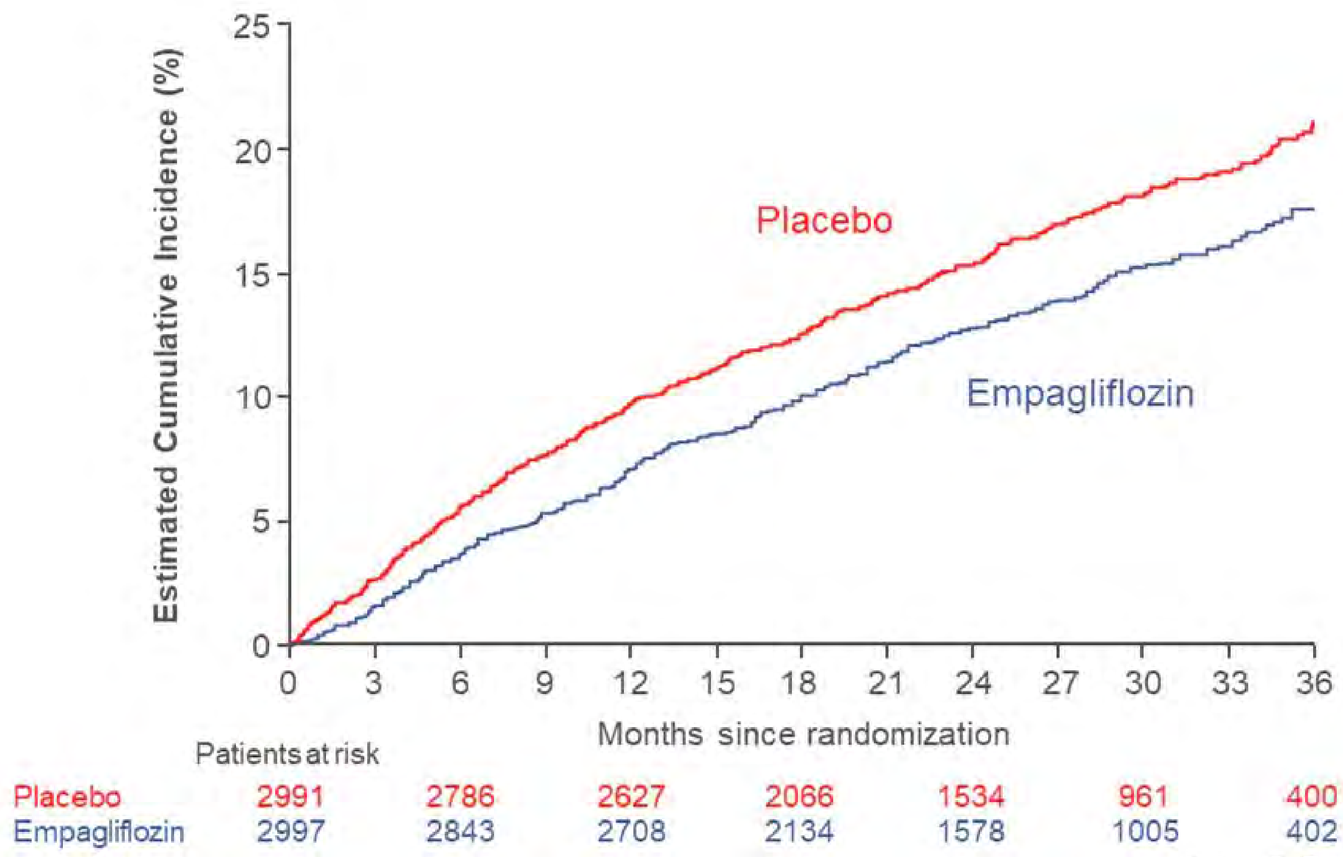
SECONDARY ENDPOINTS

- First and recurrent adjudicated HF hospitalisation events
- Slope of change in eGFR (CKD-EPI)

Anker S, Butler J, et al. Eur J Heart Fail. 2019;21:2179-87.

PACC Post-Acute Cardiology Care

Primary Endpoint - Composite of Cardiovascular Death or Heart Failure Hospitalization



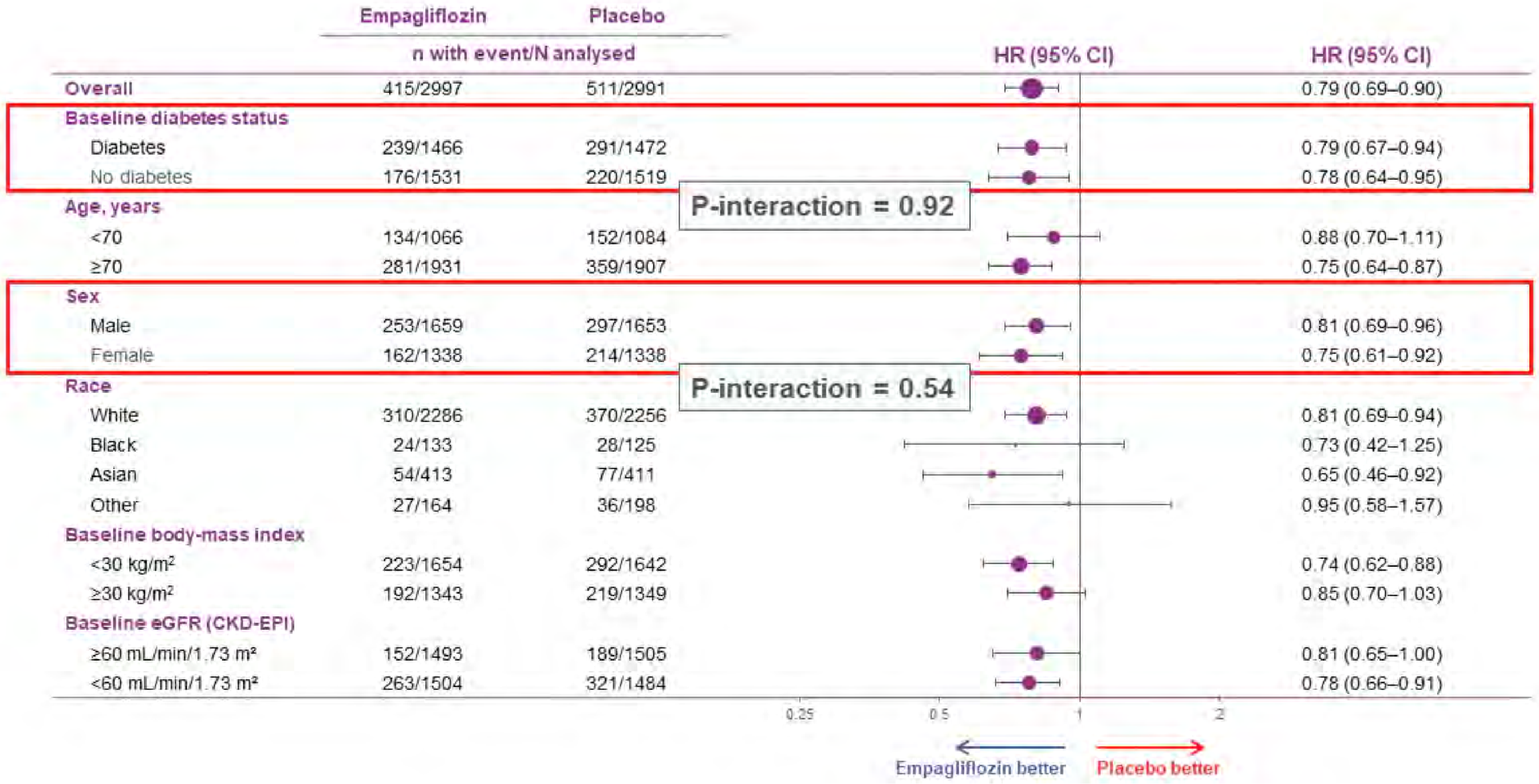
HR 0.79
(95% CI 0.69, 0.90)
P = 0.0003

Placebo:
511 patients with event
Rate: 8.7 per 100 patient-years

Empagliflozin:
415 patients with event
Rate: 6.9 per 100 patient-years

Anker S, Butler J, et al. N Engl J Med. 2021;385:1451-61.

Primary Endpoint: Effects in Subgroups (1 of 2)



Anker S, Butler J, et al. N Engl J Med. 2021;385:1451-61.

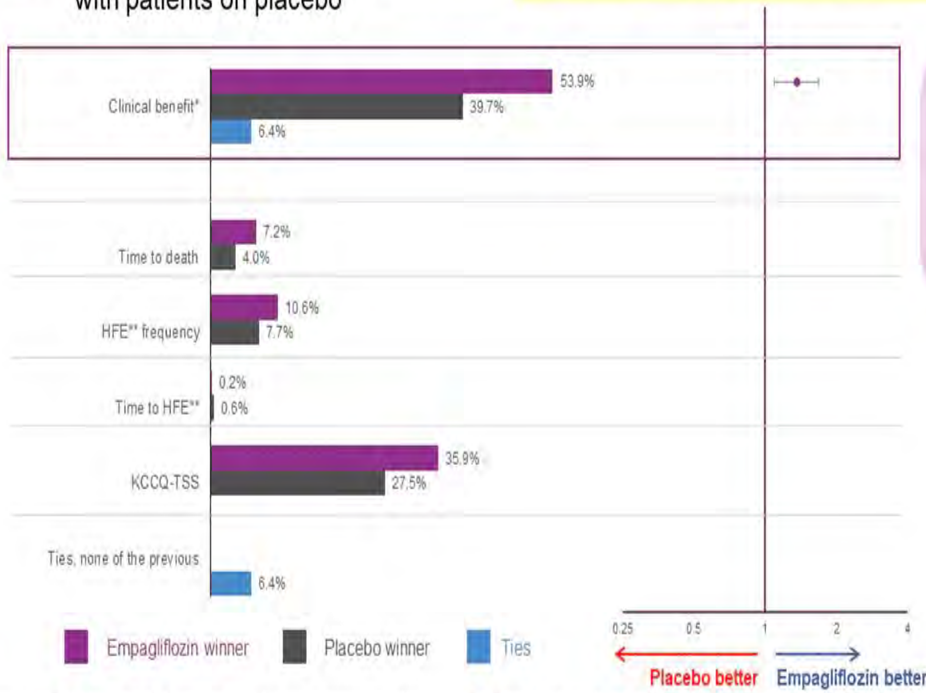
SGLT2 Inhibitors in Acute HF - EMPULSE

Empluse - Key Inclusion Criteria

- Hospitalized with primary diagnosis of acute HF (de novo or decompensated chronic HF), regardless of ejection fraction or diabetes status
- Randomization ≥24 hours and ≤5 days after admission (post-stabilization and still in hospital)
- Stabilization criteria (in hospital):
  - Systolic blood pressure ≥100 mmHg and no symptoms of hypotension within 6 hours
  - No increase in intravenous (IV) diuretic dose within 6 hours
  - No IV vasodilators including nitrates within 6 hours
  - No IV inotropic drugs within 24 hours
- NT-proBNP ≥1600 pg/mL or BNP ≥400 pg/mL (50% more for patients with atrial fibrillation) during index hospitalization or within 72 hours pre-admission

Primary Endpoint

- Patients treated with empagliflozin were 36% more likely to experience a clinical benefit* compared with patients on placebo



Stratified win ratio: 1.36
(95% CI: 1.09, 1.68)
p=0.0054

Death:
Empagliflozin: 4.2%
Placebo: 8.3%

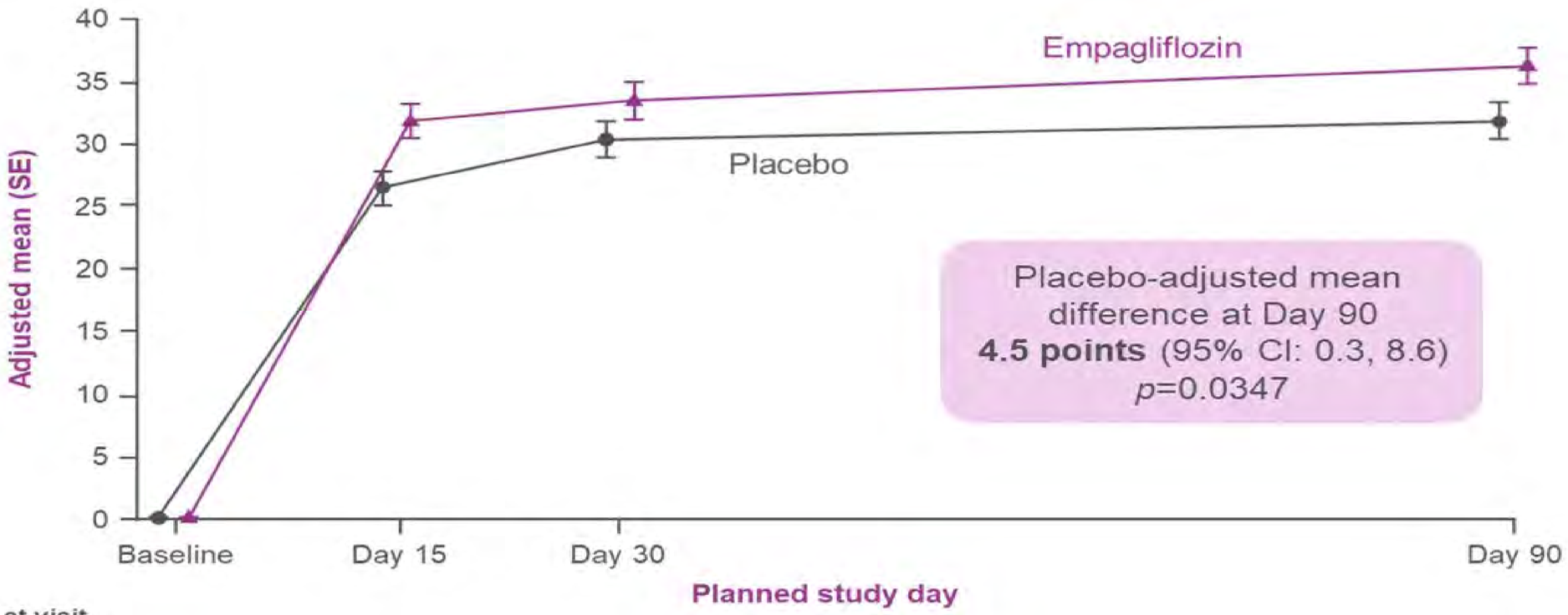
HF event:
Empagliflozin 10.6%
Placebo 14.7%

Numbers reflect percentage of comparisons. For the components of the win ratio these numbers do not reflect randomized comparisons. *Composite of death, number of HFEs, time to first HFE and change from baseline in KCCQ-TSS after 90 days of treatment. **HFE includes hospitalizations for heart failure, urgent heart failure visits, and unplanned outpatient visits.

Voors AA, et al. Presented at AHA Scientific Sessions 2021.

SGLT2 Inhibitors in Acute HF - EMPULSE

Secondary Endpoint: Change in KCCQ-TSS at Day 90

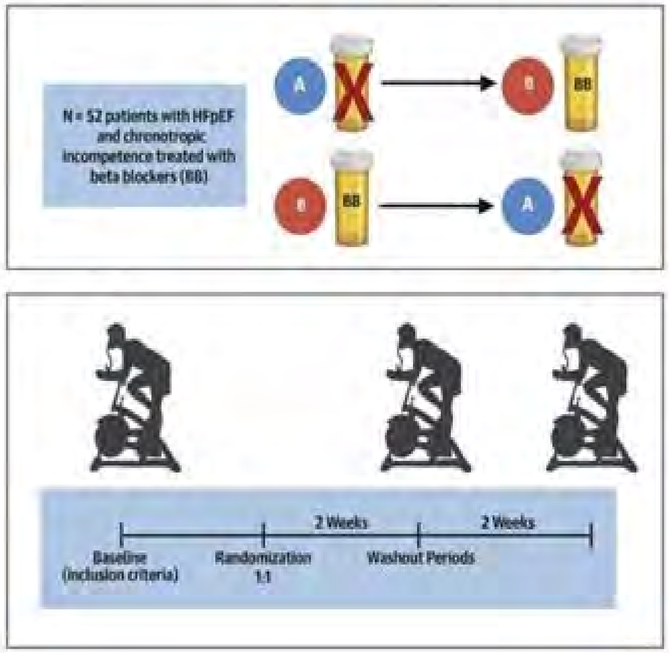


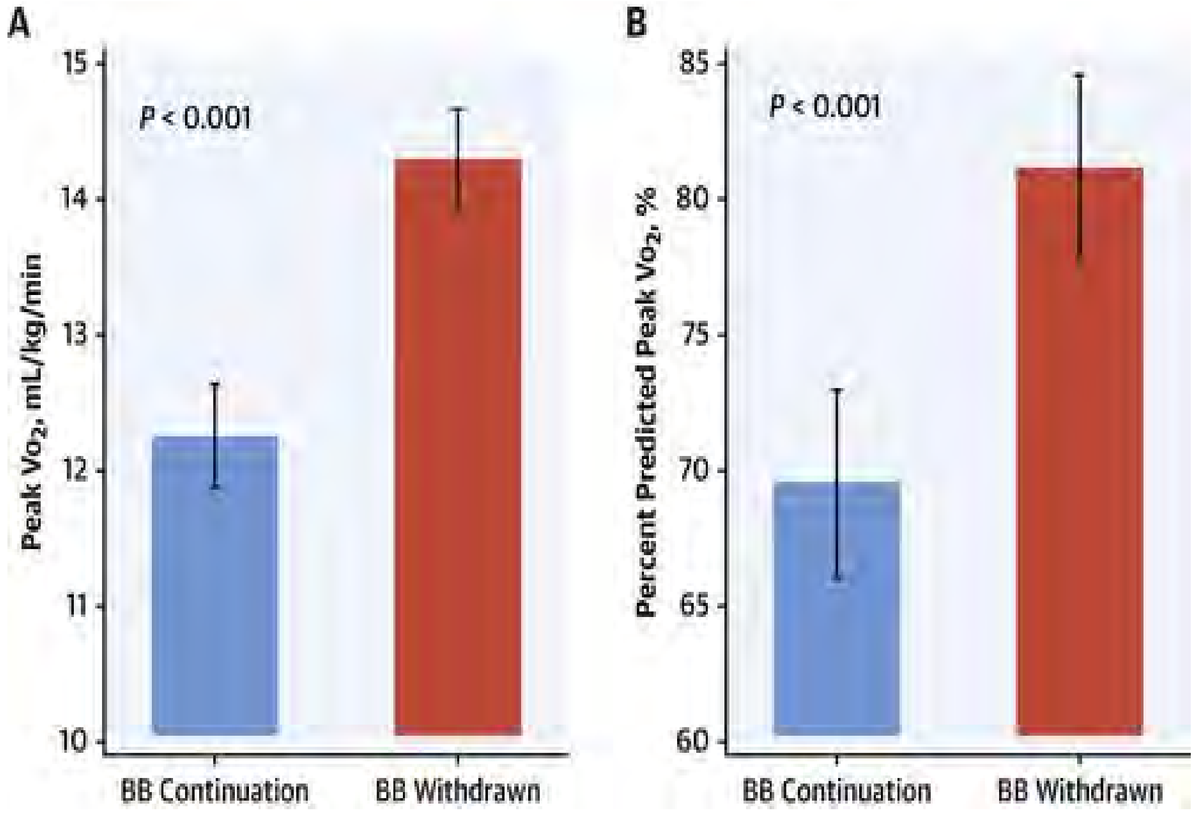
No. with data at visit				
Placebo	250	240	234	221
Empagliflozin	245	233	237	230

CI, confidence interval; KCCQ-TSS, Kansas City Cardiomyopathy Questionnaire total symptom score.

Voors AA, et al. Presented at AHA Scientific Sessions 2021.

Effect of β-Blocker Withdrawal on Functional Capacity in Heart Failure and Preserved Ejection Fraction





JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Patricia Palau et al. J Am Coll Cardiol 2021; 78:2042-2056.

DRUGS TO AVOID IN CHF

- NSAIDs and COX-2 inhibitors
- Nondihydropyridine CCBs (avoid only for systolic heart failure)
- –Diltiazem
- –Verapamil
- Pioglitazone, rosiglitazone-Frequently exacerbates edema
- Cilostazol (Pletal) – decrease survival in Class II-IV CHF
- Dronedarone (Multaq) – risk of death doubles with decompensated CHF or Class IV CHF

A Few Pearls

Diuretics:

- No mortality benefit, may increase mortality in long term use, now need to really recondiser use in the setting of newer therapies.

ACE/ARB/ARNI

- Monitor for volume depletion and electrolyte disturbances, Hypotension can occur within hours, hyperkalemia within a few days

Beta Blockers:

- Not indicated for HFpEF patients
- Monitor for fatigue, diminished exercise tolerance, bradycardia or increased dyspnea. Check an EKG orthostatics and consider dose adjusting

PROGRAMATIC CONSIDERATIONS – The 7 M's

Monitoring

WEIGHTS

Labs

Meals

Healthy, low sodium options

Medications

HFrEF – thoughtful use of diuretics BB, ACE/ARB, MRA, hydralaizine/nitrates

HFpEF – thoughtful use of diuretics, SGLT2, ARNI antihypertensives

Multiple Co-Morbidities

Optimize pulmonary and renal disease management

Movement

Daily activity, not just for CV benefits, but provides clinical insight

Mentoring

Engage the patient/caregiver in the proves, if community discharge, make weights interactive, tell them what their medications are for

Motivations

What does patient want, what are goals of care

Non-Congested Symptomatic HFpEF Patients - Practical Tips

- SNF setting may be ideal for initiation of MRA
  - Ease of monitoring/laboratory evaluation

- Chronotropic Incompetence
  - Indication/Dosing of Beta Blockers

- Peripheral Vasculature Dysfunction
  - Exercise

- Set-up for Success!
  - Dietary and exercise education
  - Collaboration with HF Clinic/Community Cardiologist

Tufts Medical Center

Skilled Nursing Facility Care for Patients With Heart Failure: Can We Make It “Heart Failure Ready?”

Nicole M.Orr MD, Rebecca Boxer MD, MS, Mary Dolansky RN, PhD, Larry Allen MD, MHS, Daniel E. Forman MD

Impact of Specialty Oversite During Transitions to Post-Acute Care

Tufts Medical Center

- 2 years in Model 2 Bundle BPCI
- Cardiologist led HF program vs other programs
- Transitional care components included obtaining cardiac relevant hospital documentation
- Communication between cardiologist and community and SNF providers
- *Consistent focus on clinical rounds to geriatric conditions, co-morbidities and functional status
- Verbal handoff upon community D/C for high risk patients

SNFs in Genesis BPCI Model 3 (N=32)	# SNFs	Total # Patients	# Patients readmitted w/in 90 Days	90-Day Episodic Readmission Rate	Total # 90-Day Readmissions/ HF Episode	# Patients readmitted w/in 30 Days	30-Day Episodic Readmission Rate
St. Joseph's Center	1	22	6	27.3%	47.1%	1	4.5%
All BPCI-enrolled SNFs	31	813	364	44.8%	65.6%	192	23.6%
Other SNFs with HF Programs	7	291	142	48.8%	74.8%	69	23.7%

Nicole M. Orr, Leah Nazarian, In-House Cardiology Consultation Reduces Readmission Rates and Costs for Patients in Skilled Nursing Facilities: 2 Years' Experience in the Heart Failure Bundle Payment Care Improvement Initiative, Abstract #408

PACC Post-Acute Cardiology Care

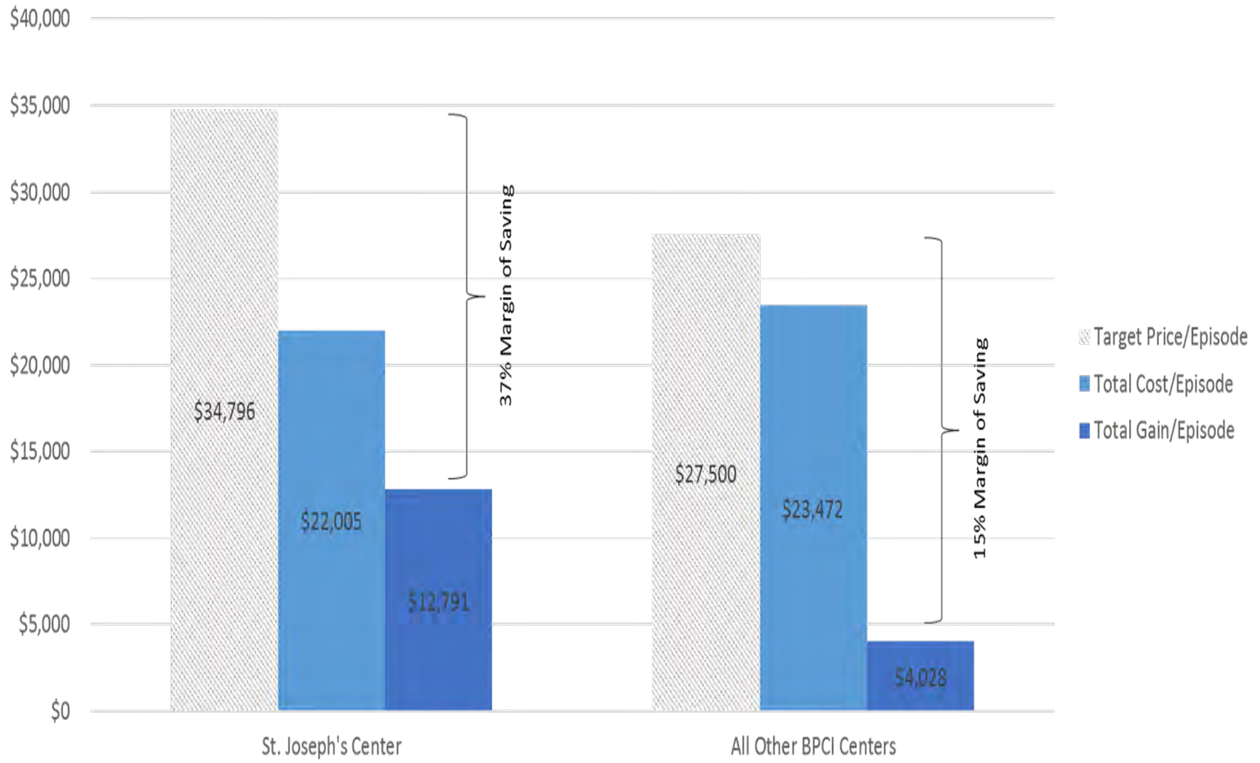
In-House Cardiology Consultation Reduces Readmission Rates and Costs: Experience in Heart Failure Bundle Payments for Care Improvement Initiative

Tufts Medical Center

Increasing DRG Complexity

MS-DRGs of HF Episodes	HF Episodes at St Joseph's Center		All HF Episodes in Other 31 BPCI Centers		All HF Episodes in Other 7 BPCI Centers with HF Programs	
293: Heart Failure & Shock without Complication or Comorbidity or Major Complication or Comorbidity	0	0%	50	6%	19	6%
292: Heart Failure & Shock with Complication or Comorbidity	5	23%	234	29%	98	34%
291: Heart Failure & Shock with Major Complication or Comorbidity	17	**77%**	533	**65%**	175	**60%**

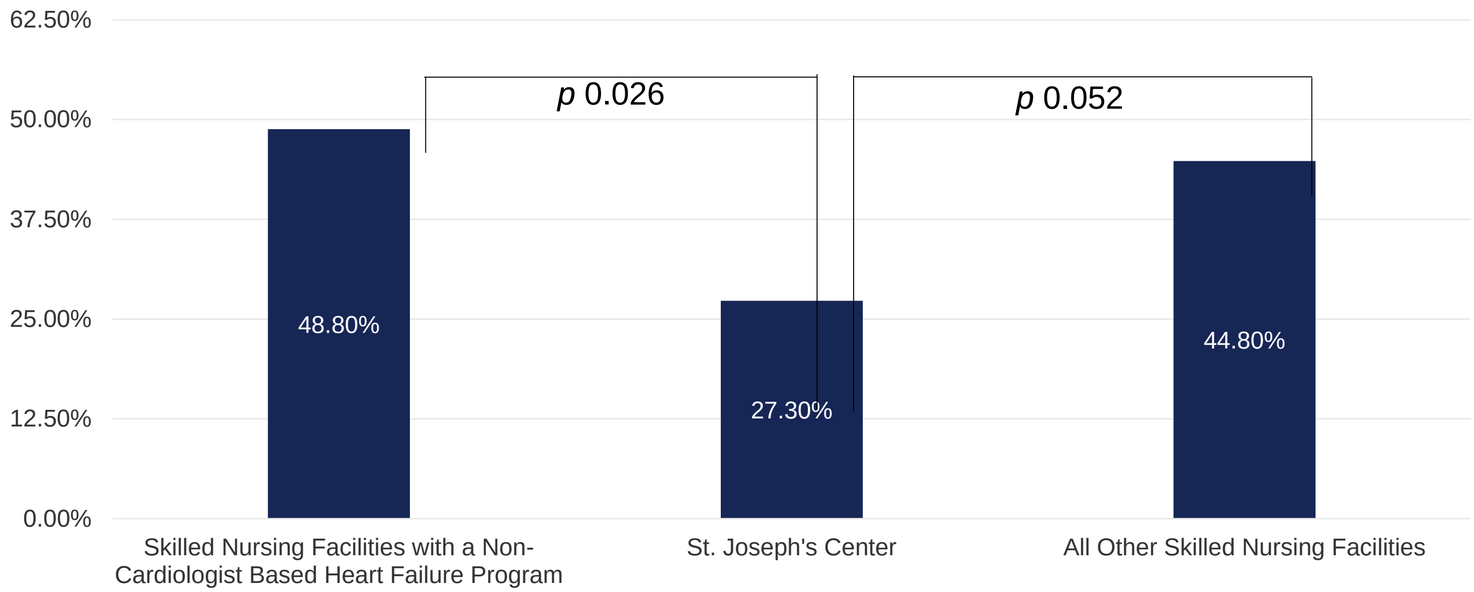
Decreasing Percentage of Complex Patients



Nicole M. Orr, Leah Nazarian, In-House Cardiology Consultation Reduces Readmission Rates and Costs for Patients in Skilled Nursing Facilities: 2 Years' Experience in the Heart Failure Bundle Payment Care Improvement Initiative, Abstract #408

PACC Post-Acute Cardiology Care

Impact of Specialty Oversite During PAC Stay



Percent of Patients with a 90-Day Readmission

Nicole M. Orr, Leah Nazarian, In-House Cardiology Consultation Reduces Readmission Rates and Costs for Patients in Skilled Nursing Facilities: 2 Years' Experience in the Heart Failure Bundle Payment Care Improvement Initiative, Abstract #408

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www.postacutecardiologycare.com

PACC
Post-Acute Cardiology Care

CASE

- 71 yo female with HFpEF, COPD, AFIB, SSS s/p PPM, obesity hypoventilation syndrome, s/p 6 day inpatient stay for dyspnea.
- Hospital course: Slight suggestion of CHF by lab and radiographic data. Developed AKI after 2 doses IV furosemide 40 mg. Diuretics held, discharged on 40 mg oral furosemide daily to SNF level care for restorative rehab
- Medications: Furosemide 40 mg daily, Carvedilol 6.25 mg BID, aspirin 81 mg, Coumadin 2.5 mg, pravastatin 20 mg
- Had been started on CHF protocol
- CC – CHF/SOB

Leadership: The Missing Ingredient in Nursing Home Quality

Michael R. Wasserman, MD, CMD

Chair, Public Policy Committee

California Association of Long Term Care Medicine

Disclosures

- Shareholder, Sanolla
- Board of Directors, AMDA-The Society of Post Acute and Long Term Care Medicine
- Editorial Board, The Merck Manual
- Advisory Board, Presidium, The Key
- Board of Directors, California Association of Long Term Care Medicine (CALTCM)

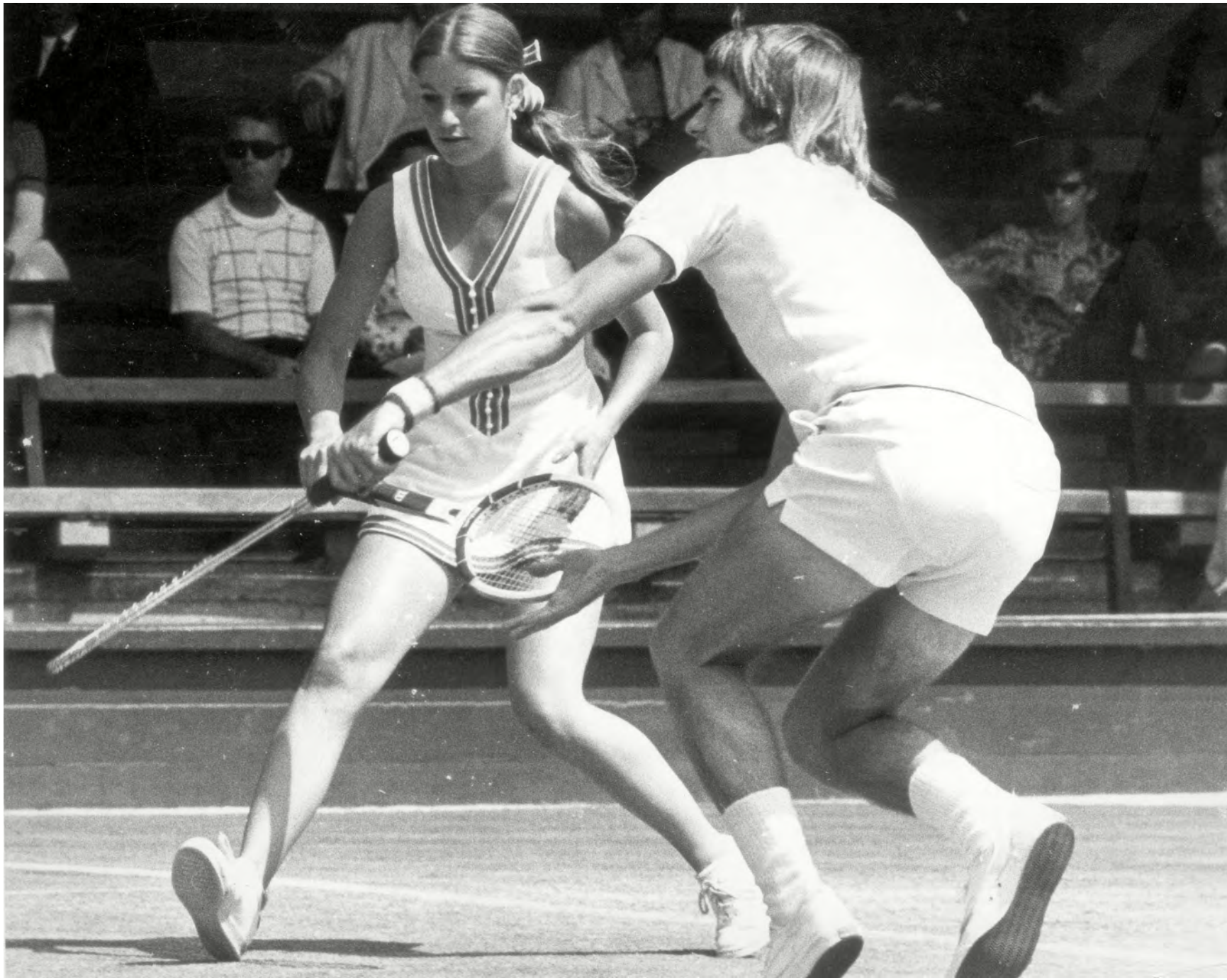
I also have a strong bias against ageism, which I will never remain quiet about!

Learning Objectives

By the end of the presentation, participants will be able to:

- Understand fiduciary and moral/ethical drivers of nursing home decision making
- Understand the difference between transformational and transactional leadership styles
- Describe Bonoma-Slevin Leadership Styles
- Understand the importance of leadership in a nursing home

1974



NURSING HOME CARE IN THE UNITED STATES: FAILURE IN PUBLIC POLICY

INTRODUCTORY REPORT

PREPARED BY THE

SUBCOMMITTEE ON LONG-TERM CARE

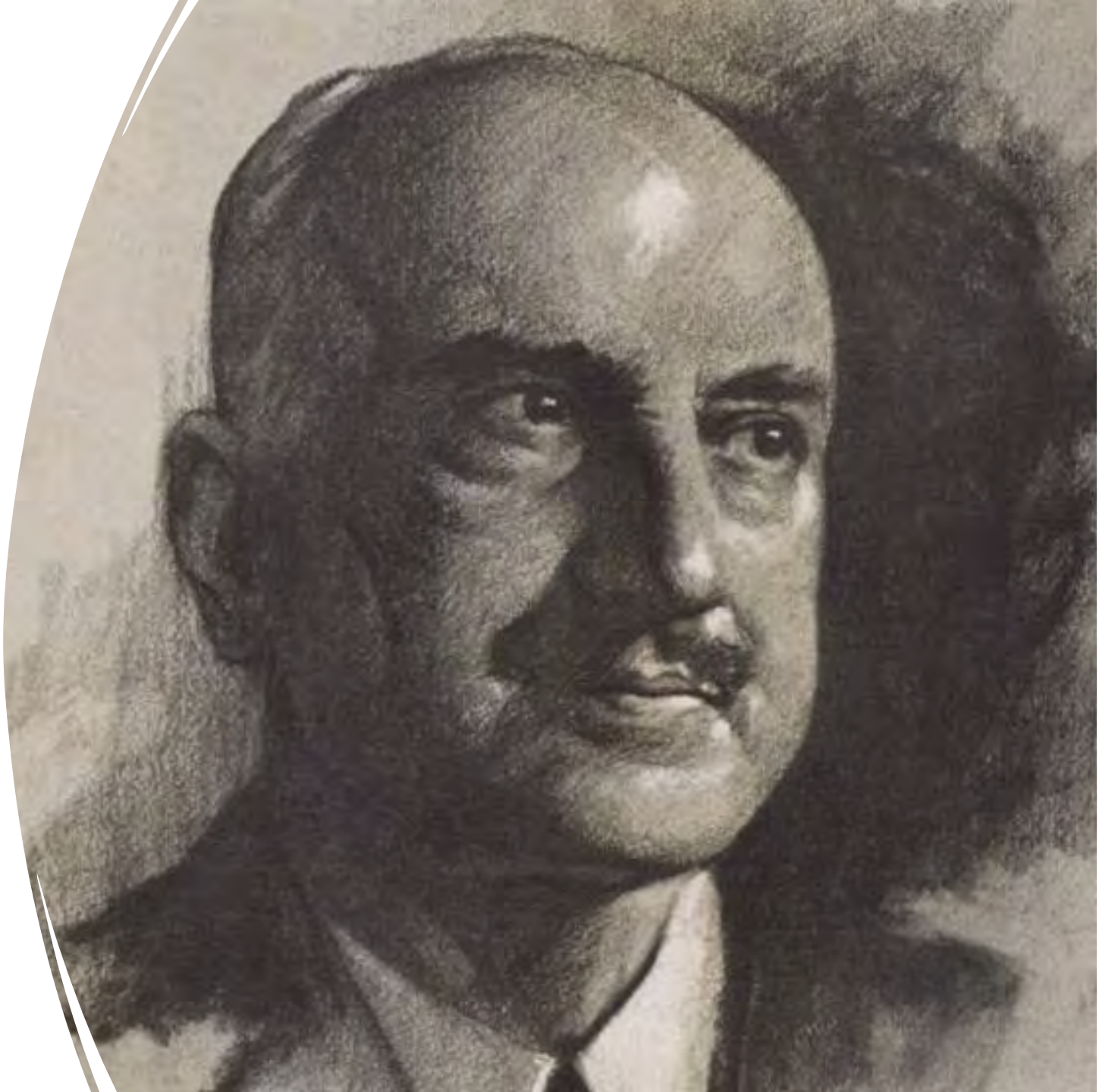
OF THE

SPECIAL COMMITTEE ON AGING

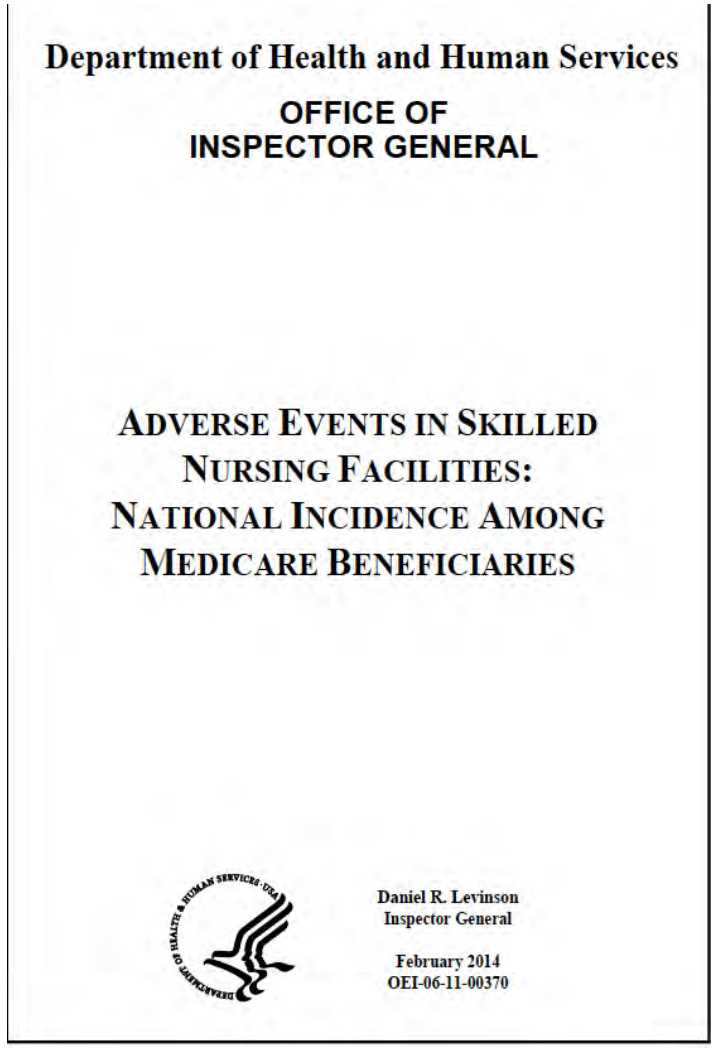
UNITED STATES SENATE

DECEMBER 1974

“Those who cannot remember the past are condemned to repeat it” - George Santayana



2014



Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

ADVERSE EVENTS IN SKILLED NURSING FACILITIES: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES

Daniel R. Levinson
Inspector General

February 2014
OEI-06-11-00370

2014 OIG Report on SNF's

22% of Medicare beneficiaries with adverse events

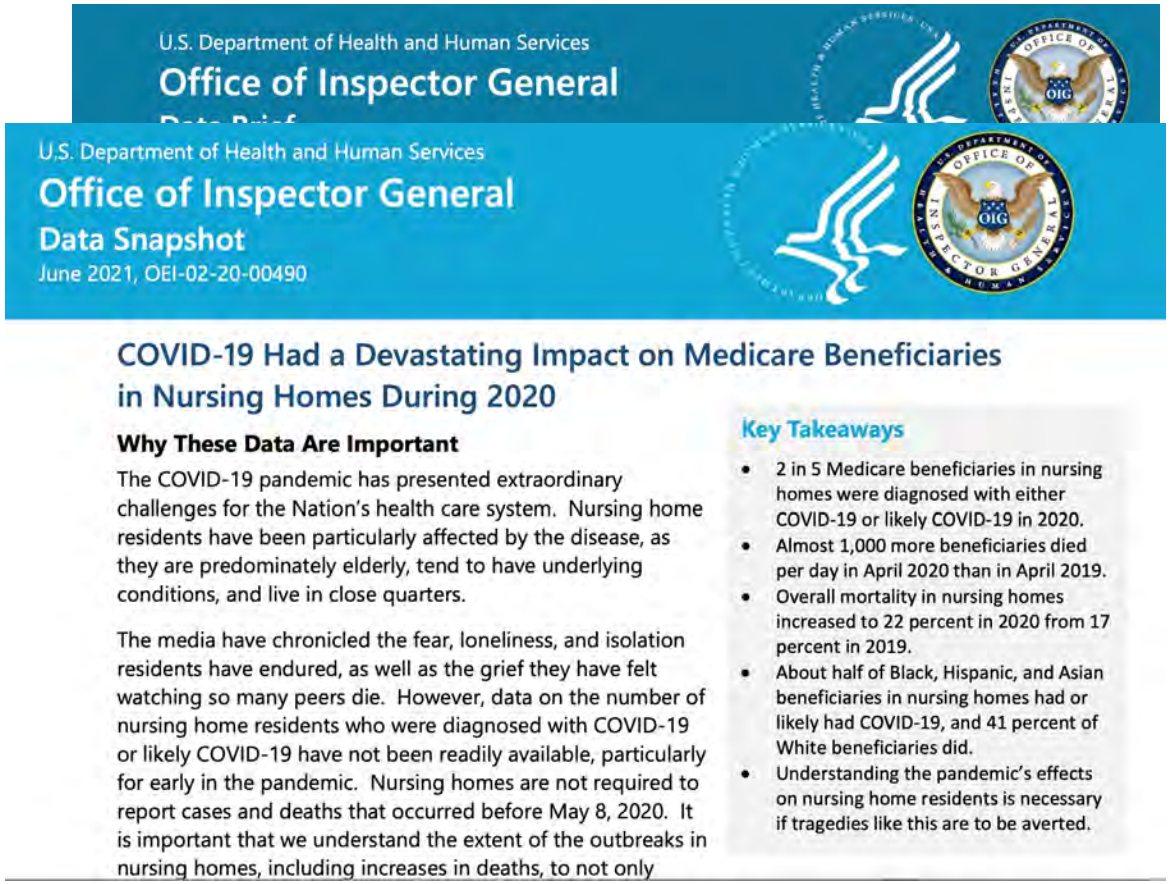
11% experienced temporary harm

59% of adverse events/harm preventable

Preventable harm due to

- Substandard treatment
- Inadequate resident monitoring
- Failure or delay of necessary care

2021 & 2023 OIG Reports on COVID-19 in Nursing Homes



U.S. Department of Health and Human Services

Office of Inspector General

Data Snapshot

June 2021, OEI-02-20-00490

COVID-19 Had a Devastating Impact on Medicare Beneficiaries in Nursing Homes During 2020

Why These Data Are Important

The COVID-19 pandemic has presented extraordinary challenges for the Nation's health care system. Nursing home residents have been particularly affected by the disease, as they are predominately elderly, tend to have underlying conditions, and live in close quarters.

The media have chronicled the fear, loneliness, and isolation residents have endured, as well as the grief they have felt watching so many peers die. However, data on the number of nursing home residents who were diagnosed with COVID-19 or likely COVID-19 have not been readily available, particularly for early in the pandemic. Nursing homes are not required to report cases and deaths that occurred before May 8, 2020. It is important that we understand the extent of the outbreaks in nursing homes, including increases in deaths, to not only

Key Takeaways

- 2 in 5 Medicare beneficiaries in nursing homes were diagnosed with either COVID-19 or likely COVID-19 in 2020.
- Almost 1,000 more beneficiaries died per day in April 2020 than in April 2019.
- Overall mortality in nursing homes increased to 22 percent in 2020 from 17 percent in 2019.
- About half of Black, Hispanic, and Asian beneficiaries in nursing homes had or likely had COVID-19, and 41 percent of White beneficiaries did.
- Understanding the pandemic's effects on nursing home residents is necessary if tragedies like this are to be averted.

“Cargo Cult Science” (1974) and Nursing Homes Today

- ***Care Coordination Demonstration***
- ***NHVBP Demonstration***
- ***QAPI Demonstration***
- ***All negative studies!***
- ***CMS implements them!***

WHAT'S MISSING IN ORDER TO MAKE THESE PROGRAMS WORK?

The Geriatrics Approach to Care

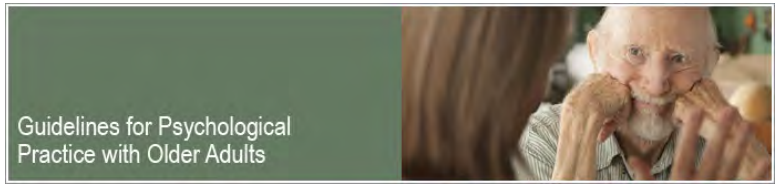
The Structure to Allow

The Leadership to Implement

Function

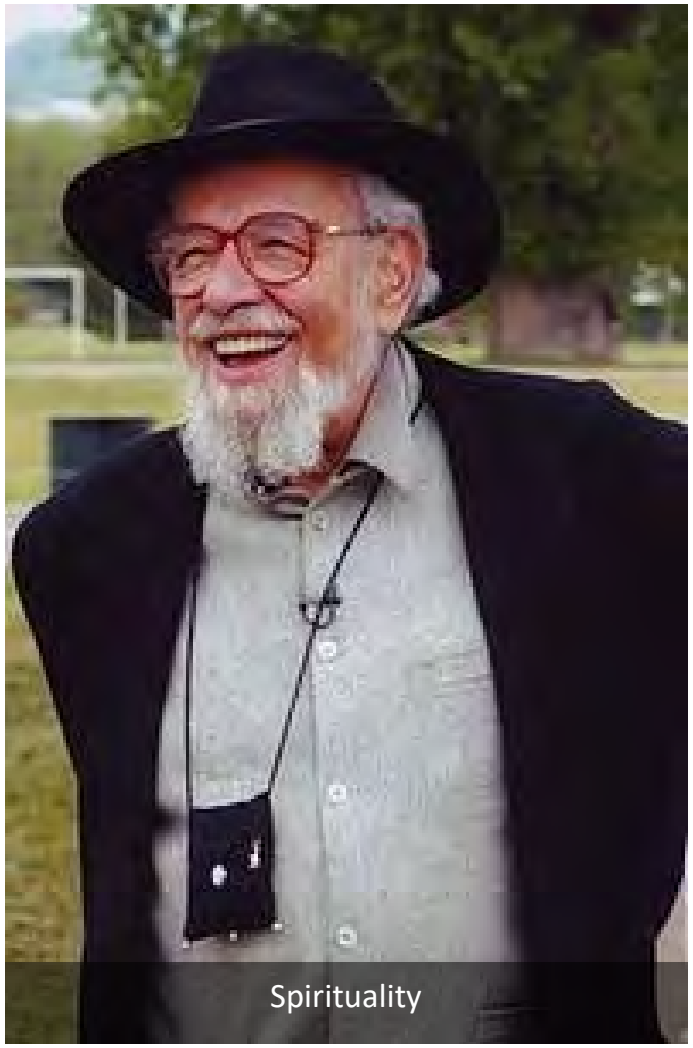
Person Centered Care

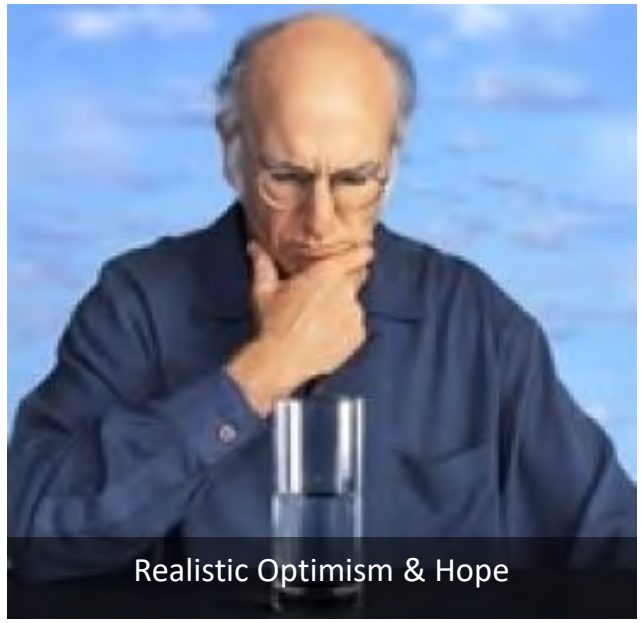
Managing Chronic Disease



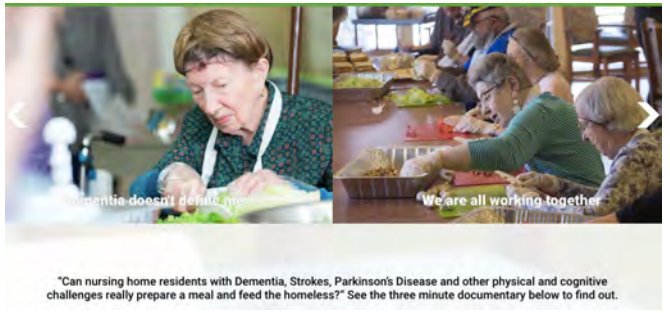
Psychological and Social Aspects of Care

The Geriatrics Approach to Care





The Geriatrics Approach to Care



Purpose

Teamwork

Respect Dignity & Autonomy

Sensitive to Financial Condition

The Geriatrics Approach to Care

The Geriatrics Approach to Care Works!

- Acute Care of the Elderly (ACE) units
- Geriatric Resources for Assessment and Care of Elders (GRACE)
- Program for All inclusive Care of the Elderly (PACE)
- Optimistic

ACE Unit Meta-analysis*

- Fewer falls (risk ratio (RR) = 0.51, 95% CI = 0.29–0.88)
- Less delirium (RR = 0.73, 95% CI = 0.61–0.88)
- Less functional decline at discharge from baseline (RR = 0.87, 95% CI = 0.78–0.97)
- Shorter length of hospital stay (weighted mean difference (WMD) = 0.61, 95% CI = 1.16 to 0.05)
- Fewer discharges to a nursing home (RR = 0.82, 95% CI = 0.68–0.99)
- Lower costs (WMD = $245.80, 95% CI = $446.23 to $45.38)
- More discharges to home (RR = 1.05, 95% CI = 1.01–1.10)

*Fox MT, Persaud M, Maimets I, O'Brien K, Brooks D, Tregunno D, Schraa E. Effectiveness of acute geriatric unit care using acute care for elders components: a systematic review and meta-analysis. J Am Geriatr Soc. 2012 Dec;60(12):2237-45. doi: 10.1111/jgs.12028. Epub 2012 Nov 23. PMID: 23176020; PMCID: PMC3557720.

GRACE PROGRAM: Geriatric Resources for Assessment and Care of Elders (GRACE) model: GRACE Team Care”

NP/SW team overseen by a Geriatrician

Focus on geriatric conditions and medication management

Provides recommendations for care and resources for implementation and follow-up

Incorporates proven care transition strategies

Provides home-based and proactive care management

Integrates with community resources and social services

Develops relationships through longitudinal care

GERIATRICS IN PRIMARY CARE: ENHANCED PRIMARY CARE (GRACE)*

- Improvements in health-related QOL
- Better quality of care for geriatric conditions
- Fewer ED visits
- Reduction in hospitalizations in the high risk group.
- Increases in chronic and preventive care costs were offset by reductions in acute-care costs -- intervention was cost neutral in the first 2 years
- Replication of this model has been successful in Medicare managed-care and VA health care settings
- Consistent improvement in quality of care and reductions in hospital utilization

*Butler, D.E., Frank, K.I., Counsell, S.R. (2015). The GRACE Model. In: Malone, M., Capezuti, E., Palmer, R. (eds) Geriatrics Models of Care. Springer, Cham. https://doi.org/10.1007/978-3-319-16068-9_10

GRACE Homebound Study*

34% decrease in hospital admissions

29% decrease in hospital bed days

44% decrease in sub-acute admits

53% decrease in sub-acute bed days

22% decrease in ED visits

*Steven R. Counsell et al., "Dissemination of GRACE Care Management in a Managed Care Medical Group," poster Presentation at the Annual Scientific Meeting of the American Geriatrics Society, May 2011.

PACE (PROGRAM FOR ALL-INCLUSIVE CARE OF THE ELDERLY)

- All Medicare and Medicaid services through single delivery point
- Targeted to frail older adults with a host of chronic care needs
- Provider-based model of care
- Participants at the center of the plan of care developed by an interdisciplinary team
- Full continuum of preventive, primary, acute, rehabilitative, and long-term care services
- Comprehensive care in a fiscally responsible manner for families, health care
- Providers, government programs, and others that pay for care
- Historically staffed by Geriatricians

OPTIMISTIC*,**

- 19 geriatrics-trained RNs in nursing homes
- RNs helped administer care to patients
- Worked to support, educate, and train facility staff to hone their skills
- Focus on improving the quality of geriatric medical practice and palliative care
- Improved potentially avoidable hospitalizations by 29.3%.
- Reduced all-cause hospitalizations by 21.2%.
- Lowered per-resident expenditures on all-cause ED visits by 30.9%

*Blackburn, J., Balio, C.P., Carnahan, J.L. *et al.* Facility and resident characteristics associated with variation in nursing home transfers: evidence from the OPTIMISTIC demonstration project. *BMC Health Serv Res* **21**, 492 (2021). https://doi.org/10.1186/s12913-021-06419-y

**Kathleen T Unroe, MD, MHA, Susan E Hickman, PhD, Jennifer L Carnahan, MD, MPH, Zach Hass, PhD, Greg Sachs, MD, Greg Arling, PhD, Investigating the Avoidability of Hospitalizations of Long Stay Nursing Home Residents: Opportunities for Improvement, *Innovation in Aging*, Volume 2, Issue 2, June 2018, igy017, https://doi.org/10.1093/geroni/igy017

The Geriatrics Approach to Care

Structure to Allow

Leadership to Implement

COVID-19 has "Unmasked" Underlying Issues in Post Acute & Long Term Care

Is there enough money in long term care?

- Operations
- Real estate
- Related parties

Are there enough trained staff?

- Wages and Benefits
- Are staff valued, respected and treated honorably?
- Is training sufficient?
- Are most NHAs and DONs offered adequate training?

Who is responsible and accountable for quality?

- Regulators
- Operators
- Consultants/Managers
- Real estate owners

Examples of related parties that have an impact on nursing home finances

HEALTH AFFAIRS BLOG

RELATED TOPICS:
NURSING HOMES | QUALITY OF CARE | MEDICARE | PAYMENT | AFFORDABLE CARE ACT | MEDICAID | PHARMACEUTICALS

These Administrative Actions Would Improve Nursing Home Ownership And Financial Transparency In The Post COVID-19 Period

Charlene Harrington, Anne Montgomery, Terris King, David C. Grabowski, Michael Wasserman

FEBRUARY 11, 2021 10.1377/hblog20210208.597573

- Real estate
- Medical supplies
- Service providers
- Wound Care
- Construction
- Management

Impact of Real Estate Ownership on Nursing Homes

Lease and Triple Net (Real Estate Taxes, Insurance and Maintenance Costs)

- Real estate owner collects their rent; operations pays for maintenance, property taxes and insurance

Appreciation

- Real estate owner benefits from appreciation of property

Leveraging of Assets

- Real estate owners able to collateralize the asset to borrow money
- Is borrowed money spent on capital improvements?
- **Is borrowed money spent on quality improvement?**

Responsibilities of Finance, Operations and Clinical Components of Nursing Homes

Fiduciary Responsibility

To Employer/Shareholders

- Care
- Loyalty
- Good Faith
- Confidentiality
- Prudence

Primarily financial in nature

Moral/Ethical Responsibility

To Patients/Residents

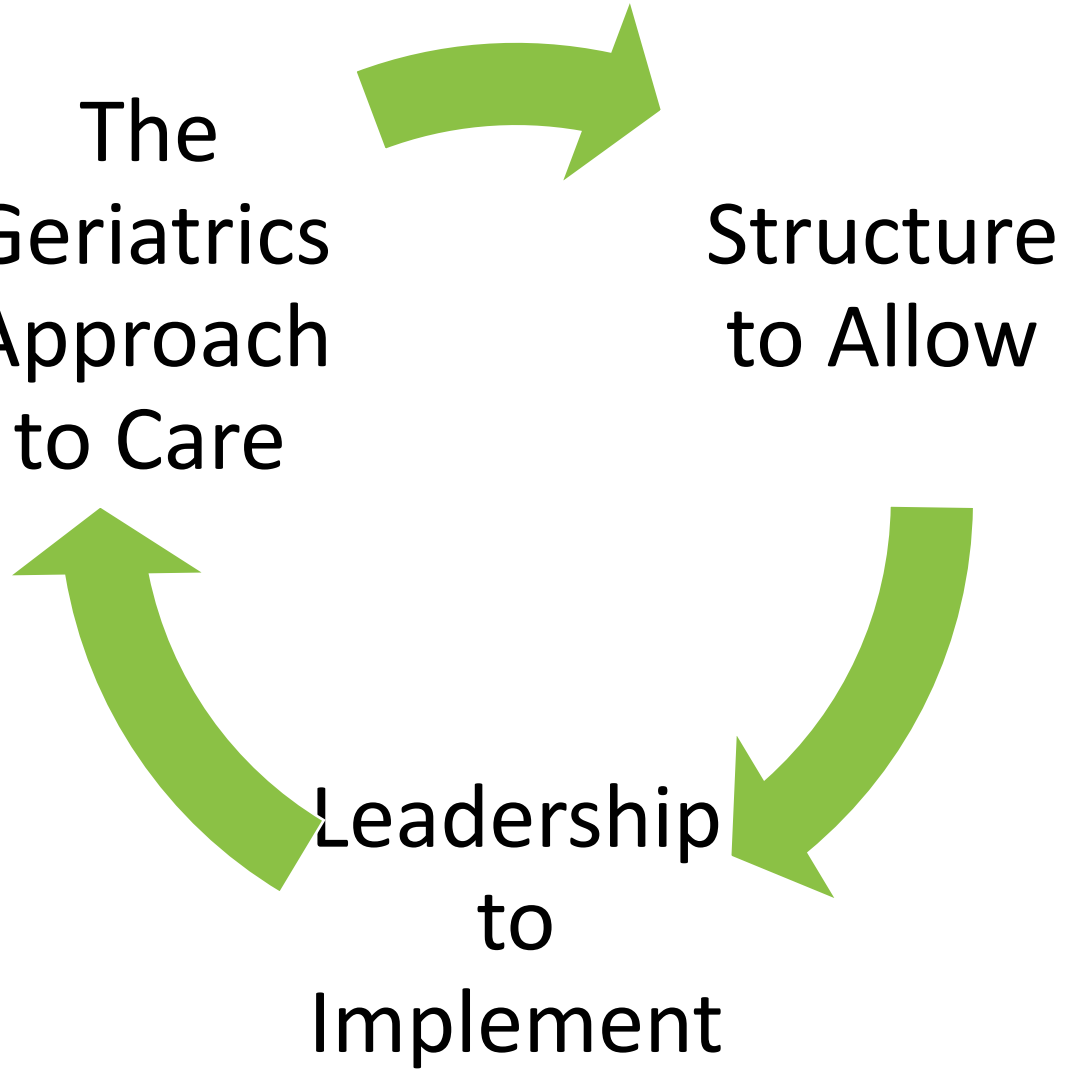
Hippocratic Oath

- Do no harm
- Commitment to person centered care
- Professionalism

Primarily clinical in nature

Nursing Home as a 3-Sided Scale: Structural Challenge to Keep the Scale Balanced

What's *Really* Missing in Post Acute & Long Term Care?



Leadership is Key!

My Mentors and Colleagues, Leaders All!

“Full Range of Leadership Model”-Avolio & Bass*

Transformational	Transactional	Passive-avoidant
• Motivates followers to do more than what is expected of them	• Emphasizes the exchange relationship between leader and follower; both encouraged to meet their own needs	• Passive management-by-exception or avoidance of leadership • Laissez-faire or absence of leadership

*Poels, J., Verschueren, M., Milisen, K. *et al.* Leadership styles and leadership outcomes in nursing homes: a cross-sectional analysis. *BMC Health Serv Res* **20,** 1009 (2020). https://doi.org/10.1186/s12913-020-05854-7

Transformational Leadership

- Increase levels of motivation and morality among followers
- Transformational leadership will often result in performance that surpasses the expected outcomes

Transformational Leadership

- *Associations with Staff*
  - Increased wellbeing
  - Higher job satisfaction
  - Decreased intention to leave
  - Decreased burn-out rate
- *Associations with Health Outcomes*
  - Higher patient satisfaction
  - Higher quality of care
  - Lower mortality
  - Fewer medication errors

Transactional Leadership

Emphasizes the exchange relationship between leader and follower;

- Both encouraged to meet their own needs.
- Two components
  - Providing followers with material or psychological rewards *contingent* on the fulfillment of obligations
  - Active management by exception refers to a leader actively monitoring the work of followers so that, in case of errors, corrective actions can be undertaken.

Transactional leadership will often result in expected outcomes

Passive-Avoidant Leadership

Passive management by exception, reflecting avoidance of leadership

Laissez-faire, which means absence of leadership

Leadership styles and leadership outcomes in nursing homes: a cross-sectional analysis*

Joris Poels, Marc Verschueren, Koen Milisen, and Ellen Vlaeyen

- IN THIS STUDY
  - Head nurses and DON scored significantly lower on transformational and transactional leadership styles and significantly higher on passive-avoidant leadership styles.
  - All leadership outcomes were significantly lower for head nurses. Similar results, however not statistically significant, were found concerning leadership outcomes of DON.

*Poels, J., Verschueren, M., Milisen, K. *et al.* Leadership styles and leadership outcomes in nursing homes: a cross-sectional analysis. *BMC Health Serv Res* **20,** 1009 (2020). https://doi.org/10.1186/s12913-020-05854-7

Bonoma-Slevin Leadership Types

Consensus manager

- Seeks input from the work group and allows the work group's input to influence decision making

Consultative autocrat

- Seeks input but makes all important decisions on his or her own

Autocrat

- Does not seek any input and makes all decisions on his or her own.

Shareholder manager

- Fails to solicit input from the staff on decision making and neglects to share important information with the staff that would enable them to make better decisions on their own

Leadership Styles in Nursing Homes*

NHA leadership styles (%)	
Consensus manager	30.9
Autocrat	28.4
Consultative autocrat	26.5
Shareholder manager	14.2

*Christopher Donoghue, PhD, Nicholas G. Castle, PhD, Leadership Styles of Nursing Home Administrators and Their Association With Staff Turnover, *The Gerontologist*, Volume 49, Issue 2, April 2009, Pages 166–174, https://doi.org/10.1093/geront/gnp021

Leadership Style & Staff Turnover*

Table 2. RN, LPN, and NA Turnover Rates by NHA Leadership Style

	NHA leadership style			
	Shareholder manager (%)	Autocrat (%)	Consultative autocrat (%)	Consensus manager (%)
RN turnover	44.3	18.5	8.4	6.5[a]
LPN turnover	57.1	26.0	13.7	5.4[a]
NA turnover	74.3	71.4	56.8	47.4[b]

Notes: NA = nurse's aide; RN = registered nurse; LPN = licensed practical nurse; NHA = nursing home administrator.
[a]Analysis of variance (ANOVA) SNK test found significant differences between all figures in the row ($p < .05$).
[b]ANOVA SNK test found significant differences between all figures in the row, except for the difference between shareholder managers and autocrats ($p < .05$).

*Christopher Donoghue, PhD, Nicholas G. Castle, PhD, Leadership Styles of Nursing Home Administrators and Their Association With Staff Turnover, *The Gerontologist*, Volume 49, Issue 2, April 2009, Pages 166–174, https://doi.org/10.1093/geront/gnp021

Table 3. Regression Coefficients for the Effects of Leadership Style on Nursing Home Quality Indicators

Variables	(1) Percent physical restraint use (LSR)	(2) Percent with moderate to severe pain (LSR)	(3) Percent low-risk residents with pressure sores (LSR)	(4) Percent high-risk residents with pressure sores (LSR)	(5) Percent had a catheter inserted and left in bladder (LSR)	(6) 5-Star quality measure score[a]	(7) 5-Star health inspection score[a]
NHA leadership styles[b]							
Consensus manager	0.64*** (0.20)	0.49*** (0.11)	0.62** (0.22)	0.74 (0.37)	0.51 (0.30)	7.16** (2.05)	0.19* (0.05)
Consultative autocrat	0.83* (0.35)	0.56 (0.39)	0.95 (0.42)	0.86 (0.47)	0.69 (0.35)	3.11 (2.05)	0.03 (0.03)
Shareholder manager	0.35 (0.16)	0.88* (0.40)	1.38 (0.22)	0.44 (0.34)	0.39* (0.18)	4.13* (1.92)	0.15 (0.9)
Autocrat	1.12** (0.45)	1.77** (0.30)	0.46* (0.18)	0.78* (0.31)	1.90 (0.63)	1.72 (3.01)	0.18 (0.10)
DON leadership styles[b]							
Consensus Manager	0.57* (0.23)	0.44* (0.20)	0.76** (0.18)	0.51** (0.20)	0.40*** (0.10)	5.53** (1.67)	0.15** (0.41)
Consultative Autocrat	0.69 (0.43)	0.38 (0.21)	0.89** (0.28)	0.72 (0.33)	0.88* (0.25)	3.13 (2.28)	0.05* (0.02)
Shareholder Manager	0.83* (0.37)	1.21 (0.16)	1.20 (0.15)	0.55 (0.40)	1.04 (0.04)	4.46 (4.15)	–0.02 (0.01)
Autocrat	1.43** (0.17)	1.20 (0.19)	1.12 (0.15)	0.90 (0.47)	0.91 (0.49)	–2.22* (1.03)	0.11 (0.09)
Combination of leadership styles[c]							(2.51)
NHA/DON dissimilar styles	0.99 (0.56)	0.82* (0.37)	0.84 (0.54)	0.95 (0.66)	1.05* (0.02)	1.14 (1.32)	–0.06 (0.03)
NHA/DON both Consensus Managers	0.97* (0.43)	0.51** (0.21)	0.79 (0.53)	0.62* (0.24)	0.79*** (0.19)	4.02** (1.85)	0.08** (0.02)
Pseudo R^2	0.29	0.32	0.37	0.26	0.29	0.39 (R^2)	0.37 (R^2)

Leadership Styles and Outcomes*

*Castle NG, Decker FH. Top management leadership style and quality of care in nursing homes. Gerontologist. 2011 Oct;51(5):630-42. doi: 10.1093/geront/gnr064. Epub 2011 Jun 30. PMID: 21719632.

Leadership and Vaccine Confidence*

By organizational leadership	Safe	Effective at preventing people from getting sick	Adequately tested for safety and effectiveness specifically among people of color.
Poor	27.3%	15.2%	15.2%
Average	35.8%	29.6%	25.9%
Good	51.2%	46.3%	39.0%
p-value	0.09	0.02*	0.07

*Niznik JD, Harrison J, White EM, Syme M, Hanson LC, Kelley CJ, Porter L, Berry SD. Perceptions of COVID-19 vaccines among healthcare assistants: A national survey. J Am Geriatr Soc. 2022 Jan;70(1):8-18. doi: 10.1111/jgs.17437. Epub 2021 Sep 8. PMID: 34449885; PMCID: PMC8657352.

The Geriatrics Approach to Care

Structure to Allow

Leadership to Implement

WHAT IS CARGO CULT SCIENCE?

“In the South Seas there is a Cargo Cult of people. During the war they saw airplanes land with lots of good materials (cargo), and they want the same thing to happen now”

“So they’ve arranged to make things like runways, to put fires along the sides of the runways, to make a wooden hut for a man to sit in”

“with two wooden pieces on his head like headphones and bars of bamboo sticking out like antennas—he’s the controller—and they wait for the airplanes to land.”

“They’re doing everything right. The form is perfect. It looks exactly the way it looked before. But it doesn’t work. No airplanes land. So I call these things Cargo Cult Science, because they follow all the apparent precepts and forms of scientific investigation, but they’re missing something essential, because the planes don’t land.”

CARGO CULT SCIENCE APPROACH TO LONG-TERM CARE OVER THE DECADES

Regulations

Check lists

Penalties

Aren’t we just building runways and wooden airplanes?

What’s the right approach?

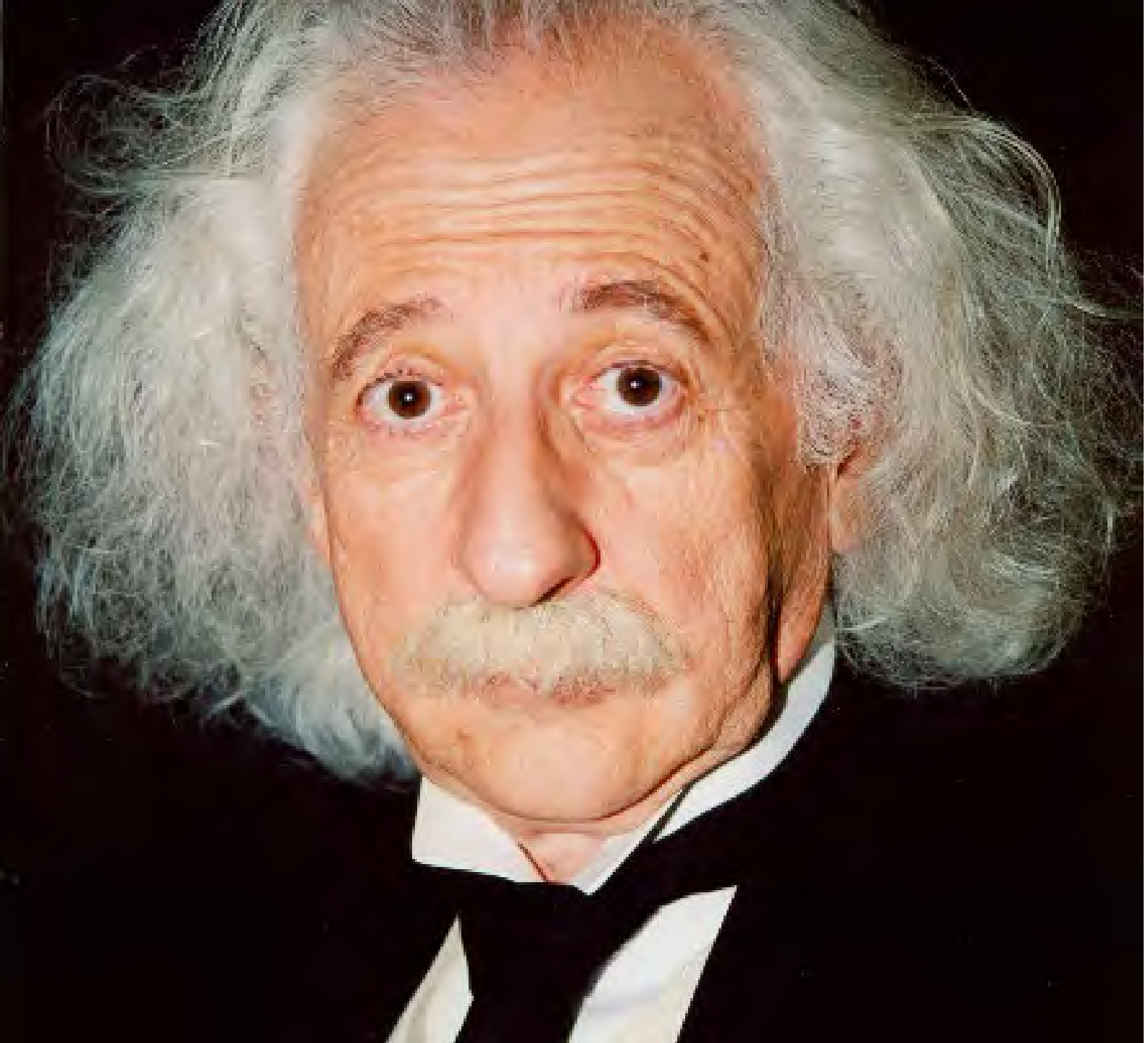
The Geriatrics Approach to Care

Structure to Allow

Leadership to Implement

WE ARE THE KEEPERS OF THE
GERIATRICS APPROACH TO CARE

If not us, then who?



Questions???

California Association of Long Term Care Medicine

@CALTCM

#CALTCM

@Wassdoc

Check the CALTCM Website (CALTCM.org) and e-newsletter, the CALTCM Wave, for updates.

University of Colorado **Anschutz Medical Campus**

COPD in the Nursing Home

Guideline Updates and Treatment Considerations

Matthew Griffith MD MPH

CMDA Conference April 28, 2023

Objectives

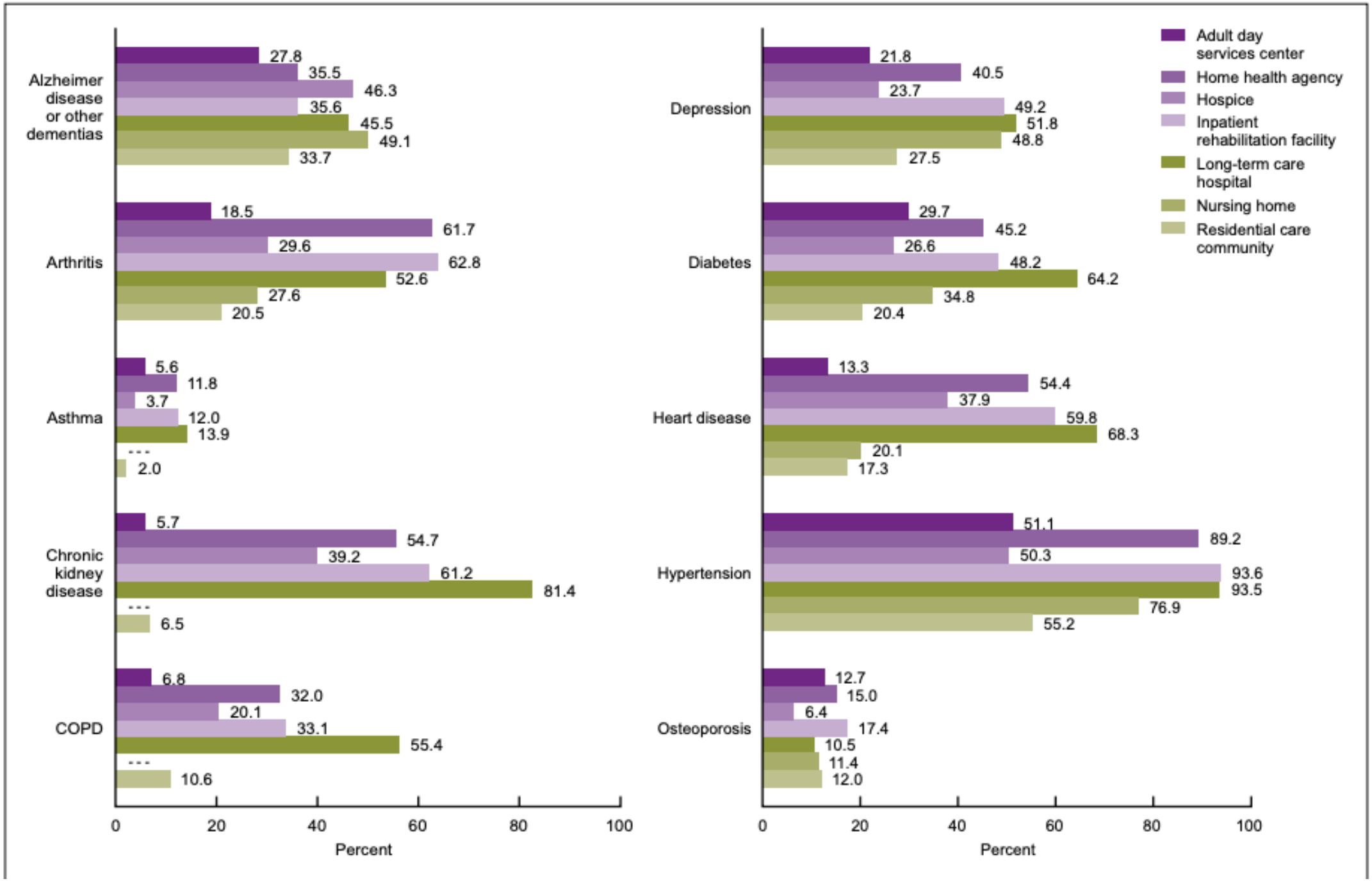
- Identify 2 indications for escalating current COPD treatment
- Identify 2 indications for de-escalating potentially unnecessary or harmful COPD treatments
- Identify 4 different devices used to deliver inhaled medications for COPD and their indications

Chronic Obstructive Pulmonary Disease

Prevalence

- Historic data regarding prevalence shows significant variation across PALTC settings
- Likely due to fact is is not specifically recorded on MDS reports
- Also is chronically under diagnosed in the general population.

Figure 24. Percentage of post-acute and long-term care services users with selected diagnoses, by sector: United States, 2017 and 2018



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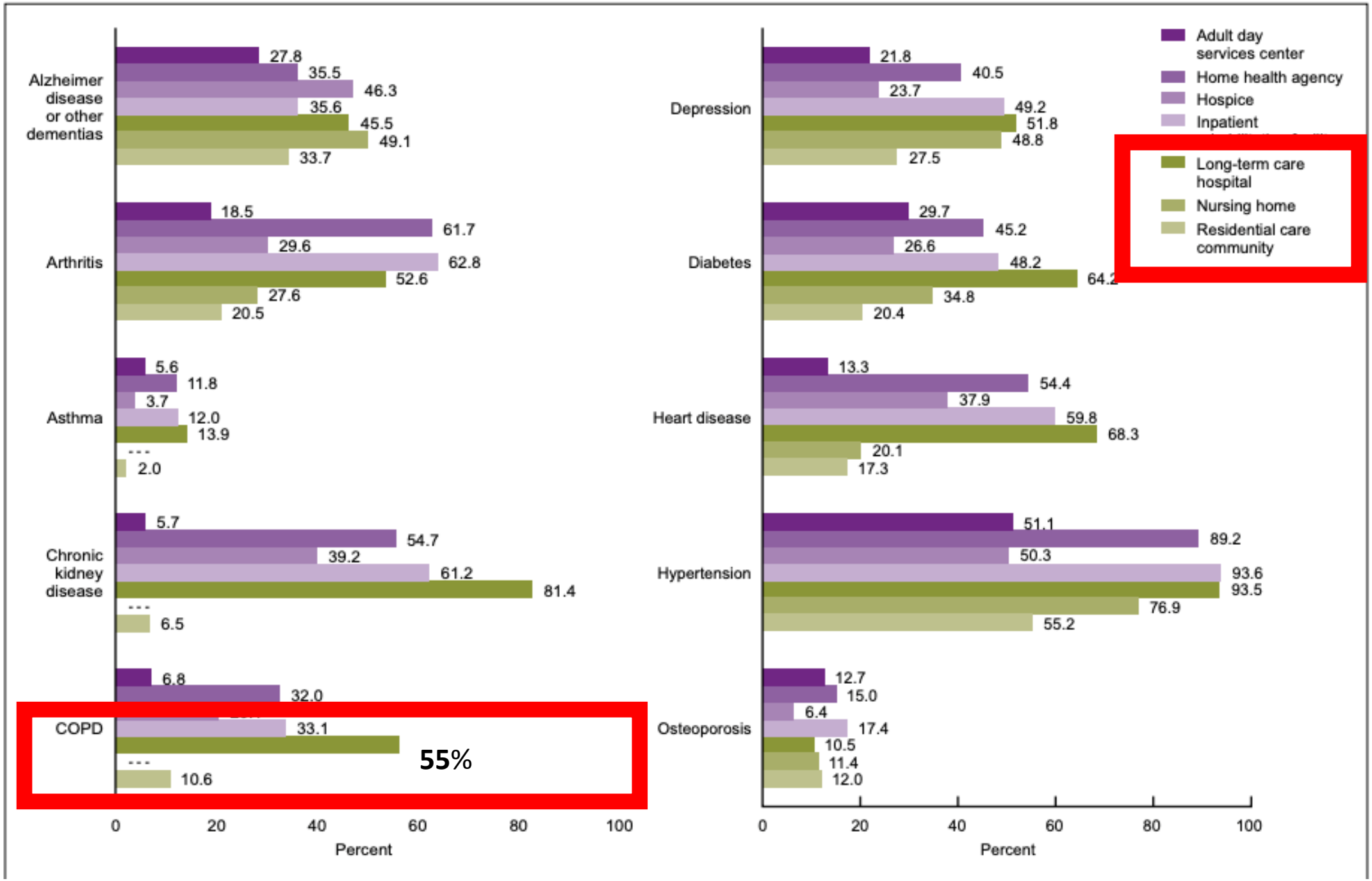


Chronic Obstructive Pulmonary Disease

Diagnosis

- History of tobacco use, second-hand smoke, or exposure to organic (e.g., wood) smoke
- Diagnosed by spirometry
  FEV1/FVC Ratio
- <u>UPDATES</u>
- ATS/ERS no longer recommend a fixed cutoff of FEV1/FVC ratio to diagnose COPD
- Recommend use of lower limit of normal
- Often well below former cutoff of 70%

Chronic Obstructive Pulmonary Disease

Implications

- Older adults previously diagnosed with COPD no longer meet COPD diagnostic criteria
- This is meant to encourage further evaluation of dyspnea for patients who have borderline FEV1/FVC ratios

Chronic Obstructive Pulmonary Disease

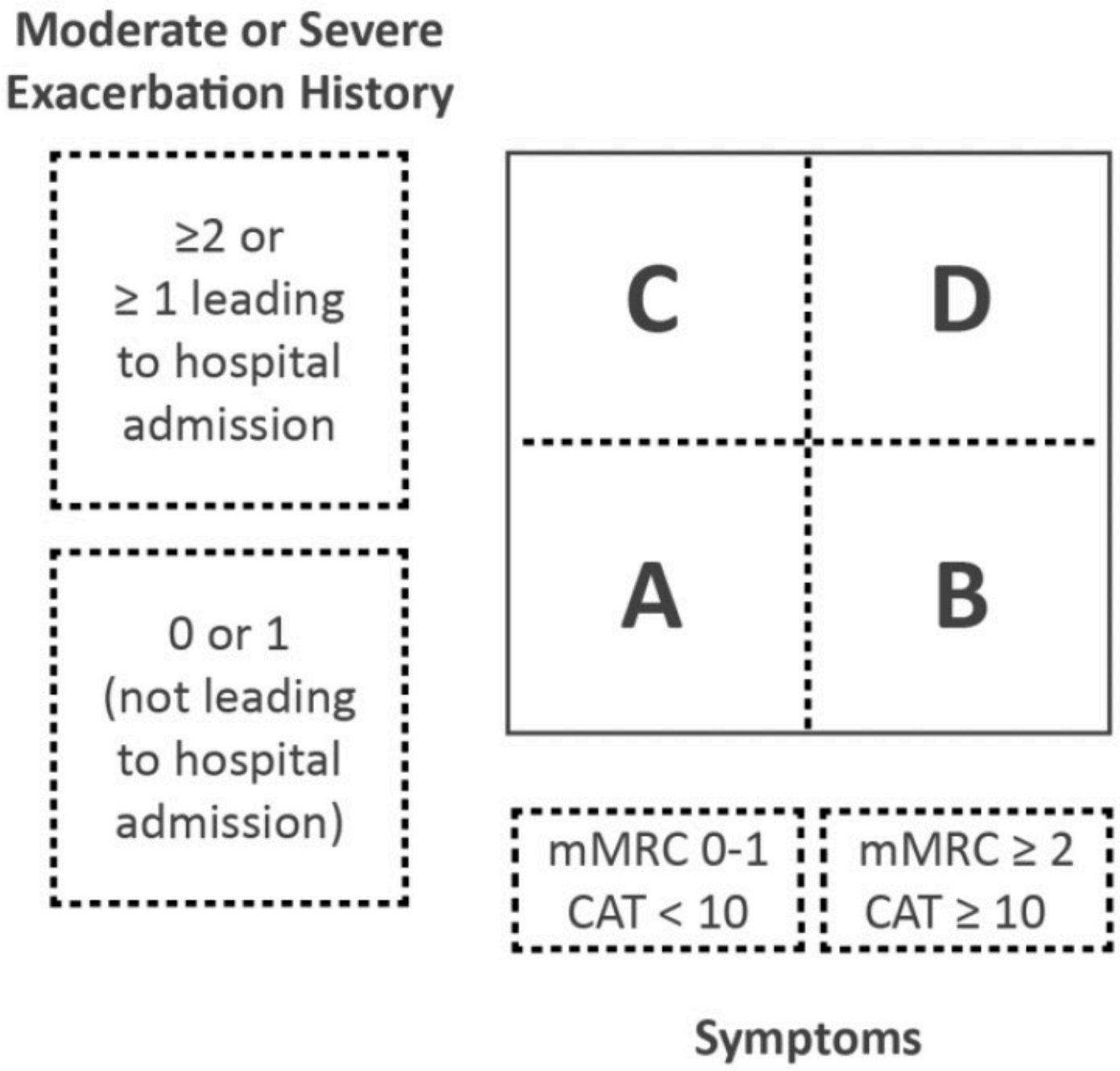
Recommendation

- For patients who are not improving with COPD treatment, consider a referral to a pulmonologist for spirometry

Chronic Obstructive Pulmonary Disease

Assessment

- Severity of symptoms should be assessed AT LEAST annually
- Global Initiative for Chronic Obstructive Lung Disease (GOLD) Categories have been updated



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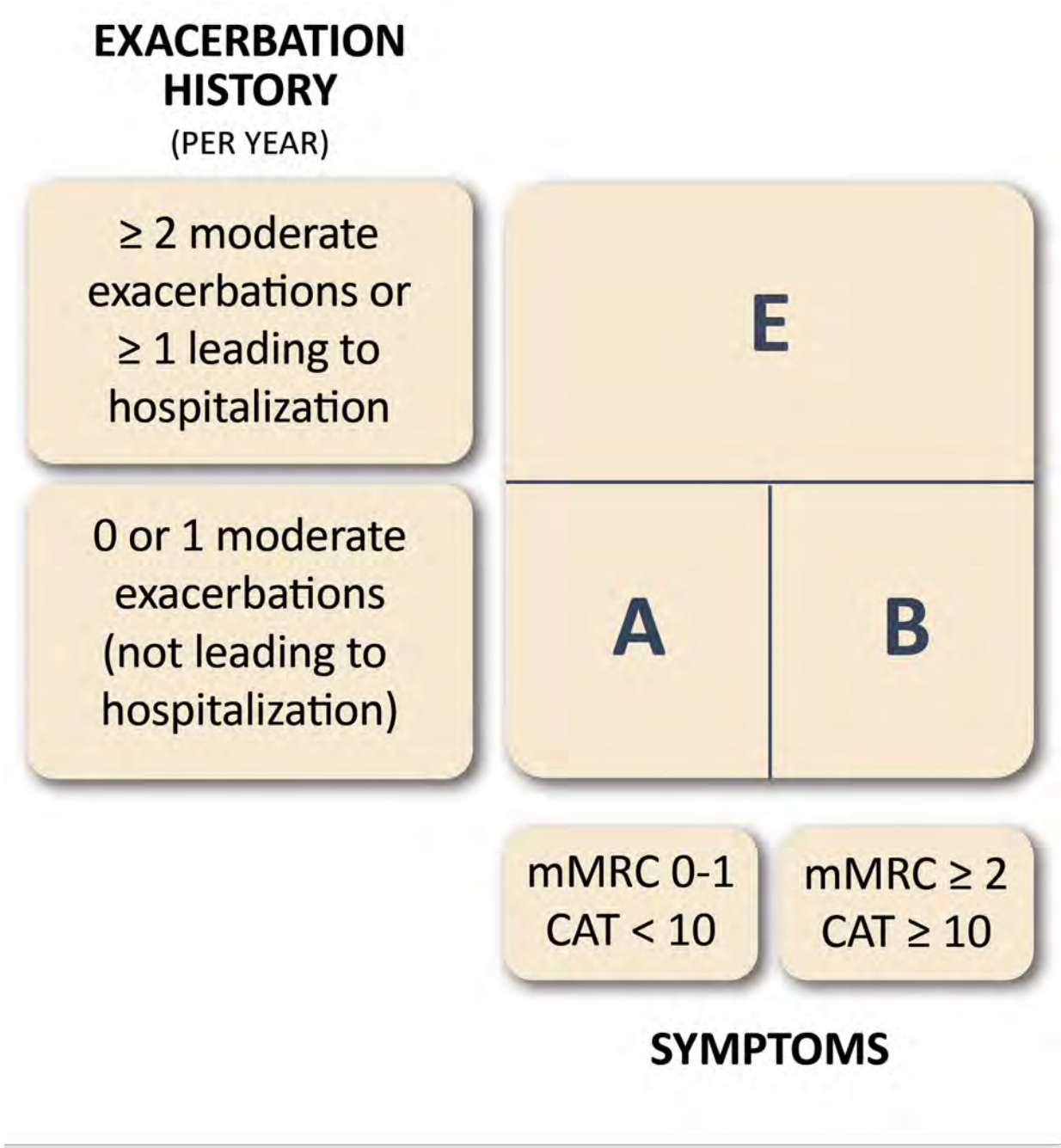
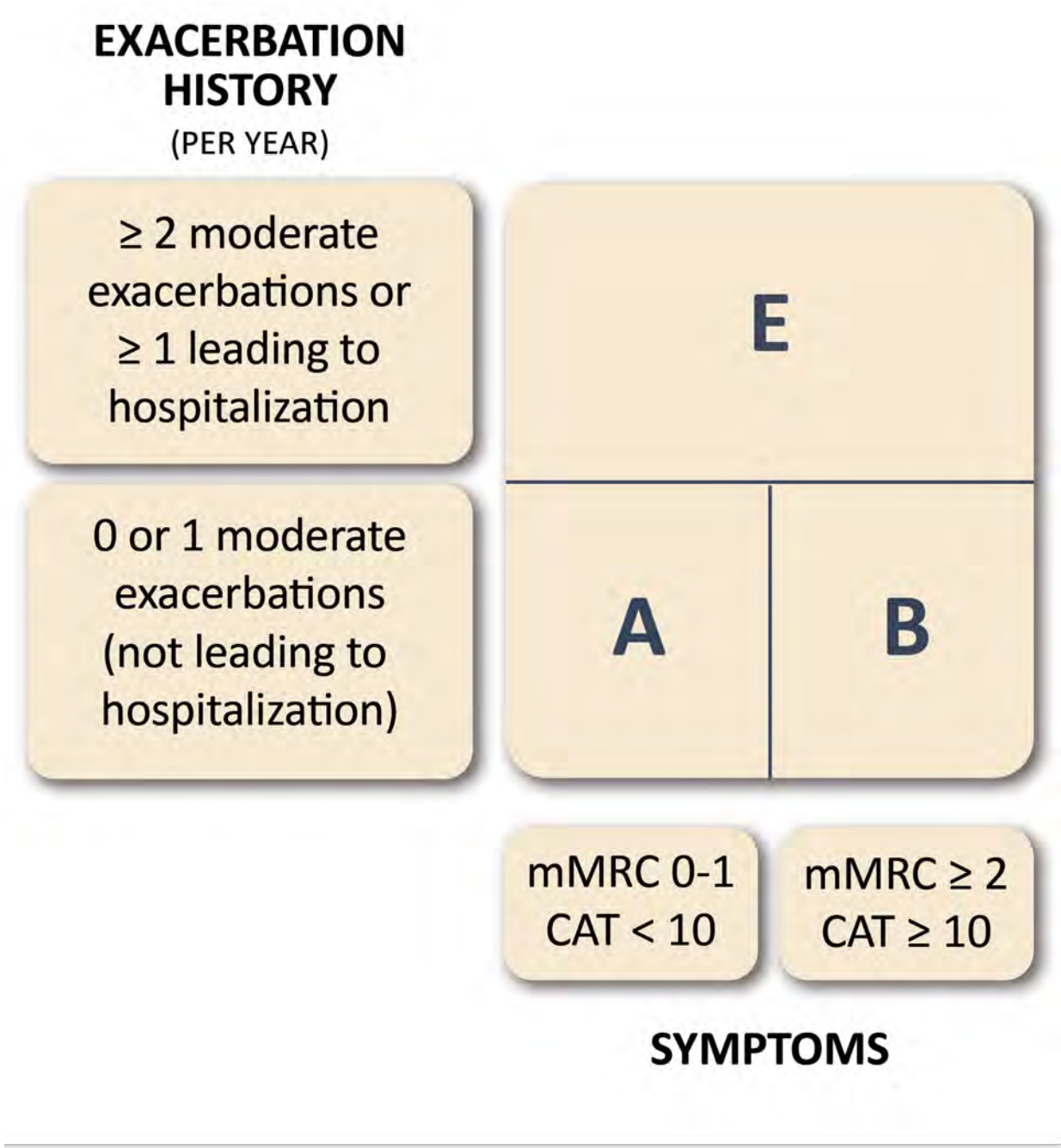


Chronic Obstructive Pulmonary Disease

Assessment

- Severity of symptoms should be assessed AT LEAST annually
- Two validated patient-reported assessment tools
  - COPD Assessment Test (CAT)
  - Modified Medical Research Council Score (mMRC)



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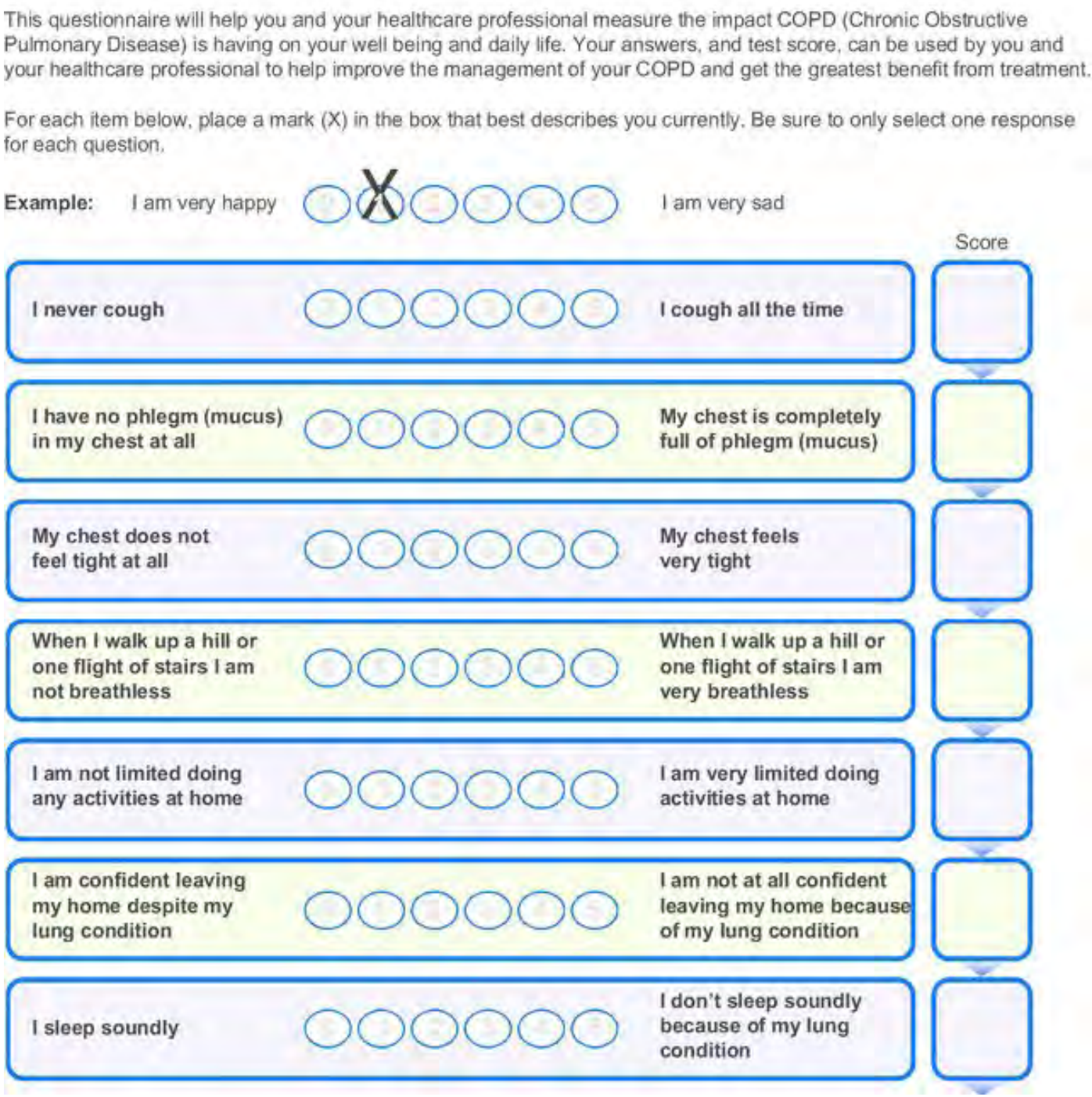

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your well being and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy ○○X○○○ I am very sad

Score

I never cough	○○○○○○	I cough all the time
I have no phlegm (mucus) in my chest at all	○○○○○○	My chest is completely full of phlegm (mucus)
My chest does not feel tight at all	○○○○○○	My chest feels very tight
When I walk up a hill or one flight of stairs I am not breathless	○○○○○○	When I walk up a hill or one flight of stairs I am very breathless
I am not limited doing any activities at home	○○○○○○	I am very limited doing activities at home
I am confident leaving my home despite my lung condition	○○○○○○	I am not at all confident leaving my home because of my lung condition
I sleep soundly	○○○○○○	I don't sleep soundly because of my lung condition

Chronic Obstructive Pulmonary Disease

Assessment

- Severity of symptoms should be assessed AT LEAST annually
- Two validated patient-reported assessment tools
  - COPD Assessment Test (CAT)
  - Modified Medical Research Council Score (mMRC)

mMRC Breathlessness Scale

Grade	Description of Breathlessness
0	I only get breathless with strenuous exercise
1	I get short of breath when hurrying on level ground or walking up a slight hill
2	On level ground, I walk slower than people of the same age because of breathlessness, or have to stop for breath when walking at my own pace
3	I stop for breath after walking about 100 yards or after a few minutes on level ground
4	I am too breathless to leave the house or I am breathless when dressing

Chris Stenton. The MRC breathlessness scale. Occup Med (Lond)(2008)58(3): 226-227 doi:10.1093/occmed/kqm162, Table 1.
By permission of Oxford University Press on behalf of the Society of Occupational Medicine.
A mMRC score of 1 or more suggests significant symptoms.

mMRC=modified Medical Research Council

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Development of MDS-Based Predication Model for COPD Severity in Nursing Home Residents

Barbara Blaylock, PhD[1], Xiaoli Niu, PhD[2], H. Edward Davidson, PharmD, MPH[3], Stefan Gravenstein, MD, MPH[4], Ronald DePue, PharmD[2], G. Rhys Williams, ScD[2], and Karl E. Steinberg, MD, CMD[5]

Table 3. Multivariate Multinomial Logit Regression on GOLD A to D Groups (Reference = GOLD A).

	GOLD B		GOLD C		GOLD D	
Independent variable	OR	95% CI	OR	95% CI	OR	95% CI
Sex						
Female	0.89	(0.26-3.01)	6.66	(0.34-130.58)	0.84	(0.21-3.30)
Male [ref]						
Age	0.98	(0.91-1.05)	1.00	(0.90-1.12)	0.96	(0.89-1.03)
BMI	1.01	(0.94-1.08)	0.85	(0.71-1.02)	0.95	(0.88-1.03)
Any LABD use	4.15	(1.13-15.21)[a]	0.57	(0.04-8.09)	12.33	(2.91-52.2)[a]
Any dyspnea	5.79	(1.17-28.65)[a]	0.55	(0.03-9.02)	16.94	(3.10-92.76)[a]
PHQ-9 Total Severity Score	1.20	(0.93-1.54)	1.35	(0.98-1.85)	1.28	(0.99-1.64)
Long-form ADL score	0.98	(0.84-1.15)	1.13	(0.86-1.48)	1.07	(0.90-1.27)
Bathing						
Independent, supervision, or limited assistance	0.48	(0.10-2.22)	10.88	(0.25-469.19)	0.17	(0.03-1.02)
Extensive assistance, total dependence, or did not occur [ref]						
Mobility assistance						
Not wheelchair dependent	0.21	(0.04-1.15)	0.12	(0.01-1.66)	0.12	(0.02-0.75)[a]
Wheelchair dependent [ref]						
Balance: Toilet						
Steady or able to stabilize without assistance	0.54	(0.07-4.17)	0.27	(0.01-7.63)	1.12	(0.12-10.42)
Able to stabilize with assistance or did not occur [ref]						
Anemia	1.17	(0.36-3.85)	0.19	(0.02-1.84)	0.88	(0.23-3.32)
Coronary artery disease	0.53	(0.07-3.77)	5.05	(0.35-72.82)	0.36	(0.05-2.83)
Heart failure	1.27	(0.32-4.97)	8.92	(0.87-91.10)	2.46	(0.56-10.71)
Hypertension	2.03	(0.56-7.32)	16.54	(0.82-331.62)	2.32	(0.53-10.10)
Diabetes mellitus	1.40	(0.33-5.88)	0.59	(0.05-7.06)	2.23	(0.48-10.30)
Anxiety	2.13	(0.49-9.19)	1.17	(0.06-21.82)	2.67	(0.56-12.79)
Depression	0.65	(0.19-2.30)	0.06	(0.00-0.79)[a]	0.79	(0.20-3.13)

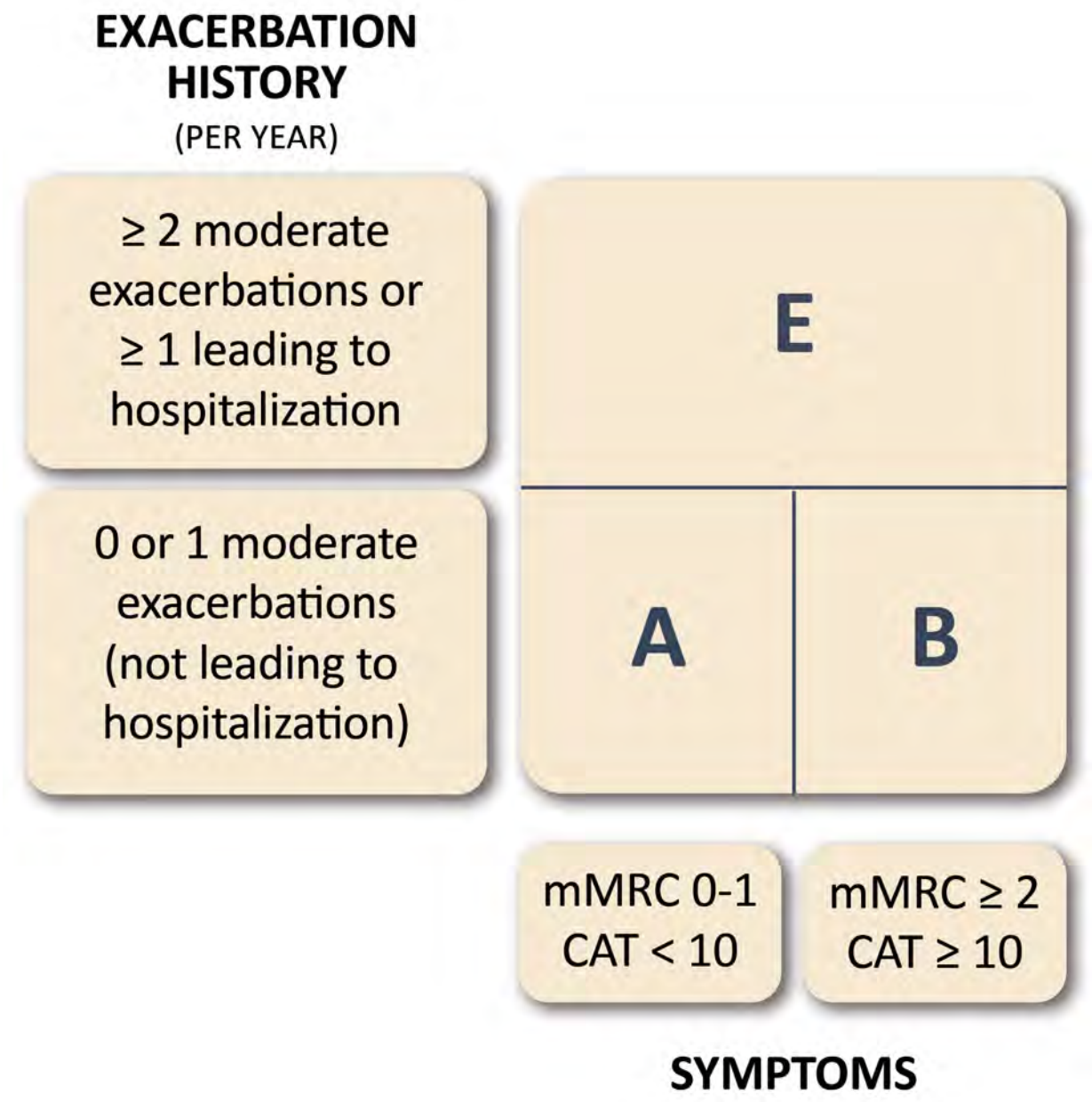
MDS variables mapped to GOLD group (reference = GOLD A) with multivariate multinomial logit model.
Abbreviations: ADL, activity of daily living; BMI, body mass index; CI, confidence interval; GOLD, Global Initiative for Chronic Obstructive Lung Disease; LABD, long-acting bronchodilator; MDS, Minimum Data Set; OR, odds ratio; PHQ-9, Patient Health Questionnaire–9; ref, reference category.
[a]Indicates significance versus GOLD A at $P < 0.05$.

PMID: 34963317

Chronic Obstructive Pulmonary Disease

Assessment

- MDS Dyspnea Assessment can potentially replace either CAT or mMRC scales to establish a GOLD score of A or B/E
- Exacerbation history must be determined annually from clinical chart



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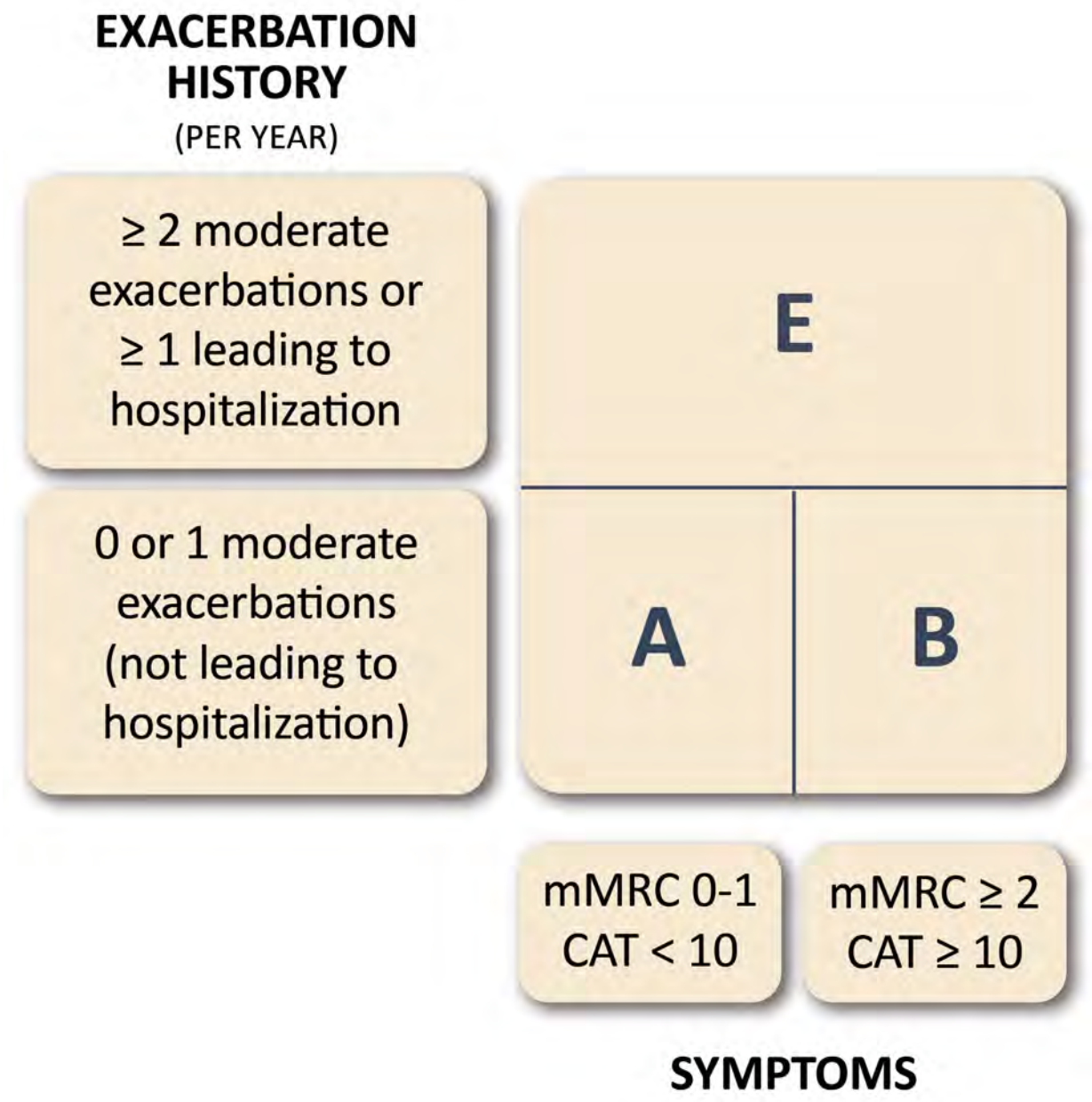


Chronic Obstructive Pulmonary Disease

Treatment

- Medication
  - Only about 25-35% of LTC residents with COPD receive a LAMA or LABA containing medication regimen
  - 40% of patients with 2 or more exacerbations in prior year were only on PRN albuterol

- Delivery Device

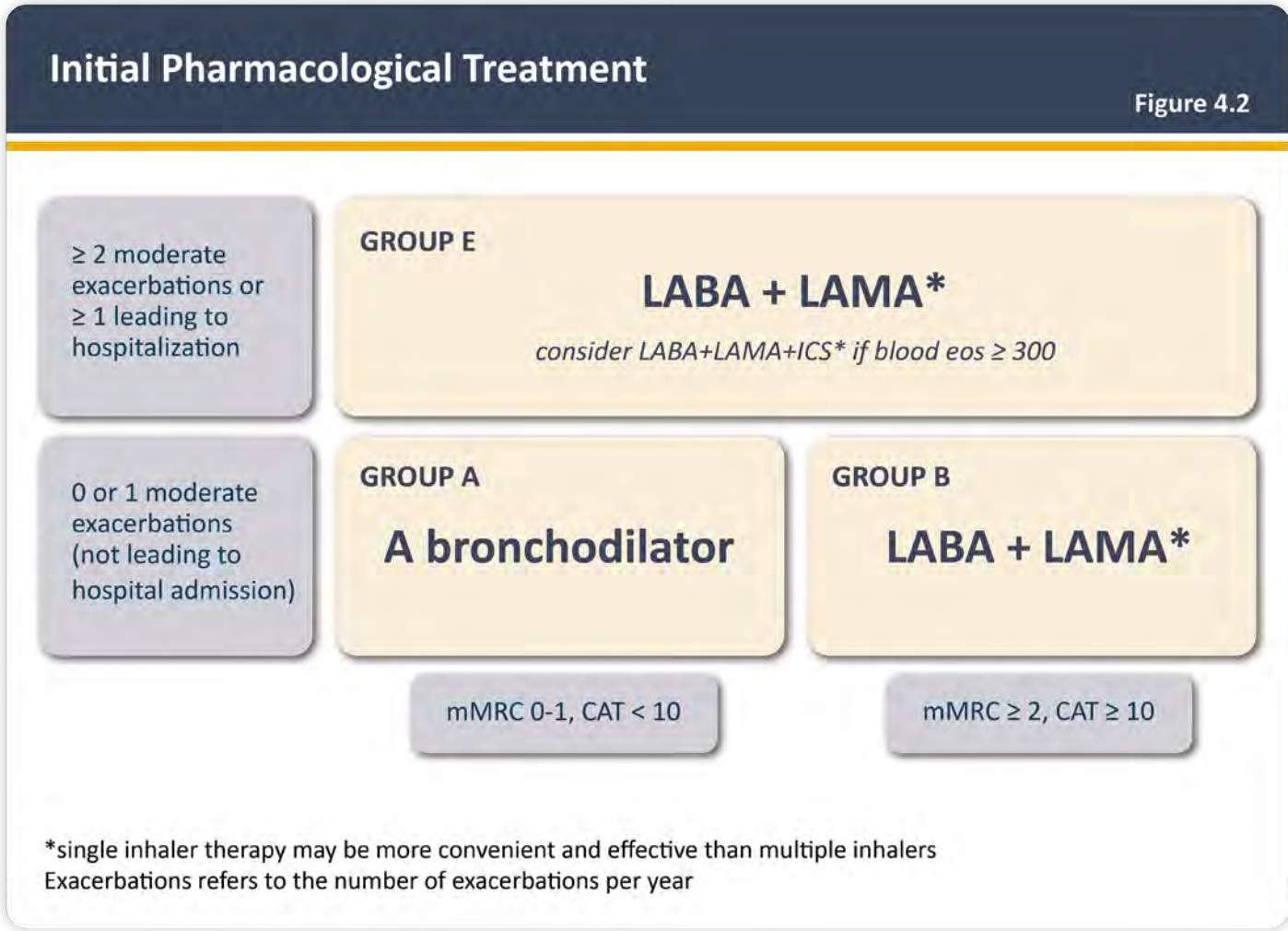
- 25% have a nebulized form of medication available (usually only albuterol)

PMID: 23127147

Chronic Obstructive Pulmonary Disease

Treatment

- Medication
- LABA + LAMA is the preferred initial inhaled medication regimen for all patients with symptomatic COPD
  - **Stiloto (Olodaterol + Tiotropium)***
  - **Anoro (Vilanterol + Umeclidinium)***
  - Duaklir (Formoterol + Aclidinium)
  - Bevespi (Formoterol + Glycopyrrolate)



* - once daily

What if Meds Don't Work

Selective Escalation

- Single Inhalers

Trelegy (fluticasone, umeclidinium, vilanterol)

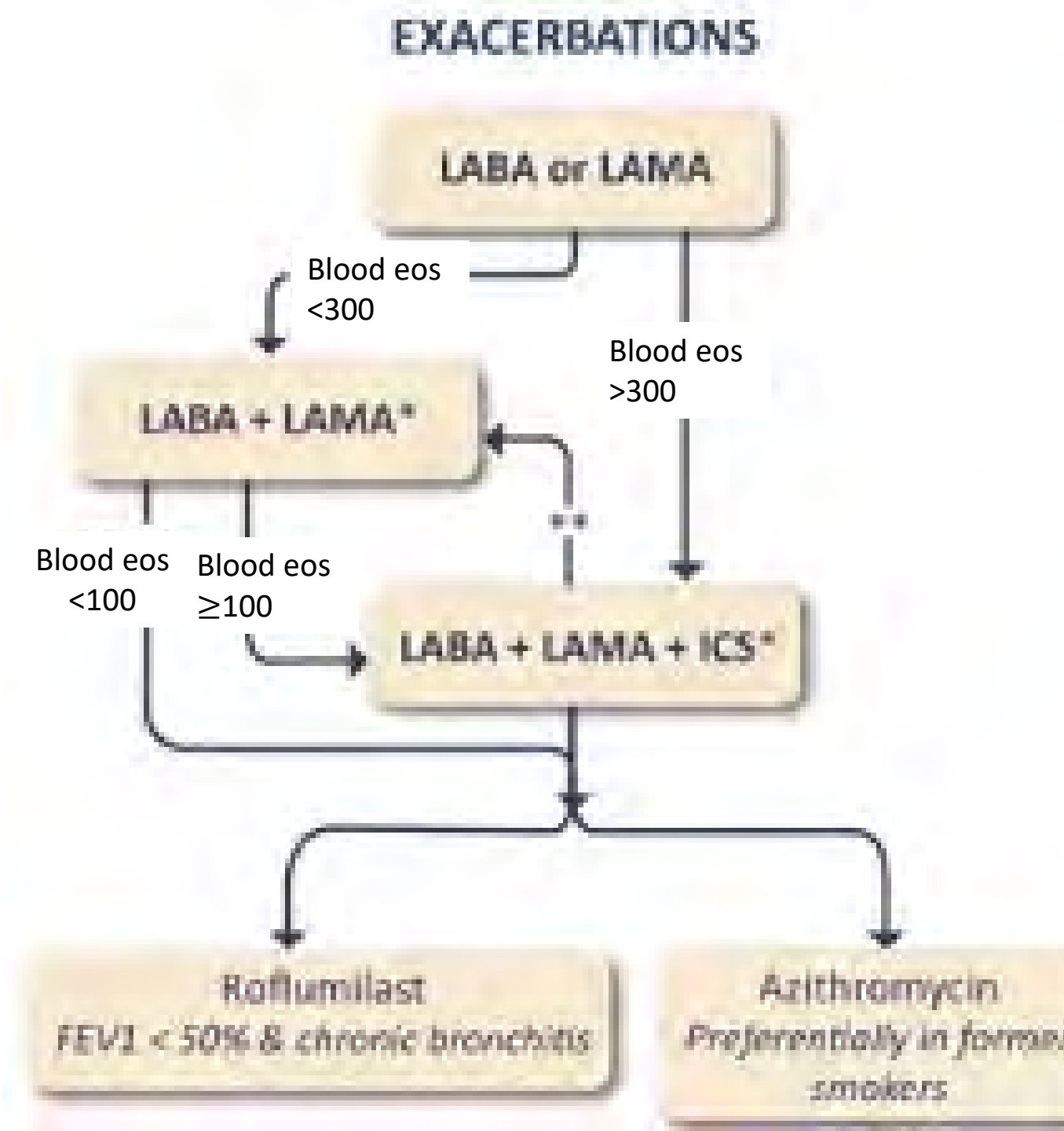
Breztri (budesonide, glycopyrrolate, formoterol)

- Two Inhaler Therapy (ICS/LABA + Tiotropium)

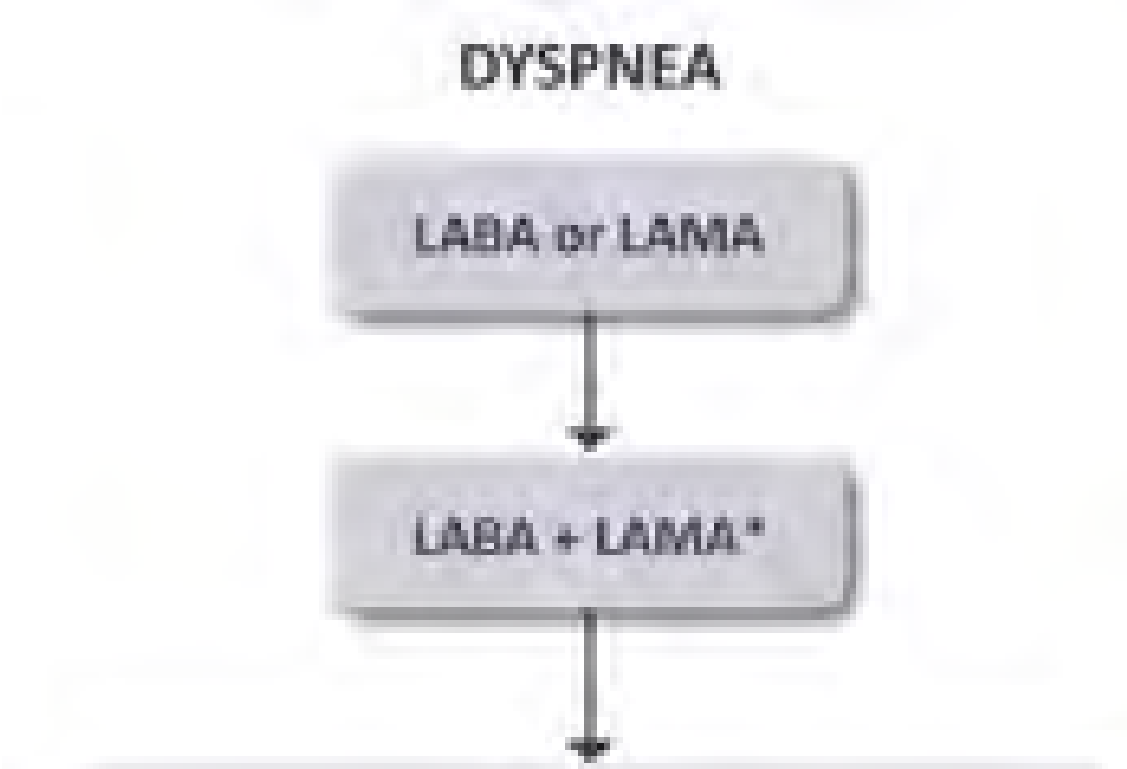
Wixela/Advair (fluticasone + salmeterol)

Symbicort (budesonide + formoterol)

Dulera (mometasone + formoterol)



What if Meds Don’t Work?



- Consider switching inhaler device or molecules
- Implement or escalate non-pharmacologic treatment(s)
- Investigate (and treat) other causes of dyspnea

Non-Pharmacologic Therapies

Non-Pharmacologic Management of COPD*

Table 4.9

Patient Group	Essential	Recommended	Depending on Local Guidelines
A	Smoking Cessation (can include pharmacological treatment)	Physical Activity	Flu Vaccination Pneumococcal Vaccination Pertussis Vaccination COVID-19 Vaccinations Shingles Vaccination
B and E	Smoking Cessation (can include pharmacological treatment) Pulmonary Rehabilitation	Physical Activity	Flu Vaccination Pneumococcal Vaccination Pertussis Vaccination COVID-19 Vaccinations Shingles Vaccination

*Can include pharmacologic treatment

Pulmonary Rehab in LTC

- Patients enrolled regardless of symptoms (only COPD dx)
- Excluded patients with CAD, CHF, MSK disorders, or "mentally challenged" (could not complete patient questionnaires with assistance)

Inpatient Pulmonary Rehabilitation Program in a Long-Term Care Facility

Short-Term Outcomes and Patient Satisfaction

ABSTRACT

The purpose of the current study was to evaluate short-term outcomes of inpatient pulmonary rehabilitation (IPR) programs for older patients with chronic obstructive pulmonary disease (COPD). IPR comprises medical management, exercise, nutrition counseling, and coping skills education programs, among other interventions. The current study used a pretest–posttest design with 21 participants evenly split by gender between the ages of 46 and 95. Effects of IPR on functional tolerance exercise capacity and perceived dyspnea on exertion level had a statistically significant difference by the end of the program. Scores for health-related quality of life and subscales of symptoms, impact, and activity in participants younger than 65 were not statistically significant, whereas St. George's Respiratory Questionnaire scores for participants older than 65 showed a statistically significant improvement. Results showed that early IPR is an effective intervention for the management of symptoms of COPD in older adults recovering from a COPD exacerbation. [*Journal of Gerontological Nursing, 41*(8), 44-52.]

disease causing persistent airflow limitations. It is generally associated with chronic and enhanced inflammatory response in the lungs and airways (GOLD, 2013). Although COPD may be prevented and treated, it cannot be cured with medical treatments. Progression of the disease is characterized by a cascade of systemic effects that lead to deteriorating respiratory function, resulting in compromised exercise tolerance capacity, perceived dyspnea on exertion, chronic cough with or without sputum production, wheezing, and respiratory failure (Qaseem et al., 2011), and decreased health-related quality of life (HRQoL) (Pasqua et al., 2009).

PMID: 26248143

Pulmonary Rehab in LTC

- Intervention
- 3h/week x 6-8 weeks
- Exercise training
  -Walking
  -Cycling
- TENS
- Dyspnea management education
- Upper extremity weight training

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PMID: 26248143

Pulmonary Rehab in LTC

- Outcome
- Improved exercise tolerance (6 minute walk test)
    - 70% increase
- Improved symptom scores

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ABSTRACT

The purpose of the current study was to evaluate short-term outcomes of inpatient pulmonary rehabilitation (IPR) programs for older patients with chronic obstructive pulmonary disease (COPD). IPR comprises medical management, exercise, nutrition counseling, and coping skills education programs, among other interventions. The current study used a pretest–posttest design with 21 participants evenly split by gender between the ages of 46 and 95. Effects of IPR on functional tolerance exercise capacity and perceived dyspnea on exertion level had a statistically significant difference by the end of the program. Scores for health-related quality of life and subscales of symptoms, impact, and activity in participants younger than 65 were not statistically significant, whereas St. George's Respiratory Questionnaire scores for participants older than 65 showed a statistically significant improvement. Results showed that early IPR is an effective intervention for the management of symptoms of COPD in older adults recovering from a COPD exacerbation. [*Journal of Gerontological Nursing, 41*(8), 44-52.]

disease causing persistent airflow limitations. It is generally associated with chronic and enhanced inflammatory response in the lungs and airways (GOLD, 2013). Although COPD may be prevented and treated, it cannot be cured with medical treatments. Progression of the disease is characterized by a cascade of systemic effects that lead to deteriorating respiratory function, resulting in compromised exercise tolerance capacity, perceived dyspnea on exertion, chronic cough with or without sputum production, wheezing, and respiratory failure (Qaseem et al., 2011), and decreased health-related quality of life (HRQoL) (Pasqua et al., 2009).

PMID: 26248143

Medication Side-Effects

- LAMA and LABA Agents

- Increased risk of cardiac events (MI, CHF, tachycardia, arrythmia)

- However even among adults with advance stage heart failure, risks were low and there was a signal for survival benefit among patients on medication[a]

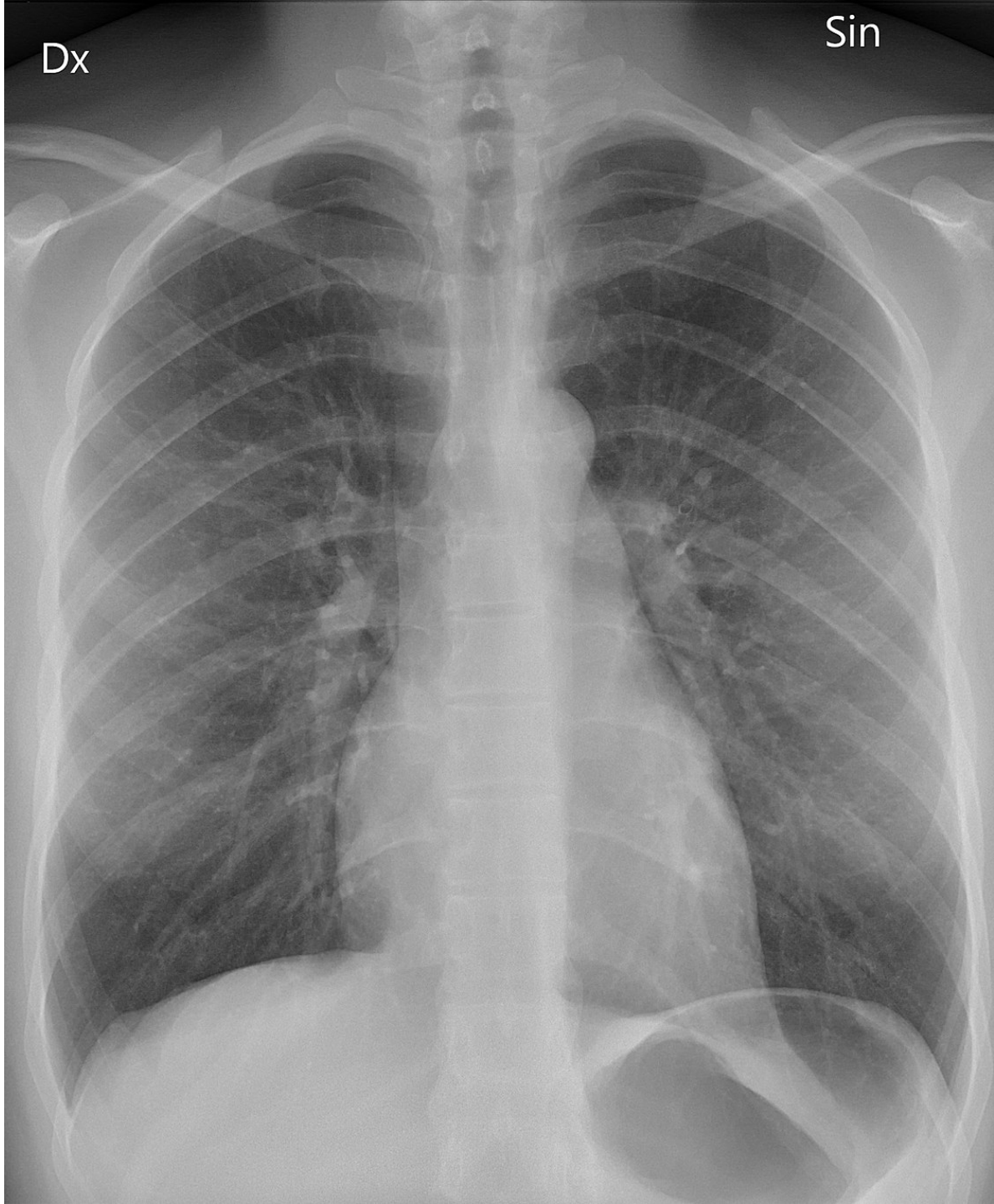
- Inhaled Corticosteroid

- Increased risk of pneumonia, severe pneumonia, cataract, glaucoma and long bone fractures

a- Su VY, Yang YH, Perng DW, et al. Real-world effectiveness of medications on survival in patients with COPD-heart failure overlap. *Aging (Albany NY).* 2019;11(11):3650-3667.

Medication Side-Effects

- No reason to avoid LAMA/LABA inhaled medications in any patient population
- ICS should be used cautiously and de-escalated when appropriate



Inhaler Devices

Metered Dose Inhaler

- **Advantages**

Can be used with a spacer

- **Disadvantages**

Need to generate sufficient force to activate

Must clean spacer appropriately

Inhaler Devices

Dry Powder Inhaler

- **<u>Advantages:</u>**

  Less Force to Activate

  Breath Activated, Less temporal correlation

- **<u>Disadvantages</u>**

Must be held level after activation

Must generate sufficient inspiratory force to pull medication out of device

Inhaler Devices

Soft Mist Inhaler

- **Advantages:**

  No need to generate inspiratory force

  Potentially more of a natural breathing position

- **Disadvantages**

  Cannot be used with spacer

Inhaler Device

Nebulizer

- **<u>Advantages</u>**

No breathing coordination needed

No need for patient to activate device

No maximal inspiratory force

- **<u>Disadvantages</u>**

Requires machine or medical air

Requires training to set up

No medication combinations

Inhaler Devices

Which to Choose

- Older adults and those with dementia can rarely perform correct technique without direct supervision and coaching
- Likely MDI with spacer is ideal first choice
- If patients have ongoing dyspnea then transition to nebulizer
- If ongoing exacerbations, optimize medications then transition to nebulizer

Smoking Cessation

- Smoking cessation has survival benefits even if stopping after age 80
- Adults over 65 are less likely to smoke than younger adults (~9%)
- However, prevalence has not changed despite significant fall among younger adults
- Older adults less likely to stop smoking or attempt to stop smoking

Smoking Cessation

- Older adults more likely than younger adults to successfully quit with nicotine replacement therapy alone
- Worth a trial among patients with concerns or contraindications to varenicline (Chantix)

Summary

- COPD is extremely common among adults in nursing homes and often undertreated
- A mix of pharmacologic and non-pharmacologic therapies are effective in treating symptoms
- Overtreatment can have health consequences
- Choice of inhaler device matters a lot in this population


University of Colorado Anschutz Medical Campus
THANK YOU

In Pursuit of Belonging *Diversity, Equity and Inclusion in PALTC*

Diane Sanders-Cepeda, DO CMD
Senior Medical Director
UnitedHealthcare Retiree Solutions

Speaker Disclosure

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

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

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

What Can We Do?

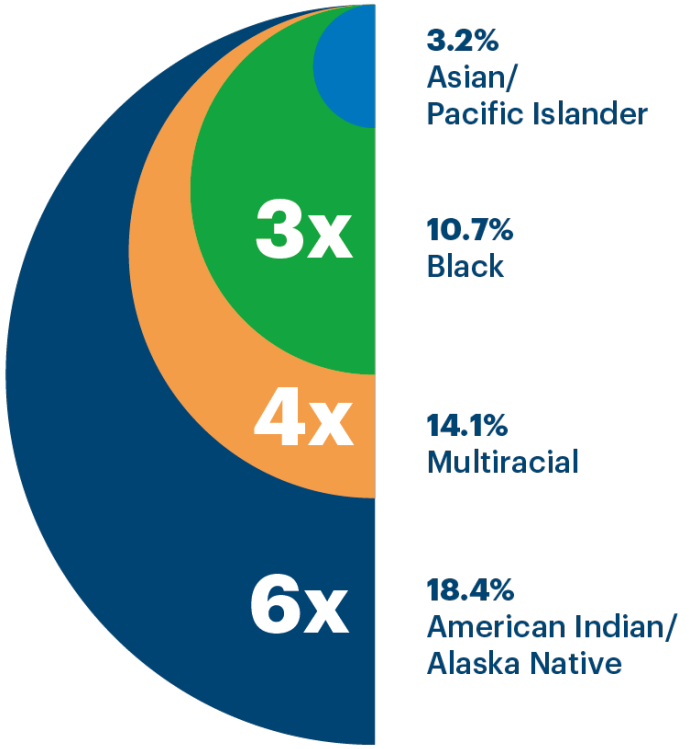
What's Missing in the DEI equation?

Racial Disparities plagued Healthcare Before COVID

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

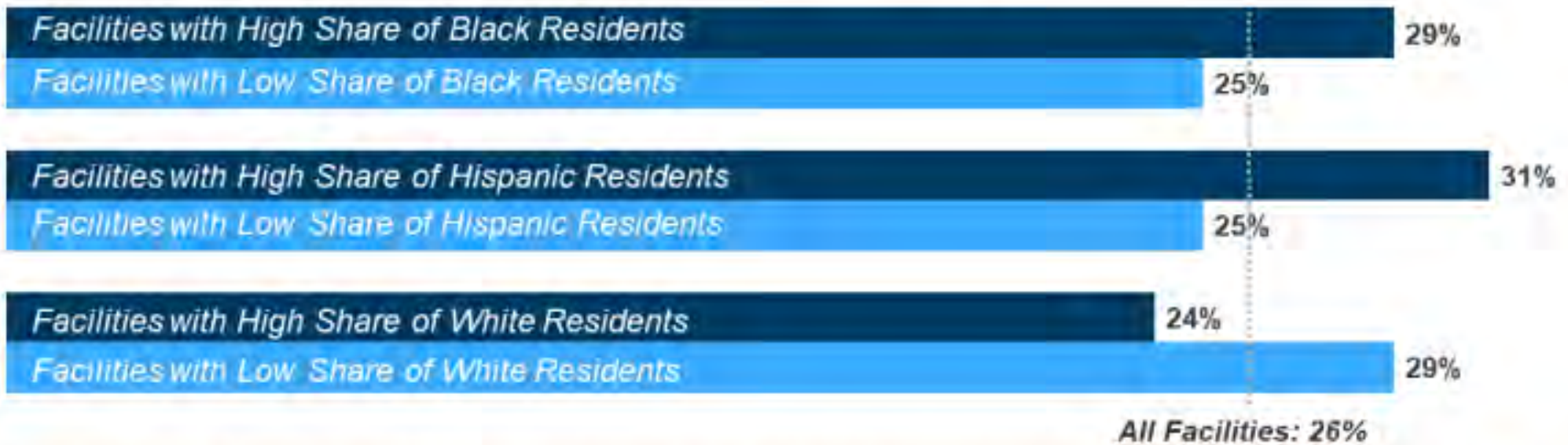
Compared to Asian/Pacific Islander adults (3.2%), the percentage of adults with multiple chronic conditions was 6x higher forAmerican Indian/Alaska Native adults (18.4%), 4x higher for Multiracial adults (14.1%), and 3x higher for Black adults (10.7%).

Source: CDC, Behavioral Risk Factor Surveillance System



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):



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)

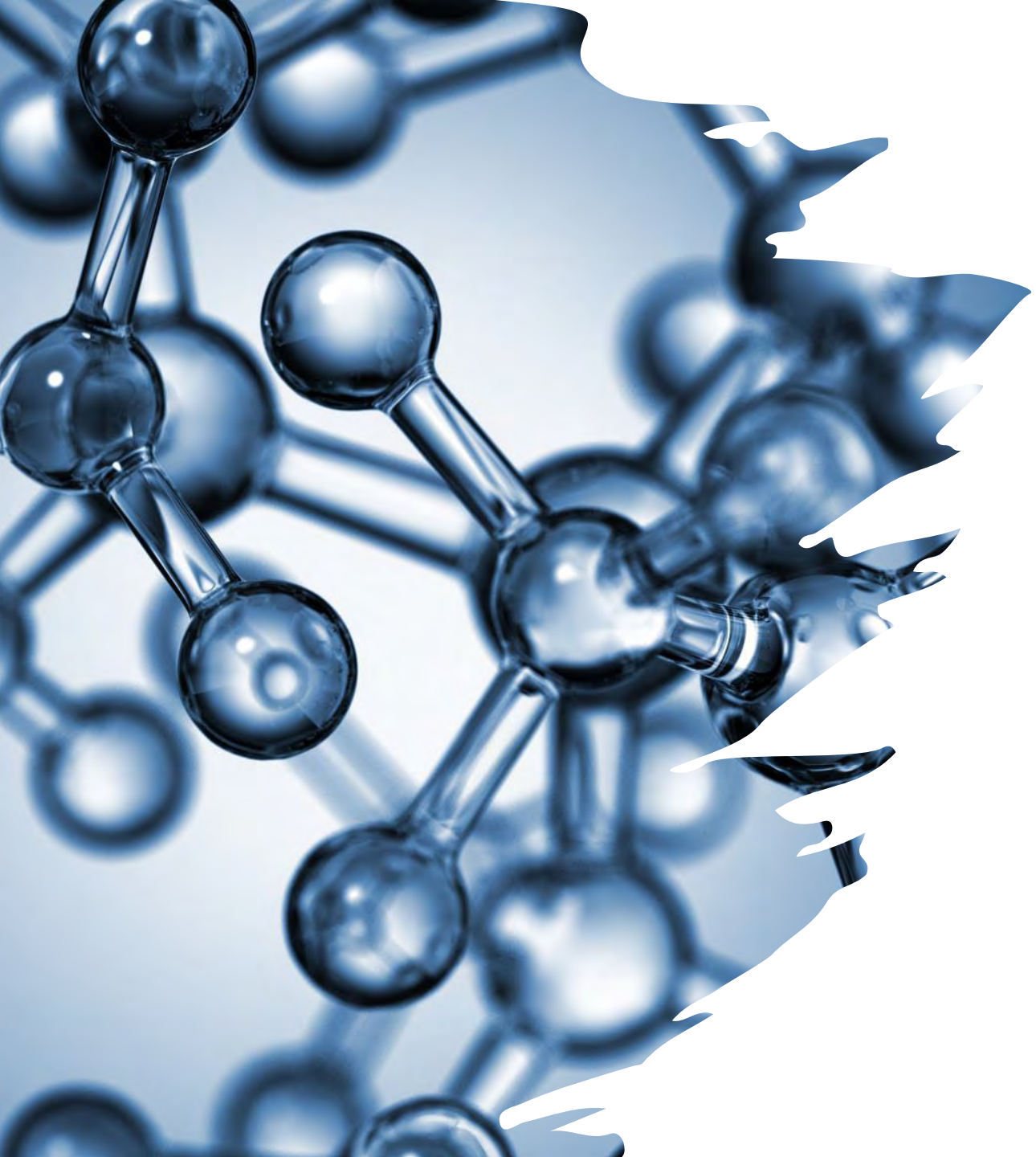
KFF

LOCAL

In Baltimore, a struggling, black-owned nursing home keeps covid-19 at bay

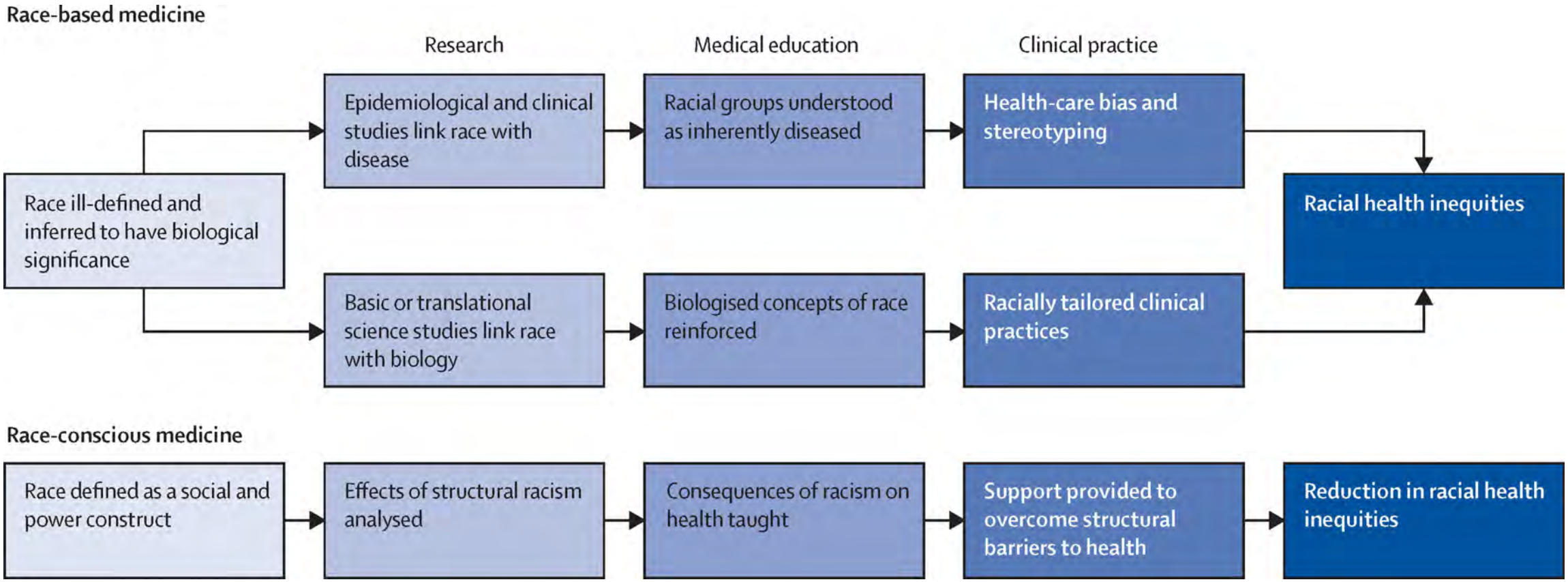
By Rebecca Tan

July 24, 2020 at 7:00 a.m. EDT



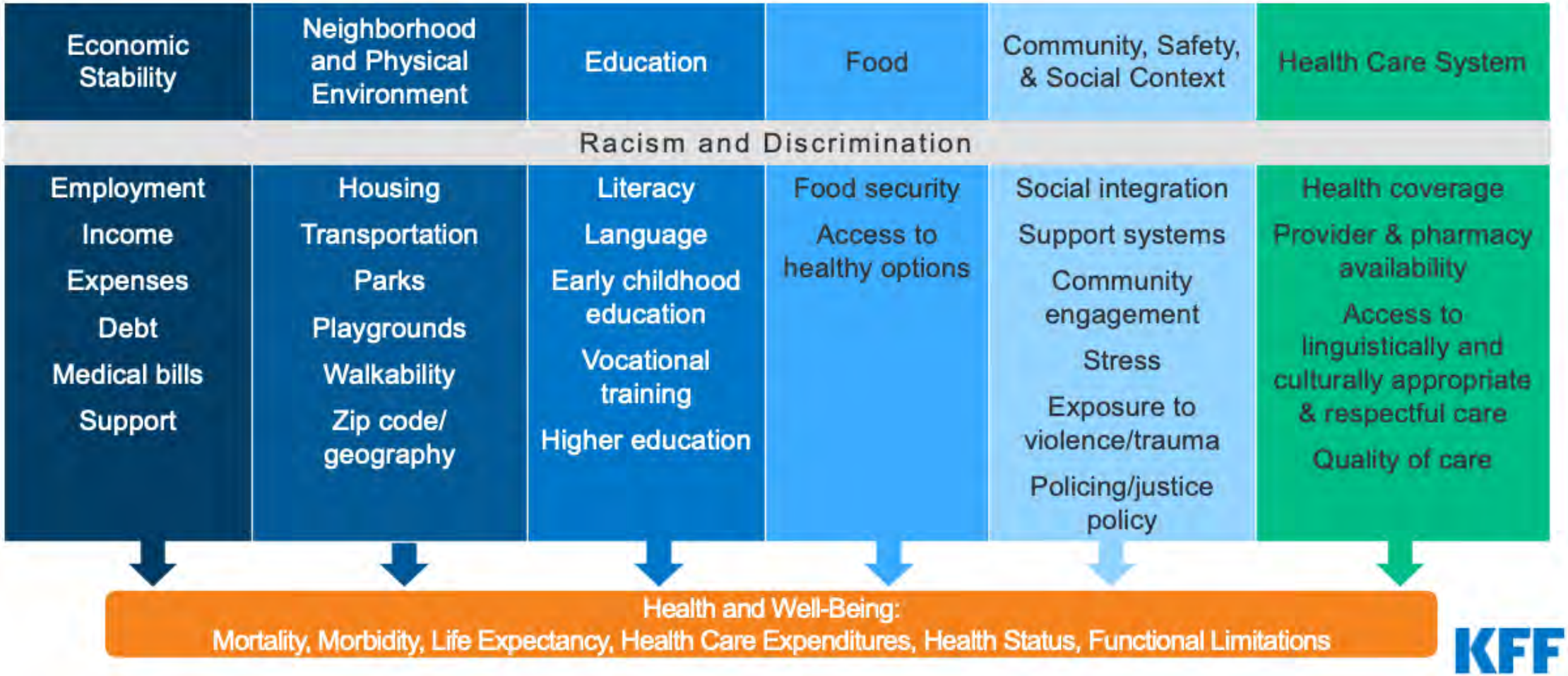
How should we address Racial Disparities?

Accept	Accept Race & Ethnicity as social constructs
Target	Target Social Determinants of Health
Create	Create a Culture of Trust



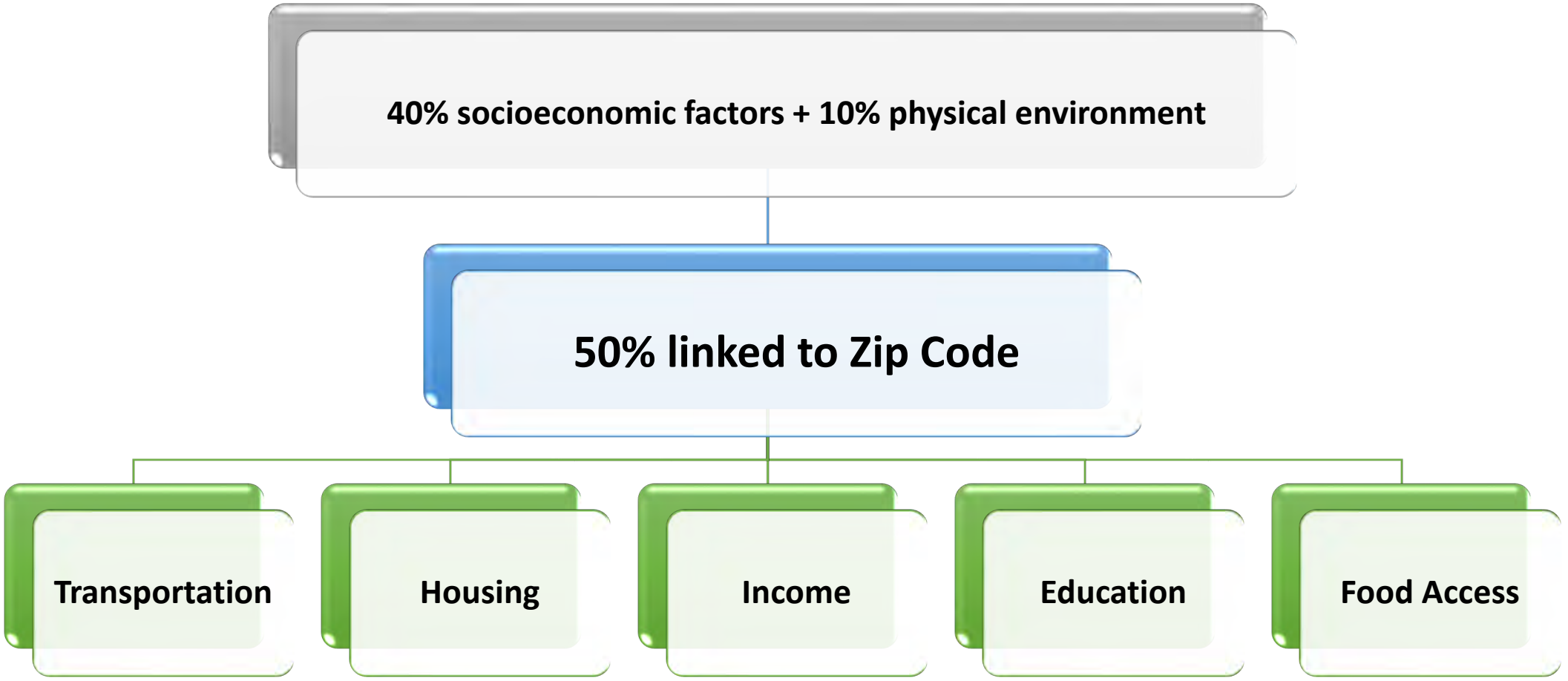
McPhil et. al. Lancet., October 2020

Health Disparities are Driven by Social and Economic Inequities



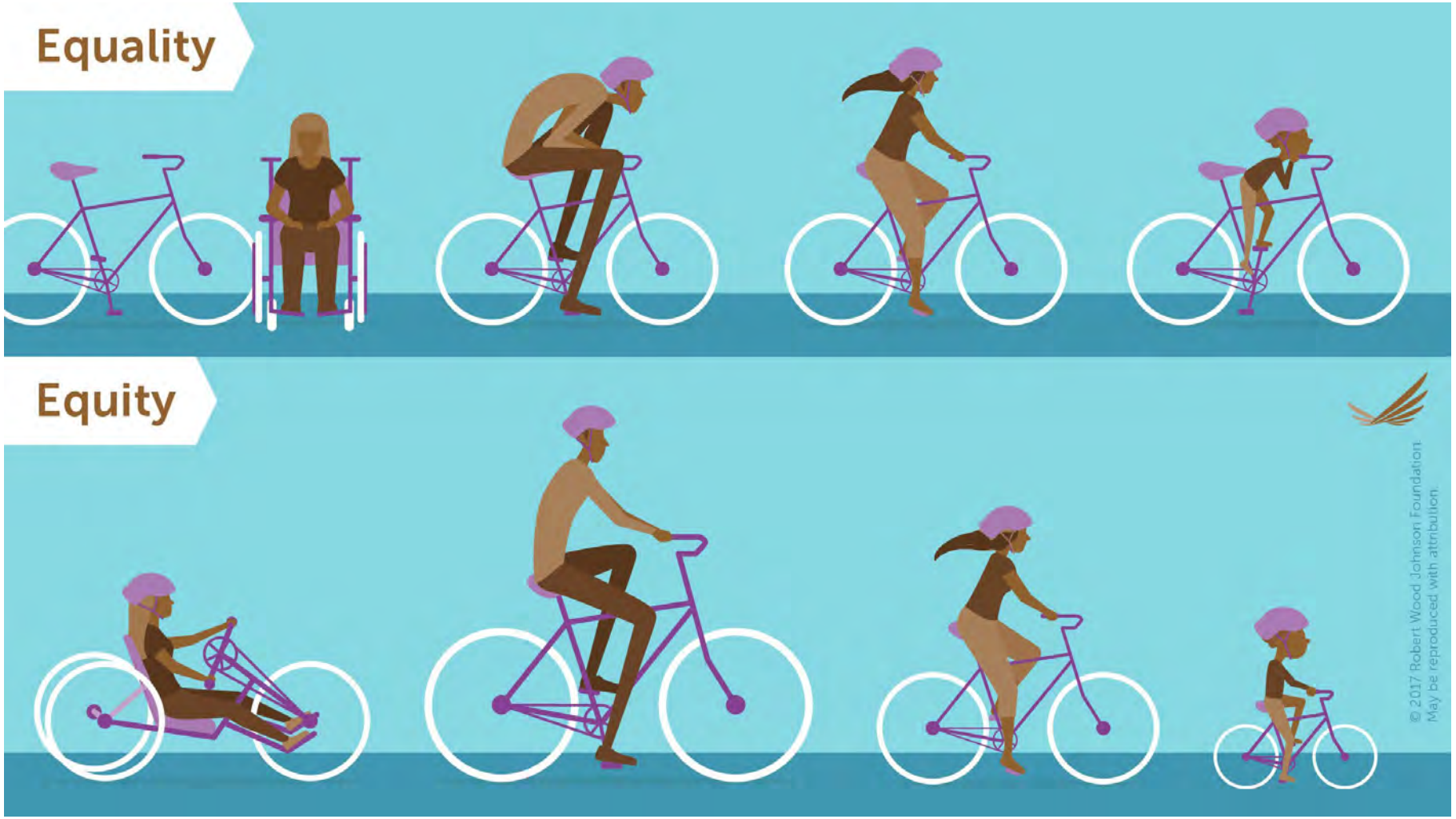
https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/

What your Zip Code can tell us…

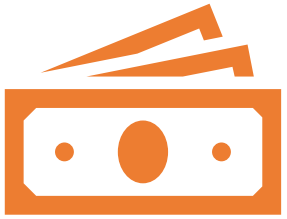


Office of Disease Prevention and Health Promotion. Social Determinants of Health. Healthy People 2030. U.S. Department of Health and Human Services. Social Determinants of Health - Healthy People 2030 | health.gov

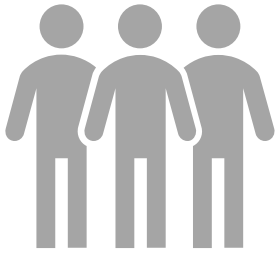
Equality vs. Equity



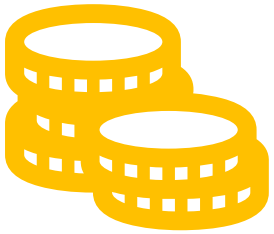
Staffing Challenges



Wages, pay inequities

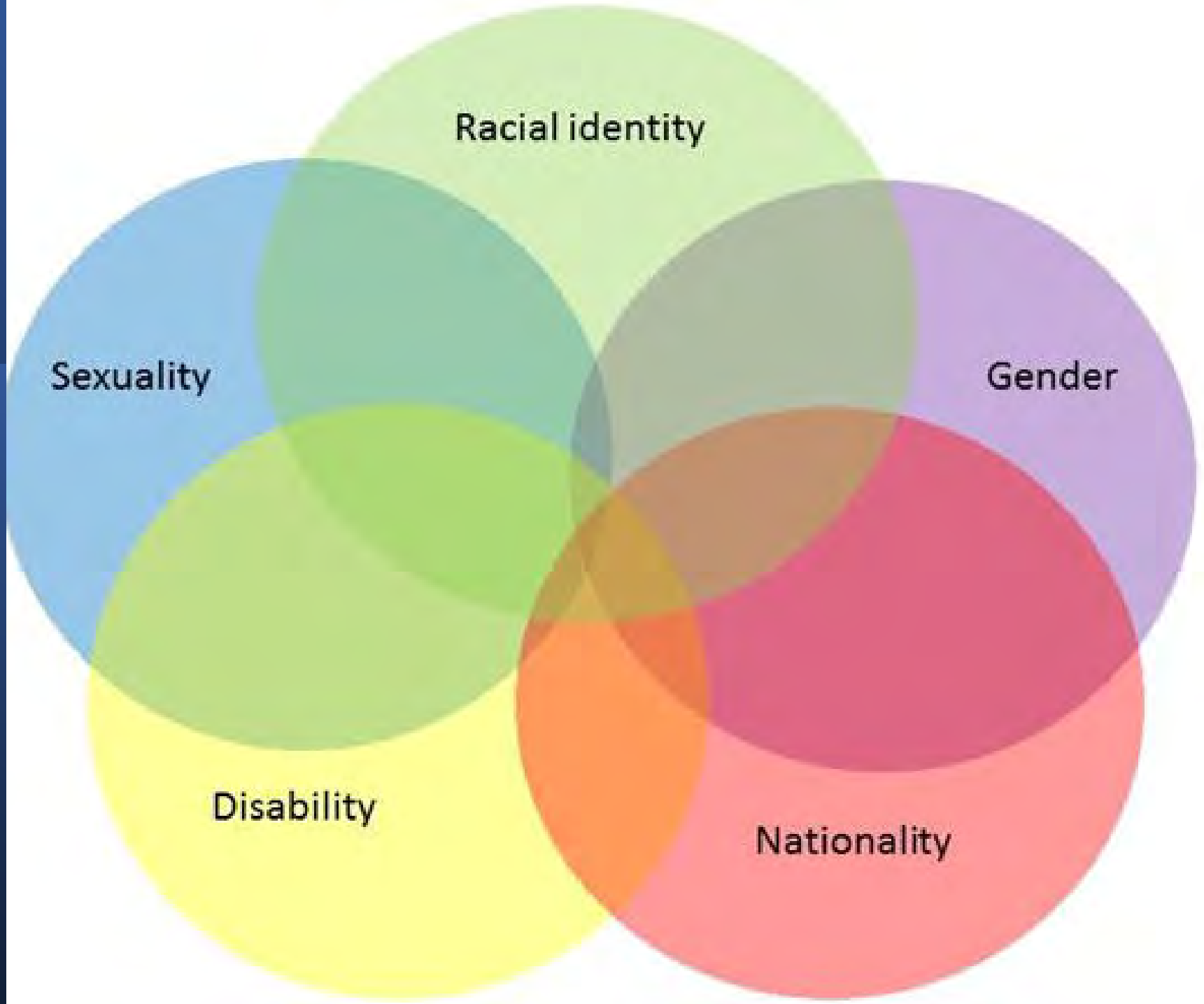


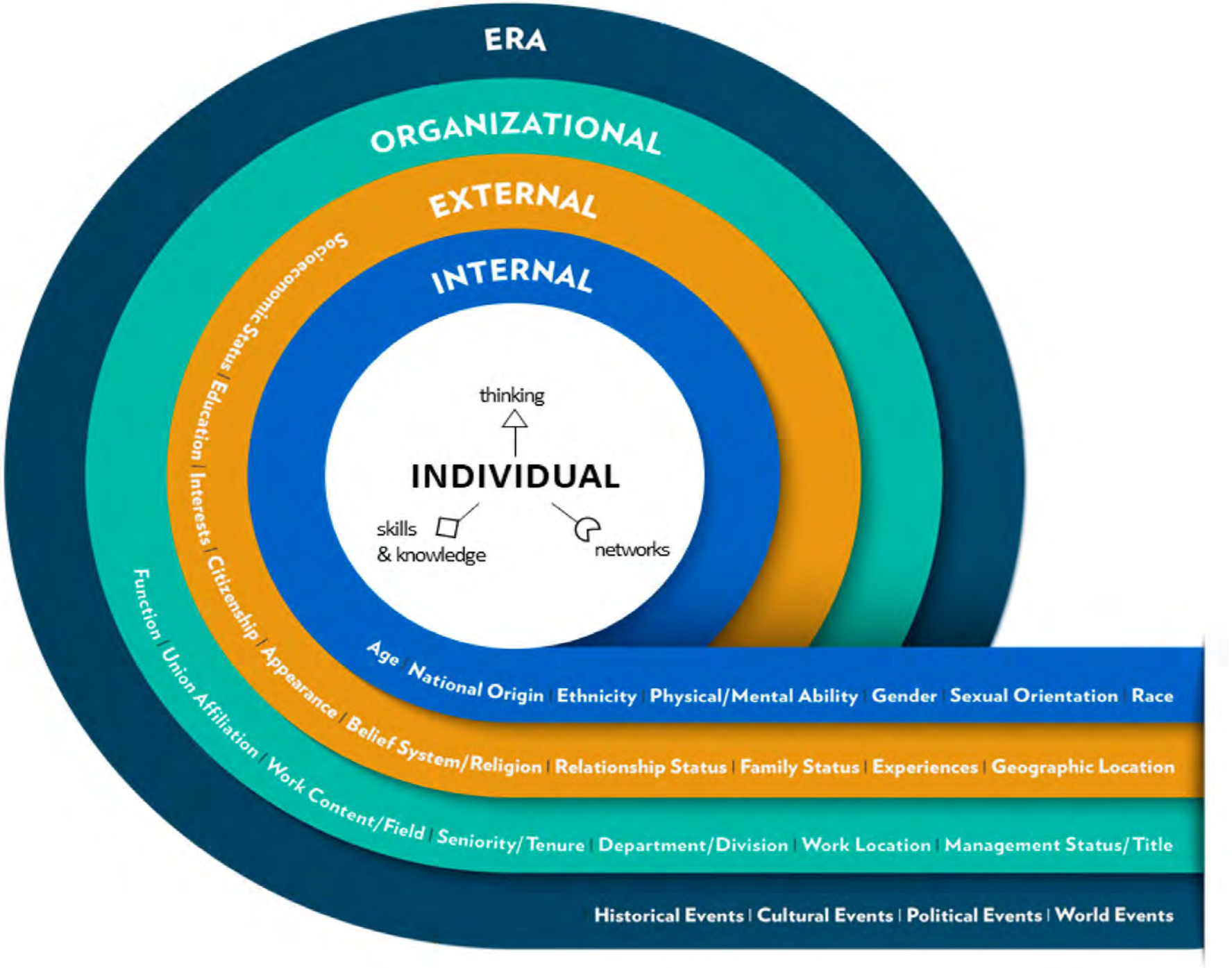
Staffing shortages



Lack of Value

Understanding Intersectionality



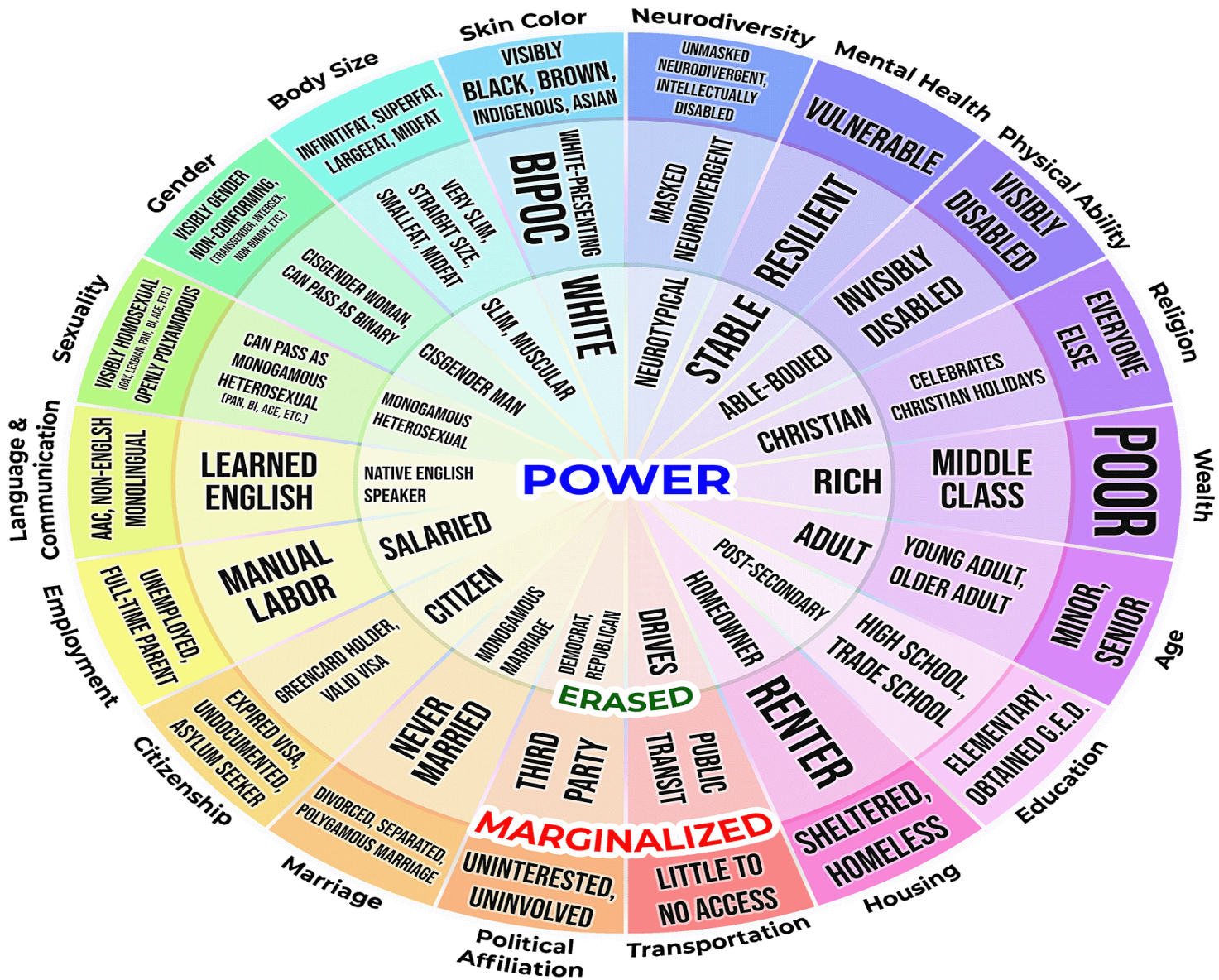


Why does Intersectionality Matter?


What’s Your Lived Experience?

INTERSECTIONALITY
WHEEL OF PRIVILEGE

As Observed in the USA



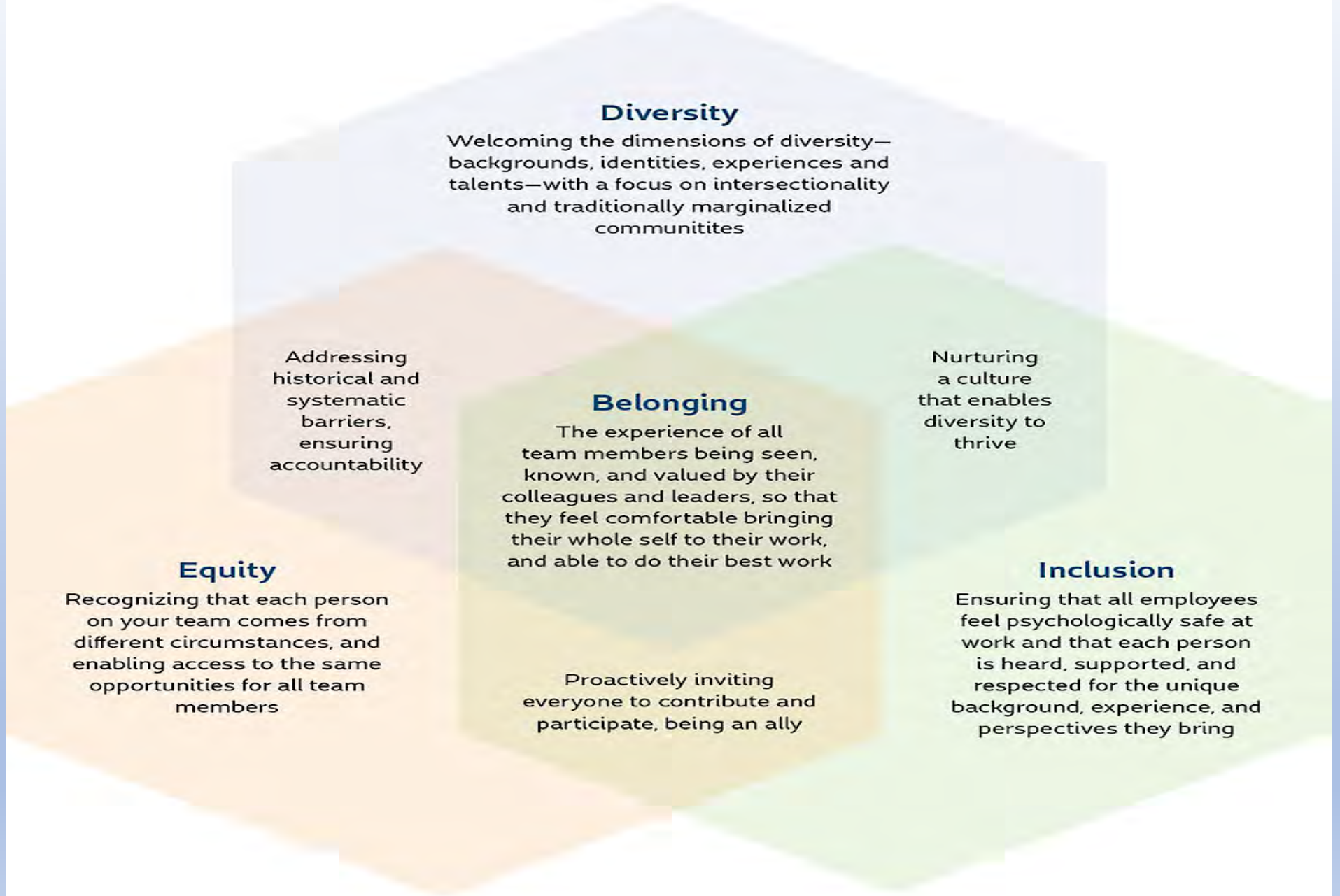
Adapted from Sylvia Duckworth, Canadian Council for Refugees, and Olena Hankivsky, PhD

TODAY

Florida reporter saves nurse trapped in car during Hurricane Ian

Tony Atkins came to the rescue after a woman found herself stuck in flood waters on her way to work.

The Missing Part of The Equation….


Diversity
Welcoming the dimensions of diversity—backgrounds, identities, experiences and talents—with a focus on intersectionality and traditionally marginalized communitites
Addressing historical and systematic barriers, ensuring accountability
Nurturing a culture that enables diversity to thrive
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
Equity
Recognizing that each person on your team comes from different circumstances, and enabling access to the same opportunities for all team members
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
Proactively inviting everyone to contribute and participate, being an ally


What Will You Do?


Questions?

Thank you for your time!

Diane Sanders-Cepeda, DO CMD

Diane_sanders-cepeda@uhc.com

linkedin.com/in/diane-sanders-cepeda-5430aa208







Health Facilities & Emergency Medical Services Division

Colorado Medical Directors Association
April 28, 2023

COLORADO
Health Facilities & Emergency Medical Services Division
Department of Public Health & Environment

REACH

Our Mission

Protect the health, safety and welfare of all health care system users

Ensure access to quality health care for all Coloradans

HFEMSD's Philosophy of Regulation

Reliable to all stakeholders, citizens and visitors

Efficient, effective and elegant in all service interactions

Accountable, transparent and collaborative interactions

Compliant through balanced sanctions and fair practices

Helpful whenever possible

Nursing Facilities

- 222 Currently licensed nursing facilities
- 3 Closures - Parkmoor Village HealthCare Center, Colorado Springs, Good Samaritan Society - Bonell Community, Greeley & Cripple Creek Care Center, Cripple Creek
- 129 Recertification surveys were conducted 1/1/22 – 12/31/22
- 350 federal complaint investigations completed 1/1/22 – 12/31/22
- 39 state complaint investigations completed 1/1/22 – 12/31/22

Nursing Facilities

Federal Updates

- CMS is requiring 20% of all nursing homes receive a stand alone/complaint infection control survey be conducted 10/22-9/23.

- CMS has identified these areas for special consideration during survey: Behavioral Health, Immunizations, Language and Communication and an optional area identified on survey

Initial Inspections

State Fiscal Year 20-21: 123
State Fiscal Year 21-22: 133

Re-Licensure Inspections

State Fiscal Year 20-21: 254
State Fiscal Year 21-22: 361

Licensure Infection Control Inspections

State Fiscal Year 21-22: 7

Occurrences Investigations

State Fiscal Year 20-21: 4,330
State Fiscal Year 21-22: 5,505

Complaint Intakes

State Fiscal Year 20-21: 1,841
State Fiscal Year 21-22: 1,822

Health Facility Enforcement

(7/1/2021 – 6/30/2022)

- Initial fitness reviews - 153
- Change of Ownership Fitness Reviews - 154
- Cease and desist letters for facilities operating without a license - 3
- Intermediate conditions including fines and/or requirements to retain a consultant – 230
- License Summary Suspensions/Revocations – 5
- Conditional Licenses Issued – 7
- License Denials/Invalid License Notices – 47
- Appeals of Nursing Home Discharges Handled by Department - 1
- Matters referred to the Office of Administrative Court - 21

Recent Projects

Home & Community Facilities

- Currently have 4 openings in Home Care/Hospice program; 3 RN's, 1 Generalist
- Home Care program is training 2 new RN surveyors
- Assisted Living Residences program is currently hiring. There are 9 open positions for Health Professional III positions.
- Both programs are in the process of developing internal Train the Trainer programs to build on our vigorous training curriculum.
- Stakeholder meetings for regulation updates for the ALR Safety bill and the Dementia training and Visitation bills that were passed last year.

Recent Projects (cont.)

Behavioral Health & Community Services Branch

- Behavioral Health Entity project update:
  - Phase 1 regulations were effective June 14, 2021
  - Transition year started July 1, 2021 for current BH providers obligated to move into the new BHE regulations
  - All providers moved into the new BHE licensing chapter by July 1, 2022
  - All BHE's have successfully completed the required transition to date
  - The Division created the BHE website with provider resources, toolkits and FAQs
  - Due to HB22-1278, BHE's will transition from CDPHE to the BHA for oversight beginning July 1, 2023 at the time of their licensure renewal date

- Secure Transportation Services update:
  - Pleased to share a new toolkit, "Secure Transportation Program Implementation for Counties," developed to provide counties and commissioners with the information needed to develop and implement a secure transportation licensing and permitting program.
  - The State Board of Health adopted rules in June 2022, establishing the minimum requirements for licensing and operating secure transportation services, and gives counties the authority to license secure transportation services (starting January 2023), issue permits for secure transportation service vehicles, and enforce the promulgated regulations.

Recent Projects (cont.)

Emergency Medical & Trauma Services

- 2022 Legislation
  - Transitioning Ground Ambulance licensing from counties to the state, effective July 1, 2024
  - Established a 5-year taskforce to evaluate the sustainability of Colorado's EMS system
  - Created the Office of Cardiac Arrest to monitor and analyze data from sudden cardiac arrests statewide

- Hybrid (remote/on-site) trauma designation reviews continue

Some Leadership Changes!

- Elaine McManis
  - Division Director (appointed Spring ‘22)

- Newly appointed Deputy Division Directors (April 1, 2023)
  - Kara Johnson-Hufford
  - Peter Myers

- Dr. Jeff Beckman, HFEMSD Medical Director

The Health Facilities and EMS Division wishes to thank all of Colorado's health facility providers for their cooperation and dedication to the care of Colorado citizens!!

Questions?

Jo Tansey
Branch Chief, Acute and Nursing Facilities
jo.tansey@state.co.us

Arnall Golden Gregory LLP

CMDA- The Colorado Society for Post-Acute and Long-Term Care Medicine
(Colorado Medical Directors Association)

Medical Errors and the Law

April 28, 2023

Alan C. Horowitz, Esq., RN
Arnall Golden Gregory LLP
Alan.Horowitz@agg.com
(267) 968-0167

Speaker Disclosures

Arnall Golden Gregory LLP

Alan C. Horowitz, Esq., RN has no relevant financial relationship(s).

Learning Objectives

By the end of the presentation, participants will be able to:

- Understand that there are both mandatory and voluntary reporting requirements for disclosing medical errors
- Appreciate that medical errors are generally caused by flawed systems
- Explore how medical errors (and near misses) can promote a culture of safety rather than blame and shame
- Understand how a defendant in a criminally negligent homicide case involving a medication error was found not guilty
- Learn how Colorado's "Apology Law" can reduce litigation for medical errors

The Definition of Medical Error

- Commission or omission of an action with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, **independent of whether there were any negative consequences**
- Preventable errors may be more common in older adults
- May be particularly true in nursing homes

Wu AW, Cavanaugh TA, McPhee SJ, Lo B, Micco GP. To tell the truth: ethical and practical issues in disclosing medical mistakes to patients. J Gen Intern Med. 1997;12:770-775.

How Big is the Problem?

- 44,000 – 98,000 deaths/yr. IOM *To Err is Human: Building a Safer Health System* (1999)
- 440,000 deaths/yr. Leapfrog Group, *Journal of Pt. Safety* (2013)
- >250,000 deaths/yr. due to medical error in the U.S (*Medical error—the third leading cause of death in the US*) BMJ May 3, 2016

How Big is the Problem? OIG Report

- *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, Report OEI-06-11-00370 (February 27, 2014)

- "An estimated 22 percent of Medicare beneficiaries experienced adverse events during their SNF stays.

- Physician reviewers determined that 59 percent of these adverse events and temporary harm events were clearly or likely preventable. They attributed much of the preventable harm to substandard treatment, inadequate resident monitoring, and failure or delay of necessary care. Over half of the residents who experienced harm returned to a hospital for treatment, with an estimated cost to Medicare of $208 million in August 2011. This equates to $2.8 billion spent on hospital treatment for harm caused in SNFs in FY 2011."

Is There a Disconnect?

- Survey of more than 2,600 physicians from US and Canada revealed:
- 98% of physicians endorsed disclosing serious errors to patients, but…
- Only 58% made full disclosure
- Can we learn from the FAA's ASRS?

- Source: Gallagher TH, Waterman AD, Garbutt JM, et al.*US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. Arch Intern Med 2006;1661605-11.*

Aviation Safety Reporting System

- Federal Aviation Safety Reporting System (ASRS)

  – Designed by NASA
  – Voluntary reporting of events/incidents and near misses
  – Confidential
  – Non-punitive
  – Collects and analyzes data
  – Independent (operated by NASA, no enforcement ability)
  – Immunity (limited)
  – Enhances human factors research, makes recommendations
  – Served as model for other industries re: error/near miss reporting

Mandatory versus Voluntary Disclosure?

- Federal Law
  - 42 CFR § 483.10(g)(14)
  - PSQIA of 2005
- State Law
- Contractual

Mandatory versus Voluntary Disclosure?

- 42 CFR 483.10(g)(14)
- A facility must immediately inform the resident; consult with the resident's physician; and notify, consistent with his or her authority, the resident representative(s), when there is –
- (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
- (B) A significant change in the resident's physical, mental, or psychosocial status (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
- (C) A need to alter treatment significantly (that is, a need to discontinue or change an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

Medical Errors and Criminally Negligent Homicide: Two Different Outcomes

Arnall Golden Gregory LLP

Vanderbilt University Medical Center, TN (RN found Guilty)

Rx: Versed; RN administered vecuronium instead of versed.

Centura St. Anthony Hospital, Denver, CO (RN found Not Guilty)

Rx: “Penicillin G benzathine150,000 units IM.”

Jury was shown all the systems problems

No need for Rx (attending physician was on vacation)

Ten-fold increase in dose (1,500,000 units dispensed)

Penicillin was given IV instead of IM

Other mistakes were made

“Former nurse guilty of homicide in medication error death
A former Tennessee nurse has been found guilty of criminally negligent homicide in the accidental death of a patient because of a medication error.”

ByTRAVIS LOLLER Associated Press
March 25, 2022, 2:14 PM

A Legal Nightmare: Denver Nurses Indicted in Newborn Death

Arnall Golden Gregory LLP

ISMP provided a systems analysis and expert testimony at trial. ISMP identified *over 50 different failures in the system* that allowed this error to occur, go undetected,

Rx: “Penicillin G benzathine 150,000 U IM.”

Latent Failures:

Limited knowledge about this nonformulary drug. The pharmacist consulted both the infant’s progress notes and Drug Facts and Comparisons to determine the usual dose of penicillin G benzathine for an infant. However, she misread the dose in both sources as 500,000 units/kg, a typical adult dose, instead of 50,000 units/kg. Consequently, the pharmacist also incorrectly read and prepared the order as 1,500,000 units, a ten-fold increase

A unit dose system was not used in the nursery, the pharmacy dispensed the tenfold overdose in a plastic bag containing two full syringes of Permapen 1.2 million units/2 mL each, with green stickers on the plungers to "note dosage strength."

A Legal Nightmare: Denver Nurses Indicted in Newborn Death

Arnall Golden Gregory LLP

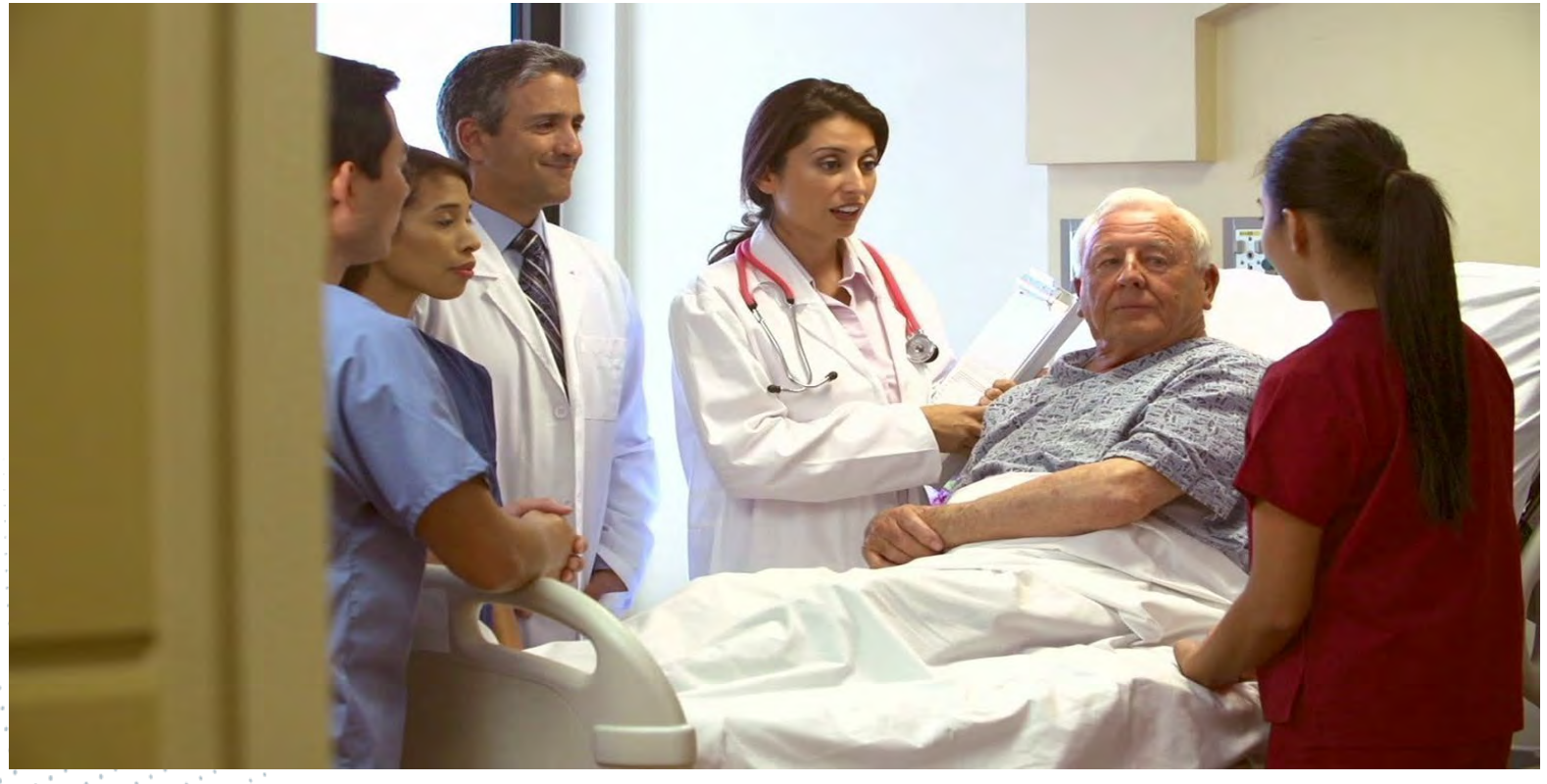
The Neofax monograph on penicillin G did not specifically mention penicillin G benzathine; instead, it noted the treatment for congenital syphilis with aqueous crystalline penicillin G IV slow push or penicillin G procaine IM. Nowhere in the two-page monograph was penicillin G benzathine mentioned, and no specific warnings regarding "IM use only" for penicillin G procaine and penicillin G benzathine were present.

Believing that aqueous crystalline penicillin G and penicillin G benzathine were the same drug, the nurse practitioner concluded that the drug could be safely administered IV. The nurses knew that, while taught that only clear liquids can be injected IV, certain milky white substances, such as IV lipids and other lipid-based drug products, can be given IV. Therefore, they did not recognize the problem of giving penicillin G benzathine, a milky white substance, intravenously.

While preparing for drug administration, neither nurse noticed the tenfold overdose, and neither noticed that the syringe was labeled by the manufacturer "IM use only." The manufacturer's warning is very difficult to see because it is not prominently placed, and the syringe must be rotated 180° away from the drug name to view it. The nurses began to administer the first syringe of Permapen slow IV push. After about 1.8 mL was administered, the infant became unresponsive, and resuscitation efforts were unsuccessful.

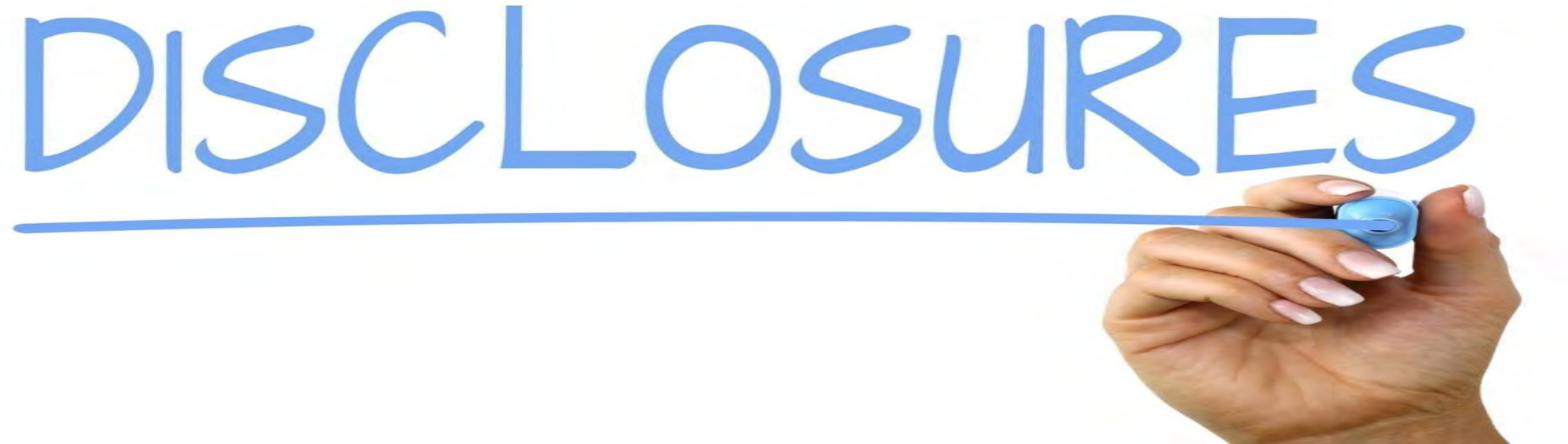
Legal Defense: It Was a Flawed System, Not a Flawed Nurse

Is Honesty the Best Policy?



A Better Way?

- Full Disclosure
- Compensation (as appropriate)
- Extreme Honesty
- “I’m Sorry”
- CANDOR
- Apology laws



Currently 39 States and D.C. Have "Apology Laws"

- ✓Apology laws have increased physician apologies, expedited claim resolution, and decreased the number of claims and payments for malpractice claims.

- ✓Few authoritative studies are available given variables (partial vs. full apology laws, surgical vs. non-surgical, definition of "adverse event" or "error," only errors with adverse outcomes).

Communication and Optimal Resolution (CANDOR) - MedStar Health

- ✓Engage patients and families in disclosure following adverse events.
- ✓Implement a Care for the Caregiver program for providers involved in adverse events.
- ✓Investigate and analyze an adverse event to learn from it and prevent future adverse events.
- ✓Review and revise the organization's current processes to align with the CANDOR process.
- ✓Establish a resolution process for the organization.

Communication and Optimal Resolution (CANDOR)

Arnall Golden Gregory LLP

"MedStar saved an estimated $70 million between 2012 and 2017 by reducing costs related to patient safety events, including medical liability payments."

"The programs have reduced their medical liability because the most important thing about CANDOR besides the open and honest communication is that there's a requirement for learning,"

University of Michigan Health System (UMHS) has fully disclosed and offered compensation to patients for medical errors (since 2001)

Arnall Golden Gregory LLP

Results:

- ✓After full implementation of a disclosure-with-offer program, the average monthly rate of new claims decreased from 7.03 to 4.52 per 100,000 patient encounters
- ✓The average monthly rate of lawsuits decreased from 2.13 to 0.75 per 100,000 patient encounters
- ✓Median time from claim reporting to resolution decreased from 1.36 to 0.95 years.
- ✓Average monthly cost rates decreased for total liability, patient compensation, and non-compensation-related legal costs.
- ✓since implementing the “I’m sorry” strategy, malpractice claims against UMHS fell from 121 in 2001 to 61 in 2006. 50% decrease in claims

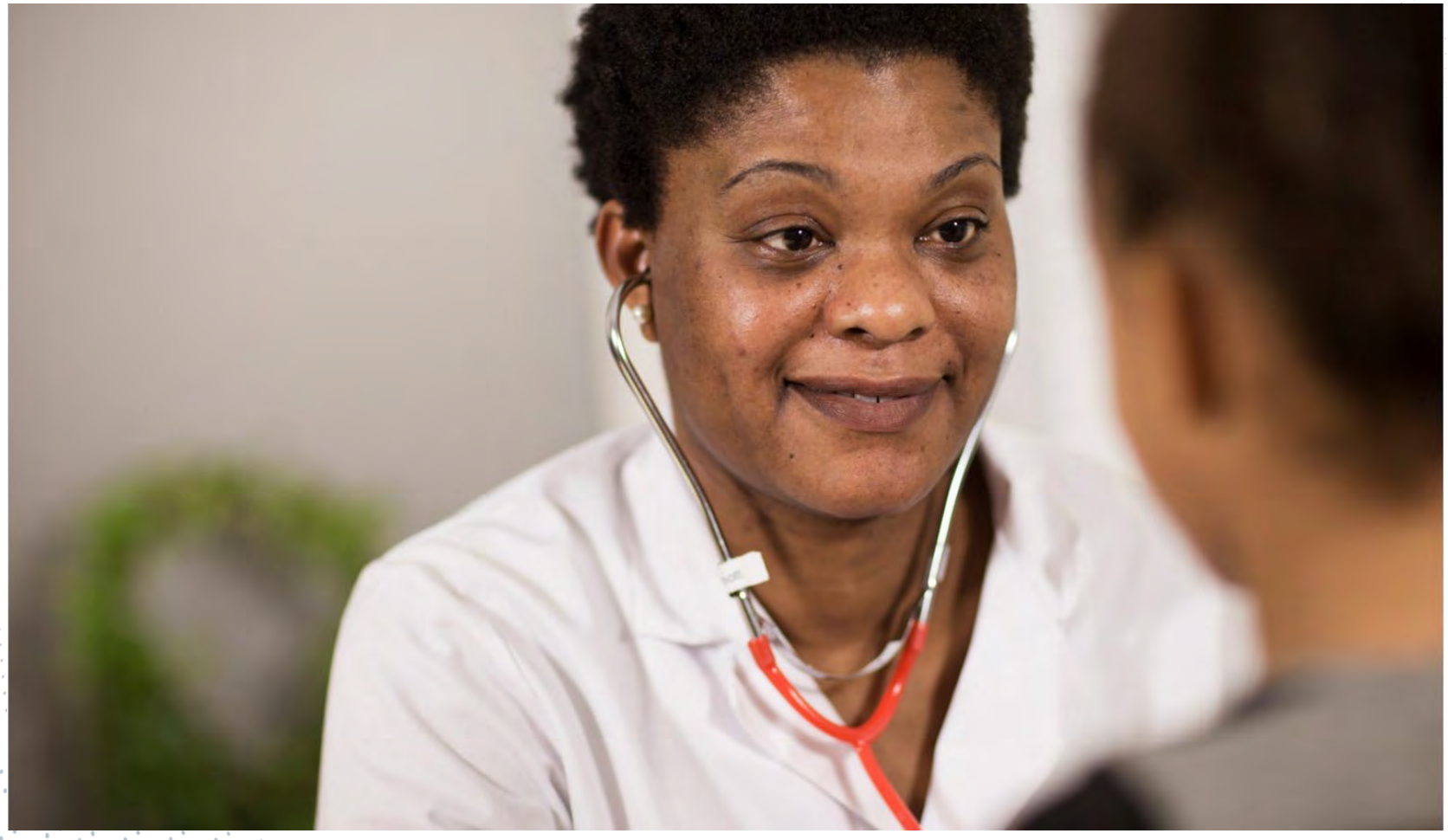
Communication and Resolution Programs (CRP)

Arnall Golden Gregory LLP

"Anecdotal reports from the University of Michigan Health System and other early adopters of CRPs suggest that these programs can substantially reduce liability costs and improve patient safety."

Mello MM, Boothman RC, McDonald T, et al. *Communication-and-resolution programs: the challenges and lessons learned from six early adopters*. Health Aff 2014; 33: 20–29.

How Does Colorado Treat Admissions & Apologies?



Colorado Revised Statutes Title 13. Courts and Court Procedure § 13-25-135. Evidence of admissions--civil proceedings--unanticipated outcomes--medical care

Arnall Golden Gregory LLP

- "In any civil action brought by an alleged victim of an unanticipated outcome of medical care, or in any arbitration proceeding related to such civil action, any and all statements, affirmations, gestures, or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence which are made by a health-care provider or an employee of a health-care provider to the alleged victim, a relative of the alleged victim, or a representative of the alleged victim and which relate to the discomfort, pain, suffering, injury, or death of the alleged victim as the result of the unanticipated outcome of medical care shall be inadmissible as evidence of an admission of liability or as evidence of an admission against interest."

Colorado Candor Act (2019)

- A brief overview of the process is as follows:

- The process is initiated by the health care provider.
- The written notice must be sent to the patient within 180 days of the incident.
- The notice must include specific details about the patient's rights and the nature of the communications/discussions under the Colorado Candor Act.
- Under the Colorado Candor Act, health care providers and facilities may investigate and communicate about how the incident occurred and what steps are being taken to prevent a similar outcome in the future.
- As part of their assessment, health care providers and facilities can determine whether an offer of compensation is warranted.
- To facilitate open communication under the Colorado Candor Act, discussions and offers of compensation under the Act are privileged and confidential.

Extreme Honesty Policy – Veterans Administration Medical Center (VAMC), Lexington, KY

Arnall Golden Gregory LLP

In 1987, the Veterans Affairs Medical Center (VAMC) in Lexington, Kentucky instituted a then-controversial program of disclosing medical errors and apologizing and compensating patients for them. Apart from the ethical and moral rationale for transparency and full disclosure, the VAMC believed that a policy of extreme honesty or full disclosure might reduce malpractice claims.

Twelve years after the VAMC instituted its policy, it reported that hospital administration and staff supported it and, counterintuitively, it yielded unanticipated financial results.

Source: *Extreme honesty: Medical errors and full disclosure,* Alan C. Horowitz, iAdvanceSenior Care, May 31, 2016.

Veterans Health Administration: Directive 1004.08.

- ✓Revised policy to ensure consistent practice in disclosing adverse events related to a patient's clinical care (replaced earlier versions 2005-2012)

- ✓The Directive provides direction for disclosing medical mistakes to patients and their families. The policy addresses actions that specific VHA staff members should take during the disclosure process. (October 31, 2018)

Patient Safety and Quality Improvement Act of 2005 (PSQIA)

The PSQIA established a voluntary reporting system designed to enhance the data available to assess and improve patient safety and health care quality issues.

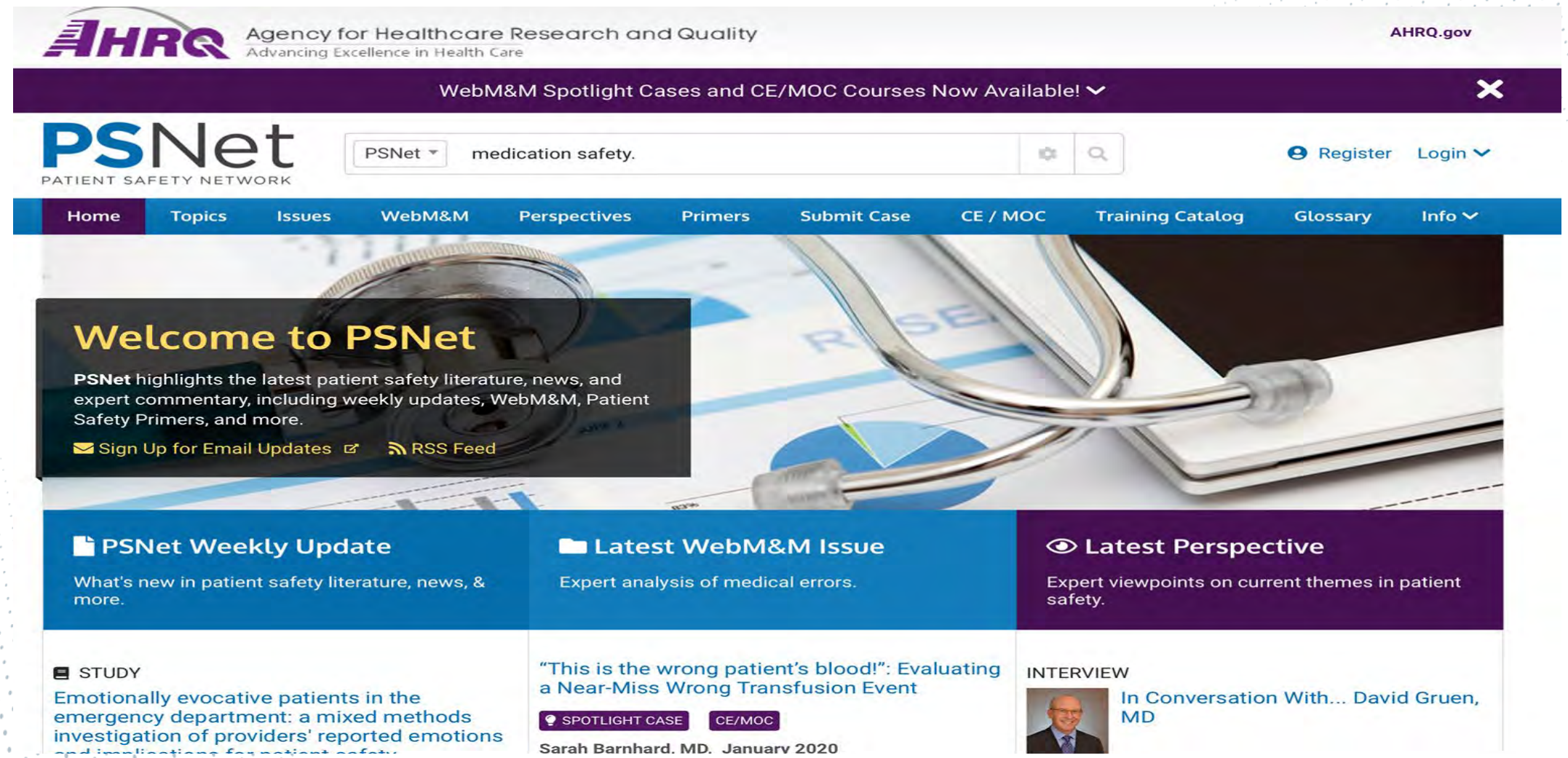
To incentivize the reporting and analysis of medical errors, the PSQIA provides a Federal privilege and confidentiality protections for patient safety information, called patient safety work product (PSWP).

Patient Safety Organization (PSO)

Patient Safety Work Product (PSWP)

Patient Safety Network Website

Arnall Golden Gregory LLP



Ethics

The American College of Physicians ethics manual states that “Physicians should disclose to patients information about procedural or judgment errors made during care, as long as such information is material to the patient's well-being. Errors do not necessarily imply negligent or unethical behavior, but failure to disclose them may”

The AMA Code of Ethics: “Situations occasionally occur in which a patient experiences significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred”

Sorry Works! Coalition

- The Sorry Works! Coalition is comprised of doctors, lawyers, insurers, and patient advocates.
- Dedicated to promoting full disclosure and apologies for medical errors
- If a standard of care was not met (and there is a negative outcome) providers and their insurer should :
- Apologize, admit fault, provide an explanation of what happened and how the hospital will ensure that the error is not repeated, and offer compensation.
- The Sorry Works! protocol is based on the landmark disclosure program developed at the Department of Veterans Affairs Hospital in Lexington, Kentucky.

Resources

- *To Err is Human: Building a Safer Health System* IOM
- *Medical errors – the third leading cause of death in the U.S.* BMJ 2016;353:i2139
- *Communication and Optimal Resolution (CANDOR) Toolkit, AHRQ available at: https://www.ahrq.gov/patient-safety/settings/hospital/candor/modules.html*
- Kraman SS, Hamm G. *Risk management: extreme honesty may be the best policy.* Ann Intern Med, 1999 Dec 21;131(12):963-7.
- Available at: https://pubmed.ncbi.nlm.nih.gov/10610649/
- *Liability claims and costs before and after implementation of a medical error disclosure program,* Ann Intern Med 2010 Aug 17;153(4):213-21.
- *Apologies and legal liability. Saying sorry is not the same as admitting legal liability, BMJ 2009 Feb 10;338:b520.*
- *The Role of Apology Laws in Medical Malpractice,* May 2021 JAAPL.200107-20;

Resources

- The Patient Safety and Quality Improvement Act of 2005 (PSQIA) amends the Public Health Service Act (42 U.S.C. 299 et. seq.; P.L. 109-41)
- Mello MM, Boothman RC, McDonald T, et al. *Communication-and-resolution programs: the challenges and lessons learned from six early adopters.* Health Aff 2014; 33: 20–29.
- Wojcieszak D, Banja J, Houk *C.The Sorry Works! Coalition: making the case for full disclosure*, Jt Comm J Qual Patient Saf 2006 Jun;32(6):344-50.
- Kachalia A, Kaufman S, Boothman RC, et. al. *Liability claims and costs before and after implementation of a medical error disclosure program*. Ann Intern Med 2010 Aug 17;153(4):213-21.
- Horowitz A, *Extreme honesty: Medical errors and full disclosure*, iAdvanceSenior Care, May 31, 2016, available at: https://www.iadvanceseniorcare.com/extreme-honesty-medical-errors-and-full-disclosure

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Additional Recommended Resources

1. Wu AW, Cavanaugh TA, McPhee SJ, Lo B, Micco GP. To tell the truth: ethical and practical issues in disclosing medical mistakes to patients. *J Gen Intern Med*. 1997;12:770-775.
2. Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population-based review of medical records. *BMJ*. 2000;320:741-744.
3. Kapp MB. Resident safety and medical errors in nursing homes: Reporting and disclosure in a culture of mutual distrust. *J Leg Med*. 2003;24:51-76.
4. Kohn JT, Corrigan JM, Donaldson MS, eds. *To Err is Human: Building A Safer Health System*. Washington, DC: National Academy Press; 2000.
5. Lamb RM, Studdert DM, Bohmer RMJ, et al. Hospital disclosure practices: results of a national survey. *Health Aff (Millwood)*. 2003;22:73-83.
6. Hilfiker D. Facing our mistakes. *N Engl J Med*. 1984;310:118-122.
7. Sulmasy LS, Bledsoe TA. American college of physicians ethics manual. *Ann Intern Med*. 2019;170:S1-S32.
8. American Medical Association. *Code of Medical Ethics: Current Opinions, E-8.121—Ethical Responsibility to Study and Prevent Error and Harm*. Available at: http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8121.page. Accessed May 16, 2013.
9. American Nurses Association. *Code of Ethics for Nurses with Interpretive Statements*. Available at: http://www.nursingworld.org/codeofethics. Accessed May 16, 2013.
10. American Medical Association. *Code of Medical Ethics. Opinion 8.6 Promoting Patient Safety*. Available at: https://www.ama-assn.org/delivering-care/ethics/promoting-patient-safety. Accessed September 02, 2019.
11. Kraman SS, Hamm G. Risk management: extreme honesty may be the best policy. *Ann Intern Med*. 1999;131:963-967.

Thank you!

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COPIC GUIDE FOR THE COLORADO CANDOR ACT

JULY 2020

Nobody wants to see an adverse outcome in health care, yet despite best efforts, these types of incidents occur. How providers deal with them and address the needs of patients is important because the provider-patient relationship forms the foundation of health care. Now, medical providers and facilities in Colorado have a new tool to utilize in these situations—the Colorado Candor Act.

FAQs: Colorado Candor Act

WHAT IS CANDOR?

Candor can be defined as "the quality of being open and honest." This term has been adopted in health care to describe a framework for addressing adverse medical incidents in a way that preserves the provider-patient relationship, allows for open communication, and supports improvements in patient safety.

The focus on Candor emerged out of efforts by the Agency for Healthcare Research and Quality (AHRQ). AHRQ developed a toolkit that promoted a shift to an environment that encourages open, honest conversations with patients after adverse outcomes occur. The process is also designed to investigate and learn from what happened, to address the patients' needs alongside providers' needs, and to disseminate any lessons learned in order to improve future outcomes.

Since then, the Candor framework has been utilized in various health care systems and demonstrated positive results. In addition, Candor-related legislation has been passed in Massachusetts, Oregon, and Iowa.

WHAT ARE THE ORIGINS OF THE COLORADO CANDOR ACT?

The Colorado Candor Act originated from discussions between the Colorado Academy of Family Physicians (CAFP) and legislators at the beginning of the 2019 state legislative session. CAFP served as a strong advocate for the health care community and its patients by highlighting the benefits of Candor. CAFP worked closely with other stakeholders, including the Colorado Trial Lawyers Association and patient safety advocates, to garner support for this bipartisan measure that eventually passed as legislation (SB 201).

WHAT TYPES OF INCIDENTS QUALIFY UNDER THE ACT?

Adverse health care incidents arising from or related to patient care resulting in the physical injury or death of a patient.

WHEN DID THE COLORADO CANDOR ACT TAKE EFFECT?

The Act went into effect on July 1, 2019.

WHAT TYPES OF MEDICAL PROVIDERS AND FACILITIES CAN UTILIZE THE COLORADO CANDOR ACT?

Physicians, physician assistants, podiatrists, licensed practical and registered nurses, advanced practice nurses, pharmacists, and others who are licensed, certified, registered or otherwise permitted to provide health care services in Colorado.

In addition, hospitals/health care facilities including clinics, community health centers, community mental health centers, surgical centers, and residential care or nursing homes are eligible to participate jointly with a health care provider involved in the adverse health care incident.

HOW DOES THE CANDOR PROCESS BENEFIT PATIENTS?

Patients who have an adverse incident, and their families, are able to engage in open discussions with the provider(s) involved. This helps them understand why the incident occurred and what is being done to prevent similar issues in the future. Patients become a part of the process by helping to identify and implement procedures designed to improve patient safety. The Candor process is also designed to expedite the process of addressing an adverse outcome and offering patients compensation when warranted.

HOW DOES THE CANDOR PROCESS BENEFIT PROVIDERS?

As with patients, the open discussions allow for providers to address concerns, offer their perspective on what happened and why, and work together to preserve the provider-patient relationship. The Candor process is meant to be non-adversarial. It allows providers to participate in and learn from the process without creating undue burdens that take the provider away from patient care.

HOW DOES THE CANDOR PROCESS START?

The process is initiated by the health care provider involved in the incident. The provider, or the provider jointly with the health facility, needs to provide the patient with written notice of the desire to enter into an open discussion (under the Colorado Candor Act) with the patient. The notice must include specific details about the patient's rights and the nature of the communications and discussions under the Colorado Candor Act.

CONTINUED ON PAGE 2

CANDOR FAQs (FROM PAGE 1)

WHAT SHOULD MEDICAL FACILITIES/HOSPITALS BE AWARE OF WITH THE CANDOR PROCESS?

The Colorado Candor Act does not change the process for health care facilities to review systems issues, the facility's quality management process, or the quality of care rendered by individual providers. The Act does not change the current process of reporting certain occurrences to Colorado Department of Public Health and Environment (CDPHE) or CDPHE's ability to investigate and access medical records and other information allowed under current law.

WHY ARE THE DISCUSSIONS CONFIDENTIAL AND PRIVILEGED?

To facilitate open communication between providers and patients in a way that is not hindered by the threat of these communications being used against the provider or facility in subsequent litigation.

CAN A PATIENT STILL FILE A LAWSUIT AFTER A CANDOR DISCUSSION?

The Colorado Candor Act does not limit a patient's ability to use the legal system. Patients can choose to withdraw from the Candor process at any time. However, the discussions and communications that occurred during the Candor process, including any offers of compensation, remain privileged and confidential. Under the Act, an offer of compensation does not constitute an admission of liability. In addition, if a patient chooses to accept an offer of compensation, a provider or facility may require a patient to sign a release of liability, so he or she cannot bring a subsequent lawsuit.

WHAT REPORTING REQUIREMENTS APPLY TO THE COLORADO CANDOR ACT?

Because no payments are made as a result of a written complaint or claim demanding payment based on a practitioner's provision of health care services, incidents handled through the Candor process are not required to be reported to the National Practitioner Data Bank.

Patients participating under the Colorado Candor Act do not waive their right to file a complaint with the relevant licensing board or the Colorado Department of Public Health and Environment, which oversees health care facilities. Where indicated, a provider's actions can also be addressed through Colorado's professional review process for physicians, PAs, APNs, or a facility's quality management process for other licensed health care professionals.

States outside of Colorado may require notification of incidents where there is compensation under the Candor process for providers who are licensed in those states, including through the Interstate Medical Licensure Compact.

WHAT ARE SOME OF THE OTHER BENEFITS OF THE COLORADO CANDOR ACT?

A health care provider/health facility that participates in open discussions under the Act may provide de-identified information about an adverse health care incident to any patient safety-centered nonprofit organization for use in patient safety research and education. Such a disclosure does not constitute a waiver of the privilege for open discussions and is not a violation of the Act's confidentiality requirements.

Overview of the Candor Process

1 The process is initiated by the health care provider.

A health care provider involved in the adverse health care incident, or the provider jointly with the health facility, needs to provide the patient with written notice of the desire to enter into an open discussion under the Colorado Candor Act.

As with all incidents, COPIC insureds should call a COPIC occurrence specialist nurse during business hours, 8am–5pm (Mountain time), Monday through Friday, by calling (800) 421-1834. The occurrence specialist nurse will evaluate the incident with our internal team to determine if it is appropriate to utilize the Colorado Candor Act.

2 The written notice must be sent to the patient within 180 days of the incident.

This time period is defined as 180 days after the provider knew or should have known about the incident.

3 The notice must include specific details about the patient's rights and the nature of the communications and discussions under the Colorado Candor Act.

The notice must include the following:

- The patient's right to receive a copy of the medical records related to the incident and to authorize the release of the records to any third party;
- The patient's right to seek legal counsel and have legal counsel present during any open discussions;
- A copy of the relevant statute of limitations with notice that the time for a patient to bring a lawsuit is limited and will not be extended merely by engaging in an open discussion;

CONTINUED ON PAGE 3

CANDOR PROCESS (FROM PAGE 2)

- If the health care provider or health facility is a public entity or public employee, a copy of the deadline for filing under the Governmental Immunity Act, which won't be extended by engaging in an open discussion;
- Notice that if the patient chooses to engage in an open discussion with the health care provider or health facility, all communications made in the course of the discussion under the statute are:
  - Privileged and confidential,
  - Not subject to discovery, subpoena, or other means of legal compulsion for release, and
  - Not admissible in evidence in a judicial, administrative, or arbitration proceeding arising directly out of the adverse incident.
- An advisement that communications, work product, documents, and other materials that are otherwise subject to discovery and not prepared specifically for use in an open discussion are not confidential.

If the patient agrees in writing to engage in an open discussion, the patient, health care provider, or health facility engaged in the discussions may include other persons in the open discussion, who must acknowledge in writing that the communications are privileged and confidential.

4 Under the Colorado Candor Act, health care providers and facilities may investigate, disclose, and communicate about how the incident occurred and what steps are being taken to prevent a similar outcome in the future.

The health care provider/facility that agrees to engage in an open discussion may:

- Investigate how the incident occurred and gather information regarding the medical care.
- Disclose the results of the investigation to the patient.
- Communicate to the patient the steps that will take place to prevent future occurrences of the incident.

5 As part of their assessment, health care providers and facilities can determine whether or not an offer of compensation is warranted.

If no offer of compensation is warranted, the provider/facility shall orally communicate that decision with the patient.

If the provider or facility determines that an offer of compensation is warranted, the provider or facility shall provide the patient with a written offer of compensation.

- If an offer is made and the patient is not represented by legal counsel, the provider/facility is required to:
  - Advise the patient of the patient's right to seek legal counsel regarding the offer of compensation; and
  - Provide notice that the patient may be legally required to repay medical and other expenses that were paid by a third party, including private health insurance, Medicare, or Medicaid.
- A health care provider/facility may require the patient, as a condition of an offer for compensation, to execute all documents and obtain any necessary court approval to resolve an adverse health care incident.

6 To facilitate open communication under the Colorado Candor Act, discussions and offers of compensation under the Act are privileged and confidential.

- Open discussion communications and offers of compensation made under the statute:
  - Do not constitute an admission of liability;
  - Are privileged and confidential and shall not be disclosed; and
  - Are not admissible as evidence in any subsequent judicial, administrative, or arbitration proceeding arising directly out of the adverse health care incident.
- Communications, memoranda, work product, documents, and other materials that are otherwise subject to discovery and not prepared specifically for use in an open discussion are not confidential.
- The limitations on disclosure includes disclosure during any discovery conducted as part of a subsequent adjudicatory proceeding arising directly out of the adverse health care incident, and a court or other adjudicatory body shall not compel a person who engages in an open discussion under the Act to disclose confidential communications or agreements made as part of the open discussion.
- The Act does not affect any other law, rule, or requirement with respect to confidentiality.

Considerations for Health Care Facilities/Hospitals

Health care facilities and hospitals follow the same Candor process as individual health care providers. However, they should examine internal systems and what adjustments should be made to integrate the Candor process. This may include the following considerations and/or "best practices":

- **Establish a Situation Management Team (SMT) to ensure a timely and effective response**:
  - An SMT is responsible for managing how a facility responds to an adverse outcome in a coordinated approach among various stakeholders within a facility.
  - The key responsibilities of an SMT are to conduct an analysis, notify the involved providers (if they are not already aware) and provide support to them, determine what type of communication with the patient is appropriate, and evaluate if compensation is warranted.
  - Members of the SMT can include risk managers, patient safety specialists, patient representatives, and medical and nursing staff leadership.

For COPIC insureds, the SMT should include members of COPIC's Candor Team. Our 20+ years of experience in dealing with communication after an adverse outcome provides expertise to guide facilities through every step of the Candor process.

- **Recognize the key exclusions that make an incident ineligible for the Candor process**.
  - A summons or complaint was received.
  - There is a written demand for compensation.
  - There is no physical injury to the patient.
- **Remember that physicians are not the only providers who can participate in the Candor process**.
  - Besides physicians, eligible providers include physician assistants, podiatrists, licensed practical and registered nurses, advanced practice nurses, pharmacists, and others who are licensed, certified, registered or otherwise permitted to provide health care services in Colorado.
- **Be conscious of the 180-day timeframe in which the initial written notice to the patient must be sent**.
- **Because Candor is "provider initiated," the facility/hospital should work with the involved provider(s) to discuss how to speak with the patient and walk through the Candor process.**
  - The Candor framework recognizes that patients want to hear from the provider(s) who was involved with their care as opposed to an administrative representative from the facility.
- **Establish a clear contact who will work directly with the patient throughout the entire Candor process**.
- **Develop patient communication pieces designed to help them understand the Colorado Candor Act**.

COPIC has developed a Patient FAQs and Program Overview, which is available for insured facilities/hospitals to use.

- **Ensure the proper documentation is used at every step of the process**.
- **Educate medical staff about the Colorado Candor Act, and how it can be initiated and utilized**.

The Colorado Candor Act framework shares underlying principles with Seven Pillars[1], another recognized approach to addressing adverse events in health care facilities and systems. The components of Seven Pillars are:

1) Patient safety incident reporting—Reinforce a culture that encourages timely reporting.

2) Investigation—Conduct a preliminary review of the incident to determine if patient harm occurred and if a root cause analysis should be performed; the investigation should examine the system as well as provider performance.

3) Communication and disclosure—Maintain ongoing communication with the patient and family throughout the process; providers involved should be trained in communication skills required in these situations such as empathy, sincerity, active listening, patience, and tact.

4) Apology and remediation (if appropriate)—Ensure that when patient harm did occur, saying "we're sorry" includes subsequent action such as explaining what is being done to prevent similar outcomes and offers of compensation, if warranted.

5) System improvement—Identify and implement system improvements aimed at preventing a recurrence; patients and families may be invited to participate in this aspect of the process.

6) Data tracking and performance evaluation—Collect data associated with the incident and utilize this for internal quality assurance, research, and dissemination to relevant stakeholders.

7) Education and training—Build a robust education platform based on analysis of adverse events, and utilize case-based, interactive education for all members of the health care team.

[1] https://www.ncbi.nlm.nih.gov/pubmed/20194217

DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

1. REASONS FOR ISSUE: This Veterans Health Administration (VHA) directive establishes the policy to ensure consistent practice in disclosing to patients or to the patient's personal representative the occurrence of adverse events related to the patient's clinical care.

2. SUMMARY OF MAJOR CHANGES: This is a revised directive that:

a. Adds responsibilities for the Deputy Under Secretary for Health for Community Care.

b. Removes the requirement that VA medical facility leaders must confer with District Chief Counsel prior to initiating an institutional disclosure. Consultation with District Chief Counsel is now at the discretion of VA medical facility leadership.

c. Provides an updated graphical user interface (GUI) Text Template required for documenting institutional disclosure of adverse events to patients (see Appendix A).

d. Provides a link to an updated flow chart depicting the process for assessment of adverse events that might require large-scale disclosure (see Appendix B).

3. RELATED ISSUES: VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009; VHA Handbook 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated November 12, 2014; VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015; VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

4. RESPONSIBLE OFFICES: The National Center for Ethics in Health Care (10E1E) is responsible for the management of this directive. Questions about policy interpretation pertaining to clinical disclosure or institutional disclosure should be directed to the National Center for Ethics in Health Care at 202-632-8457 or vhaethics@va.gov. Questions about quarterly reporting of institutional disclosures should be directed to the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value (10E2) at 202-461-7254 or VHA10E2ERiskManagementStaff@va.gov. Questions about large-scale disclosure decisions should be directed to the Office of the Principal Deputy Under Secretary for Health (10A) at 202-461-7008 or VHA10AAction@va.gov.

5. RESCISSION: VHA Handbook 1004.08, Disclosure of Adverse Events to Patients, dated October 2, 2012, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of October, 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

Richard A. Stone, M.D.
Executive in Charge

DISTRIBUTION: Emailed to the VHA Publications Distribution List on November 1, 2018.

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

CONTENTS

DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

1. PURPOSE

This Veterans Health Administration (VHA) directive provides the policy for the disclosure of adverse events to patients or their personal representatives related to clinical care. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b). ***NOTE:*** *Information pertaining to adverse events in research can be found in VHA Handbook 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated November 12, 2014, and VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015.*

2. BACKGROUND

a. VHA believes that there is an unwavering ethical obligation to disclose to patients harmful adverse events that have been sustained in the course of their Department of Veterans Affairs (VA) care, including cases where the harm may not be obvious, or where there is a potential for harm to occur in the future (see paragraphs 13.k.–13.z.).

b. The commitment to disclose the occurrence of harmful adverse events to patients is consistent with the VA core values of integrity, commitment, advocacy, respect, and excellence; it demonstrates professionalism, and respect for the patient; and is foundational to providing care. While any such disclosure must be in keeping with applicable law, the explicit intent is to inform patients about substantive issues related to their care, and not to manage the institution's risk.

c. This directive is consistent with The Joint Commission standards that patients, and when appropriate, their families be told of unanticipated outcomes of care (see paragraphs 13.q.–13.r.).

d. Disclosure of adverse events to patients and the reporting of adverse events to regulatory agencies are separate requirements. Actions taken to disclose adverse events to patients in no way remove the need to report adverse events and close calls as required under VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011; VHA DIR 1070, Adverse Drug Event Reporting and Monitoring, dated September 12, 2014, and VHA Handbook 1100.17, National Practitioner Data Bank (NPDB) Reports, dated December 28, 2009.

e. Despite the ethical obligation to disclose adverse events to patients, there are legal requirements that establish limits on the information that may be shared and with whom it may be shared. Release of protected health information (verbally or in record form) must always be done according to law and VA standards. Assistance regarding information that may be released is available through the facility's Privacy and Freedom of Information Act (FOIA) Officer(s), or designee. The following paragraphs describe the most common standards regarding the release of information:

(1) Confidentiality statutes and regulations, such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, limit disclosure of

any record containing a patient's personal information to others without the patient's authorization or other legal authority. ***NOTE:*** *The patient's personal representative is authorized to have access to the patient's protected health information except as noted in this paragraph and in paragraph 2.e.(2) (see VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016, and VA Handbook 6300.4, Procedures for Processing Requests for Records Subject to the Privacy Act, dated August 19, 2013).*

(2) Under 38 U.S.C. 7332 (b)(2)(F), VHA may disclose information related to the patient's treatment for substance abuse, including alcohol, sickle cell anemia, or infection with the Human Immunodeficiency Virus (HIV) to the patient's surrogate if the patient lacks decision-making capacity and the practitioner deems the information necessary for the surrogate to make an informed decision regarding the patient's treatment. Otherwise such information may not be disclosed, even after a patient's death, without a special authorization or other exception. Questions about release of such information in the case of an adverse event are to be referred to the VA medical facility's Privacy Officer. ***NOTE:*** *Consultation with VHA's Privacy Officer may also be necessary (see VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016).*

(3) Under 38 U.S.C. 5705, VHA may not communicate to patients or their personal representative's information that is obtained from quality management activities. Quality management or quality assurance (QA) activities are those that are conducted by or for VA in the process of conducting systematic health care reviews for the purpose of improving the quality of health care or improving the utilization of health care resources in VA medical facilities. Examples of QA activities include Root Cause Analyses (RCA) or peer reviews for quality management.

f. Disclosure of an adverse event or close calls, as discussed in paragraph 2.c. is a separate action from QA review, analysis, or investigation of an adverse event. The purpose of a QA activity is to allow for effective self-evaluation in the interest of improving the quality of care. When a disclosure of information is made, the information that is being disclosed must not originate with a QA document; in other words, any information that is shared with the patient regarding the adverse event must come from a source other than a QA document. QA documents may contain information protected under other confidentiality statutes, such as the Privacy Act (see paragraph 1.e(1) for limitations related to those statutes). Assistance regarding the release of information that also might be the product of a QA activity is available through the facility's FOIA Officer(s), or designee. Other specific questions regarding information that may not be disclosed to the patient or representative may be found in VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

3. DEFINITIONS

a. **Adverse Event.** Adverse events are untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers. ***NOTE:*** *To determine*

which incidents need to be considered for root cause analysis, consult VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

b. **Clinical Review Board.** The Clinical Review Board (CRB) is a multi-disciplinary board convened at the request of the Principal Deputy Under Secretary for Health in response to adverse events that may pose a clinically significant risk of harm to multiple patients or members of patients' families, but the probability of harm and/or the severity of the potential harm cannot be determined. The CRB uses a transparent and systematic process to consider whether disclosure is ethically warranted in light of the indeterminate risk.

c. **Close Call.** A close call is an event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention. Such events have also been referred to as near miss incidents.

d. **Disclosure of Adverse Events.** For purposes of this directive, disclosure of adverse events refers to the forthright and empathetic discussion of clinically-significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future. ***NOTE:*** *Depending on the nature of the adverse event, the disclosure process may involve any or all of the three types of disclosure defined in (1) through (3) below. See paragraphs 7–10 for additional information on the three types of disclosure, including what must be disclosed, by whom, when, and how*

(1) **Clinical Disclosure of Adverse Events.** Clinical disclosure of adverse events is a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient's care (see paragraph 8). ***NOTE:*** *Clinicians may also be involved in communicating information as part of an institutional disclosure or a large-scale disclosure, but this is not considered a clinical disclosure.*

(2) **Institutional Disclosure of Adverse Events.** Institutional disclosure of adverse events, sometimes referred to as administrative disclosure, is a formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse (see paragraph 9). ***NOTE:*** *VA medical facility leaders may also be involved in communicating information as part of a large-scale disclosure, but this is not considered an institutional disclosure*.

(3) **Large-scale Disclosure of Adverse Events.** Large-scale disclosure of adverse events, sometimes referred to as notification, is a formal process by which VHA officials assist with coordinating the notification to multiple patients, or their personal representatives, that they may have been affected by an adverse event resulting from a systems issue (that is, a problem that might require system improvement at one or more

facilities). This process also generally includes public notification and direct communication to key stakeholders (see paragraph 10).

e. **Epidemiologic Investigation.** An epidemiologic investigation is a study of potentially affected populations to ascertain whether there is a linkage between health effects, for example, an infection, and a cause, for example, an exposure.

f. **Exposure.** Exposure is the proximity to, or contact with, an environmental condition, for example, an infectious pathogen, a toxic chemical, or radiation, in such a manner that transmission of harmful effects may occur.

g. **Look-back.** A look-back is an organized process for identifying patients or staff with exposure to potential risk incurred through past clinical activities, with the explicit intent to notify them and offer care and recourse, as appropriate.

h. **Personal Representative.** A personal representative is a person who, under applicable law, has legal authority to act on behalf of an individual. This authority may include power of attorney, legal guardianship of an individual, the appointment as the executor of the estate of a deceased individual, or the authority granted to someone under Federal, state, local, or tribal law, such as the parent of a minor. The personal representative generally is the patient's surrogate for the informed consent process (see Title 38 Code of Federal Regulations (CFR) 17.32(e) for authorized surrogates for informed consent. For information on the disclosure of a patient's health information to a personal representative, see VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

i. **Subject Matter Expert Review Panel.** The Subject Matter Expert (SME) Review Panel is a panel convened to conduct fact-finding, including, as needed, site visits, literature reviews, and risk assessment regarding events that have the potential to require a large-scale disclosure.

j. **Surrogate Decision Maker.** A surrogate decision maker, also referred to as surrogate, refers to an individual authorized under VHA policy to make health care decisions on behalf of a patient who lacks decision-making capacity (see VHA Handbook 1004.01, Informed Consent for Clinical Treatment and Procedures, dated August 14, 2009, for information about surrogate selection, priority, and the surrogate's role in health care decision-making).

4. POLICY

It is VHA policy to disclose harmful or potentially harmful adverse events to patients or their personal representatives in order to maintain trust between patients and VA health care professionals, and to ensure uniform practice across all VA medical facilities.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health, or designee is responsible for ensuring overall VHA compliance with this directive.

b. **Principal Deputy Under Secretary for Health.** The Principal Deputy Under Secretary for Health, or designee is responsible for oversight of the large-scale disclosure process, including:

(1) Appointing the Chairperson of the CRB from the Deputy Under Secretary-level, for example, Deputy Under Secretary for Health for Policy and Services or Deputy Under Secretary for Health for Operations and Management.

(2) Concurring or non-concurring with the recommendation of the Deputy Under Secretary for Health for Operations and Management's coordinated triage process or SME Review Panel to disclose, not disclose, or to convene a CRB, and providing a written record of this decision to the Deputy Under Secretary for Health for Operations and Management.

(3) If a decision is made to convene the CRB, communicating the charge to the CRB Chairperson and simultaneously notifying the Deputy Under Secretary for Health for Operations and Management and other relevant VA Central Office programs, for example, the Office of the General Counsel (OGC), Office of Public and Intergovernmental Affairs (OPIA), and Office of Congressional and Legislative Affairs (OCLA), to begin preparations for a possible disclosure.

(4) Concurring or non-concurring with the CRB recommendations, and communicating that decision to the Deputy Under Secretary for Health for Operations and Management and the CRB Chairperson.

(5) Requesting further information or guidance from the CRB, as needed, prior to making a final decision.

(6) Ensuring that Veterans Benefits Administration (VBA) Central Office is notified when Veterans' benefits may be affected by a decision to make a large-scale disclosure.

(7) Ensuring that VA medical facility and VISN leadership is notified that an epidemiologic investigation is going to take place, and the establishment of a clear line of authority, access, and accountability.

(8) Ensuring a mechanism for maintaining CRB-related documents relating to large-scale disclosure of adverse events.

(9) Assigning responsibility for leading, organizing, and conducting any required VHA look-back program and epidemiologic investigation as part of, or following, a large-scale disclosure to patients.

c. **Deputy Under Secretary for Health for Community Care.** As VA continues to provide Veterans with access to community care, the agency is committed to ensuring that eligible Veterans receive the same high quality of care no matter where it is provided. VA Community Care providers, like all health care professionals, have an ethical obligation to disclose to patients, harmful adverse events that have occurred in the course of their care. This obligation is specified in all codes of professional ethics for health care professionals, and exists independent of any contractual obligation with VA. This obligation is also reflected in the Joint Commission's standards related to patient safety and patient rights (see paragraph 13.r.). To promote and support these standards of professionalism, the Deputy Under Secretary for Health for Community Care is responsible for coordinating contracts, tools, technologies, and processes to detect, report, and investigate adverse events and other patient safety events, and improve patient safety for Veterans who receive care in the community.

d. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management, or designee is responsible for:

(1) Ensuring a coordinated triage process for a review of each potential adverse event that may require large-scale disclosure (see Appendix B). The triage process must include designated staff from the offices of: the Deputy Under Secretary for Health for Operations and Management; the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; the Deputy Under Secretary for Health for Policy and Services; and other offices and field-based SMEs, as needed, to recommend, based on preliminary information, that the adverse event:

(a) Involves a negligible or clinically-insignificant risk of harm and, therefore, requires no large scale-disclosure so the issue can be closed; or

(b) Requires large scale-disclosure or referral to an appropriately constituted CRB or SME Review Panel (see paragraphs 1.e.–1.h.) for a more detailed review;

(2) Ensuring that potential cases are referred to the SME Review Panel or CRB for more detailed review;

(3) Providing oversight to the SME Review Panel, summarizing the SME Review Panel findings regarding risk, and submitting a written report and recommendation to the Principal Deputy Under Secretary for Health concerning whether there is a negligible risk of harm and no disclosure is required; or there is a clinically-significant risk of harm and disclosure is required; or there is an indeterminate risk of harm and a CRB needs to be convened to consider whether disclosure is ethically warranted based on factors other than risk alone;

(4) Developing, maintaining, and implementing standard operating procedures for the implementation of large-scale disclosures;

(5) Implementing a decision by the Principal Deputy Under Secretary for Health to conduct a large-scale disclosure with coordination among appropriate field and Central

Office programs including OGC, OPIA, OCLA, and others. Implementation includes notification of field sites, activation of a site visit team, a review of written materials and statements by OGC, and other appropriate offices (see Appendix B);

(6) Designating and facilitating any required look-back activities and epidemiologic investigations;

(7) Conducting an After Action Review of the event with appropriate SME participation and submitting a report to the Under Secretary for Health; and

(8) Ensuring a mechanism for maintaining documents related to large-scale disclosure of adverse events.

(9) Leading the Subject Matter Expert Review panel (see paragraph 1.h.)

e. **Chairperson of the Clinical Review Board.** The Chairperson of the CRB is appointed by the Principal Deputy Under Secretary for Health, and is responsible for:

(1) Convening and chairing the CRB;

(2) Ensuring that CRB deliberations and recommendations follow the process outlined in paragraph 1.f–1.g, and Appendices B and C;

(3) Providing, on behalf of the CRB, written recommendations and justifications to the Principal Deputy Under Secretary for Health that disclosure is recommended or that no disclosure is recommended. If the CRB concludes that there is insufficient information to make a recommendation, the Chairperson is responsible for providing the Principal Deputy Under Secretary for Health with a plan and timeline for a definitive CRB recommendation;

(4) Providing a written statement to the Principal Deputy Under Secretary for Health regarding whether the CRB recommendation regarding disclosure was unanimous and, if not, the number of assenting and dissenting votes and the related rationales;

(5) Ensuring that a CRB recommendation in favor of large-scale disclosure addresses:

(a) Notification to potentially-affected patients, patients' personal representatives, patients' next-of-kin, and other involved parties consistent with information disclosure policies (see paragraph 2.e., and VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016);

(b) Notification to involved facilities for required clinical follow up with potentially-affected patients, and other involved parties; and

(c) The need for inquiry into similar processes at other facilities; and

(6) Ensuring a mechanism for maintaining CRB-related documents relating to large-scale disclosure of adverse events.

f. **CRB Membership.**

(1) The CRB is made up of appropriate representatives from the following member offices: Office of the Deputy Under Secretary for Health for Operations and Management; National Center for Ethics in Health Care; Office of Nursing Services; National Center for Patient Safety; Office of Patient Care Services; Office of Specialty Care Services; Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; and OGC. The SME Review Panel Chairperson also serves as a member.

(2) The CRB Chairperson and each member office, with the exception of OGC, has one vote in the CRB decision. When the Chair of the SME Review Panel represents one of the member offices, the member office still only has one vote in the CRB decision.

(3) The CRB may include non-voting members (for example, SMEs from VHA programs, the relevant field facility or facilities, program offices, and VHA experts), as needed. The CRB may solicit input from outside experts for example, equipment manufacturers, as appropriate.

g. **Clinical Review Board.** The CRB is responsible for:

(1) Considering those adverse events where it is unclear whether there is a clinically-significant harm or potential harm to patients as determined by the Principal Deputy Under Secretary for Health following the SME Review Panel's findings.

(2) Reviewing the information and risk assessment provided by the SME Review Panel, seeking clarifications as necessary.

(3) Considering all available clinical, scientific, and epidemiologic information and discussing additional non-clinical factors (as described in Appendix C) to determine whether a recommendation for disclosure of the adverse event to patients and families is appropriate.

(a) Determining if an epidemiologic investigation is recommended.

(b) Ensuring that all documents relevant to the CRB's deliberations are provided to the CRB Chairperson.

h. **Subject Matter Expert Review Panel.**

(1) The SME Review Panel is a standing panel that meets as necessary to review and make recommendations on cases referred by the Principal Deputy Under Secretary for Health concerning adverse events that potentially warrant large-scale disclosure.

(2) The SME Review Panel is led by the Deputy Under Secretary for Health for Operations and Management, or designee, and is made up of appropriate SMEs from the office of the Assistant Deputy Under Secretary for Clinical Operations; Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; the National Center for Patient Safety; the Office of Patient Care Services; the Office of Nursing Services, and other program offices (for example, Sterile Processing Service, National Infectious Disease Service, Office of Informatics and Analytics, Office of Specialty Care Services), as needed.

(3) The SME Review Panel is responsible for:

(a) Conducting fact-finding, including site visits if needed, literature reviews, risk assessments, and summarizing findings regarding risk to patients, and if relevant, members of patients' families.

(b) Submitting a written report to the Principal Deputy Under Secretary for Health with one of the following three findings and corresponding recommendations:

1. There is a negligible risk of harm, considering both the probability of harm and the severity of potential harm; therefore, no disclosure is required and the issue should be closed.

2. There is a clinically-significant risk of harm, considering both the probability of harm and the severity of potential harm; therefore, disclosure is required and there is no need to convene a CRB.

3. There is an indeterminate risk of harm, considering both the probability of harm and the severity of potential harm; therefore, a CRB should be convened to consider whether disclosure is ethically warranted based on factors other than risk alone.

(c) Ensuring that all documents relevant to the SME Review Panel's deliberations are provided to the SME Review Panel Chairperson.

i. **Assistant Deputy Under Secretary for Health for Patient Care Services.** The Assistant Deputy Under Secretary for Patient Care Services is responsible for providing appropriate expertise regarding large-scale disclosure recommendations to the Deputy Under Secretary for Health for Operations and Management coordinated triage process, SME Review Panel, and CRB, and support to VAMCs and VISNs as required or requested.

j. **Assistant Deputy Under Secretary for Health for Quality, Safety, and Value.** The Assistant Deputy Under Secretary for Health for Quality, Safety, and Value, or designee is responsible for:

(1) Participating in the CRB and the SME Review Panel processes.

(2) Providing a representative from the National Center for Patient Safety to participate in the CRB and SME Review Panel processes.

(3) Interpreting and updating the risk management content of this directive, as requested by the National Center for Ethics and Health Care.

(4) Completing a quarterly review and analysis of institutional disclosures reported by each VISN office and providing recommendations to appropriate program offices based on analysis of the quarterly review.

k. **Chief Officer for Specialty Care Services.** The Chief Officer for Specialty Care Services is responsible for providing appropriate expertise regarding large-scale disclosure recommendations to the Deputy Under Secretary for Health for Operations and Management coordinated triage process, SME Review Panel, and CRB, and support to VAMCs and VISNs as required or requested.

l. **Executive Director, National Center for Ethics in Health Care.** The Executive Director, National Center for Ethics in Health Care, or designee is responsible for:

(1) Participating in the CRB process.

(2) Participating in the Deputy Under Secretary for Health for Operations and Management triage process and SME Review Panel process, as requested.

(3) Interpreting policy questions pertaining to disclosure of adverse events.

m. **Veterans Integrated Service Network Director.** The VISN Director, or designee is responsible for:

(1) Submitting an Issue Brief to the Deputy Under Secretary for Health for Operations and Management immediately upon receiving communication from a VA medical facility Director or from appropriate reports that an adverse event has been discovered that is not an isolated case but rather a systems issue affecting multiple patients and thus that may require large-scale disclosure (see Appendix B).

(2) Participating in the Field-VA Central Office process for determining the need for and implementation of large-scale disclosure decisions, as requested (see Appendix B).

(3) Ensuring a mechanism for maintaining all VISN-related documents relating to large-scale disclosure of adverse events.

(4) Providing a report quarterly, and as requested, to the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value, on the number and types of institutional disclosures provided by facilities within the VISN. The report must include the date of the adverse event, date of institutional disclosure, number of unique patients, whether there was a patient death, department(s) involved, and a brief description of the triggering event for each institutional disclosure.

n. **VA Medical Facility Director.** The VA medical facility Director, or designee is responsible for:

(1) Promoting an ethical health care environment and culture in which appropriate disclosure of adverse events is routine practice.

(2) Ensuring that clinical and institutional disclosures of adverse events are performed openly and promptly with patients or their personal representatives.

(3) Ensuring that relevant staff are aware of this directive.

(4) Ensuring that the patient (or the patient's personal representative if the patient is deceased, incapacitated, or otherwise unable to take part in the disclosure process) is provided (e.g., by the Risk Manager or other assigned staff member) with contact information for designated VA health care staff, as needed, to respond to questions regarding the disclosed information or clinical events associated with an adverse event.

(5) Ensuring that the patient or patient representative is referred (e.g., by the Risk Manager or other assigned staff member) to the VACO National Torts Group for coordination of document requests, if it is known that a tort claim has been filed.

(6) Ensuring that adverse events that may require institutional disclosure are communicated immediately to District Chief Counsel.

(7) Submitting an Issue Brief to the VISN Director and District Chief Counsel immediately following the discovery at the facility of an adverse event that is not an isolated case, but rather a systems issue affecting multiple patients which might require a large-scale disclosure (see Appendix B).

(8) Participating in the VA Central Office fact-finding process, CRB process, large-scale disclosure implementation, look-back, and epidemiologic investigations, as requested. This includes ensuring that sufficient resources are available to perform these processes in a proper and timely manner. For example, a case manager may be needed to coordinate clinical, laboratory, communications, and other aspects of the investigations (see Appendices B and C).

(9) Ensuring that institutional disclosures are correctly documented in CPRS, to include:

(a) Ensuring that the updated graphical user interface (GUI) Text Template (Institutional Disclosure of Adverse Event) (Appendix A) is associated with the progress note title, Institutional Disclosure of Adverse Event.

(b) Ensuring that the progress note title, Institutional Disclosure of Adverse Event is mapped to the national standard title of Communication of Adverse Event.

(c) Ensuring that a User Class and Business Rules are created to restrict the entering of the GUI Template/Progress Note, Institutional Disclosure of Adverse Event to specific users (for example, Risk Manager, Patient Safety Manager, Quality Manager, Chief of Staff). Business rules for initial progress note creation must also be applied to

the creation and signature of any addenda attached to this progress note. Access restrictions are only to be placed on entering, not on viewing.

(d) Ensuring that the updated Institutional Disclosure of Adverse Event Note template (Appendix A) is used only to document institutional disclosure of adverse events.

(10) Ensuring that information about potential compensation through the Veterans Benefits Administration and the Federal Tort Claims Act is provided to patients or patient representatives as part of the institutional disclosure process.

(11) Ensuring a mechanism for maintaining documents relating to large-scale disclosure of adverse events.

(12) Providing a report quarterly, and as requested, to the VISN Director, regarding the number and types of institutional disclosures that have been provided by the facility.

o. **VA Medical Center Chief of Staff and Associate Director of Patient Care Services.** The VA Medical Center Chief of Staff and Associate Director of Patient Care Services are responsible for:

(1) Immediately notifying the VA medical facility Director regarding the discovery of any significant adverse event that is brought to their attention.

(2) Participating in discussions and institutional disclosures with others, for example, clinicians, facility senior management team, District Chief Counsel, VISN staff, patients, or personal representatives, as appropriate, concerning the adverse event.

(3) Participating in any look-back or epidemiologic investigations required.

p. **VA Medical Facility Risk Manager.** The VA medical facility Risk Manager, or designee is responsible for:

(1) Immediately notifying the Associate Director for Patient Care Services, Chief of Staff, or VA medical facility Director about the discovery of a significant adverse event that is brought to the attention of the Risk Manager; especially those that may require institutional disclosure or a decision regarding a large-scale disclosure of adverse events.

(2) Referring providers who have questions about the legal dimensions of disclosure of adverse events to District Chief Counsel.

(3) Establishing a dialogue with District Chief Counsel and requesting that District Chief Counsel educate providers, as needed, regarding legal dimensions of institutional disclosure of adverse events, its documentation, and its relationship to the Federal Tort Claims Act.

(4) Participating in any look-back or epidemiologic investigations required.

(5) Establishing a process for collection, tracking, and analysis of relevant information related to institutional disclosures conducted at the facility for submission to the VISN Director in a quarterly report.

q. **Health Care Providers Responsible for the Patient's Care.** Health care providers responsible for the patient's care, or designee are responsible for:

(1) Providing clinical disclosure to patients as specified in this directive.

(2) Participating in institutional disclosures, if appropriate, as requested by facility leadership.

6. ADVERSE EVENTS THAT WARRANT DISCLOSURE

Disclosure is warranted for harmful or potentially-harmful adverse events, defined broadly to include:

a. Adverse events that cause death or disability, lead to prolonged hospitalization, require life-sustaining intervention or intervention to prevent impairment or damage, or that are reasonably expected to result in death or serious or permanent disability, or that are sentinel events as defined by The Joint Commission.

b. Adverse events that have had, or are reasonably expected to have, an effect on the patient that is perceptible to either the patient or the health care team. For example, if a patient is mistakenly given a dose of a diuretic, a medication that dramatically increases urine output, disclosure is required because a perceptible effect has, or is anticipated to occur.

c. Adverse events that precipitate a change in the patient's care, for example, a medication error that necessitates extra blood tests, extra hospital days, follow-up visits that would otherwise not be required, or a surgical error that necessitates further corrective surgery.

d. Adverse events with a clinically-significant risk of serious future health consequences to patients, even if the likelihood of that risk is small, for example, an accidental exposure of a patient to ionizing radiation, a toxin, an organism, or infectious entity associated with a rare, but recognized, serious short-term or long-term effect, for example, blood borne pathogen infection or increased incidence of cancer. In some cases, however, no definite exposure of this type can be determined. Only an increased risk of exposure is known or thought to exist. In such cases, the disclosure decision needs to be based on the risks and benefits of disclosure relative to the probability of serious future health consequences. If, after disclosure in such cases, it is later determined through the look-back process or subsequent investigation that harm did not occur, or that the risk of harm is actually negligible, disclosure of the new risk information must be made to the patient. Caution must be exercised in differentiating clinically significant risk of harm from harm that is only plausible or hypothetical.

e. Any event that requires an unexpected treatment or procedure to be initiated without the patient's consent, for example, if an event occurs while a patient is under anesthesia, necessitating a deviation from the procedure the patient expected. Patients have a fundamental right to be informed about what is done to them and why.

(1) Where adverse events occur that have a potential to affect, or may have already affected multiple patients at one or more VA medical facilities, the process for large-scale disclosure must be followed (see the process providing the ethical and clinical considerations outlined in Appendices B and C).

(2) Disclosure of adverse events other than those that fall under the previous descriptions is optional and at the discretion of the providers involved. Cases must be considered individually and in relation to the specific circumstances.

(3) Disclosure of close calls to patients is discretionary, but is advisable at times, such as when the patient or family become aware that something out of the ordinary has occurred.

(a) For example, a nurse sets up a patient for a blood transfusion and, discovering that the patient is about to receive the wrong unit of blood, then abruptly stops the transfusion just before the blood enters the patient's vein. The patient deserves an explanation, even if this is not considered a clinical disclosure of an adverse event.

(b) Although the disclosure of a close call to the patient is optional, reporting close calls is required under VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

(4) There may be times when a complication that was anticipated and discussed in the informed consent process occurs. Such complications need to be discussed with the patient or patient's personal representative as part of ongoing clinical care. A serious complication may also require investigation or focused review as described in VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011. If the complication is deemed to be untoward or preventable, then an appropriate disclosure is required under this directive.

7. COMMUNICATING ADVERSE EVENTS

a. The process for disclosing an adverse event depends on the nature and circumstances of the event. VA recognizes three types of adverse event disclosure: clinical, institutional, and large-scale (see paragraphs 8, 9, and 10).

b. The process of adverse event disclosure is not necessarily a singular event, but may involve a series of conversations. For example, as more information is learned in a particular case, a clinical disclosure may need to be followed by an institutional disclosure, which itself may involve multiple conversations. In some cases, the disclosure process may ultimately involve all three types of disclosures.

c. Whenever a potential harm is disclosed to a patient, it may be necessary, after an investigation has been conducted, to follow up with the patient to inform the patient whether the potential harm that was initially disclosed did or did not, in fact, occur (for example, a patient who is initially told that the patient may have been exposed to a blood-borne virus as a result of improperly sterilized equipment, must be informed of investigation results that would have a significant impact on the patient's health or wellbeing).

d. For the patient who is deceased, incapacitated, or otherwise unable to participate in the process of adverse event disclosure, any clinical or institutional disclosure must be communicated to the patient's personal representative and may involve others, as designated by the personal representative in accordance with VHA Directive 1605.01.

e. Any release of information regarding a deceased Veteran whose clinical records are covered by 38 U.S.C. 7332, must be made in accordance with applicable law. ***NOTE:*** *For additional guidance, refer to VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016, and confer with the facility Privacy Officer, as necessary.*

f. In some cases, it may be apparent that an adverse event has occurred, but its cause is not clear. In those situations, the Veteran or the Veteran's personal representative needs to be told what has occurred and what is known about the problem. They need to be informed as to whether the problem is being investigated and if additional information will be provided to them once a review is completed.

8. CLINICAL DISCLOSURE OF ADVERSE EVENTS

Clinical disclosure is a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the course of care. A clinical disclosure is appropriate for all adverse events that cause only minor harm to the patient, except those minor harms that are discovered after the patient has completed the associated episode of care and that have no implications for the patient's future health. A clinical disclosure is also appropriate for more serious adverse events as the appropriate first step in a process that may ultimately require an institutional or large-scale disclosure. While clinical disclosure of adverse events is considered a routine part of clinical care, clinicians must be sensitive to any limitations on sharing information from the Veteran's health record (see paragraph 2.e.). In general, clinical disclosure of an adverse event proceeds as follows:

a. Clinical disclosure of adverse events that cause minor harm may be performed by any member of the clinical team involved in the patient's care. However, clinical disclosures relating to events where the harm is more than minor must be performed by the responsible practitioner, in other words, the licensed independent practitioner who has primary responsibility for the patient during the current episode of care, or that practitioner's designee. If a harm is significant enough to require an incident report or local equivalent, it should be considered more than minor. Trainees may be present for

clinical disclosures, but the disclosure itself is the responsibility of the supervising clinician or designated clinical team member.

b. During the clinical disclosure process, one or more members of the clinical team.

(1) Provides preliminary factual information, to the extent it is known, to the patient or the patient's personal representative.

(2) Expresses concern for the patient's welfare.

(3) Reassures the patient or personal representative that steps are being taken to investigate the situation, remedy any injury, and prevent further harm. ***NOTE:*** *A general statement to this effect is recommended. Statements should not be made regarding specific actions VA may undertake because those steps may not be possible to implement, or may be subject to change.*

c. Additional staff members, such as a registered nurse, social worker, chaplain, clinical ethicist, or patient advocate, may be present to help the patient or personal representative cope with the news and to offer support.

d. The patient or patient's personal representative must be provided with contact information of the designated VA health care staff to respond to questions regarding the disclosed information or clinical sequelae associated with the adverse event.

e. Clinical disclosures need to be made face-to-face with the patient or the patient's personal representative whenever possible and practical. Disclosure needs to take place in a suitable environment to ensure privacy, and without interruption, in order to provide adequate time to ensure that the patient's questions and concerns can be addressed.

f. Clinicians are expected to conduct clinical disclosures as a routine part of care. Clinical disclosures are not the occasion to discuss rights or compensation under 38 U.S.C. 1151 or the Federal Tort Claims Act.

g. Clinical disclosure must be initiated as soon as reasonably possible and generally within 24 hours of occurrence. Clinical disclosure is not required for minor harms that are discovered after the patient has completed the associated episode of care when there are no implications for the patient's future health. Under such circumstances, the benefits associated with respecting the patient's right to information about their health care are generally outweighed by the burdens associated with unnecessarily worrying or confusing patients with inconsequential information.

h. Documentation of Clinical Disclosures.

(1) Specific documentation in the Computerized Patient Record System (CPRS) is not required for all clinical disclosures. Requiring documentation of clinical disclosure for all minor events would create a barrier to making such disclosures a part of routine practice. However, as a rule, documentation of a clinical disclosure is required when

harm is more than minor. This documentation can be in a progress note for the encounter.

(2) Clinical disclosures must not be documented using the CPRS note template for institutional disclosure.

9. INSTITUTIONAL DISCLOSURE OF ADVERSE EVENTS

a. Institutional disclosure of adverse events, sometimes referred to as administrative disclosure, is a formal process by which facility leaders, together with clinicians and other appropriate individuals, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in or is reasonably expected to result in death or serious injury. Serious injury may include significant or permanent disability, injury that leads to prolonged hospitalization, injury requiring life-sustaining intervention, or intervention to prevent impairment or damage, including, for example sentinel events as defined by The Joint Commission (see paragraph 13.q.). Such adverse events require institutional disclosure regardless of whether they resulted from an error.

(1) When an adverse event has resulted in or is reasonably expected to result in death or serious injury, an institutional disclosure must be performed regardless of when the event is discovered. This disclosure is required even if clinical disclosure has already occurred. If an initial clinical disclosure has been made, it is important to determine what role, if any, the treating clinician(s) will play in the institutional disclosure process, as well as in the ongoing care of the patient.

(2) Institutional disclosure must be initiated as soon as reasonably possible and generally within 72 hours. This timeframe does not apply to adverse events that are only recognized after the associated episode of care, for example, through investigation of a sentinel event, a routine quality review, or a look-back. Under such circumstances, if the adverse event has resulted in or is reasonably expected to result in death or serious injury, institutional disclosure is required, but disclosure may be delayed allowing for a thorough investigation of the facts provided.

b. Prior to conducting an institutional disclosure, organizational leaders, for example, the VA medical facility Director, Chief of Staff, Associate Director for Patient Care Services, members of the treatment team, or others as appropriate, may confer with District Chief Counsel for assistance in deciding what is to be communicated, by whom, and how.

c. When initiating an institutional disclosure, institutional leaders invite the patient or personal representative to meet. ***NOTE:*** *The facility Risk Manager or Patient Safety Manager, treating practitioner, a mental health professional, or other VHA personnel deemed appropriate, may be included in this conference at the discretion of facility leadership.*

d. Institutional disclosure ideally needs to be made face-to-face with the patient or the patient's personal representative, unless it is neither possible nor practical. In the

rare instances when an institutional disclosure must be conveyed by other modalities, for example, telephone contact or letter, documentation of the communication must include the reason it was not done in person. Disclosure needs to take place in a suitable environment, to ensure privacy and without interruption, in order to provide adequate time to ensure that the patient's questions and concerns can be addressed.

e. If the patient is not capable of understanding either the situation or the information provided in a disclosure, and does not have a personal representative as defined in VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016, the facility must make the institutional disclosure to a family member involved in the patient's care, if available. ***NOTE:*** *The facility's or VHA's Privacy Office or District Chief Counsel need to be consulted for additional guidance regarding necessary authorizations and any limitations on what information may be provided as part of the institutional disclosure.*

f. A request made in advance of the discussion by a patient or personal representative to bring an attorney must be honored, but may influence the choice of participants on behalf of the institution.

g. Institutional disclosure of adverse events must include:

(1) An expression of concern and an apology, including an explanation of the facts to the extent that they are known.

(2) An outline of treatment options, if appropriate.

(3) Arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support, or whatever might be appropriate depending on the circumstances and within the constraints of VA's statutory and regulatory authority.

(4) Contact information regarding designated staff who are to respond to questions regarding the disclosed information or clinical sequelae associated with the adverse event.

(5) Notification that the patient or personal representative has the option of obtaining outside medical or legal advice for further guidance.

(6) Offering information about potential compensation from the Veterans Benefits Administration and under the Federal Tort Claims Act if the patient is a Veteran, or only under the Federal Tort Claims Act if the patient is not a Veteran. This information needs to include information about the procedures available to request compensation and where and how to obtain assistance in filing forms. Such information must be provided, even when not considered relevant, if requested by the patient or personal representative. There must be no assurance that compensation will be granted, as the adverse event may not give rise to and meet legal criteria for compensation.

(7) Ongoing communication whereby the Risk Manager or organizational leaders engage the patient or personal representative to keep them apprised, as appropriate, of information that emerges from investigation of the facts related to the adverse event.

h. Documentation, such as reports of contact or incident reports may be kept in a separate file at the facility's discretion and titled, Adverse Event and Close Call Report. This information must not be retrieved by a patient identifier and must be identified by a case number. ***NOTE:*** *The Adverse Event and Close Call Report is protected under 38 U.S.C. 5705.*

i. A patient or the patient's personal representative may ask whether an investigation will be conducted and if the patient or the patient's personal representative will be told of the results of an investigation. In these cases, the patient or personal representative is to be informed that the information is being reviewed or investigated, as applicable. If indicated, the individual providing the information may state that depending on the type of review conducted, information may be available under Freedom of Information Act (FOIA). In addition, the patient or personal representative may also be advised that information documented in the course of a QA activity under 38 U.S.C. 5705 is not releasable. The patient or patient representative must be referred to VACO National Torts Group for coordination of document requests, if a tort claim has been filed.

j. As noted previously, documents created in the course of 38 U.S.C. 5705–protected activities, such as RCA, local incident reports that meet the threshold QA criteria, and peer reviews for quality management, may be released only with specific authority and must not be released to patients, their attorneys, or personal representatives. The facts discovered during quality management activities, however, may reveal adverse event information that requires disclosure. Documenting information in records protected under 38 U.S.C. 5705 must never be done to shield information to which a patient or personal representative is entitled. In order to be able to reveal such information to the patient or personal representative, the information must be retrieved from a non-QA document, such as one documented in CPRS.

k. Documentation of Institutional Disclosures. Documentation of institutional disclosures must be done using the CPRS Institutional Disclosure of Adverse Event Note Template (see Appendix A). Subsequent communications with the patient or personal representative that relate to the event must be documented in an addendum to the original note.

10. LARGE-SCALE DISCLOSURE OF ADVERSE EVENTS

a. Large-scale disclosure of adverse events, sometimes referred to as notification, is a formal process by which VHA officials assist with coordinating the notification to multiple patients (or their personal representatives) that they have been or may have been affected by an adverse event involving actual or potential harm to multiple patients.

b. Events having potential for large-scale disclosure require coordination with VA Central Office for the purposes of assessment and planning. To initiate this coordination process, the VA medical facility Director, VISN Director, or Program Officer, as appropriate, must submit an Issue Brief within 24 hours of discovery of the event (see Appendix B).

c. At the time an adverse event is discovered, or near the time an adverse event occurs, clinical or institutional disclosure must proceed as usual if the potential harm to the individual patient is clear.

d. If the adverse event is only recognized after the associated episode of care (for example, through investigation of a sentinel event, a routine quality review, or a look-back), it is appropriate to wait until the required VA Central Office coordination process for large-scale disclosure is completed before making either a large-scale or institutional disclosure to an individual patient, but only if it is determined that the delay will not negatively affect the patient's health or wellbeing. The coordination process is designed to ensure that all required disclosures are based on a thorough investigation of the facts, a careful assessment of the risks involved, and the development of a plan for the best way to perform the disclosure.

e. Decisions regarding large-scale disclosure of adverse events are made by the Principal Deputy Under Secretary for Health, or designee, following a multi-step VA Central Office process that begins with the Deputy Under Secretary for Health for Operations and Management's coordinated triage process and may involve a SME Review Panel and/or the CRB. ***NOTE:*** *There are legal limitations regarding the type of information that can be released and to whom, particularly with regard to information protected under 38 U.S.C. 7332 (see paragraph 2.e.(2)). Additional guidance on large-scale disclosure is provided in Appendices B and C.*

f. A large-scale disclosure may entail any or all of the following:

(1) An offer to provide follow-up treatment, and testing when it is medically indicated based on the clinical circumstances. ***NOTE:*** *In addressing the subject of whether family members or personal contacts of patients may also be tested, the facility needs to indicate that testing, either directly or through fee-basis, of non-Veterans is limited to those otherwise eligible for VA care (see 38 U.S.C. 1781). The facility needs to be prepared to advise non-Veterans of local resources for testing and treatment if they do not have an established primary care provider.*

(2) Coordination with VA medical facilities to ensure that required clinical follow-up is provided for potentially-affected patients.

(3) Notification by VA Central Office to the Veterans Benefits Administration (VBA) Central Office component when Veterans' benefits may be implicated.

(4) Development of appropriate and effective communications strategies. This communication includes public affairs strategies such as an announcement through the media, for example, telephone, mail, newspapers, and electronic media; clear and

coherent information to patients, providers, and stakeholders; action plans for facilities and clinical providers; briefings for the Secretary of Veterans Affairs and Congress; and establishment of call centers, internet sites or social media. Large-scale disclosure communications may be delivered by clinicians, VA medical facility leaders, and/or other VA officials in person, by telephone, or in writing.

(5) Notification by VA Central Office to VA medical facility and VISN leadership if an epidemiologic investigation is going to take place, and the establishment of a clear line of authority, access, and accountability.

11. TRAINING REQUIREMENTS

There are no formal training requirements associated with this directive.

12. RECORDS MANAGEMENT

All Federal records regardless of format (paper, electronic, electronic systems) created by this directive will be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management may be directed to the facility Records Manager or Records Liaison.

13. REFERENCES

a. 5 U.S.C. 552.

b. 28 U.S.C. 2671–2680.

c. 38 U.S.C. 1151.

d. 38 U.S.C. 1781.

e. 38 U.S.C. 5705.

f. 38 U.S.C. 7332.

g. VA Handbook 6300.4, Procedures for Processing Requests for Records Subject to the Privacy Act, dated August 19, 2013.

h. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.

i. VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

j. VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015.

k. VHA Handbook 1100.17, National Practitioner Data Bank (NPDB) Reports, dated December 28, 2009.

l. VHA Handbook 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated November 12, 2014.

m. VHA Directive 1605.01, Privacy And Release Of Information, dated August 31, 2016.

n. Agency for Health Care Research and Quality Patient Safety Network. Error Disclosure. Available at: http://psnet.ahrq.gov/primer.aspx?primerID=2.

o. Amori, Geri. Disclosure of Unanticipated Events in 2013. Prologue to the Re-Release of the Three ASHRM Disclosure Monographs. Available at: http://www.ashrm.org/pubs/files/white_papers/Disclosure-of-Unanticipated-Events-in-2013_Prologue.pdf. ***NOTE:*** *This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*

p. Conway J, Federico F, Stewart K, Campbell MJ. Respectful Management of Serious Clinical Adverse Events. 2nd ed. IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2011.

q. Department of Health and Human Services – Office of Inspector General. Hospital Incident Reporting Systems Do Not Capture Most Patient Harm, January 2012. Available at: https://oig.hhs.gov/oei/reports/oei-06-09-00091.pdf. ***NOTE:*** *This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*

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s. The Joint Commission. Comprehensive Accreditation Manual for Hospitals. Rights and Responsibilities of the Individual, RI.01.02.01, 2017.

t. The Joint Commission. https://www.jointcommission.org/sentinel_event_policy_and_procedures/, June 29, 2017.

u. The Joint Commission. Chapter 2, Patient Safety Systems (PS) in 2018 Comprehensive Accreditation Manual for Hospitals, Available at: https://www.jointcommission.org/patient_safety_systems_chapter_for_the_hospital_program/.

v. Loren DJ. Garbutt J. Dunagan WC. Et. al. Risk managers, physicians, and disclosure of harmful medical errors. Joint Commission Journal on Quality and Patient Safety, 2010 Mar; 36(3):101-8.

w. Massachusetts Coalition for the Prevention of Medical Errors. When Things Go Wrong – Responding to Adverse Events, Consensus Statement of the Harvard Hospitals; 2006. Available at: http://www.ihi.org/knowledge/Pages/Publications/WhenThingsGoWrongRespondingtoAdverseEvents.aspx.

x. Lambert BL, Centomani NM, Smith KM, et al. The "Seven Pillars" response to patient safety incidents: Effects on medical liability processes and outcomes. Health Services Research, 2016 Dec; 51 Suppl 3:2491-2515.

y. Mello M, Gallagher, TH. Malpractice reform: Opportunities for leadership by health care institutions and liability insurers. New England Journal of Medicine 2010; 362(15): 1353-1356.

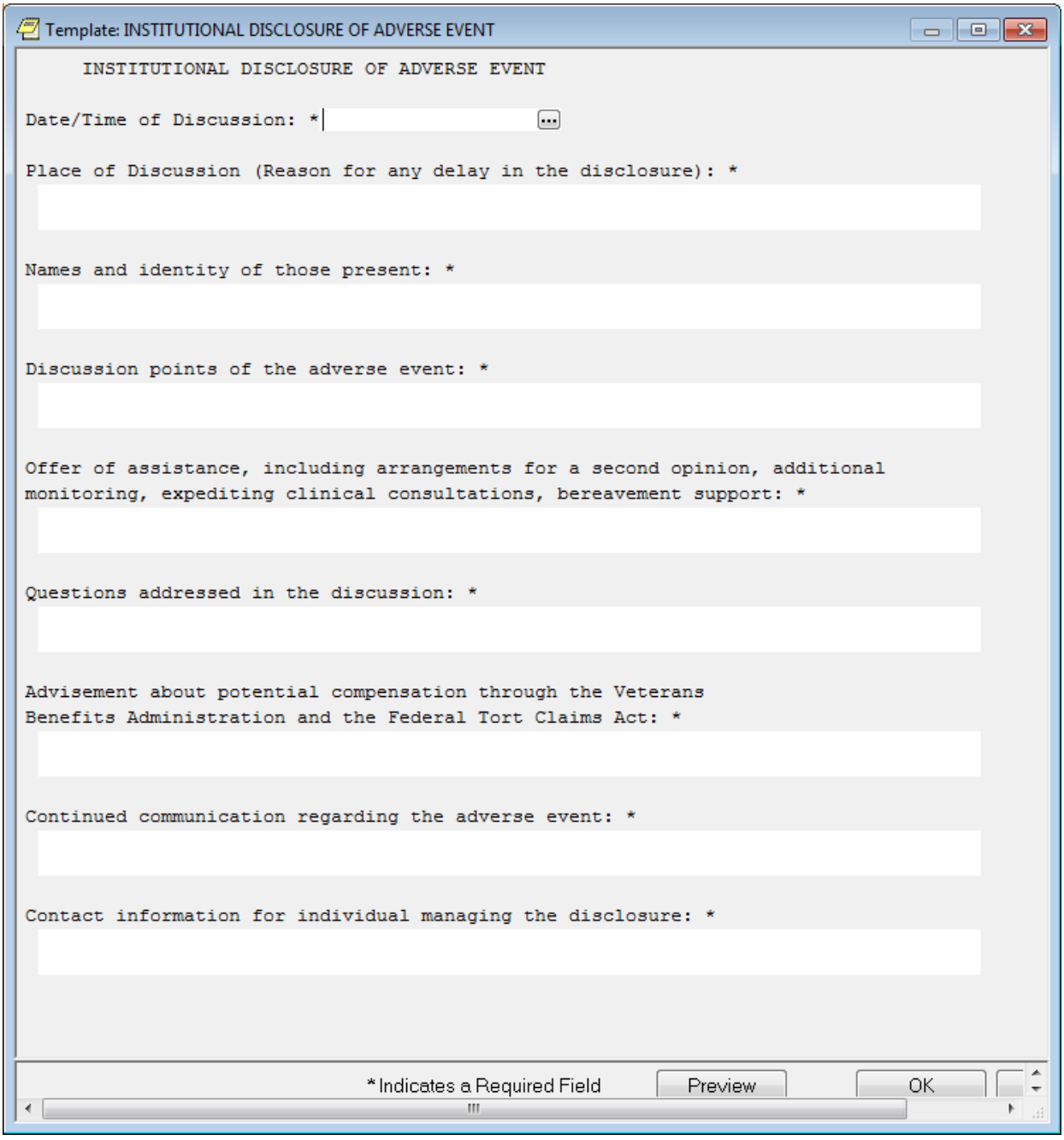
z. National Quality Forum. Safe Practices for Better Healthcare—2010 update. Published April 2010.

aa. Rutala WA, Weber DJ. How to Assess Risk of Disease Transmission to Patients When There is a Failure to Follow Recommended Disinfection and Sterilization Guidelines. Infection Control and Hospital Epidemiology 2007 Feb; 28:146-155.

bb. Wu AW, Boyle DJ, Wallace G, Mazor KM. Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement. Journal of Public Health Research. 2013 Dec;2(3):e32.

cc. Wu AW, McCay L, Levinson W, et. al. Disclosing Adverse Events to Patients: International Norms and Trends. Journal of Patient Safety. 2017 Mar;13(1):43-49

INSTITUTIONAL DISCLOSURE OF ADVERSE EVENT NOTE TEMPLATE



1. Facilities must update the Institutional Disclosure of Adverse Event Template with the following fields:

   a. Date and Time of Discussion-Drop-down calendar: *

   b. Place of Discussion (Reason for any delay in the disclosure): *

c. Names and identity of those present: *

d. Discussion points of the adverse event: *

e. Offer of assistance, including arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support: *

f. Questions addressed in the discussion: *

g. Advisement about potential compensation through the Veterans Benefits Administration and the Federal Tort Claims Act: *

h. Continued Communication regarding the adverse event: *

i. Contact information for individual managing the disclosure: *

2. All elements within the graphical user interface (GUI) template have a free text box for documenting the information.

3. Each of the elements within the GUI template is a required field (* *indicates a required field*) that must be completed before the note can be signed by the author.

4. The screenshot of this note template is available at: http://vaww.ethics.va.gov/docs/policy/Note_Template_Institutional_Disclosure_of_Adverse_Event.pdf. ***NOTE:*** *This is an internal VHA web site and can only be accessed by authorized users.*

FLOWCHART: PROCESS FOR ASSESSMENT OF ADVERSE EVENTS THAT MIGHT REQUIRE LARGE-SCALE DISCLOSURE

1. The Clinical Episode Review Team (CERT) is the name of the team that serves as the Deputy Under Secretary for Health for Operations and Management's coordinated triage process for review of each potential adverse event that may require large-scale disclosure (see paragraph 5.d.(1)).

2. The Process for Assessment of Adverse Events That Might Require Large-scale Disclosure flowchart is available at: http://vaww.ethics.va.gov/docs/policy/Large_Scale_Disclosure_Assessment_Flowchart.pdf. ***NOTE:*** *This is an internal VHA web site and can only be accessed by authorized users.*

ETHICAL LEADERSHIP DECISION PROCESS FOR LARGE-SCALE DISCLOSURE OF ADVERSE EVENTS FOR USE BY THE CLINICAL REVIEW BOARD (CRB)

Within the Veterans Health Administration (VHA), there is a presumptive obligation to disclose adverse events that cause harm or potential harms to patients. However, in the case of an adverse event that has the potential to affect dozens or even thousands of patients, a public health response also requires a determination of the probability and severity of harm resulting from the adverse event, as well as a weighing of additional factors, including, but not limited to: salient ethical principles; risk of harm to patients and potentially-affected third parties; benefit and burden of disclosure to patients, including medical, psychological, social, or economic; impact on the institution's perceived integrity and its capacity to provide care and treatment for all patients; as well as applicable policy and relevant precedent. In providing a recommendation about large-scale disclosure to the Principal Deputy Under Secretary for Health, the Clinical Review Board (CRB) needs to include the following considerations in its decision process:

1. DO WE HAVE ALL THE IMPORTANT FACTS RELEVANT TO THE DECISION?

a. What is the probability that a given patient was exposed to the adverse event?

b. What is the probability that the adverse event will cause a particular patient harm?

c. What is the nature of the potential harm?

d. What is the expected severity of the harm?

e. What is the expected duration of the harm?

f. Is there treatment available to prevent or ameliorate the harm?

g. Does the harm have the potential to extend beyond the identified patient, to third parties and what is the probability that the extension of harm would occur?

2. HAVE WE INVOLVED EVERYONE WHO SHOULD BE PART OF THIS DECISION?

In addition to the standing members of the CRB, individuals and groups need to be included on a case-by-case basis to ensure that the perspectives of all relevant Department of Veterans Affairs (VA) subject matter experts and stakeholders affected by the decision have an opportunity for input.

3. DOES THIS DECISION REFLECT ORGANIZATIONAL, PROFESSIONAL, AND SOCIAL VALUES?

a. Does the decision reflect VHA core values, such as excellence, integrity and accountability? For example, would the decision inspire a high degree of confidence in

VHA's honesty, reliability, and sincere good intent? Would the decision demonstrate an understanding of, sensitivity to, and concern for, each person's individuality and importance? Would the decision indicate that VHA is taking responsibility for collective action, is preserving the organization's reputation, and exercising appropriate stewardship of public resources?

b. Does the decision reflect values central to health care provider professionalism? For example, does the decision hold in high regard the dignity and worth of VHA's patients?

c. Does the decision reflect values central to public health practice? For example, does the decision reflect and make use of the best epidemiological evidence to improve population health? ***NOTE:*** *On a case-by-case basis, additional values may be relevant.*

4. DO THE LIKELY BENEFITS OF THE DECISION OUTWEIGH ANY LIKELY HARMS?

Although it is difficult to weigh all benefits and harms, situations prompting a decision whether to conduct large-scale disclosure of adverse events likely involves the following considerations:

a. Are there medical, social, psychological, or economic benefits or burdens to the patients, resulting from the disclosure itself?

b. What is the burden of disclosure to the institution, focusing principally on the institution's capacity to provide health care to other patients?

c. What is the potential harm to the institution of both disclosure and non-disclosure in the level of trust that Veterans and Congress would have in VHA?

NOTE: *On a case-by-case basis, additional questions may be relevant.*

5. DOES THIS DECISION ESTABLISH A GOOD MODEL FOR FUTURE DECISION MAKING?

a. Is this a good model for how similar questions need to be handled in the future?

b. Has the decision process been followed and documented in a way that can be easily referenced for any similar future cases?

6. HOW WOULD THIS DECISION LOOK TO SOMEONE OUTSIDE THE ORGANIZATION?

a. Does this decision reflect similar decisions by other large health care systems?

b. Will the decision be understood and accepted by patients and the public?

c. Was the process used to make the decision systematic, examining the question from all angles?

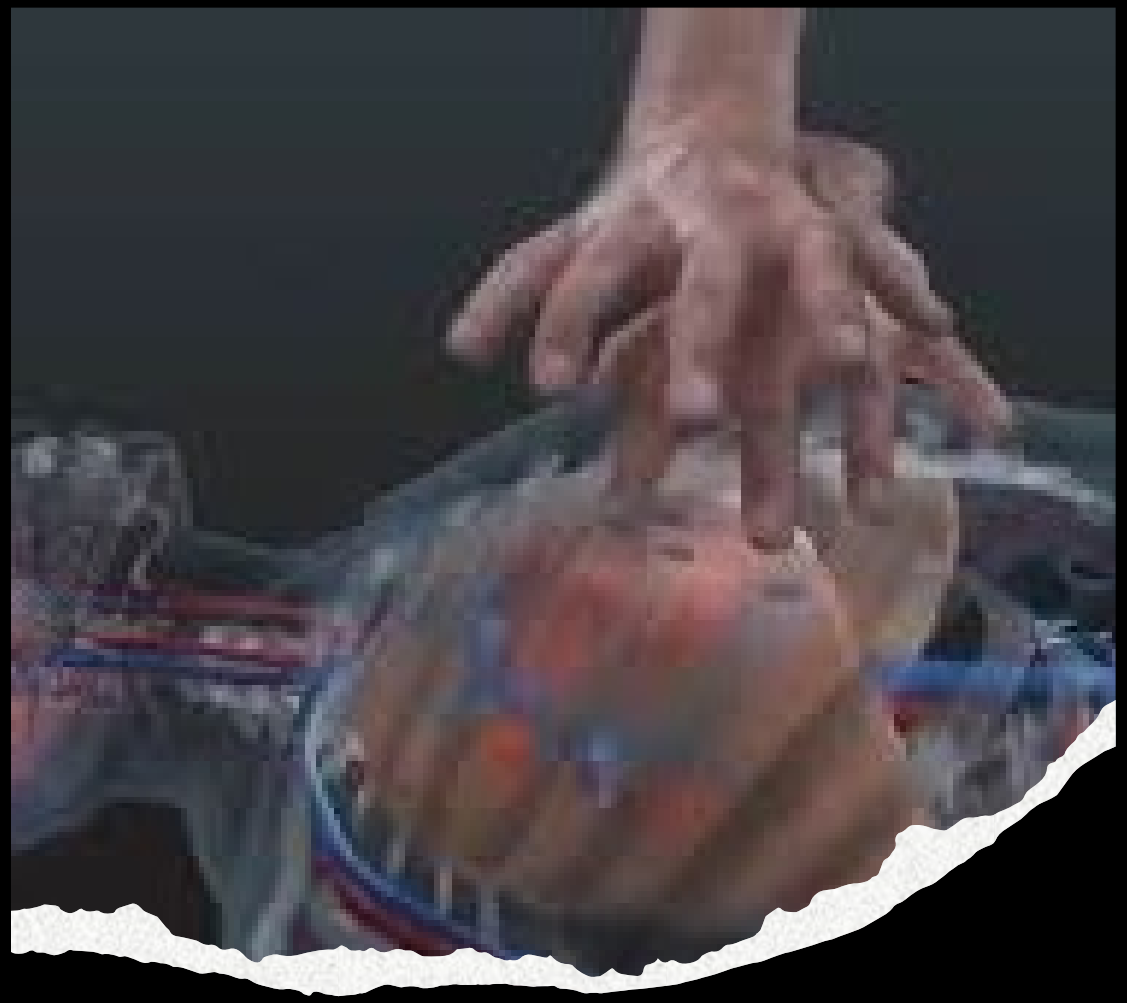
d. Was the process used to make the decision transparent, that is, was the reasoning made clear to all involved.

Do Not Resuscitate in the Nursing Home

Cari Levy, MD, PhD, CMD

University of Colorado and the Rocky Mountain Regional VA Medical Center

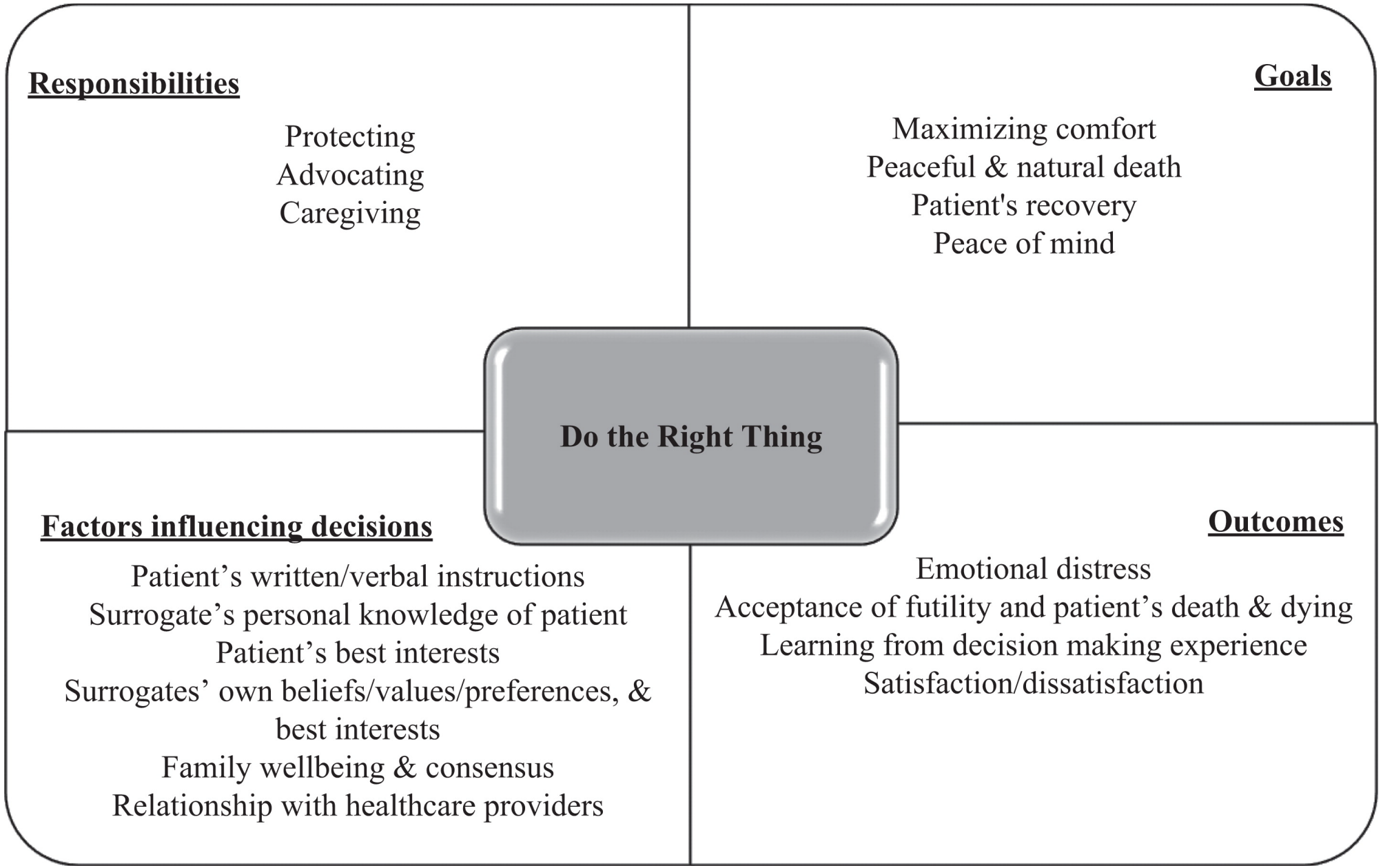
CMDA Conference April 2023



Objectives

Participants will understand:

- Prognostic implications of cardiac resuscitation
- Stability of DNR orders in nursing homes
- Proper use of DNR orders and MOST forms
- Utility of decision aids in determining preferences for CPR



Kim H, et al. *Nursing Ethics*. 2017;24(1):46-69.

Does this resident have capacity for CPR decision making?

1. **Communication.** Able to express a stable choice for or against CPR

1. **Understanding.** Recalls conversations about CPR to make the link between causal relationships, process and probabilities for outcomes

2. **Appreciation.** Able to identify options for care if heart stops and likely outcomes that will affect him or her directly

3. **Rationalization or reasoning.** Able to weigh the risks and benefits of the treatment options presented to come to a conclusion in keeping with their goals and best interests, as defined by their personal set of values

What is the overall survival for in-hospital cardiac resuscitation in a 75yo?

A. 40%

B. 20%

C. 10%

D. <10%

What is the overall survival for out-of-hospital cardiac resuscitation for an individual >70yrs?

A. 30%

B. 20%

C. 10%

D. <5%

In-hospital CPR Outcomes

- Systematic review of 29 studies
- ROSC in 38.6% of the resuscitated patients
- Overall survival rates based on age were:
  - ≥ 90 years (11.6%)
  - ≥ 80 years (15.4%)
  - 70–79 years (18.7%)
  - Long-term survival (6 mo-1 year) ≥70 yrs = 5.7- 21%
- Of those who survived until hospital discharge, 1-year survival 88%
- 63% of survivors were less functional upon hospital discharge compared to their state at the time of admission

van Gijn Myke S et al. April 2014 Age and Ageing 43(4. DOI: 10.1093/ageing/afu035

Out-of-Hospital CPR Outcomes

Meta-analysis for survival performed on 19 studies

Out-of-Hospital Arrest	**70-79yrs**	**80-89yrs**	**>=90yrs**
Survival until discharge	4–12%	2.8–8%	1.7–3.9%
One-month survival	5.4–5.7%	0.9–7%	0–2.4%
CPC 1–2 at discharge/1-month	10.5%	0.9%	0.5–1.8%
One-year survival	3.2–10%	0–6%	0%

Cerebral Performance Category (CPC) scores: 1, good cerebral function; 2, moderate cerebral disability (independent in activities of daily life); 3, severe cerebral disability (dependent on assistance); 4, coma; 5, death.

Zanders R, et. al. Eur Geriatr Med. 2021 Aug;12(4):695-723. Epub 2021 Mar 8. PMID: 33683679

Prognosis following CPR among NH residents

Retrospective study of pre-hospital CPR data from the German Resuscitation Registry between 2011-2018

- N=2,900 patients, Mean age 83.7 years
- 1880 patients (64.8%) died at the site of attempted resuscitation
- 902 patients (31%) died in the hospital
  - 618 (21%) within 24 hours
  - 279 (10%) died between 24 hours-30 days
- 118 patients **(4.0%) discharged alive**
  - 64 (2.2%) with a CPC of 1 or 2
  - 30 (1.0%) with unknown CPC
  - 24 (0.8%) with a CPC of 3 or 4
- For only 1056 cases (36.4%) CPR was initiated before the arrival of the emergency medical services

Conclusion: CPR can lead to a good neurological outcome **rarely** in a nursing home.

The large percentage of CPR attempts that were initiated only after a delay indicates that NH staff may often be uncertain how to proceed. Uncertainty among caregivers points to a potential for advance care planning.

Günther A, et al. 2020 Nov 6;117(45):757-763. PMID: 33533330

Prognosis following CPR in NHs (2)

- Aged ≥65 years who experienced cardiac arrest in a NH or private residence from the population-based registry of out-of-hospital cardiac arrests in Tokyo, Japan, from 2014 to 2018
- 37,550 patient records (NH = 6,271; Home = 31,279)
- Patients in the NH group were significantly older and more often had witnessed arrest, bystander CPR, and shock delivery using an automated external defibrillator
- 1-month survival was significantly higher **in the NH (2.6%** vs 1.8%, P < .001)
- Best scenario (daytime emergency call, witnessed arrest, bystander CPR provided), 1-month survival in the NH group = 8.0% (95% CI 6.4-9.9%)
- 0% survived if not witnessed, no bystander CPR

Shibahashi K, Sakurai S, Sugiyama K, Ishida T, Hamabe Y. J Am Med Dir Assoc. 2022 Aug;23(8):1316-1321. doi: 10.1016/j.jamda.2021.09.009. Epub 2021 Oct 8. PMID: 34627752.

Stability of DNR Orders in LTC

	N (%)	
No. Changes*	CPR at Admission	DNR at Admission
0	31,036 (55.43)	57,372 (92.16)
1	22,541 (40.25)	2179 (3.50)
2	1196 (2.14)	2383 (3.83)
3	1022 (1.83)	128 (0.21)
4	98 (0.17)	151 (0.24)
5	84 (0.15)	21 (0.03)
6	10 (0.02)	15 (0.02)
7	8 (0.01)	1 (0.00)
9	1 (0.00)	0 (0.00)
12	0 (0.00)	1 (0.00)
Total	55,996 (100.00)	62,251 (100.00)

Mukamel DB, et al. Med Care. 2013 Aug;51(8):666-72. PMID: 23685402

Stability of DNR/Full Code Orders (2)

- The most important factors influencing change from CPR to DNR were hospitalizations and nursing home transfers
- Race and ethnicity with black race (relative to white) predicted no change from CPR to DNR
- Those who enter with full-code preference have a high probability of changing their status to DNR during their stay.
- Offer the opportunity to revisit choices periodically, documenting changes in end-of-life choices when they occur

Misinterpretation of DNR Orders

- 26.8% of staff nurses and 30% of PCPs surveyed believed that a patient with a DNR order could not receive any/at least one of a list of simple treatments (antibiotics, PT, IV fluids, pain relief, oxygen, nasogastric feeding or airway suctioning)

- A higher percentage of staff nurses (26.8%) and primary care physicians (22.5%) believed that a patient with a DNR order could not be referred to hospital from home/a nursing home, when compared with other healthcare groups ($p<0.001$).

O'Brien H, et al. J Med Ethics. 2018 Mar;44(3):201-203. doi: 10.1136/medethics-2016-103986. Epub 2017 Nov 3. PMID: 29101301.

Acute Myocardial Infarction in Nursing Home Residents: Adherence to Treatment Guidelines Reduces Mortality, But Why Is Adherence So Low?

Cari R. Levy, MD, Tiffany A. Radcliff, PhD, Elizabeth T. Williams, MS, and Evelyn Hutt, MD

Table 2. *Acute Myocardial Infarction Guideline Adherence for "Ideally Eligible" Patients by Admission Status from Nursing Home and Community*

Guideline	Overall Study Sample		Admitted from Nursing Home (NH)		Admitted from Community (C)		Difference (NH − C)
Ideally Eligible for:	Sample Size, n	% Adherence	Sample Size, n	% Adherence	Sample Size, n	% Adherence	% Difference
Aspirin	82,384	85.0	4370	68.7	78,014	85.9	−17.2*
Beta blocker	35,056	60.8	1214	43.8	33,842	61.5	−17.6*
Reperfusion	16,770	60.3	214	30.4	16,506	60.7	−30.3*

* $P < .001$.

- 30-day mortality for NH patients who were ideally eligible for aspirin but did not receive aspirin was significantly higher compared with NH patients who were ideally eligible but did receive aspirin
  - **49.2% versus 26.0%,** $p<0.001$

- Mortality was significantly higher for NH patients who were ideally eligible for beta-blockers but did not receive a beta-blocker
  - **35.3% versus 18.6%,** $p<0.001$

Do Orders Limiting Aggressive Treatment Impact Care for Acute Myocardial Infarction?

Tiffany A. Radcliff, PhD, Aram Dobalian, PhD, JD, and Cari Levy, MD

Table 3. *Probit Regression (Model 2) Results with LAT as a Covariate*

Guideline	LAT Coefficient, (dF/dx)§	Overall Predicted Probability*		Predicted Difference* LAT - No LAT
		LAT Order	No LAT Order	
Aspirin	−0.063†	0.65	0.84	−0.19
Beta blockers	−0.086†	0.30	0.51	−0.21
Reperfusion	−0.040†	0.19	0.38	−0.19

* Results are adjusted for all covariates listed in Table 1 other than mortality and include the eligible sample (all cases), with a covariate to adjust for ideal eligibility.

† $P < .01$.

§ dF/dx represents the discrete change in LAT status from not having one to having one in place.

Medical Orders for Scope of Treatment (MOST/POLST) Forms

JAMDA 22 (2021) 1672–1677

ELSEVIER

JAMDA

journal homepage: www.jamda.com

Special Article

POLST Is More Than a Code Status Order Form: Suggestions for Appropriate POLST Use in Long-Term Care

Check for updates

Susan E. Hickman PhD [a,b,*], Karl Steinberg MD, CMD [c], John Carney MEd [d], Hillary D. Lum MD, PhD [e,f]

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[b] *Indiana University Center for Aging Research, Regenstrief Institute, Indianapolis, IN, USA*
[c] *California State University, Institute for Palliative Care, Oceanside, CA, USA*
[d] *Center for Practical Bioethics, Kansas City, MO, USA*
[e] *VA Eastern Colorado Geriatric Research Education and Clinical Center, Aurora, CO, USA*
[f] *Division of Geriatric Medicine, University of Colorado School of Medicine, Aurora, CO, USA*

MOST ≠ DNR Order

- In the absence of additional information, code status is sometimes erroneously assumed to represent preferences for other kinds of treatments.
- Code status alone is not predictive of preferences for other kinds of interventions.
- MOST forms address this limitation of code status orders by including a broader range treatments that are highly relevant to long-term care residents with advanced serious illness or associated with end of life, such as preferences for hospitalization
- The potentially inappropriate group includes a growing population of younger residents with chronic mental illness and/or physical disability, and residents who are admitted for short stay, post-acute rehabilitation following a hospitalization or procedure such as joint replacement.
- Although some of these residents may be POLST appropriate, many are not.

CPR
Decision Aid

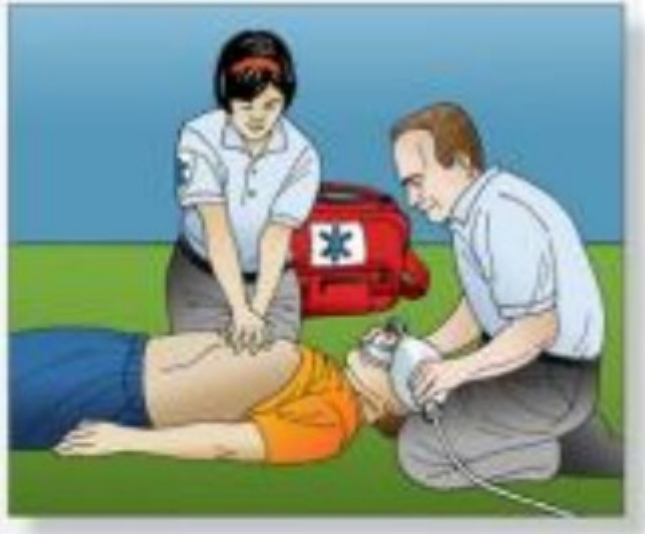
COALITION for COMPASSIONATE CARE of CALIFORNIA

What is CPR?

CPR (Cardio-Pulmonary Resuscitation) is an attempt to restart a person's heart when the heart has stopped beating or cannot pump blood.

How is CPR done?

Many people have seen CPR on television. TV often makes CPR look quick and easy. But it is not.

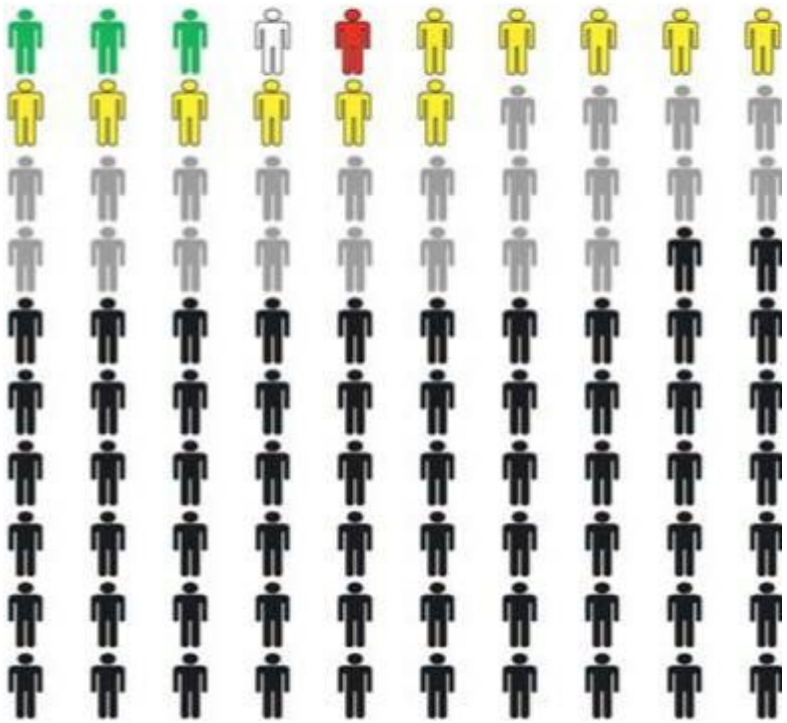


During CPR:

- The chest is pushed down two (2) or more inches many times each minute to make the heart pump.
- Strong electrical shocks may be given through the chest to make the heart beat at a normal rate.
- Medicine may be given, usually through an IV (intravenous) line.
- A mask may be placed on the face or a tube in the windpipe (trachea). These are often used to assist with breathing.

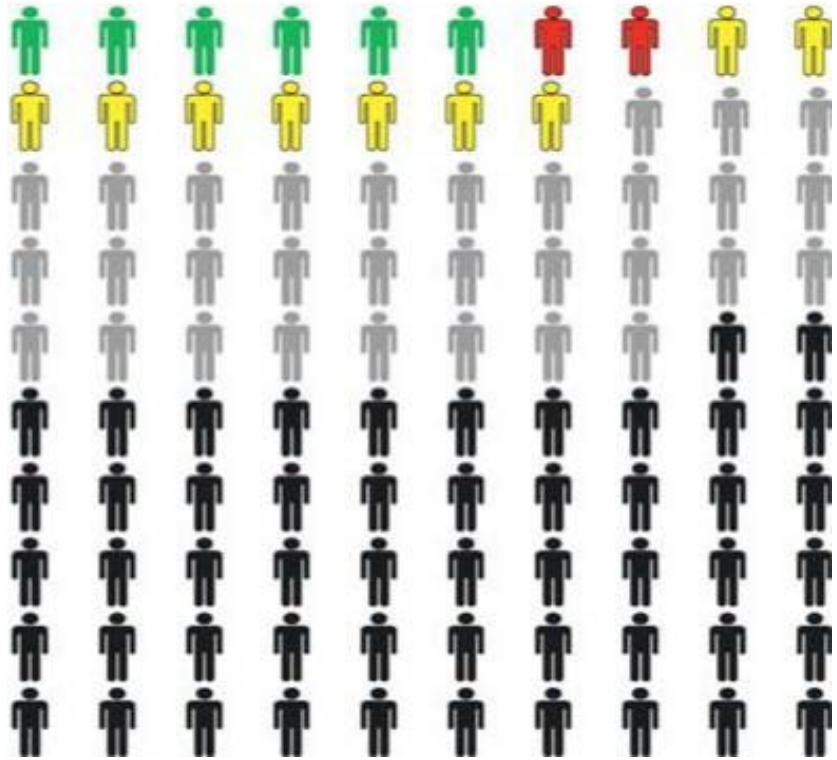
Patients at least 65 years old, witnessed arrest (n = 1222)

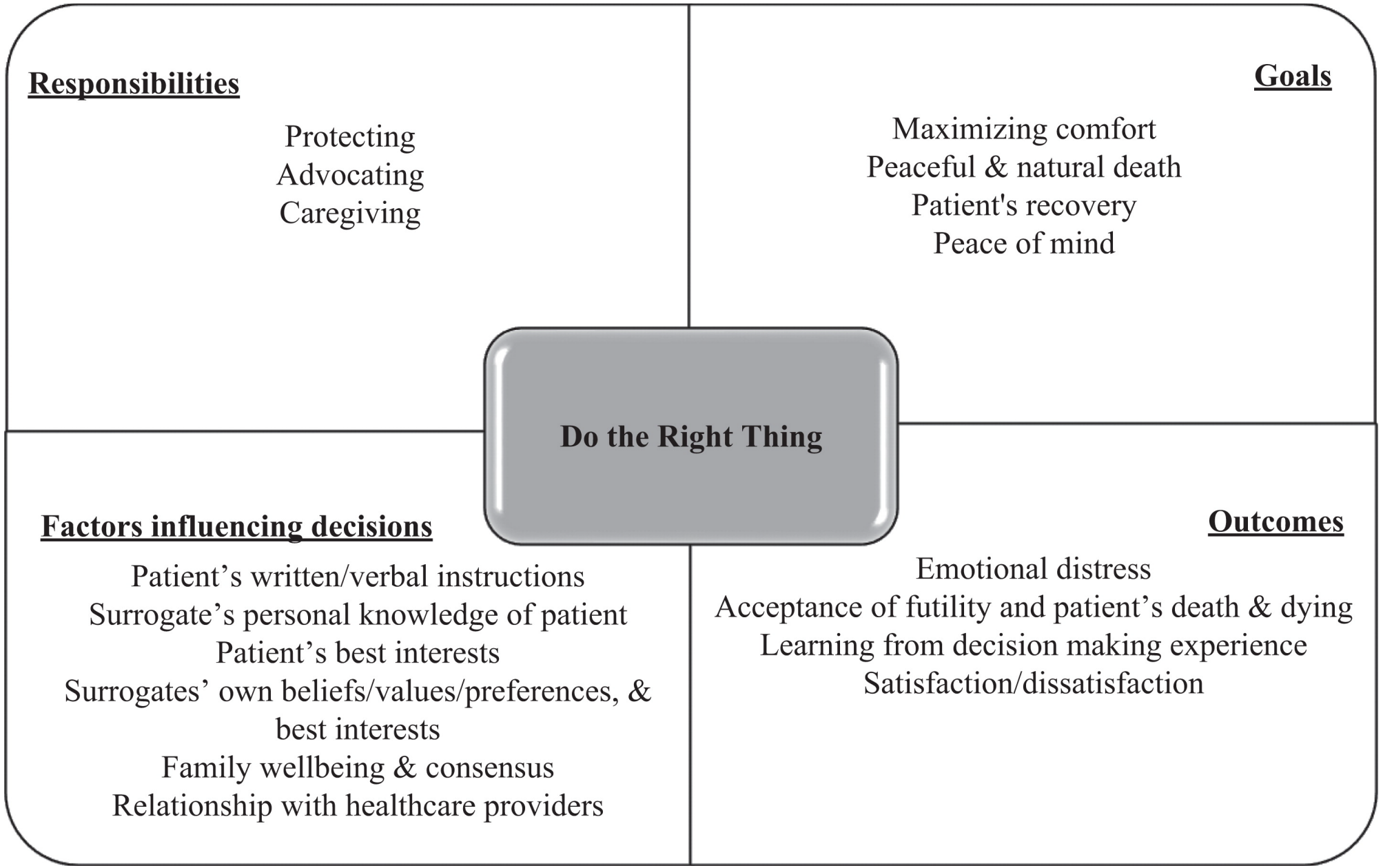
Discharged alive, CPC 1 or 2	2.8%
Discharged alive, CPC unknown	1.2%
Discharged alive, CPC 3 or 4	0.9%
Death in hospital after more than 30 days	0.0%
Death in hospital between 24 hours and 30 days	11.1%
Death in hospital within 24 hours	22.0%
Death without transport to hospital	61.9%



Patients at least 85 years old, initially shockable (n = 100)

Discharged alive, CPC 1 or 2	6.0%
Discharged alive, CPC unknown	0.0%
Discharged alive, CPC 3 or 4	2.0%
Death in hospital after more than 30 days	0.0%
Death in hospital between 24 hours and 30 days	9.0%
Death in hospital within 24 hours	31.0%
Death without transport to hospital	52.0%





Kim H, et al. *Nursing Ethics*. 2017;24(1):46-69.

What is the overall survival for in-hospital cardiac resuscitation in a 75yo?

A. 40%

B. 20%

C. 10%

D. <10%

What is the overall survival for out-of-hospital cardiac resuscitation for an individual >70yrs?

A. 30%

B. 20%

C. 10%

D. <5%

Take Home Points

Out-of-hospital CPR ≠ In-Hospital CPR

DNR ≠ Do Not Treat

MOST ≠ DNR Order

An informed decision is a person-centered decision

Telligen Update: Together We Can Accomplish So Much

Christine LaRocca, MD, Telligen Medical Director

CMDA's 28th Annual Conference PALTC 2023

April 28, 2023

Objectives

- Describe the role of Telligen, Colorado's Quality Innovation Network-Quality Improvement Organization (QIN-QIO), and the no-cost quality improvement support we offer
- Summarize data and outcomes from Telligen's partnership with nursing homes during the COVID-19 pandemic
- Identify current focus areas and explain how Telligen assists homes to improve quality using the framework of Quality Assurance and Performance Improvement (QAPI)

About Telligen

- **Nearly 50 years** providing expertise and support for measurable results in population health improvement
- More than **600 clinical and technical** professionals supporting clients nationwide
- A **100-percent employee-owned** company
- Comprehensive quality improvement program = Telligen QI Connect™

What Do QIN-QIOs Do?

QIO Program Purpose

- To improve the efficiency, effectiveness, economy and quality of services delivered to Medicare beneficiaries

QIN-QIOs

- Bring Medicare beneficiaries, providers and communities together in data-driven initiatives that increase patient safety, make communities healthier, better coordinate post-hospital care and improve clinical quality
- Provide technical assistance and convene learning and action networks at no-cost to support healthcare QI at the community level

Telligen QI Connect™

Telligen QI Connect™ is operated by Telligen, which is funded by CMS to deliver improvement services at no cost to you or your organization.

Telligen QI Connect™ is a network of partners working on quality improvement initiatives that place healthcare providers and consumers at the center to make healthcare safer, more accessible and more cost-effective through the Centers for Medicare & Medicaid Services (CMS) Quality Innovation Network-Quality Improvement Organization (QIN-QIO) and Hospital Quality Improvement Contractor (HQIC) programs.

Focus Areas

COVID-19 Response

Public Health Emergency Preparedness

Hospital Leader Engagement

Behavior Health and Opioid Misuse

Immunizations

Patient Safety

Antibiotic Stewardship

Nursing Home Quality

Chronic Disease Management

Care Coordination

Ongoing Rapid Response to Nursing Homes

Weekly referrals from CMS focus on:

- COVID-19 outbreaks
- Increasing COVID-19 vaccination rates

Our support includes:

- A dedicated Quality Improvement (QI) specialist
- Completing an infection prevention and control assessment (includes onsite/virtual visit)
- Conducting a root cause analysis of assessment results
- Setting a Specific Measurable Attainable Relevant Timebound (SMART) goal
- Establishing a 30-day QI plan specific to infection prevention and control

Results

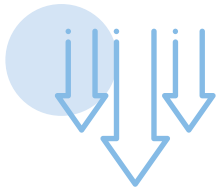
- **Since April 2020: 1,461 facilities assisted (178 nursing homes in Colorado)**
  - 33 virtual/onsite visits in CO
- **Common recommendations from virtual/onsite visits:**
  - Increasing compliance of donning and doffing Personal Protective Equipment (PPE)
  - Ensuring performance of hand hygiene
  - Adapting training and materials for environmental services
- **Testimonial**

"Our facility opted for a virtual visit to aid in the selection of a priority gap in our infection control program… having another set of eyes is a valuable resource. Our facility used Root Cause Analysis, Fishbone tool, PDSA worksheet, and the Quality Improvement Initiative Plan. Telligen has provided and will continue to provide on-going support. I look forward to working with them for many more years."

Julie Arana, RN, BSN | Director of Nursing | Walsh Healthcare Center

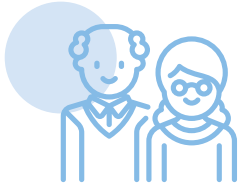
Outcomes

Results from Telligen's quality improvement interventions in 916 nursing homes:



34% reduction in COVID-19 infection rates compared to matched control group

1,803 prevented deaths due to COVID-19



15,496 prevented COVID-19 cases among nursing home residents

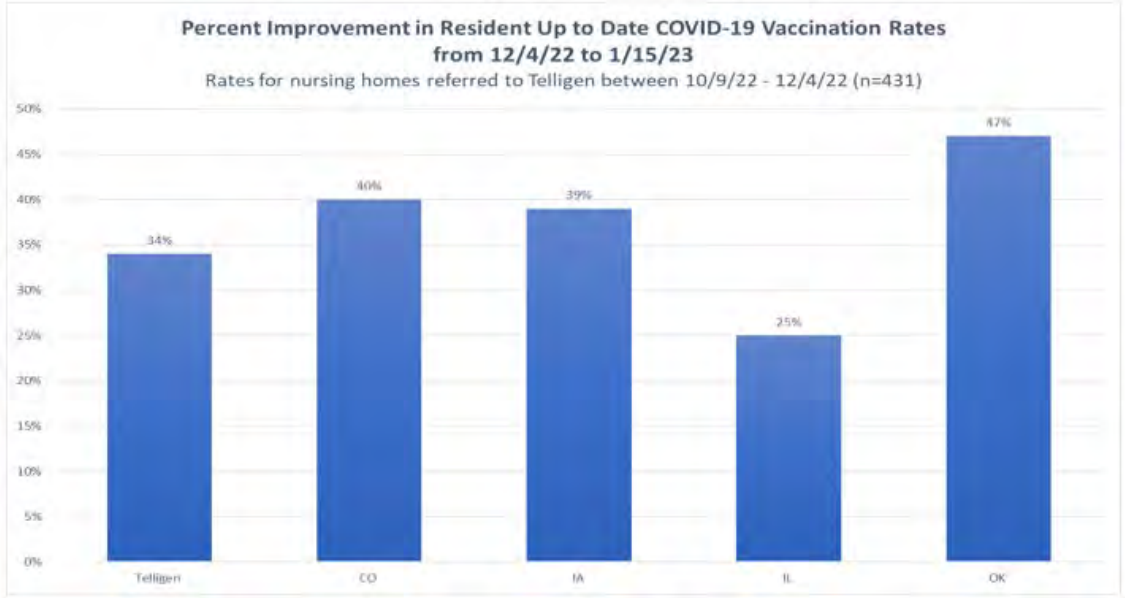
5,733 prevented hospitalizations due to COVID-19

Six-week Sprint to Increase COVID-19 Bivalent Booster Rates

Telligen Supported Nursing Homes by:

- Conducting onsite visits to nursing homes with vaccination rates below 10% to offer quality improvement support
- Recognizing high “Up to Date” rates with the Blue Ribbon in COVID-19 Vigilance Award
- Launching a social media campaign across LinkedIn, Facebook and Twitter
- Supporting implementation of evidence-based tools and providing education on COVID-19 therapeutics
- Creating our Vax Hub website to include on-demand tools, resources and learning modules
- Hosting a national webinar featuring expert Dr. Anuj Mehta, *Don’t be AmBivalent about the Bivalent Boosters: Understanding the Emerging Science Behind the Updated Boosters*

Results:



Resources

- Telligen's *Vax Hub* provides on-demand tools, resources, and learning modules related to the COVID-19 vaccine and bivalent booster.
- *We Can Do This* is a COVID -19 public education campaign to increase vaccine confidence and awareness about treatments while reinforcing basic prevention measures.

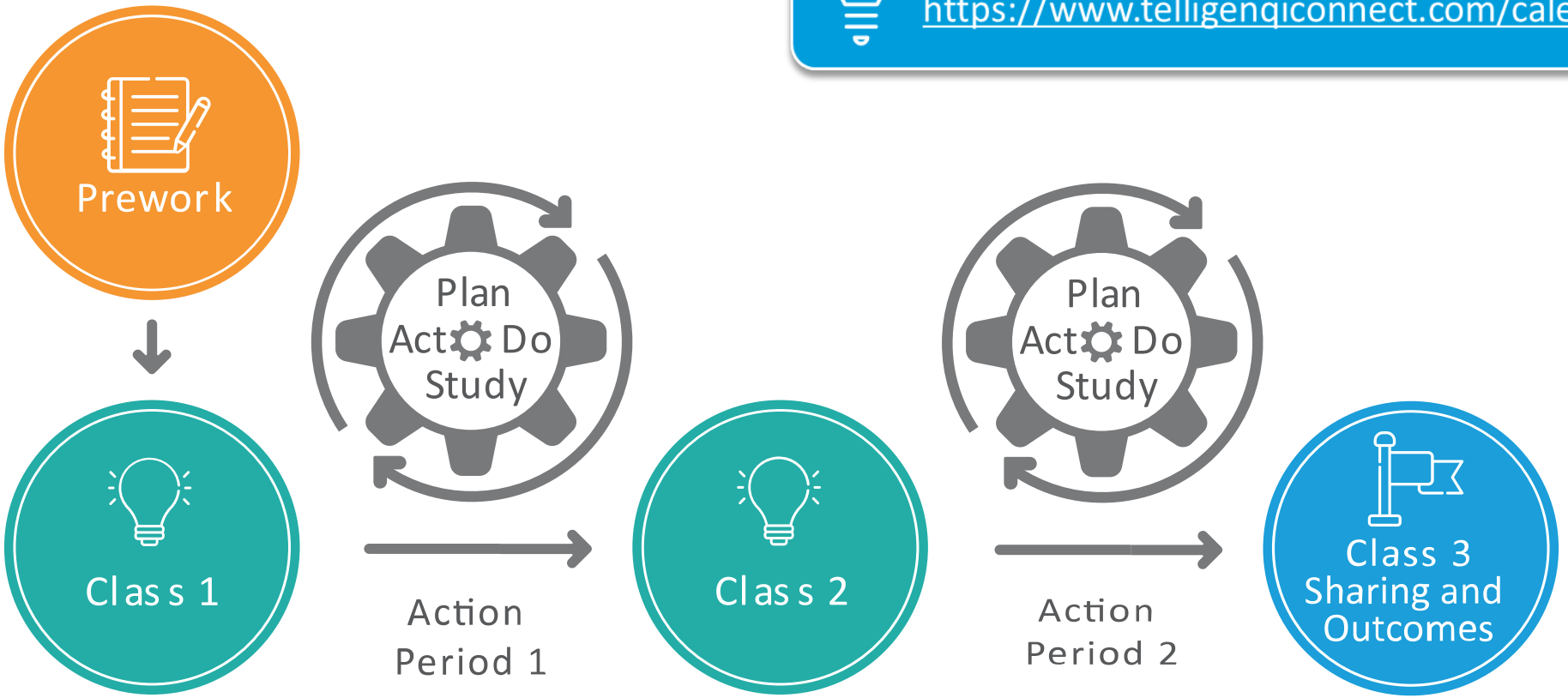
Quality Assurance and Performance Improvement (QAPI)

Quality Improvement (QI) Tools, Training and Coaching

- Evidence-based resources and tools to support QAPI programs
- Root Cause Analysis (RCA) and Plan-Do-Study-Act (PDSA) interactive sessions
- Data analysis – assist in improving publicly reported quality measures
- On-site and virtual observational assessments
- On-Demand Learning – trainings on RCA, PDSA, and certificate for participation

On-going Interactive QAPI Classes and Workshops

Check out the next class dates and times:
https://www.telligenqiconnect.com/calendar



Nursing Home Enhanced Technical Assistance (TA)

What is Technical Assistance?

Technical assistance is the process of providing targeted, one-on-one support to your organization to increase your capacity for quality improvement and to improve processes based on your goals. Examples of Telligen's technical assistance are below:

- Directed Plan of Correction assistance for F880 deficiencies
- National Healthcare Safety Network (NHSN) reporting assistance
- Five Star - identifying quality measures and providing TA on process improvements to maximize scores
- INTERACT (Interventions to Reduce Acute Care Transfers) – assistance with improving processes related to acute changes in condition and reducing the percentage of avoidable transfers to the emergency department
- Coalition Building - utilizing the Leadership and Organizing in Action (LOA) framework to connect NHs with community providers

Additional Areas of Technical Assistance

- Adverse Drug Events (ADEs) - resources to reduce or eliminate risks that could lead to ADEs from anticoagulants, opioids, and diabetes medications

- Facility Acquired Infections - sharing strategies to optimize patient outcomes for Sepsis, UTI, Pneumonia, and COVID-19

- Emergency Department (ED) Visits and Readmissions - strategies to prevent and decrease avoidable ED visits and readmissions

- Opioid Utilization - guidance and training for opioid prescribing best practices

- *Clostridioides difficile* Infection (CDI) - assistance in preventing resistant organisms, particularly onset of *C. diff*

- Health Equity and Culturally and Linguistically Appropriate Services (CLAS) - support to advance health equity, improve quality of services, and help eliminate disparities

Blue Ribbon in COVID-19 Vigilance

- Recognizes efforts nursing homes have made to prevent the spread of COVID-19
- Nursing homes who are awarded the *Blue Ribbon in COVID-19 Vigilance* receive comprehensive marketing package
- Information and Toolkit: [Blue Ribbon in COVID-19 Vigilance | Telligen QI Connect™]

Introducing Telligen's BEST In Class Program

THE BLUE RIBBON IN COVID-19 VIGILANCE AND THE BEST IN CLASS DISTINCTION ARE AWARDED TO TOP PERFORMING NURSING HOMES WHO ACHIEVE THE FOLLOWING:

	COVID-19 Vigilance	RECOGNIZED TOP PERFORMER BEST IN CLASS
Complete the COVID-19 Preparedness Assessment	✓	✓
Resident "up to date" vaccination rate is greater than or equal to 80%	✓	✓
Staff vaccination rate for a completed COVID-19 primary series is greater than or equal to 95%	✓	✓
Receive the Blue Ribbon in COVID-19 Vigilance for three quarters of 2023		✓
Complete Telligen's Emergency Preparedness Assessment		✓
At least 75% of staff have completed infection prevention and control training		✓
Reduce the number of preventable Emergency Department visits by 5% or fall within the top 25% of Telligen's enrolled nursing homes at time of award		✓

Questions?

Contact Us

- General Inquiries | QIConnect@telligen.com
- www.telligenqiconnect.com
- nursinghome@telligen.com

New Applications of High Intensity Rehab and Gait Speed in PALTC

When Failure Isn't a Bad Thing: **Improving SNF Outcomes with Progressive Rehabilitation**

Jennifer Stevens-Lapsley, PT, PhD, FAPTA

Professor
Director, Rehabilitation Science PhD Program
PT Program Section Director, Research and Development
University of Colorado

Associate Director of Research
Geriatric Research, Education and Clinical Center
VA Eastern Colorado Health Care System

www.movement4everyone.org

Jennifer.Stevens-Lapsley@cuanschutz.edu

RESTORE TEAM AT UNIVERSITY OF COLORADO

Disclosures

Financial Disclosure

Grant support from:

- National Institutes of Health (NIH)
- Agency for Healthcare Research and Quality (AHRQ)
- Veterans Affairs (VA)

Rehabilitation Training for CEUs

Objectives

1) Appreciate how medical **deconditioning** in older adults impairs functional mobility and increases rehospitalization risk.

2) Recognize the practical application of **walking speed** in predicting hospitalization risk, mortality, and discharge location.

3) Understand how SNF clinical teams could **use progressive rehabilitation and mobility targets** to improve patient outcomes and optimize value.

Impaired Function in Older Adults Following Hospitalization

Patients walk only 7 minutes per day in hospital [1]

68% of discharged are below pre-hospitalization function[2]

No improvement in outcomes compared to past [3]

SNF residents only walk 849 steps a day [4]

1. Villumsen et al, 2015; 2. Gill TM 2009; 3. Loyd 2020; 4. Stutzbach 2021

Archives of Physical Medicine and Rehabilitation

Volume 94, Issue 10, October 2013, Pages 1951–1958

Original article

Functional Status Impairment Is Associated With Unplanned

Arch Phys Med Rehabil. 2018 Jun;99(6):1067-1076. doi: 10.1016/j.apmr.2017.05.001. Epub 2017 Jun 3.

Functional Status Is Associated With 30-Day Potentially Preventable Hospital Readmissions After Inpatient Rehabilitation Among Aged Medicare Fee-for-Service Beneficiaries.

Middleton A[1], Graham JE[2], Ottenbacher KJ[2].

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Functional Status Predicts Acute Care Readmissions ..
Inpatient Rehabilitation in the Stroke Population

Original Research
Journal of General Internal Medicine
November 2015, Volume 30, Issue 11, pp 1688-1695

First online: 09 May 2015

Functional Status Outperforms Comorbidities in Predicting Acute Care Readmissions in Medically Complex Patients

Physical Function's relationship with **Rehospitalization**

Highest functional independence group		15% rehospitalization
Middle functional independence group		20% rehospitalization
Lowest functional independence group		**30% rehospitalization**

Functional performance measured with the **Functional Independence Measure (FIM)** by Hoyer et al. Arch. Phys Med & Rehabil. 2013;94;1951-8

Low physical activity persists

SNF

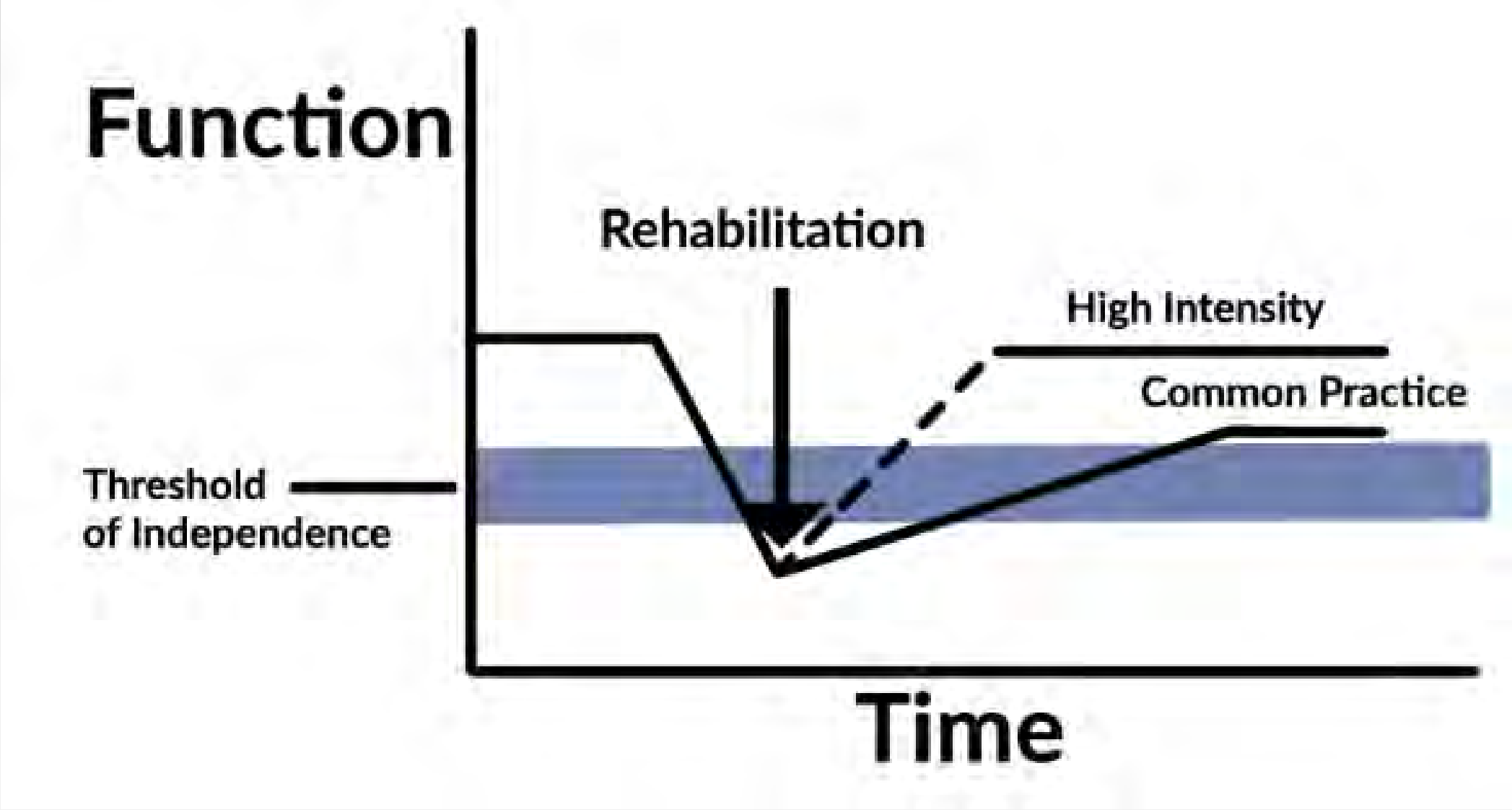
- 88% of day in bed or sitting
- 849 steps a day

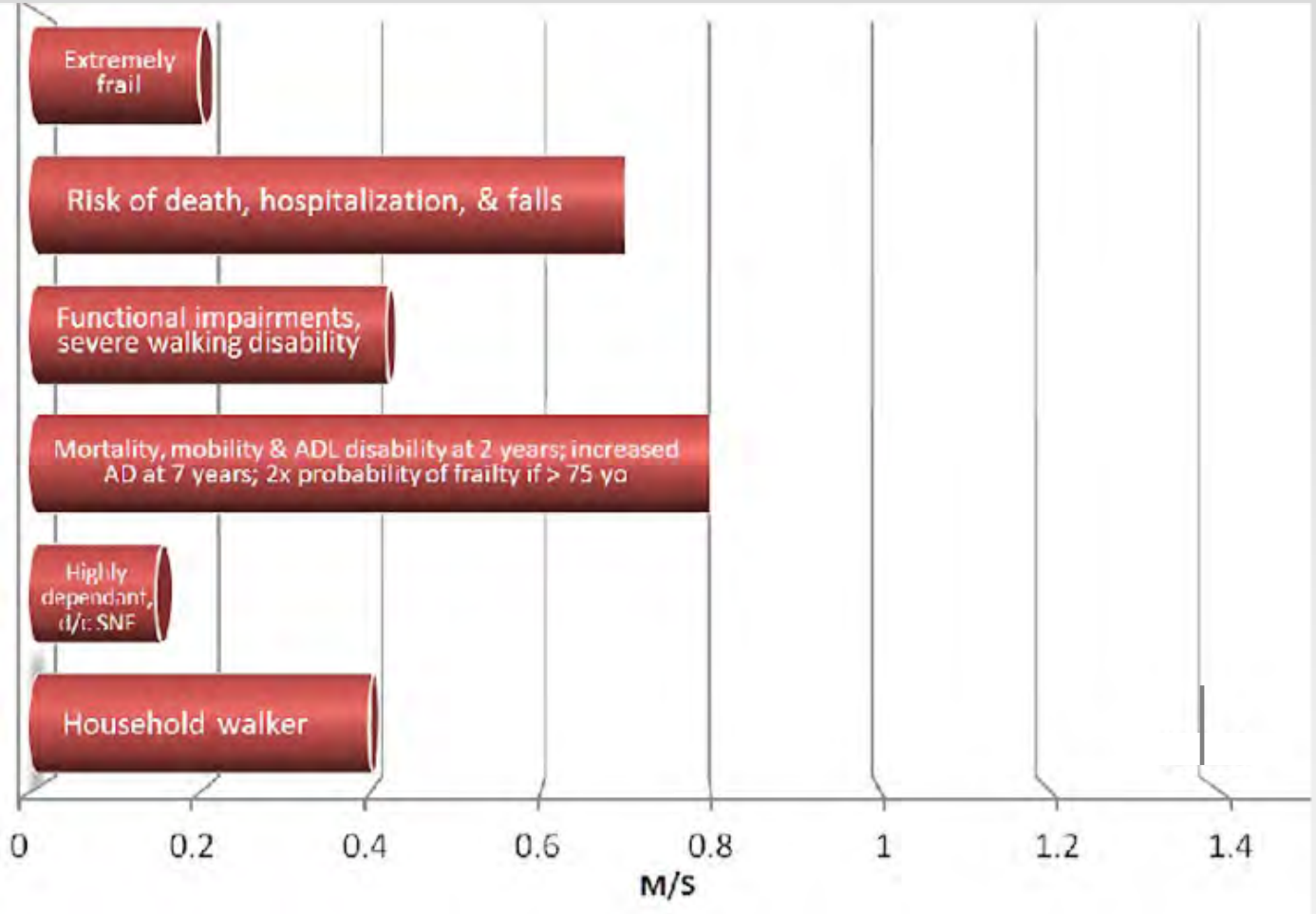
Home

- 83% of day in bed or sitting
- 922 steps a day (<10% of target)

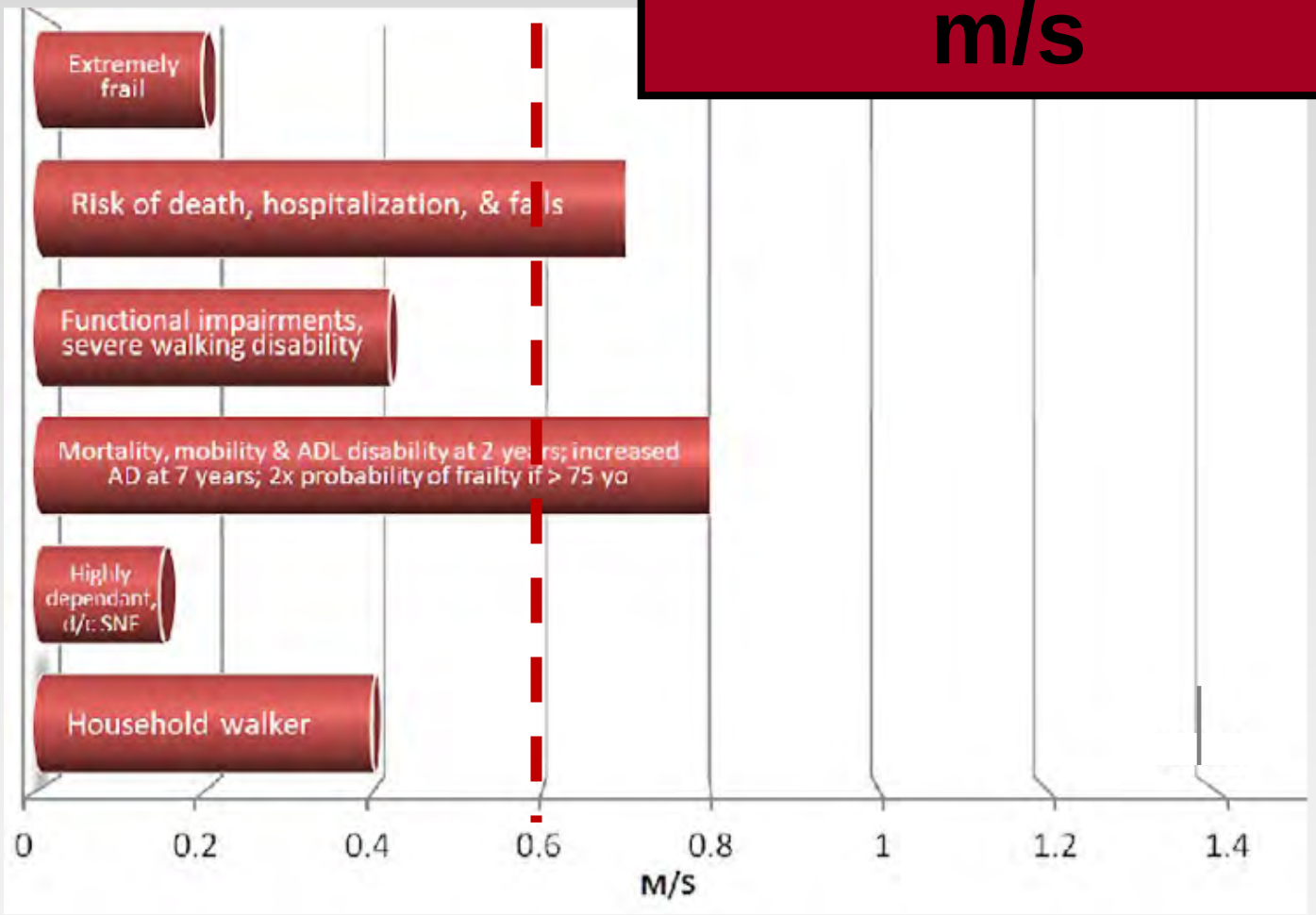
Stutzbach et al. *Disability & Rehabilitation* 2021; 1-6.

Threshold of Independence

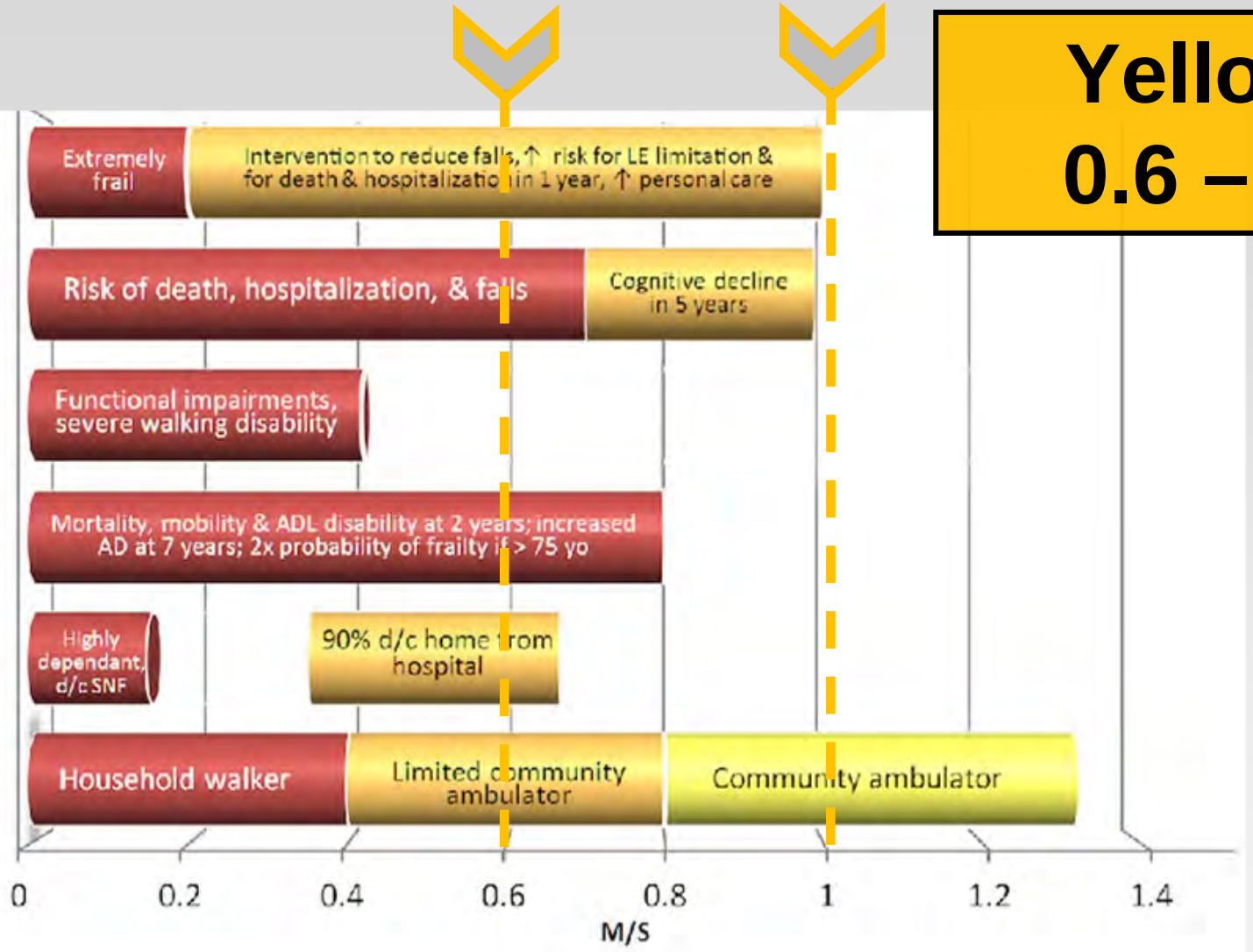



Extremely frail
Risk of death, hospitalization, & falls
Functional impairments, severe walking disability
Mortality, mobility & ADL disability at 2 years; increased AD at 7 years; 2x probability of frailty if > 75 yo
Highly dependant, d/c SNF
Household walker
0
0.2
0.4
0.6
0.8
1
1.2
1.4
M/S

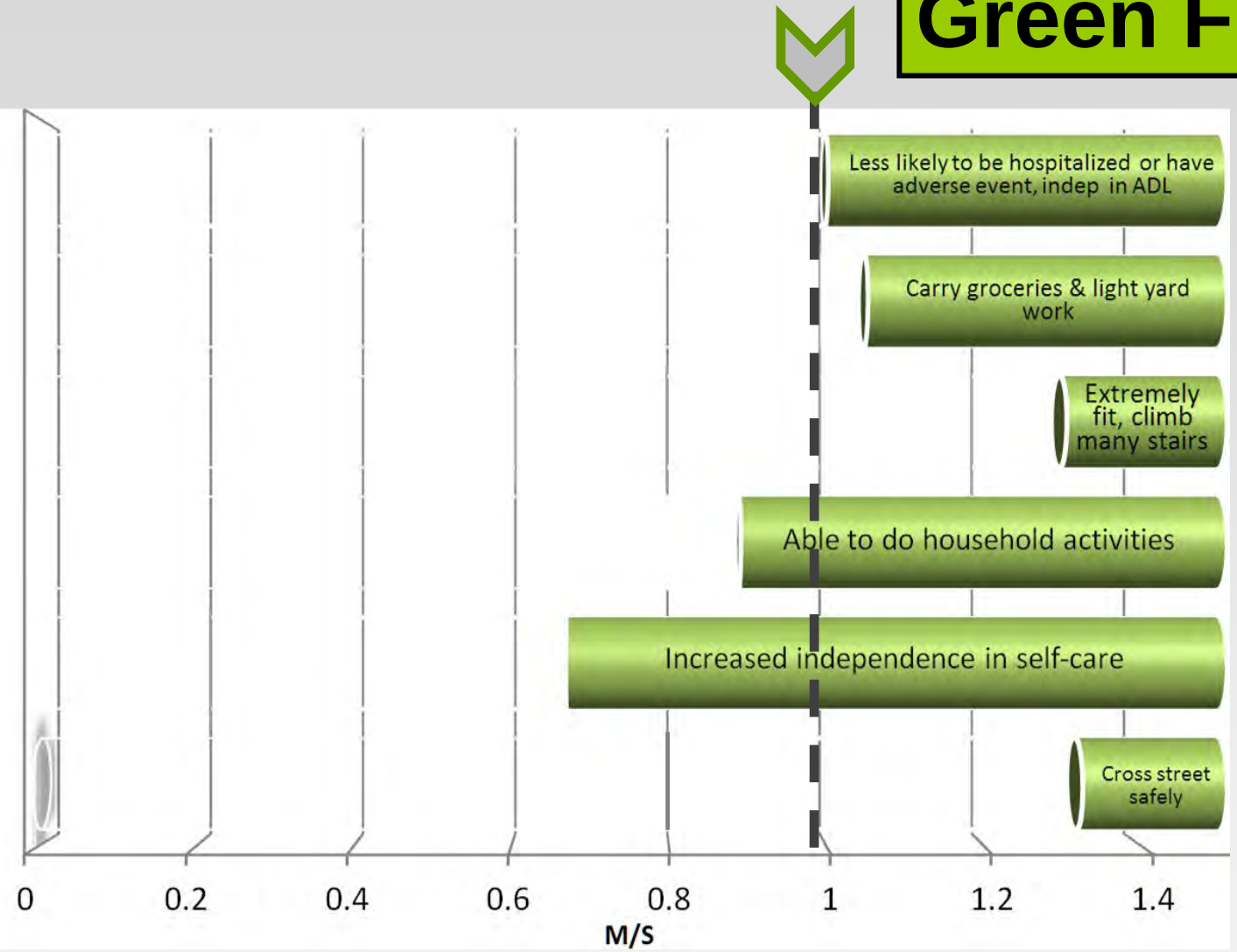
Red Flag: ≤ 0.6 m/s

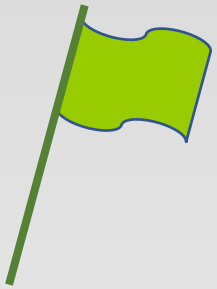


Yellow Flag: 0.6 – 1.0 m/s

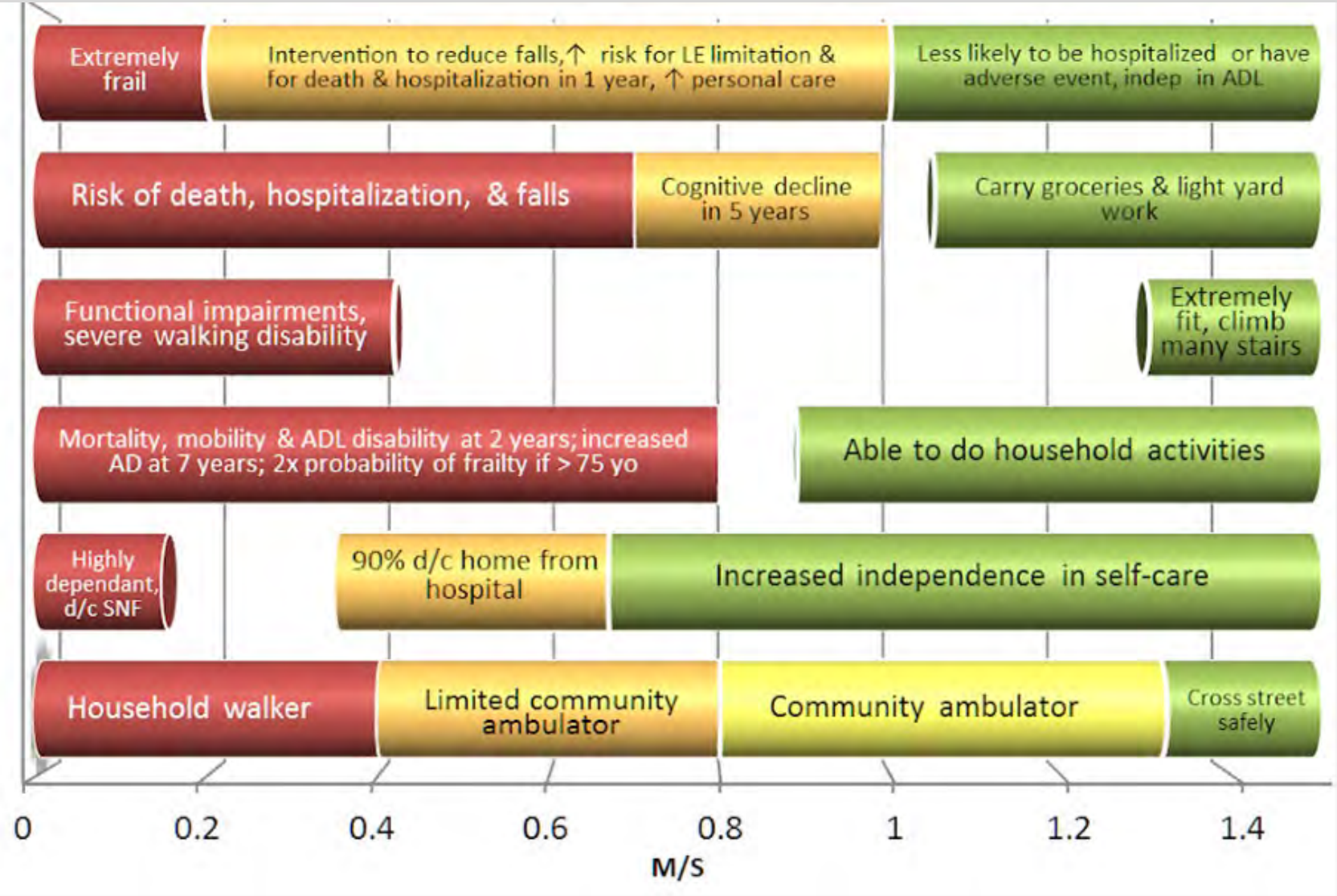


Green Flag: > 1.0 m/s

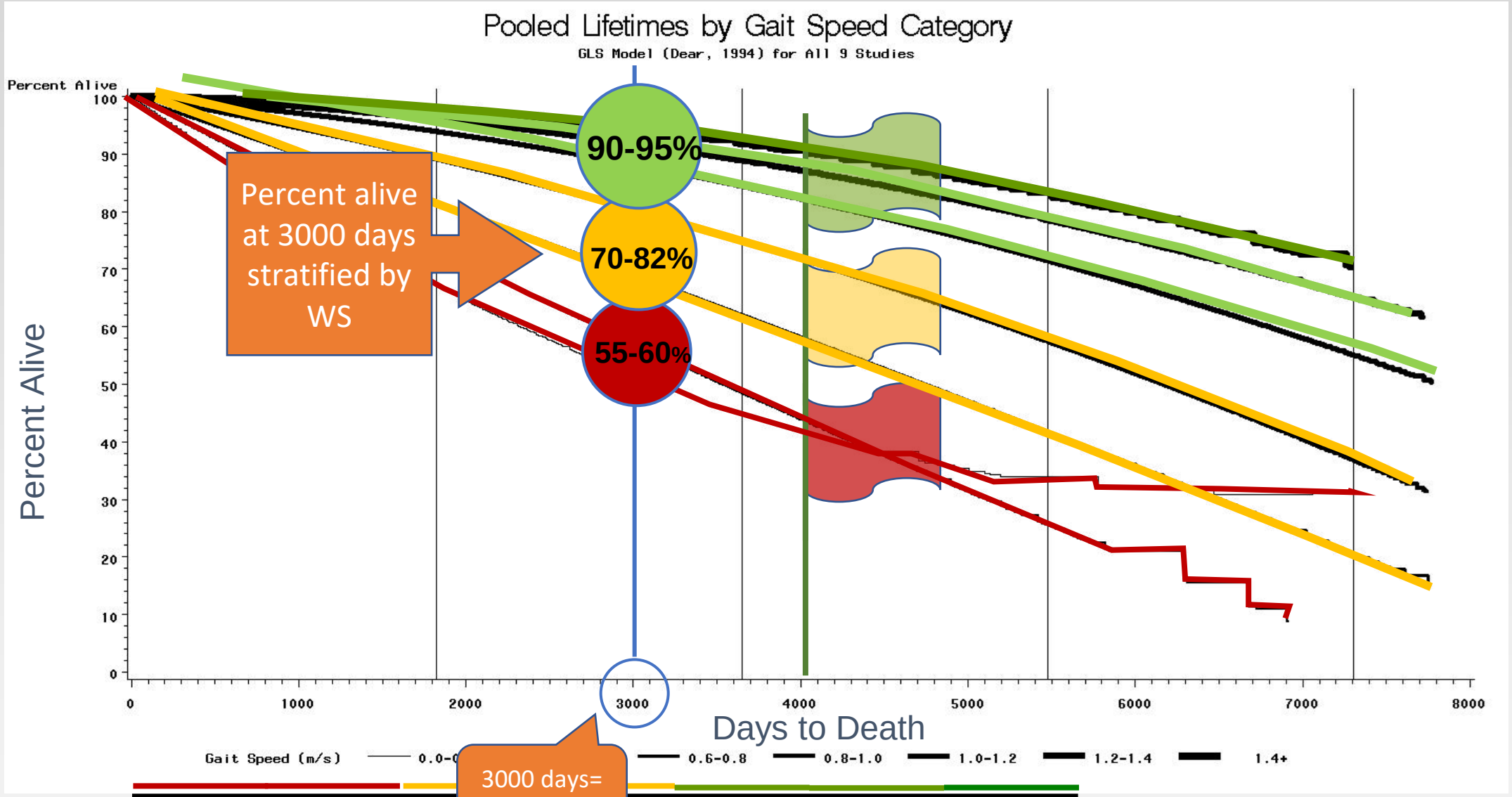


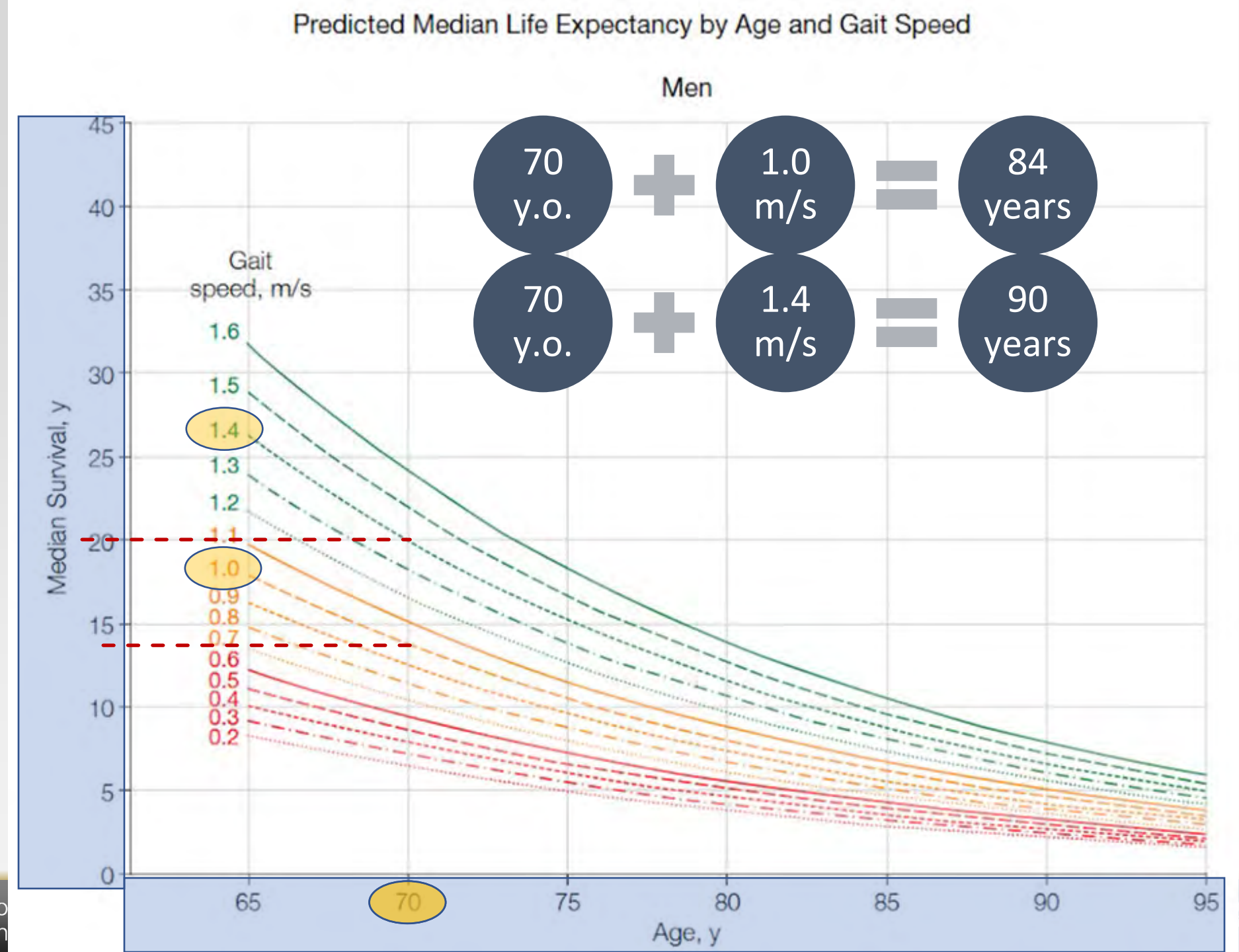


Walking Speed…Evidence across studies



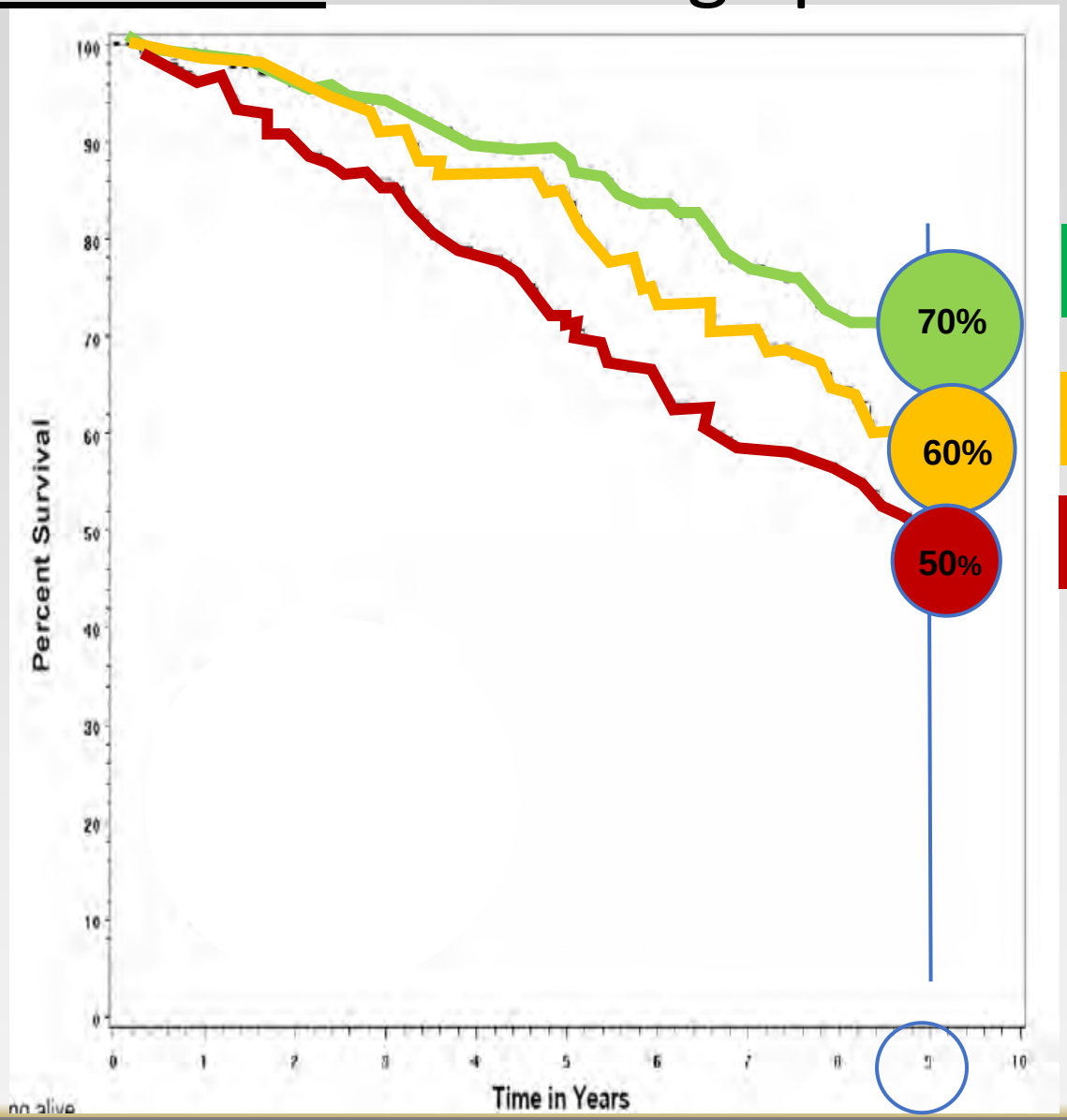
Middleton, Fritz, Lusardi JAPA 11-13


Pooled Lifetimes by Gait Speed Category
GLS Model (Dear, 1994) for All 9 Studies
Percent Alive
Percent Alive
Days to Death
90-95%
70-82%
55-60%
Percent alive at 3000 days stratified by WS
3000 days= 8.5 years
Gait Speed (m/s)
0.6-0.8
0.8-1.0
1.0-1.2
1.2-1.4
1.4+
0-.4 m/s
4-.6 m/s
1.0-1.2m/s
1.2-1.4 m/s
>1.4 m/s



Studenski et al., 2011, JAMA

Improvement in Walking Speed improves Mortality



Monitored Gait Speed Over 1 year:

Improved at 1 year by 0.1 m/s

Transient improvement

Never improved

Walking speed is a Modifiable Risk Factor

Hardy 2007

How do we improve walking speed?

Aiming for "**Failure**“ using progressive strengthening

Choosing Wisely®

An initiative of the ABIM Foundation

Don't let older adults lay in bed or only get up to a chair during their hospital stay.

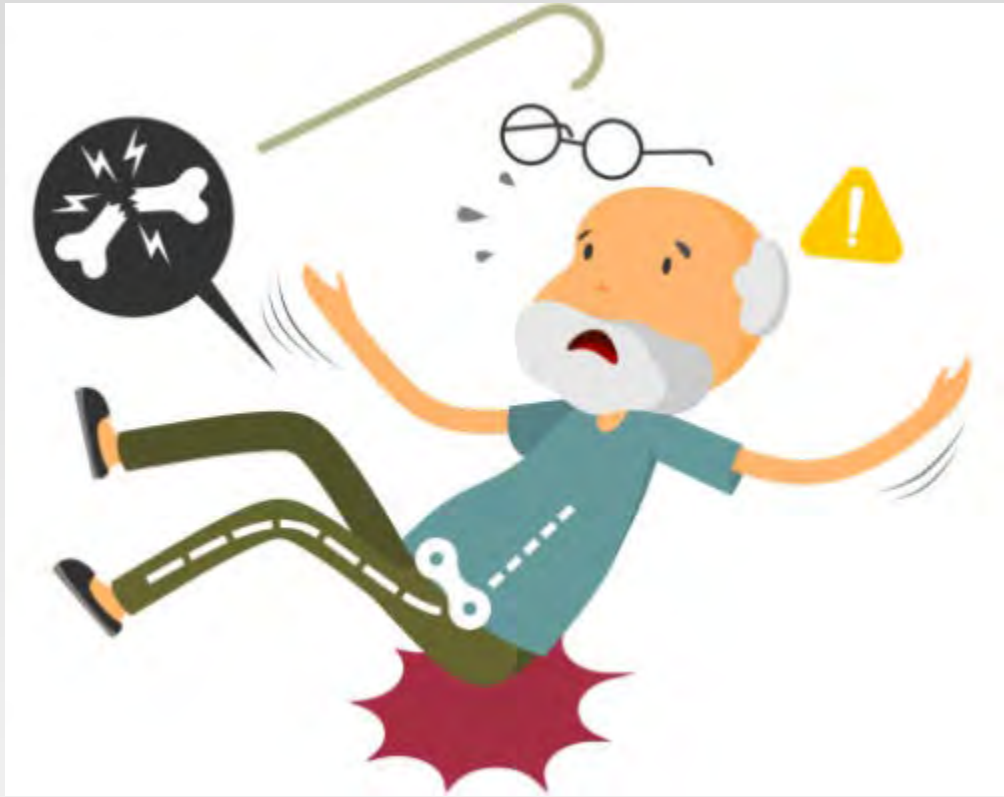
Don't prescribe under-dosed strength training programs for older adults. Instead, match the frequency, intensity and duration of exercise to the individual's abilities and goals.

Barriers for implementation of optimal practice patterns

- Fear of adverse events, penalties, or litigation

- Practice of “negative defensive medicine”

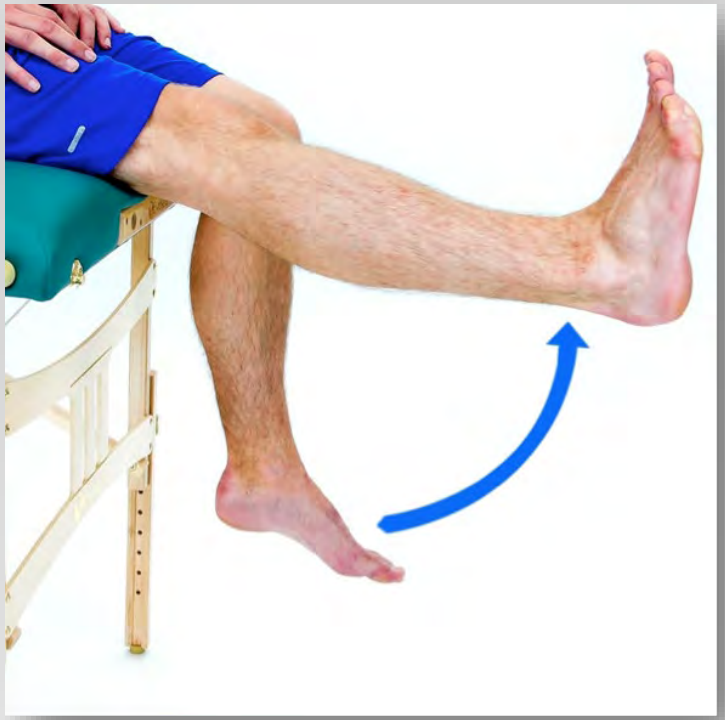
“I don’t want a fall on my shift.”



Fear of Litigation

- Have we taken the “above all else…do no harm principle” to an extreme?
- Would more evidence-based guidelines help decrease litigation fear?

Do Light Weights Generate Forces Equivalent to Daily Functional Activities?



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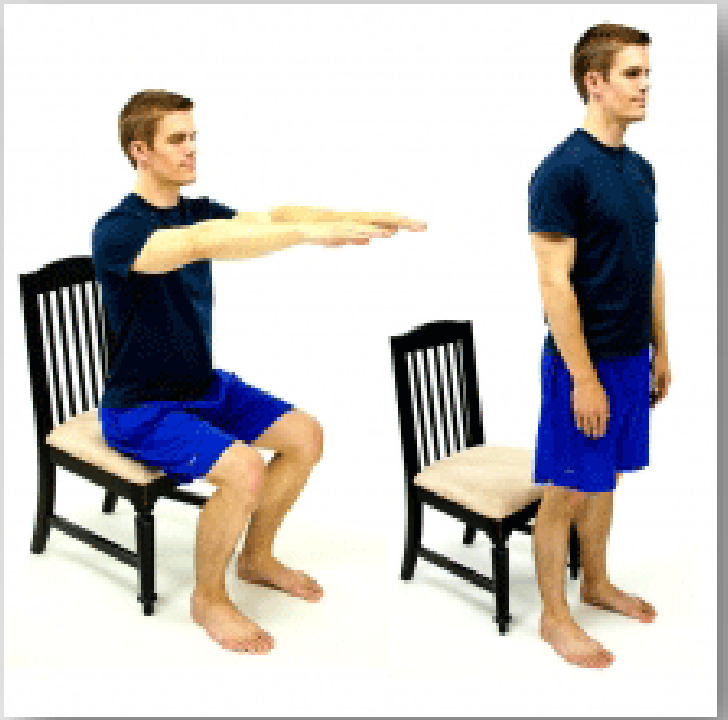
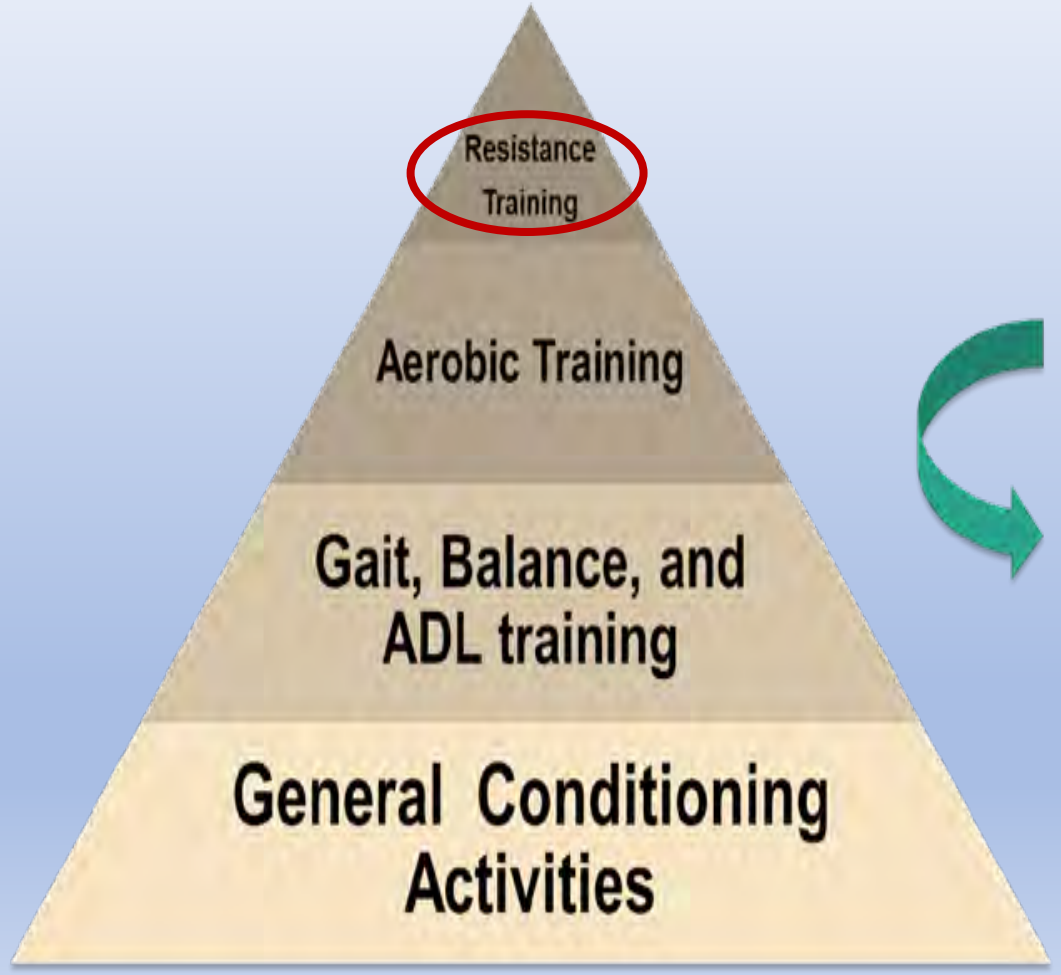


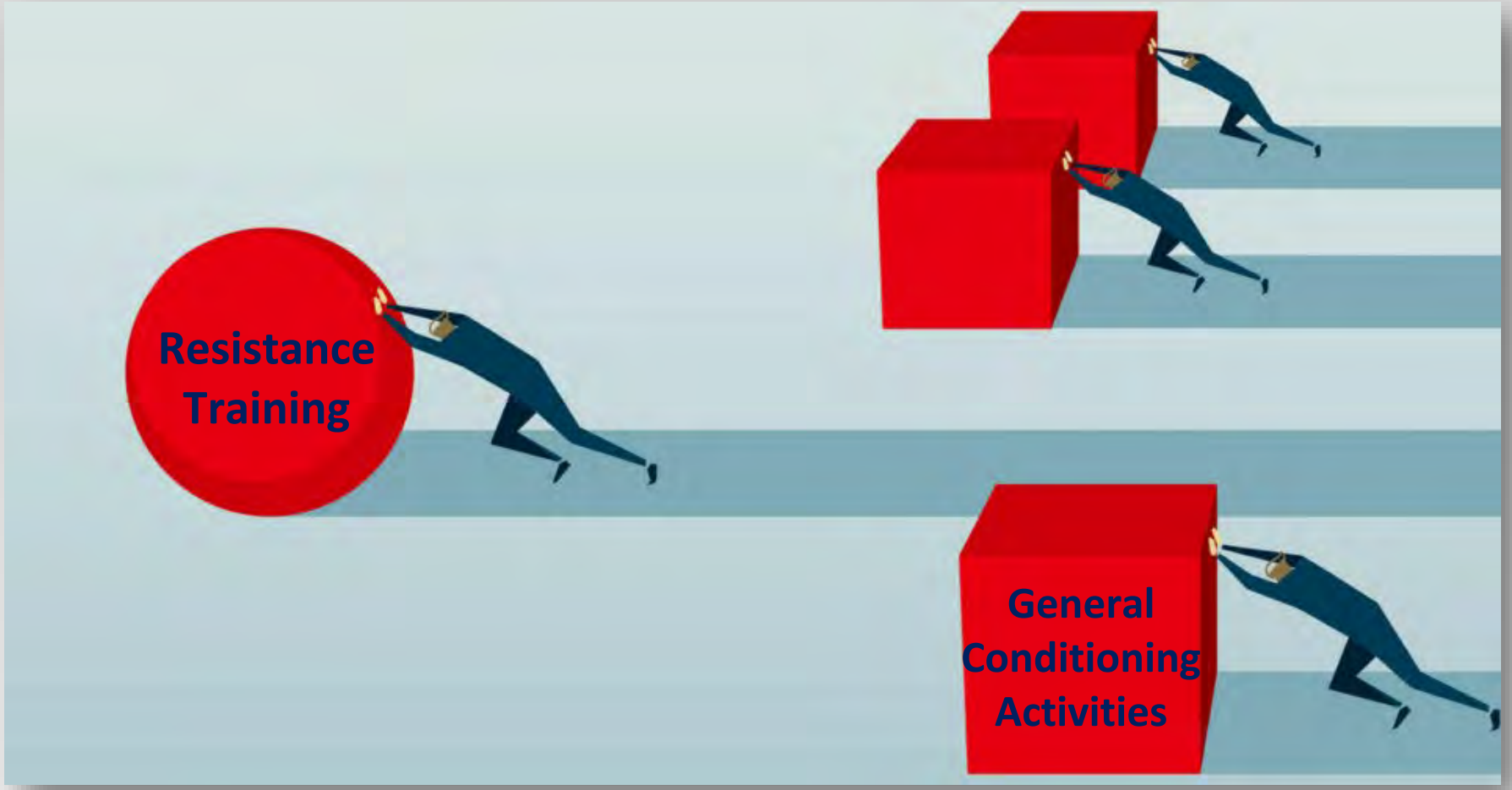
Current Rehabilitation



Progressive Rehabilitation

Low-Physiologic Intensity → **High-Physiologic Intensity**

Work Smarter, Not Harder

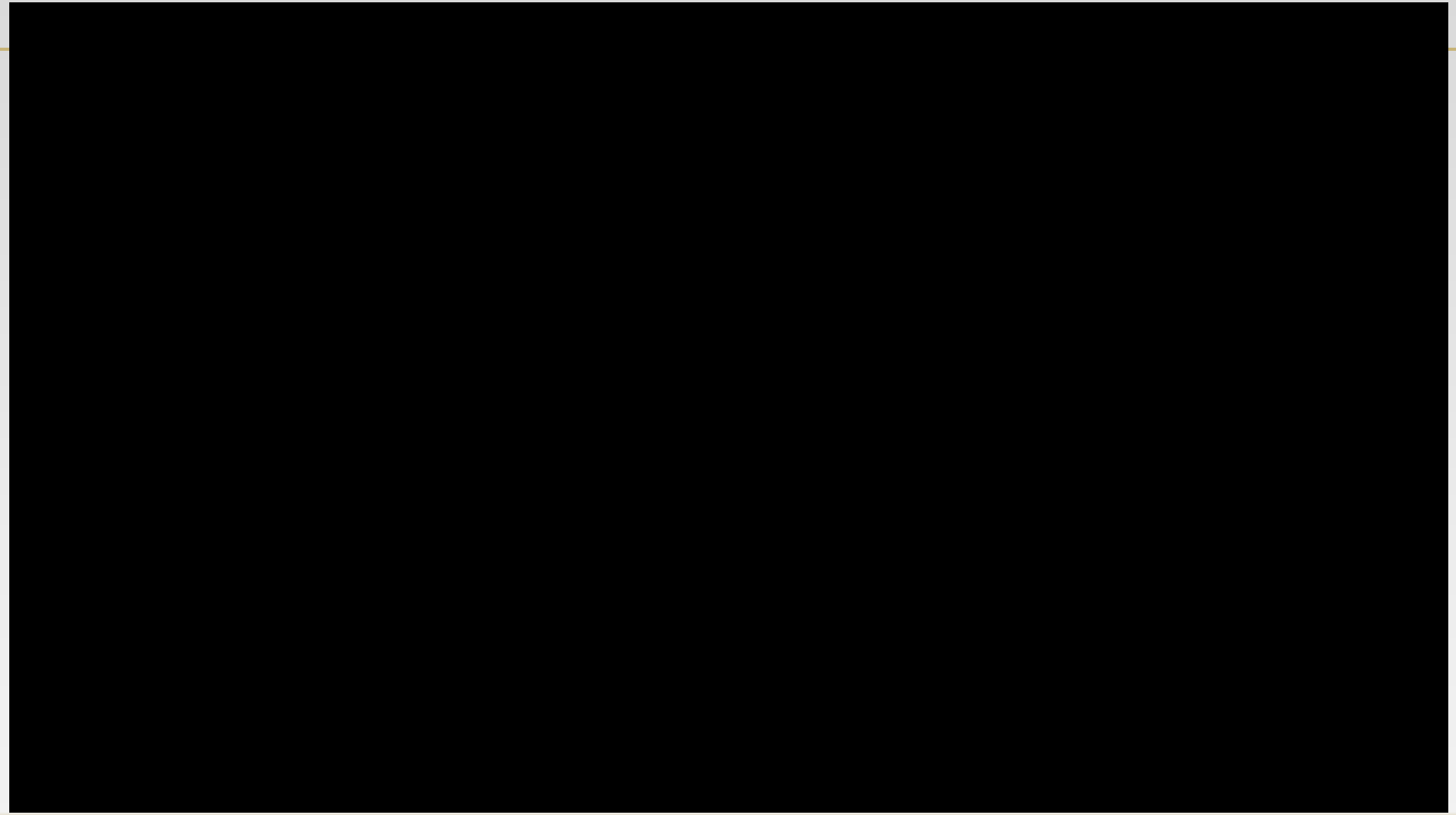


FOR MUSCLE STRENGTHING

MORE THAN 8 UP THE WEIGHT!

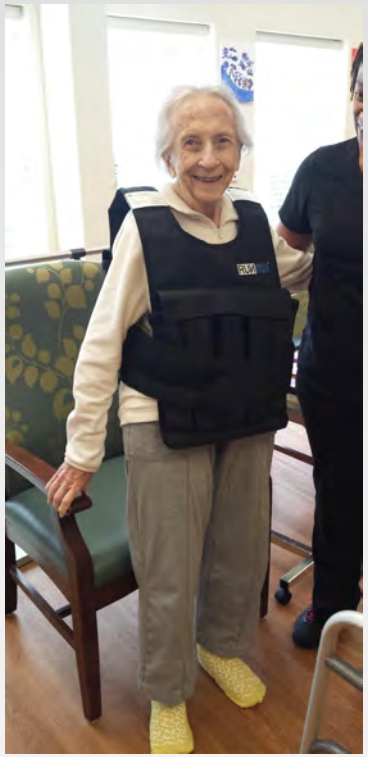
EXERCISE FORM FAILURE ON THE 9TH REPETITION IS GOOD

Video of sit to stand



RPE SCALE

1	Nothing
2	Very Easy
3	Easy
4	Comfortable
5	Somewhat Difficult
6	Difficult
7	Hard
8	Very Hard
9	Extremely Hard
10	Maximal/Exhaustion



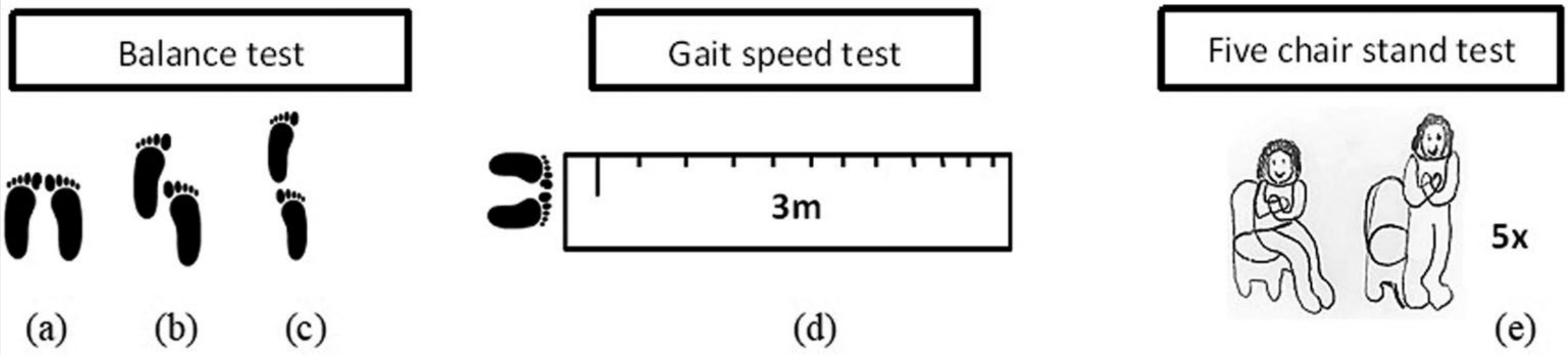
Journal of the
American Geriatrics Society

Implementation of a rehabilitation model in a Program of All-Inclusive Care for the Elderly (PACE): Preliminary data

2022

Allison M. Gustavson DPT, PhD[1,2] | Cherie V. LeDoux DPT, PhD[1] |
Michael Himawan DPT[1] | Jennifer E. Stevens-Lapsley MPT, PhD[1,3] |
Kathryn A. Nearing PhD[3,4,5]

6 weeks of high-intensity training



2x the Clinical meaningful change seen after 6 weeks

Gustavson et. al. 2022 J of American Geriatrics Society

Phys Ther. 2020 Sep 28;100(10):1746-1758. doi: 10.1093/ptj/pzaa126.

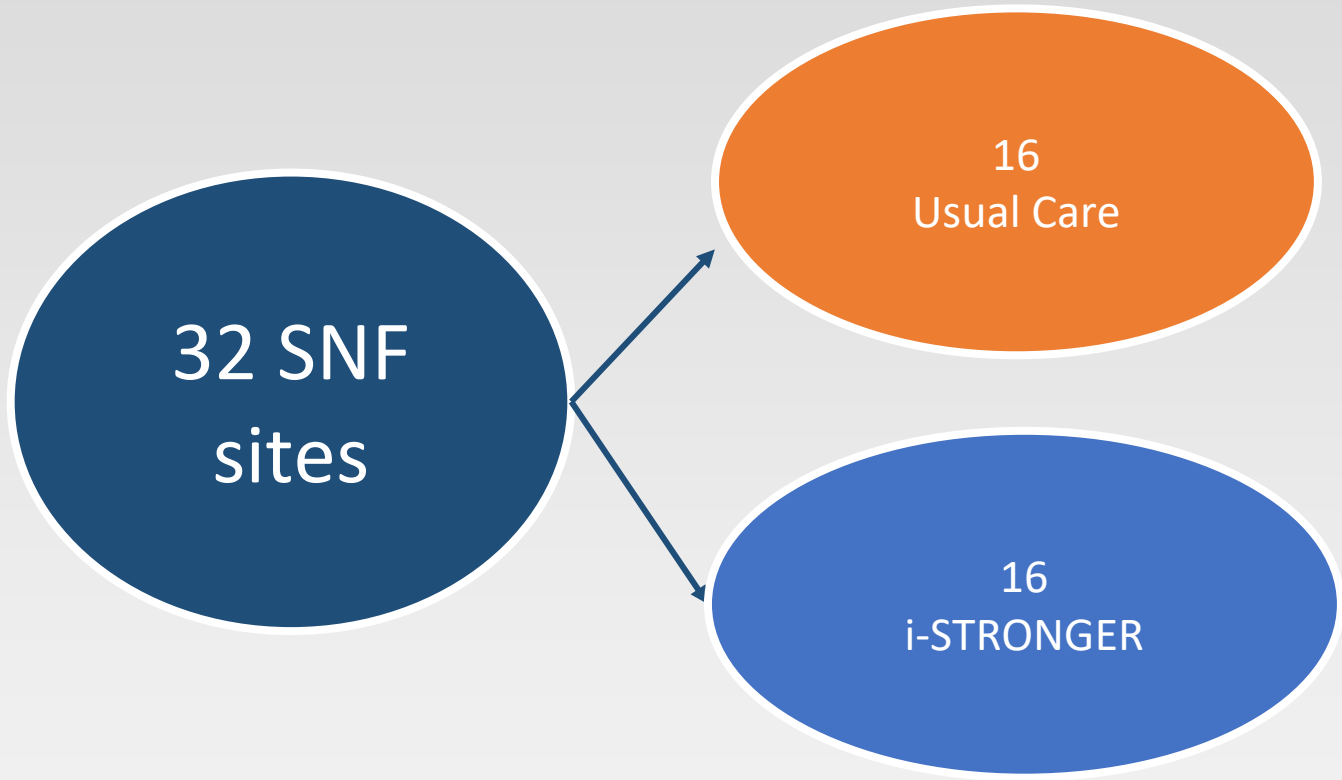
Application of High-Intensity Functional Resistance Training in a Skilled Nursing Facility: An Implementation Study

Allison M Gustavson [1], Daniel J Malone [2], Rebecca S Boxer [3], Jeri E Forster [4], Jennifer E Stevens-Lapsley [5]

High-Intensity is Feasible and Effective in the SNF

	High-Intensity vs Usual Care
Short Physical Performance Battery (SPPB)	↑0.64 points
Walking/Gait Speed	↑0.13 meters/second
Community Discharge Rate	↑20%
SNF Length of Stay Estimated Cost Savings	↓3.5 days ~$1500 per patient

Pragmatic Clinical Trial (NIH R01 AG072693)



Target: 3840 patients

High-Intensity Rehabilitation plus Mobility (HeRo)

Behavioral economics

Establish baseline

Goal selection

Gamification

Improving the Lives of Older Adults by Aiming for Failure

i-STRONGER

- **High-Intensity Rehabilitation = better lives**

- Value of measuring **gait speed & physical function**

Next steps….

- **The RESTORE team can assist** to overcome barriers to implementing high intensity rehab
  - Offer CEU educational opportunities
  - Access to an **educational platform** with a robust follow-up and ongoing support

www.movement4everyone.org

- APTA: Certified Exercise Expert for Aging Adults **(CEEAA)**

VA RR&D I21 RX002193

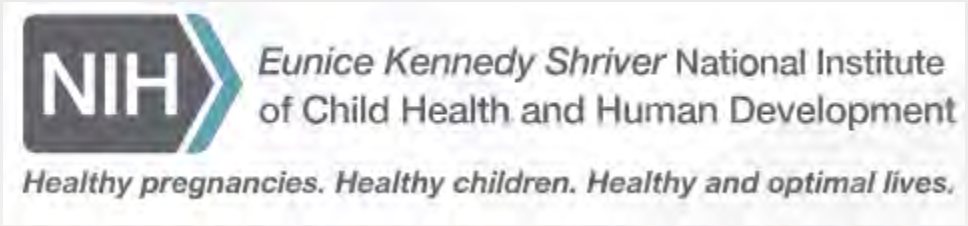
VA RR&D I01 RX001978

NIH R01 NR016209

NIH R01 AG054366

Foundation for Physical Therapy

CoHSTAR

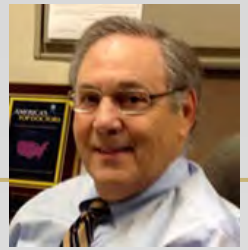


Rehabilitation Research & Development Service (RR&D)

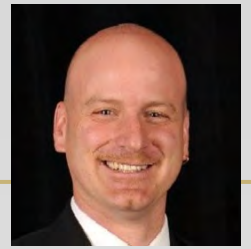
Cynthia Huang, DPT

Allison Gustavson, PT, DPT, PhD

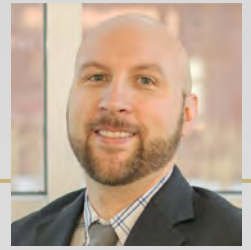
Bob Burke, MD



Bob Schwartz, MD



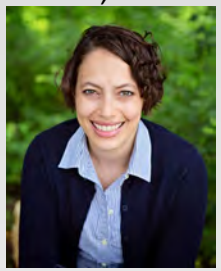
Ethan Cumbler MD



Jason Falvey, PT, DPT, GCS

Jeri Foster PhD

Jeff Wallace, MD

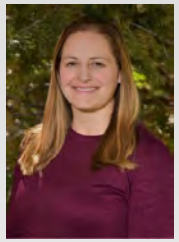


Katie Butera, PT, DPT

Wendy Kohrt PhD

Cari Levy, MD, PhD

Dan Malone, PT, PhD, CCS



Michelle Rauzi, PT, DPT, ATC

Amy Nordon-Craft, PT, DSc

Lauren Hinrichs, PT, DPT, OCS

Christine Jones, MD

Katie Seidler, MS, DPT

Kristine Erlandson, MD

Lauren Abbate, MD, PhD

Hillary Lum, MD, PhD

Kady Nearing, PhD

www.movement4everyone.org

Jennifer.Stevens-Lapsley@cuanschutz.edu

RESTORE TEAM AT UNIVERSITY OF COLORADO

Fall Prevention In Nursing Homes

It's Not Just A Problem For Tall People

CMDA Annual Conference
April 28th, 2023

Panelists

- Sara Stover, RN (DON)
- Mindy McCleery, PT, DPT (Therapy)
- David Shepherd, DO, MBA, MS, CMD (Medical Director)
- Jennifer Connelly, PharmD, BCACP, BCGP (Pharmacy)
- Lauren Shimp, NHA (Administration)
- Sonya Waganer, FNP-BC (Provider)

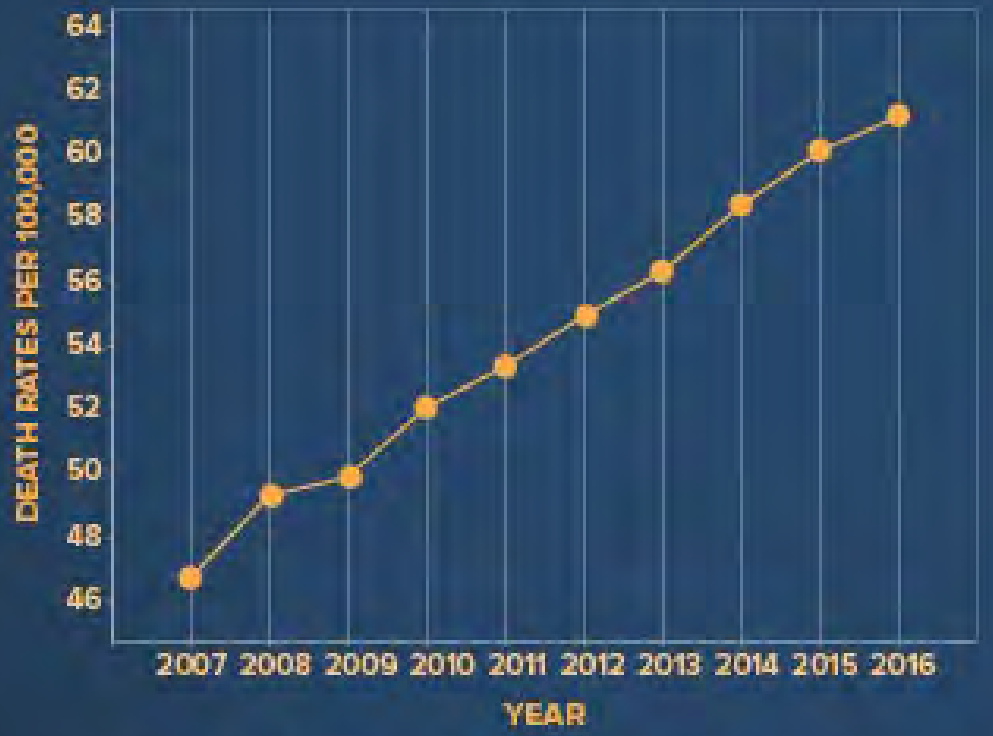
Learning objectives

1) Identify fall related risk factors and prevention strategies
2) Discuss fall related documentation and legal concerns
3) Identify and discuss fall prevention pearls and controversies
4) Stay awake so you don’t fall off your chair

Fall Death Rates in the U.S.

INCREASED 30%

FROM 2007 TO 2016 FOR OLDER ADULTS



If rates continue to rise, we can anticipate

7 FALL DEATHS

EVERY HOUR

BY 2030

Learn more at www.cdc.gov/HomeandRecreationalSafety.

Facts About Falls

- Approx 75% of NH residents fall each year with an average of 2-3 falls per year.
- Approximately one-third of persons age 65 years and one-half of those over 80 years of age fall each year.

References

1. Florence CS, Bergen G, Atherly A, Burns ER, Stevens JA, Drake C. Medical Costs of Fatal and Nonfatal Falls in Older Adults. *Journal of the American Geriatrics Society,* 2018 March, DOI:10.1111/jgs.15304
2. Bergen G, Stevens MR, Burns ER. Falls and Fall Injuries Among Adults Aged ≥65 Years — United States, 2014. MMWR Morb Mortal Wkly Rep 2016;65:993–998. DOI: http://dx.doi.org/10.15585/mmwr.mm6537a2
3. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Web–based Injury Statistics Query and Reporting System (WISQARS) [online].

Facts About Falls

- In the United States, over 350,000 hip fractures happen each year. For people over age 65, it is estimated that between 30% and 50% end up institutionalized or dead within one year.
- Falls among adults age 65 and older are very costly. Each year about $50 billion is spent on medical costs related to non-fatal fall injuries and $754 million is spent related to fatal falls.

References

1. Florence CS, Bergen G, Atherly A, Burns ER, Stevens JA, Drake C. Medical Costs of Fatal and Nonfatal Falls in Older Adults. *Journal of the American Geriatrics Society,* 2018 March, DOI:10.1111/jgs.15304
2. Bergen G, Stevens MR, Burns ER. Falls and Fall Injuries Among Adults Aged ≥65 Years — United States, 2014. MMWR Morb Mortal Wkly Rep 2016;65:993–998. DOI: http://dx.doi.org/10.15585/mmwr.mm6537a2
3. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Web–based Injury Statistics Query and Reporting System (WISQARS) [online].

Case #1: Emma Fallendown

- 85yr old female recent admission to LTC who was living with her spouse in an ALF when he passed away a little over a month ago.
- She has had two unwitnessed falls since admission where she was found on the floor in her bathroom
- She is ambulatory with no assistance devices and has not used her call light since admission.
- She wears glasses, has arthritis in her shoulders, hands and knees, and occasional back pain complaints.
- She reports feeling dizzy at times and has a PMH of possible TIAs, Hypertension, GERD, and Depression. Her family filled her room with many personal items to make her feel more at home.

Case #1: Emma Fallendown

Medications:

- Losartan 100mg
- Amlodipine 10mg
- Atorvastatin 40mg
- Sertraline 100mg
- Aspirin 81mg
- Omeprazole 20mg
- Tramadol 50mg twice daily
- Gabapentin 300mg twice daily
- Tylenol 650mg q6 prn

Case #2: Julius Tipover

- 80yr old male with advanced dementia living in a memory unit in LTC who has an average of 2-3 falls per month.
- He is ambulatory with a walker that he only uses when reminded.
- He is impulsive, difficult to redirect, sundowns, has erratic sleep patterns, and often refuses attempts at care.
- His PMH includes CHF, Osteoarthritis, Macular Degeneration, and CKD. He has a surgical hx of right hip ORIF and right TKA.
- He is incontinent of bowel and bladder and has recently lost weight.

Case #2: Julius Tipover

Medications:

- Digoxin 0.125mg daily
- Lisinopril 20mg daily
- Lasix 20mg bid
- KCL 20meq daily
- Seroquel 25mg tid
- Trazodone 100mg at hs

Fall Prevention Pearls

4 P’s

Position

Are you comfortable? Do you want to move? Are you where you want to be?

Personal Needs

Do you need to use the bathroom?

Pain

Are you uncomfortable or in pain? What can I do to help make you more comfortable?

Placement

Is the bed height correct? Is the phone, call light, remote control, water etc. all within reach?

Fall Prevention Pearls

I HATE FALLING

I=Inflammation of joints (or joint deformity)

H=Hypotension (orthostatic blood pressure changes)

A=Auditory and visual abnormalities

T=Tremor (Parkinson's disease or other cause)

E=Equilibrium (balance) problem

F=Foot problems

A=Arrhythmia, heart block, or valvular disease

L=Leg-length discrepancy

L=Lack of conditioning (generalised weakness)

I=Illness

N=Nutrition (poor; weight loss)

G=Gait disturbance

Fall Prevention Pearls

- Keep track of questions for surveyors throughout the year and ask them during your exit interview
- Keep a record of both successful fall prevention strategies and mistakes. Learn from mistakes but also remember to celebrate and share in your success.
- Don’t forget about the additive effects of polypharmacy on fall risk.
- Medication reviews involving a pharmacist should occur immediately after someone has had fall
- Vitamin D deficiency increases fracture risk
- Involve ALL staff when applying interventions and consider having a “fall expert” to coordinate implementation

Fall Prevention Pearls

- Fall risk scoring is not very helpful in nursing homes where most patients are a high fall risk but the Timed Up and Go (TUG) test is helpful at identifying higher risk patients
- Review frequent fallers at QAPI and do an in depth root cause analysis and multidisciplinary approach to interventions
- Partnering with family members can generate some unique interventions and create more trust that things are being done
- Two effective fall risk prevention tools are the 4 P's and the AHRQ program
- Providers can use the "I HATE FALLING" pneumonic to help guide assessments after a fall

More of a Good Thing: A Framework to Grow and Strengthen the PALTC Careforce

Erin O'Brien Vigne, MA, RN

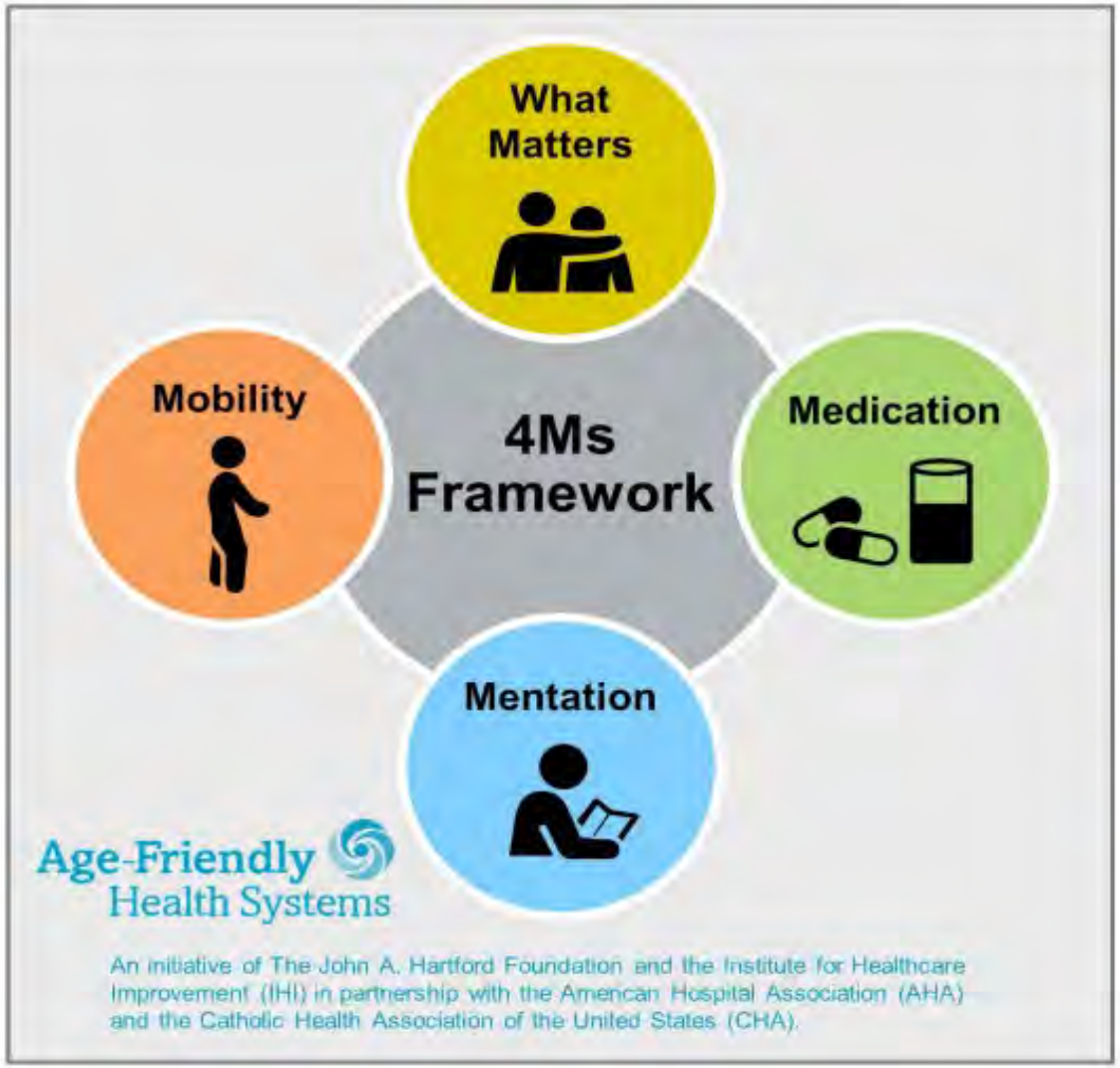
Director of Clinical Affairs

AMDA-The Society for Post-Acute and Long-Term Care Medicine

More of a Good Thing

amda The Society For Post-Acute And Long-Term Care Medicine™

4Ms Framework of an Age-Friendly Health System



What Matters

Know and align care with each older adult's specific health outcome goals and care preferences including, but not limited to, end-of-life care, and across settings of care.

Medication

If medication is necessary, use Age-Friendly medication that does not interfere with What Matters to the older adult, Mobility, or Mentation across settings of care.

Mentation

Prevent, identify, treat, and manage dementia, depression, and delirium across settings of care.

Mobility

Ensure that older adults move safely every day in order to maintain function and do What Matters.

Institute for Healthcare Improvement [IHI]. (2022, October). *Age-friendly health systems: Guide to care of older adults in nursing homes*. https://241684.fs1.hubspotusercontent-na1.net/hubfs/241684/IHI-Age-Friendly-Guide-Nursing-Homes_March28-2022.pdf

AFHS 4 Ms Applied to the *Careforce*

- What Matters (culture, compassion, respect, a voice)
- Medication (health promotion, wellness & workplace safety)
- Mentation (stress management, trauma-informed care for staff)
- Mobility (opportunities for career advancement, ongoing education and leadership)

More of a Good Thing

amda The Society For Post-Acute And Long-Term Care Medicine™

Key features of the roundtables….

- We are a community focused on co-design
- “All teach, all learn”[1]
- Small tests of change— “What can we do by next Tuesday?”
- Collation and dissemination of insights
- Moderated by JoAnne Reifsnyder, PhD, MSN, MBA, RN, FAAN

[1]Project ECHO. (2022). https://hsc.unm.edu/echo/what-we-do/about-the-echo-model.html

Roundtable Topics

- April 28 — Kick-off: The 4Ms Expanded for Staff *(Emily Nicoli, MS, RN, CRNP, Chief Nursing Officer, UnitedHealthcare Retiree Solutions)*
- May 26 — Sustaining Compassion & Calling in the Midst of Crisis: Schwartz Center Rounds
  (Beth Lown, MD, CMO, Schwartz Center for Compassionate Healthcare)
- June 23 — Career Mobility and Shared Governance
  (Erin Woodford, MSN, RN, VP of Population Health, Genesis Healthcare)
- July 28 — Health Promotion and Stress Management
  (Kelly Doran, PhD, RN, Associate Professor, University of Maryland School of Nursing)
- August 25 — Trauma-informed Care for our Careforce *(Nancy Kusmaul, PhD, MSW, Assoc. Prof. at UMBC and Paige Hector, LMSW, MSW)*
- Sept 22 — Developing Leaders for the Future *(Nancy Istenes, DO, CMD, FACP and Shauna Assadzandi, MD)*

First “small test of change”…Lori Porter, CEO

Workforce → Careforce

More of a Good Thing

amda The Society For Post-Acute And Long-Term Care Medicine™

What are Schwartz Rounds ®?

- Regularly scheduled, structured, facilitated conversations that bring caregivers together to discuss the most challenging and compelling aspects of what it's like to take care of patients and their families. Organizational teams are taught how to implement and facilitate these conversations, so participants can offer and receive support and feel heard.
- Caregivers who participated in multiple Schwartz Rounds sessions reported:
  - Improved teamwork, interdisciplinary communication, and appreciation for the roles and contributions of colleagues from different disciplines.
  - Decreased feelings of stress and isolation, and more openness to giving and receiving support.
  - Increased insight into the social and emotional aspects of patient care; increased feelings of compassion toward patients; and increased readiness to respond to patients' and families' needs.

https://youtu.be/kVf23hY1g6o

Dawson, J., McCarthy, I., Taylor, C. *et al.* Effectiveness of a group intervention to reduce the psychological distress of healthcare staff: a pre-post quasi-experimental evaluation. *BMC Health Serv Res* **21**, 392 (2021). https://doi.org/10.1186/s12913-021-06413-4

What Matters: Sustaining Compassion and Calling in the Midst of Crisis

- Modified Schwartz Rounds moderated by Dr. Beth A. Lown, MD, *Chief Medical Officer, The Schwartz Center for Compassionate Healthcare, Associate Professor of Medicine, Harvard Medical School*
- A medical director, nursing assistant and nurse each shared their story about how compassion affected them personally during COVID-19 and how it had a positive impact on their lives
- Cultures of compassion are built on social support
- Does your long-term care community have a culture of compassion? Are there ways that you and other leaders could offer better support to staff to help cultivate this culture?

https://www.theschwartzcenter.org

More in common than we realize…

“It was in that moment, in December 2020, when we were talking about the vaccine and the CNAs and nurses were telling me about their fears, what their families were worried about—it was then when I realized we were trusting one another and developing something authentic. It was my proudest moment as a Medical Director. The next week, those same CNAs and nurses lined up to get their COVID-19 vaccine and I thought to myself, ‘building these trusting relationships is everything.’”

-Leslie Eber, MD, CMD

Career Mobility & Shared Governance

- Career mobility can be upward, downward or lateral movement of employees across positions; need input from employees; programs that support ALL/ ANY movement desired by an employee are ideal
- Programs must be structured, communicated and sustained
- Destigmatize stepping down from a higher position to one of less responsibility (such as DON to floor nurse) if that is what is best for that employee at the time. Better than losing them altogether, and you still retain their leadership skills and expertise
- Allow career flexibility; observe staff, note skills and talents and offer opportunities to use those in other roles within the facility, i.e., dietary staff can help plan social activities
- Center based programs that support career mobility can be a cost-effective strategy to increase morale, retention and attract future employees to our careforce

Career Mobility…..Make it Visible & Tangible

Elevate employees through recognition. Celebrate all achievements, large and small!

More of a Good Thing

amda The Society For Post-Acute And Long-Term Care Medicine™

Medication: Health Promotion

- Start small with one program that staff has indicated is their priority (diet, exercise, quitting smoking?)
- Allow flexibility (i.e., staff can use the residents' gym before or after shifts)
- Make it FUN! That's why staff said they stayed engaged; they don't want to compete against each other
- Education often needed around health topics, such as what makes a healthy diet?
- Only 20% of employees offer **mood/stress/depression programs** for staff, yet staff consistently say this is what they most want help managing; lots of free resources available; make mental health visible, destigmatize, and prioritize
- Leadership support is critical

Linnan, Laura A et al. "Results of the Workplace Health in America Survey." *American journal of health promotion : AJHP* vol. 33,5 (2019): 652-665. doi:10.1177/0890117119842047

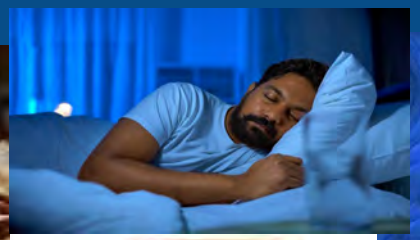
Worksite Wellness in LTC Settings: Program facilitators based on CNA feedback

Simple changes	Behavior awareness	Constant edu and tip infusion	Prizes/ competitions
Fun	Teamwork/support	Share with family and friends	Low pressure

Flannery, K., & Resnick, B. (2014). Nursing assistants' response to participation in the pilot worksite heart health improvement project (WHHIP): a qualitative study. *Journal of community health nursing*, *31*(1), 49-60.

Barriers	Solutions
Staff coverage	Rotating staff “buddies” Staff sign out board Cover pager system
Engagement	Screening and report cards Competitions (self goals) and raffles
Too much time away from residents	Handouts (condensed to 1 page) Simultaneous interventions Drop in/flexible model - staff could come when free Sustainability planning / text/ phone coaching / videos
Staff could not leave the unit for PA breaks	Set PA times so staff could plan their day Peer champions / team lead for the day / stakeholders After work and weekend activities
Different staff wanted to do different forms of exercise	First person to come to session got to pick type PA Post an exercise schedule with a consistent time slot for dance Pair participants based on PA preference

What changes can you make now?



Mentation: Trauma Informed Care

- Trauma-informed care is the adoption of principles and practices that promote a culture of safety, empowerment and healing (SAMHSA)
- We cannot expect our staff to provide trauma-informed care to residents if we are not prepared to provide trauma-informed care to staff
- Grieving and mourning is difficult, and leadership can help by showing vulnerability, transparency, and empathy

Substance Abuse and Mental Health Services Administration. (2014). *SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach*. HHS Publication No. (SMA) 14-4884. Rockville, MD: Substance Abuse and Mental Health Services Administration. https://ncsacw.acf.hhs.gov/userfiles/files/SAMHSA_Trauma.pdf

The Role of the Medical Director & Others in Leadership

- Be visible and create an intersection between leadership and frontline staff
- Hold “medical director hours” to encourage staff to stop by and get to know their medical director
- Encourage CNAs to speak first during team rounds as it helps them feel valued, heard and confident
- Build relationships with nurses and CNAs. Search them out to hear their observations and thoughts about status changes in residents, and let them know when their observations and feedback have positively impacted a resident’s care

“You show great leadership potential. Whenever a firetruck drives by, the whole office starts howling.”

The Role of the Medical Director & Others in Leadership

- Show staff you are approachable:
  - Have lunch in the breakroom
  - Have conversations with staff that aren't work related
  - Stay at the facility to do documentation where you can be seen more readily and are more accessible to staff.
- When you ask employees questions, they will start to ask you questions!
- Promote the benefits of working in the setting: more flexible work hours than acute care settings (tired of 12-hour shifts?), no overhead, no office needed
- Raise awareness of staffing needs at the national level. Political advocacy is needed around issues like federal funding and loan forgiveness for education and training

Appreciative Inquiry: A Philosophy, Not a Technique

- Focus on STRENGTHS instead of weaknesses.
  - What is your LTC community doing right?
  - What are your LTC community's ideals and goals?
  - **What are the employees' dreams and plans?**
  - What was your best day at work, and what made it so great?
  - How can you have more "best days"?

- Appreciative inquiry creates an atmosphere of possibility, bringing excitement and enthusiasm back into the organization.

- Appreciative inquiry methods place great importance on an entire system, ensuring that all employees feel heard and acknowledged.

- Result is happier employees and lower turnover, higher performing employees, more collaboration with leadership, more creativity (yes, in a nursing home!), and a stronger community.

The David L. Cooperrider Center for Appreciative Inquiry
https://www.champlain.edu/ai-home/what-is-appreciative-inquiry

Why Does Appreciative Inquiry Work?

- People like talking about their successes and actively engage in conversations that focus on what works
- When sharing positive stories, people gain confidence in their ability to deliver—it's their experiences, not someone's else's best practice

Source: The Economic Times [Sunday] 20 May 12

The David L. Cooperrider Center for Appreciative Inquiry
https://www.champlain.edu/ai-home/what-is-appreciative-inquiry

Key takeaways…Look Up!

- Evidence-based strategies to grow and strengthen the PALTC careforce are out there.
- Start tomorrow. Each of the 4Ms we discussed includes something you can begin doing immediately.
- Use the appreciative inquiry philosophy: why are staff **staying?** What are you doing right that you can expand upon?
- **Which of the “4Ms” will you choose to focus on next week?**
- **Which idea presented today most resonated with you?**
- **Who will lead the implementation of the strategy you choose? Who will be on the team?**

Opportunities are all around you.

https://paltc.org/goodthing

Register for the series at:

https://us02web.zoom.us/meeting/register/tZYsce-rrTkoH9KwXQ3PQFDnQGTVWtf2RHGV

Join email list serv:

https://groups.io/g/moreofagoodthing

University of Colorado **Anschutz Medical Campus** Movement Disorders Center

Caring for Patients with Parkinson's Disease in Post-Acute and Long-term Care Communities

Heather Heiser, MD

Disclosures

- None
- Current PGY-6 (2nd Year) Fellow at University of Colorado - Anschutz Medical Campus and Denver Health

Objectives

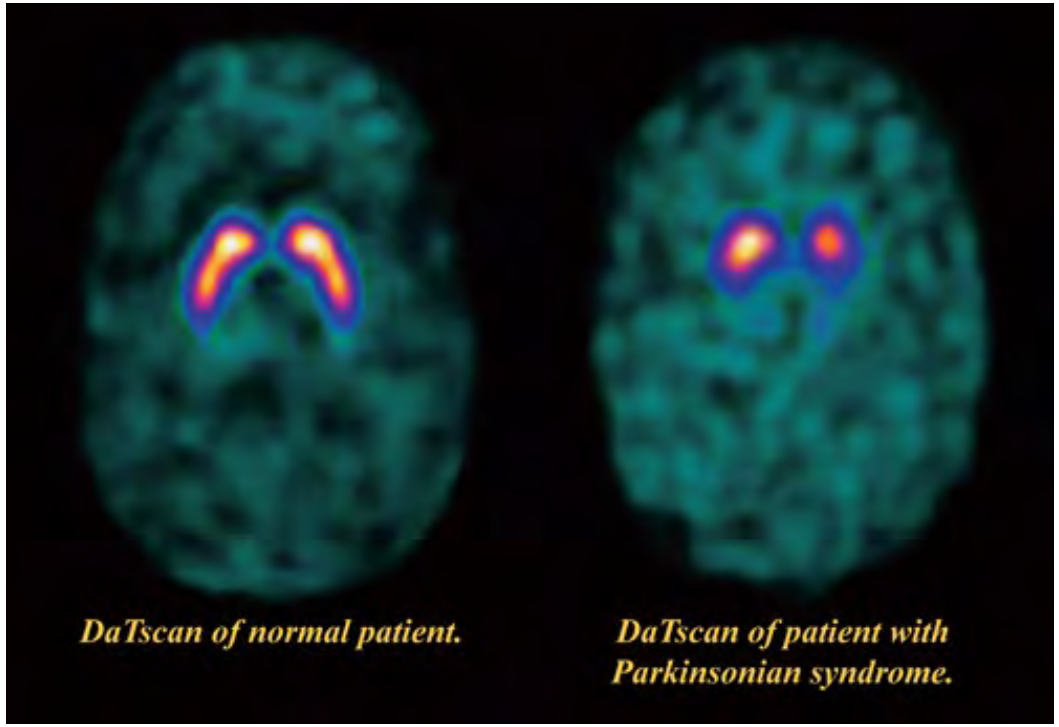
- Understand the diagnostic criteria and prognosis of Parkinson's Disease (PD)
- Discuss common safety, medication and management concerns in patients with PD residing in post-acute and long term care communities, in particular non-motor symptoms
- Discuss the approach to goals of care in patients with PD

Parkinson’s – A Clinical Diagnosis

- Presence of Bradykinesia and at least one of the following:
  - Rigidity
  - Rest Tremor
  - Postural instability
- Supportive features include
  - Decreased arm swing, micrographia, hypophonia, shortened stride length
  - Prodromal signs: RBD, anosmia, constipation, orthostatic hypotension
  - **DaT Scan – not necessary**
- Red flags for an atypical parkinsonism
  - Early, recurrent falls
  - Poor response to medication
  - Rapid progression
  - Severe early autonomic features
  - Cerebellar features
- **No concurrent exposure to neuroleptic drugs**

The “DaT”tails

- SPECT scan that measures the presynaptic dopamine transporter protein
- Reduced in PD
- FDA approval for differentiating PD from ET
- Clinically more useful in Idiopathic PD vs Drug-induced
- Certain drugs must be halted prior to scan (up to 1 week prior)



Prognosis

- Meta-analysis found that people typically live 6.9 to 14.3 years after diagnosis but there was significant heterogeneity (some reporting at least 20 years post-diagnosis)
- Cause of death on death certificates are similar to causes of non-PD patients
  - Death occurs often before the advanced stages of PD for other reasons
  - If patients do pass from PD-related symptoms, most commonly it is aspiration pneumonia

Parkinson Disease Subtype and Estimated Frequency	Disease Presentation	Response of Motor Symptoms to Dopaminergic Medication	Disease Progression
Mild motor predominant 49%-53%	• Young at onset • Mild motor symptoms	Good	Slow
Intermediate 35%-39%	• Intermediate age at onset • Moderate motor symptoms • Moderate nonmotor symptoms	Moderate to good	Moderate
Diffuse malignant 9%-16%	• Variable age at onset • Rapid eye movement sleep behavior disorder • Mild cognitive impairment • Orthostatic hypotension • Severe motor symptoms • Early gait problems	Resistant	Rapid

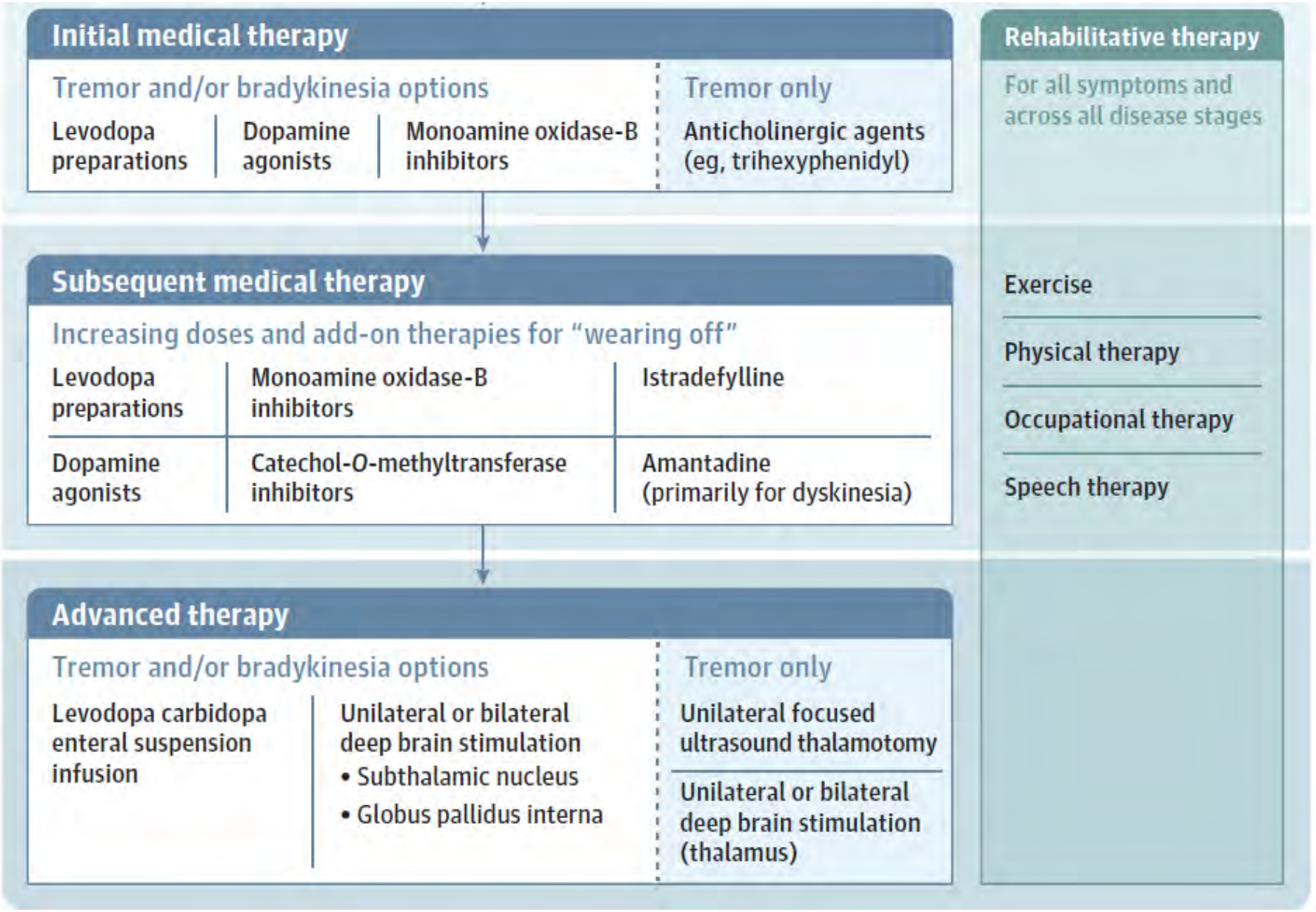
Long-Term Care – Literature Review

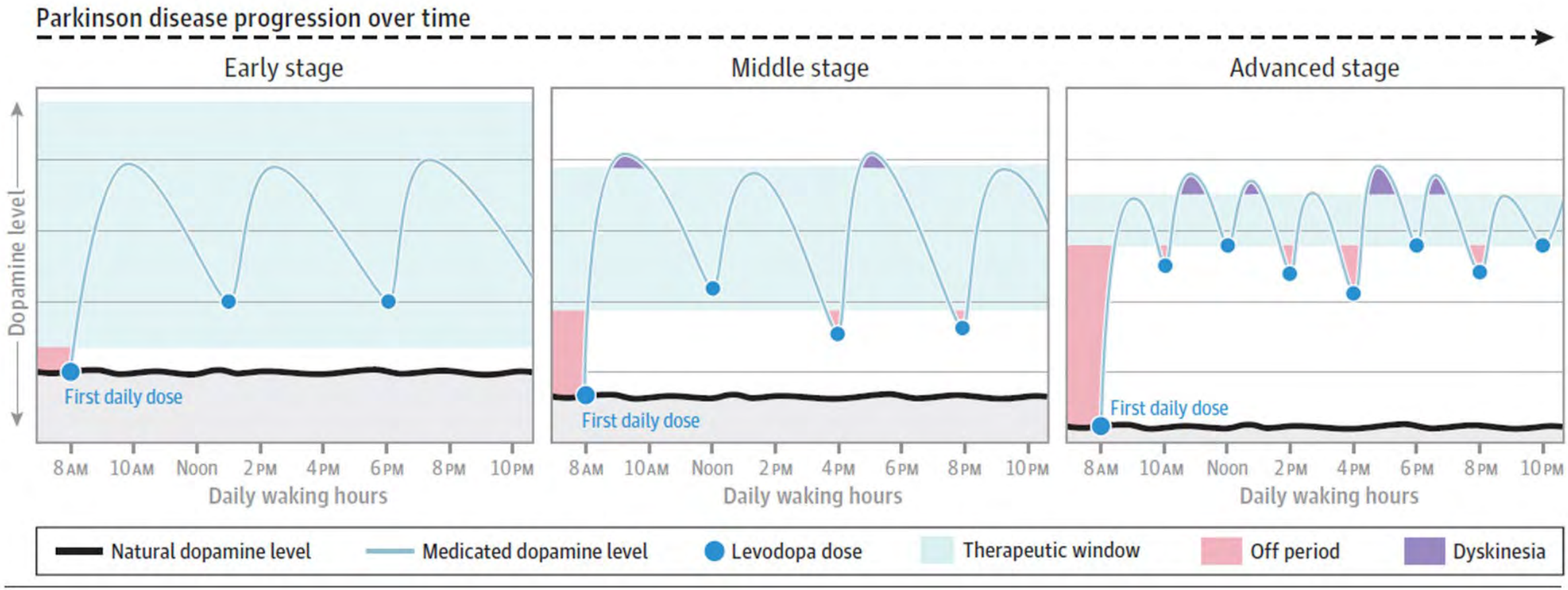
- 20% to 48% of patients with PD will spend time in long-term care
- Age typically 70-80 years old
- Mean stay of 2-3 years
- 50% wheelchair bound
- Reports of more off time, less dyskinesias

- Only 23% of PD patients were on levodopa
- 37% were on dopamine-blocking agents
- 40-50% reported with dementia
- 2-3% with hallucinations and delusions*

Improving Outcomes

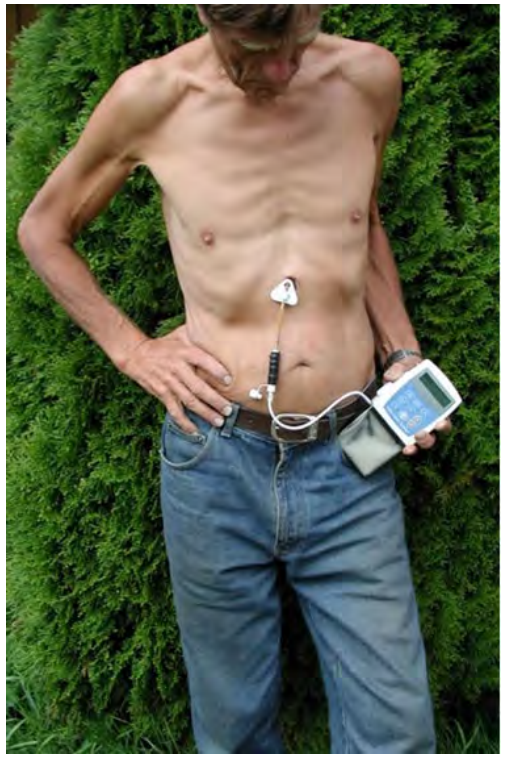
- Continued neurologic follow-up
  - Lower risk of hip fracture
  - Lower adjusted likelihood of death
- Small study of 49 patients where LTC staff underwent PD-specific curriculum, then measured 1 year outcomes:
  - Improved motor function and quality of life
  - Decreased falls, depression and fatigue

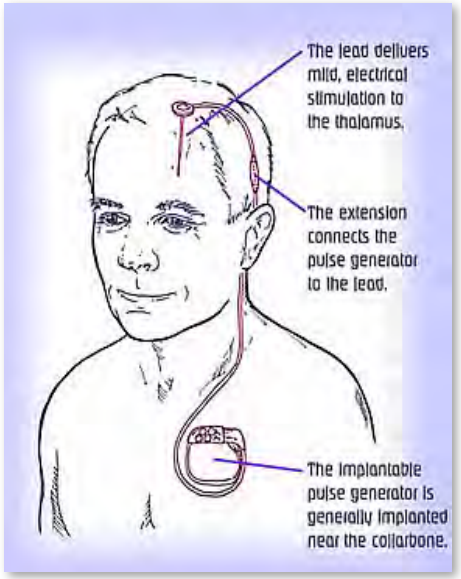

Initial medical therapy
Tremor and/or bradykinesia options
Levodopa preparations
Dopamine agonists
Monoamine oxidase-B inhibitors
Tremor only
Anticholinergic agents (eg, trihexyphenidyl)
Subsequent medical therapy
Increasing doses and add-on therapies for "wearing off"
Levodopa preparations
Monoamine oxidase-B inhibitors
Istradefylline
Dopamine agonists
Catechol-O-methyltransferase inhibitors
Amantadine (primarily for dyskinesia)
Advanced therapy
Tremor and/or bradykinesia options
Levodopa carbidopa enteral suspension infusion
Unilateral or bilateral deep brain stimulation
• Subthalamic nucleus
• Globus pallidus interna
Tremor only
Unilateral focused ultrasound thalamotomy
Unilateral or bilateral deep brain stimulation (thalamus)
Rehabilitative therapy
For all symptoms and across all disease stages
Exercise
Physical therapy
Occupational therapy
Speech therapy

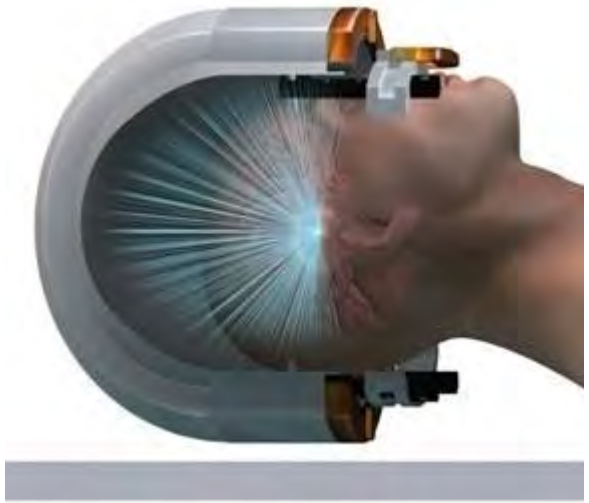


***Dyskinesias are not inherently problematic – ask the patient!

Advanced Therapeutics







March 22, 2023

AbbVie Provides Regulatory Update on ABBV-951 (Foscarbidopa/Foslevodopa) New Drug Application

Non-motor symptoms of Parkinson's

Photo from APDA

Parkinson’s Disease Dementia

- Over 75% of PWP for 15 years or more have MCI or dementia
- Characterized by decline in executive function and visuospatial domains more so than working memory and language
- Hallucinations are common – well formed, complex, animals or people
- Acetylcholinesterase (AChE) inhibitors do help!

  Rivastigmine approved for PDD and DLB

Photo from Vice.com

PDD and Psychosis: MDS Recommendations

+ Haloperidone, risperidone, aripiprazole

TABLE 6. Interventions to treat psychosis in PD

Drug	Efficacy	Safety[a]	Practice implications
Clozapine	Efficacious	Acceptable risk with specialized monitoring	Clinically useful
Olanzapine	*Not efficacious*	Unacceptable risk	*Not useful*
Quetiapine	Insufficient evidence	Acceptable risk without specialized monitoring	*Possibly useful*[b]
Pimavanserin	*Efficacious*	*Acceptable risk without specialized monitoring*[c]	*Clinically useful*

Constipation and Urination

Constipation

- Very common, prodromal symptom
- Slow motility
- Probiotics likely efficacious
- Some caution on bulking agents if patient does not hydrate

Urination

- Typically overactive bladder: nocturia, frequency, urgency
- Strong caution in using antimuscarinics
- Beta-3-adrenergics have less CNS effect
  - Mirabegron only one studied in PD
- Botulinum toxin injections

Dysphagia

- Evaluation indicated at first visit!
- Ask about post-swallowing cough or gurgle, choking, unintentional weight loss, food retention sensation, **pneumonia**
- Any of the above -> SLP evaluation and swallow study
- Patients often unaware!

  20% of PD patients will have swallowing abnormalities without complaint of difficulty subjectively

Image from: https://www.uofmhealth.org/health-library/tf7235

Orthostatic Hypotension

- Experience by over a third of PD patients
- Neurogenic, but beware concomitant BP meds and hypovolemia confounding
- Includes notable post-prandial hypotension
- Patient may have difficulty describing – consider profound fatigue/sleepiness after meals, unexplained falls/syncope
- Diagnosis:
  - Measure BP and HR while lying, sit up then wait 3 min then repeat, stand up then wait 3 min then repeat
  - Argument between 20 pt or 30 pt systolic drop without HR increase response.
- Treatment
  - Non-pharmacologic: hydration, behavioral changes, small meals, compression stockings and abdominal binders, review dopaminergic therapy
  - Medication
    - Midodrine
    - Fludrocortisone (must be taking in enough water and salt)
  - If supine HTN occurs, consider short acting anti-HTN medications

Palliative Care

- Provide early and often – consider at time of diagnosis
- Improves QOL, decreases symptom burden and reduces hospital deaths
- Non-motor symptom burden increases
  - Pain
  - Depression, anxiety
- Discuss ACP yearly (though avoid immediately after diagnosis)
- Provides caregiver support
- Consider the surprise question

- "PD challenges personhood"
  - Independence
  - Appearance
  - Social relationships
  - Identity
- Socializing is critical – isolation affects QOL and mortality
- Consider spiritualism and religion

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THANK YOU

Practical Tips for Deprescribing in Older Adults

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Disclosure Slide

- Dr. Linnebur has the following conflicts of interest related to this presentation:
  - ✓Dr. Linnebur is a member of the Expert Panel for the 2023 Updated AGS Beers Criteria® and was a member of the 2019, 2015, and 2012 expert panels

Objectives

- Apply shared decision-making principles and strategies when deprescribing
- Incorporate deprescribing pathways into clinical treatment plans
- Utilize online tools to effectively deprescribe

Deprescribing Through Shared Decision Making

Step 1
- Creating awareness that options exist

Step 2
- Discussing the options and their benefits and harms

Step 3
- Exploring patient preferences for the different options

Step 4. Making the decision

DEPRESCRIBE

Jansen J et al. BMJ 2016;353:i2893 doi: 10.1136/bmj.i2893

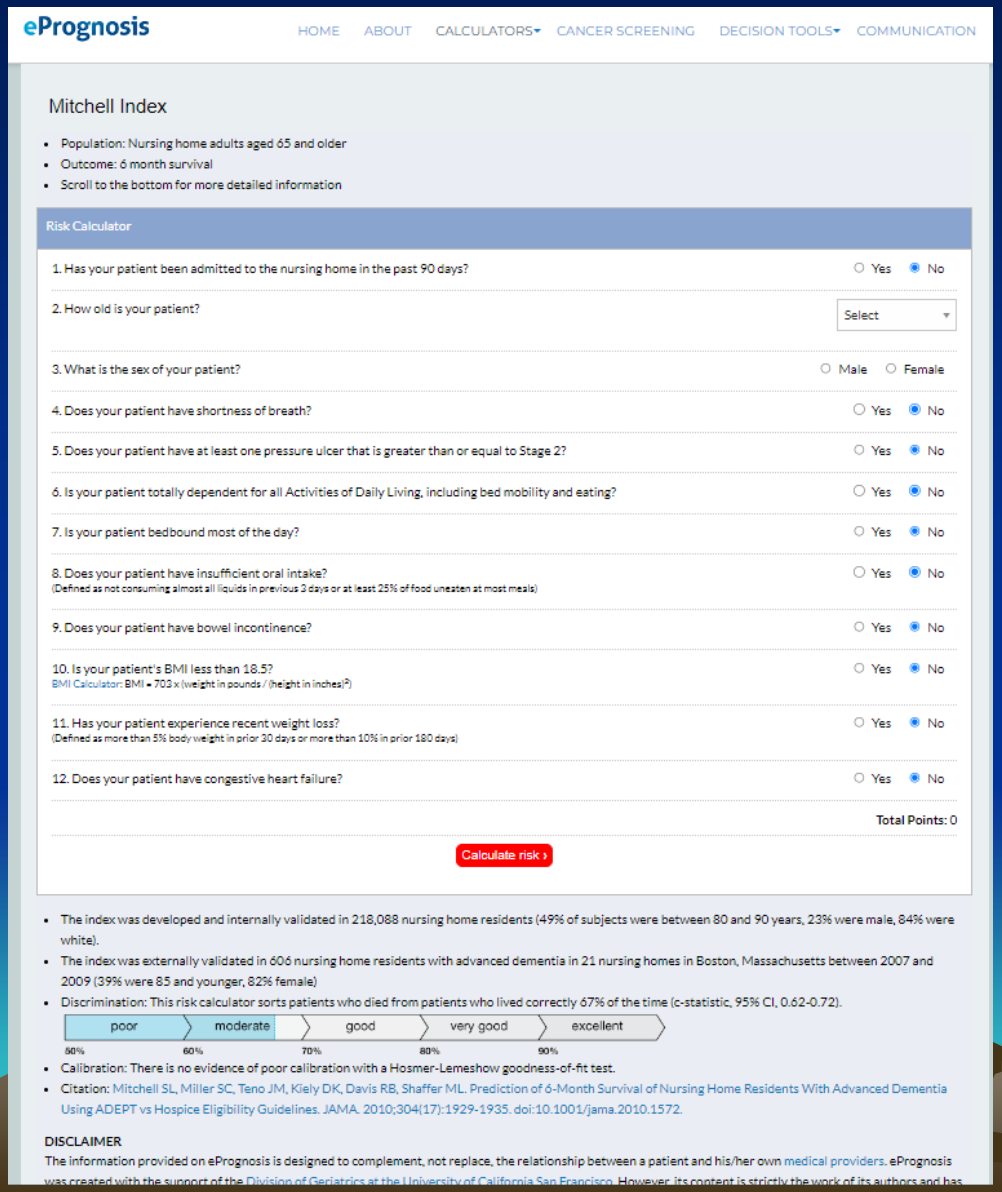
Goals of Care and Time to Benefit

Treatment Decisions in Older Adults

- Consider goals of care
  - ✓How frail is the patient?
  - ✓Is the patient more interested in palliative care or prevention meds/tx?
  - ✓What are the patient's QOL goals?
- Consider time to benefit: the time between when an intervention is initiated & when improved health outcomes occur
- To identify which patients are more likely to be helped vs harmed
  - ✓Compare time to benefit vs life expectancy

Lee SJ, Leipzid RM, Walter LC. JAMA 2013;310(24):2609-10. **Br J Gen Pract 2017; DOI: https://doi.org/10.3399/bjgp17X690533**

http://eprognosis.ucsf.edu



Making Smart Decisions: Time to Benefit vs Time to Harm

- Statins (3 years) vs prostate cancer screening (10 years)
- Immunizations: side effects immediate, benefit at 2 wks
- Pain treatment: side effects immediate, benefit immediately
- HTN treatment: hypotension immediate, benefit 6-12 mo later
- Bisphosphonates: side effects immediate, benefit 12 mo later
- Hypoglycemic agents: hypoglycemia immediate, benefit months to years later
- Aspirin: side effects immediate, reduction in CV events may take several years if it is being used for primary prevention

Lee SJ, LeipziG RM, Walter LC. JAMA 2013;310(24):2609-10.; JAMA Intern Med. 2021;181(2):179-185

Less Aggressive Treatment: ADA 2023 Standards of Care for Older Adults

Table 13.1—Framework for considering treatment goals for glycemia, blood pressure, and dyslipidemia in older adults with diabetes

Patient characteristics/ health status	Rationale	Reasonable A1C goal‡	Fasting or preprandial glucose	Bedtime glucose	Blood pressure	Lipids
Healthy (few coexisting chronic illnesses, intact cognitive and functional status)	Longer remaining life expectancy	<7.0–7.5% (53–58 mmol/mol)	80–130 mg/dL (4.4–7.2 mmol/L)	80–180 mg/dL (4.4–10.0 mmol/L)	<130/80 mmHg	Statin, unless contraindicated or not tolerated
Complex/intermediate (multiple coexisting chronic illnesses* or two or more instrumental ADL impairments or mild-to-moderate cognitive impairment)	Intermediate remaining life expectancy, high treatment burden, hypoglycemia vulnerability, fall risk	<8.0% (64 mmol/mol)	90–150 mg/dL (5.0–8.3 mmol/L)	100–180 mg/dL (5.6–10.0 mmol/L)	<130/80 mmHg	Statin, unless contraindicated or not tolerated
Very complex/poor health (LTC or end-stage chronic illnesses** or moderate-to-severe cognitive impairment or two or more ADL impairments)	Limited remaining life expectancy makes benefit uncertain	Avoid reliance on A1C; glucose control decisions should be based on avoiding hypoglycemia and symptomatic hyperglycemia	100–180 mg/dL (5.6–10.0 mmol/L)	110–200 mg/dL (6.1–11.1 mmol/L)	<140/90 mmHg	Consider likelihood of benefit with statin

https://diabetesjournals.org/care/article/46/Supplement_1/S216/148044/13-Older-Adults-Standards-of-Care-in-Diabetes-2023

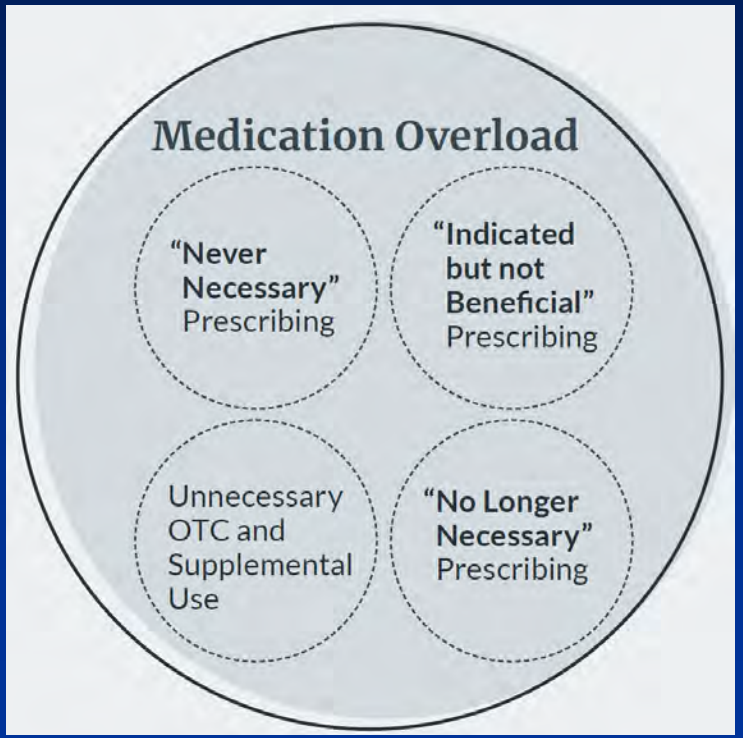
ADA Algorithm: Simplification of Complex Insulin Therapy

- Change timing of basal insulin from evening to morning
- Stop sliding scale insulin
- How to titrate basal insulin based on fasting blood glucose
- How to stop mealtime insulin and start non-insulin options to replace it
  - ✓ Examples: metformin, GLP-1 agonists, DPP4-inhibitors, SGLT-2 inhibitors, pioglitazone
- Make changes to insulin regimen every 1-2 weeks

https://care.diabetesjournals.org/content/44/Supplement_1/S168

Drugs to Consider Deprescribing

- Never necessary medications
- Indicated but not beneficial medications
- No longer necessary medications
- Unnecessary OTC meds and supplements
- Drugs causing side effects
- Drugs that the patient is interested in stopping
- Trade drugs for non-pharmacologic approaches

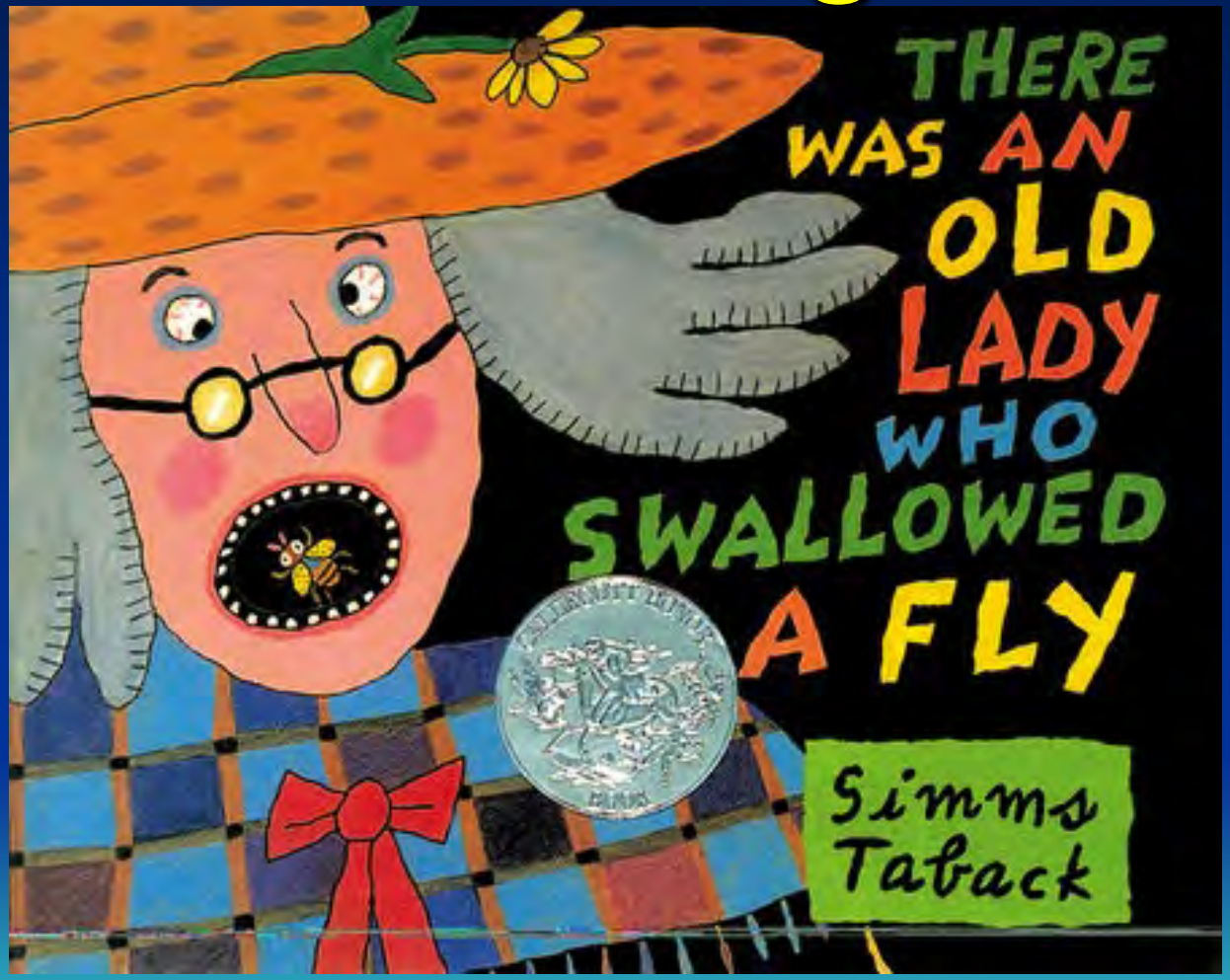


“Never Necessary Prescribing”

- **Drugs with a high risk and low benefit or with safer alternatives**
  - ✓Example: Drugs on the AGS Updated Beers Criteria®
- **Drugs that are intended to be short-term but are continued long-term**
  - ✓Examples: PPIs for ulcer ppx or treatment; Albuterol inhaler for an acute respiratory infection
- **Drugs initiated as part of the prescribing cascade**

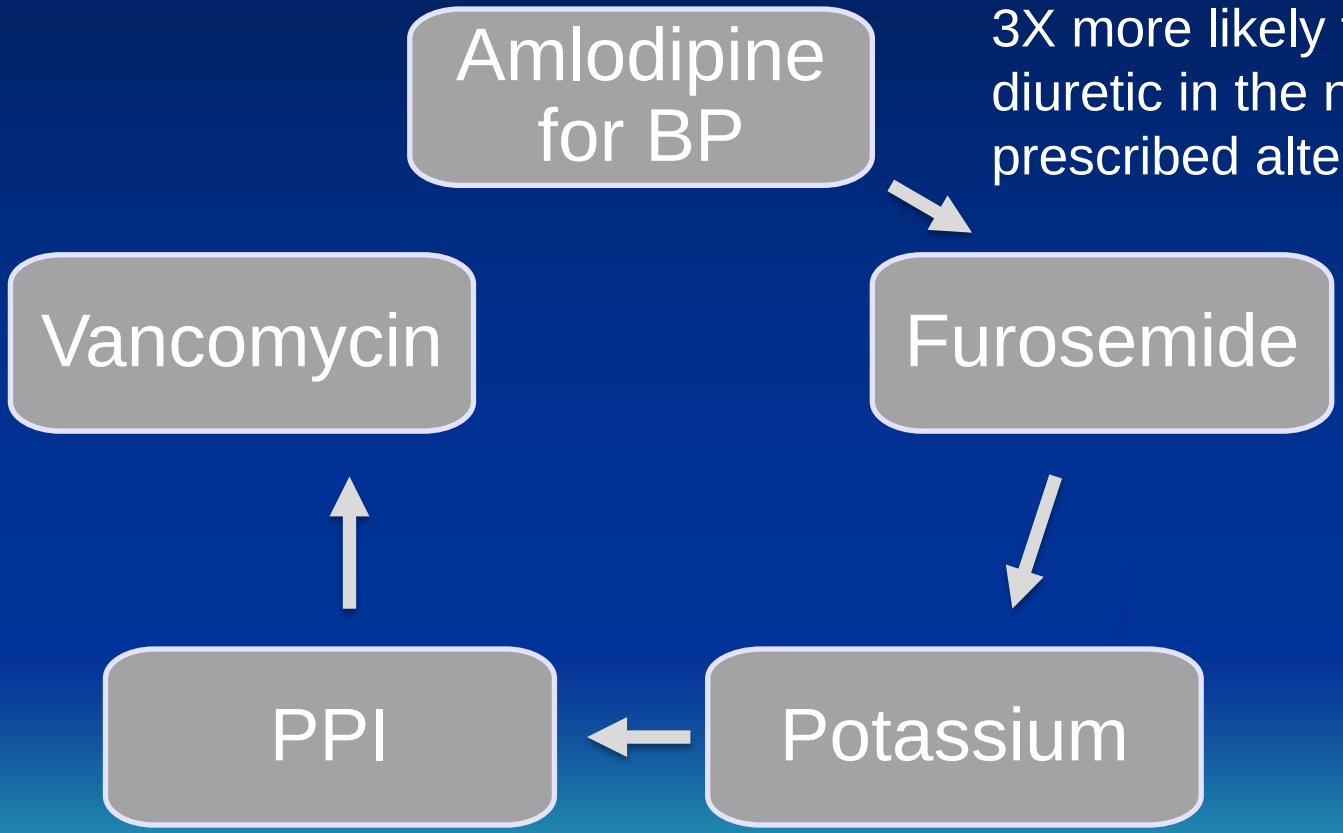
2023 Updated AGS Beers Criteria®…Coming Soon

The Prescribing Cascade



Prescribing Cascade Example

Older adults taking CCBs are 2-3X more likely to be prescribed a diuretic in the next 90 days than if prescribed alternate drug



JAMA Intern Med. 2020;180(5):643-651. doi:10.1001/jamainternmed.2019.7087

Avoiding the Prescribing Cascade

- For any new symptoms, if reasonable investigate drug causes 1st!
  - ✓ Ask your pharmacist to review drug databases and 1° literature
  - ✓ Many side effects are predictable and easy to identify
  - ✓ Rare side effects often occur in older adults
- Review for temporal relationship
- Laboratory measurements may be helpful
- Discontinue the drug or reduce the dose and monitor for symptom resolution
- If necessary, consider drug rechallenge

Other Prescribing Cascade Examples

Sertraline	→	Loperamide
Spironolactone + lisinopril	→	Kayexelate
Carvedilol	→	Albuterol, oxybutynin
Cholinesterase inhibitors	→	Oxybutynin, other bladder meds

“Indicated but Not Beneficial Prescribing”

- **Drugs that have lost their effects or only provide modest benefit**
  - ✓Example: dementia meds, sulfonylureas, antimuscarinics for UI
- **Drugs that will not be effective or show benefit in the remaining life span of the patient**
  - ✓Example: statin for primary prevention
- **Drugs that have drug-drug interactions so they are not absorbed**
  - ✓Examples: PPI + calcium carbonate/bisacodyl/clopidogrel

“No Longer Necessary Prescribing”

- **Drugs indicated for a certain time frame but never stopped**
  - ✓ Examples: bisphosphonates, anticoagulants, antiplatelets, PPIs, antidepressants, metoclopramide, estrogen
- **Drugs no longer necessary due to changes in goals of care**
  - ✓ Examples: bisphosphonates, statins, ASA, dementia meds, vitamins and minerals (e.g. calcium, vit D, vit B12)
- **Drugs used to treat a condition too aggressively**
  - ✓ Examples: DM or HTN treatment

“Unnecessary OTC and Supplement Use”

Can cause harm

- Aspirin
- Ibuprofen and naproxen
- Diphenhydramine
- Pseudoephedrine
- Omeprazole/PPIs

Often no long-term indication or data

- Multivitamins
- Fish oil
- Probiotics
- Vitamin C
- Almost everything else

EXCEPTIONS: vitamin D and B12, folate, calcium, iron, melatonin, diclofenac gel, acetaminophen, and AREDS2

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781119

Trade Drugs for Non-Pharmacologic Approaches

- Counseling/cognitive behavioral therapy/virtual reality
- Facility activities/social events
- Music therapy
- Physical therapy
- Exercise
- Heat/ice

Deprescribing Tips and Tools

Starting medications is like the bliss of marriage and stopping them is like the agony of divorce...

--Doug Danforth

General Tips to Overcome Barriers to Deprescribing

- Add in prescription drug checkups to visits
  - ✓Perform after hospitalizations as well
- View discontinuation of drugs as part of the normal prescribing process and use shared decision making
  - ✓Discuss options with patient/family and rationale for deprescribing, consider discussion of side effects and changes associated with aging
    - Continuation may cause harm
    - Discontinuation may cause harm
  - ✓Educate patient/family and monitor for harm

Common Drugs To Consider Deprescribing

- ✓Proton pump inhibitors
- ✓Benzodiazepines
- ✓NSAIDs
- ✓Anticholinergics
- ✓Insulin
- ✓Sulfonylureas
- ✓Sedative hypnotics
- ✓Antipsychotics
- ✓Statins
- ✓ASA
- ✓Cholinesterase inhibitors
- ✓Memantine
- ✓OTCs/supplements

To Taper or Not to Taper?

Best to Taper

- Beta-blockers
- Clonidine
- Benzodiazepines
- Antidepressants
- Antipsychotics
- Opioids
- Pregabalin/gabapentin
- Proton pump inhibitors
- Estrogen

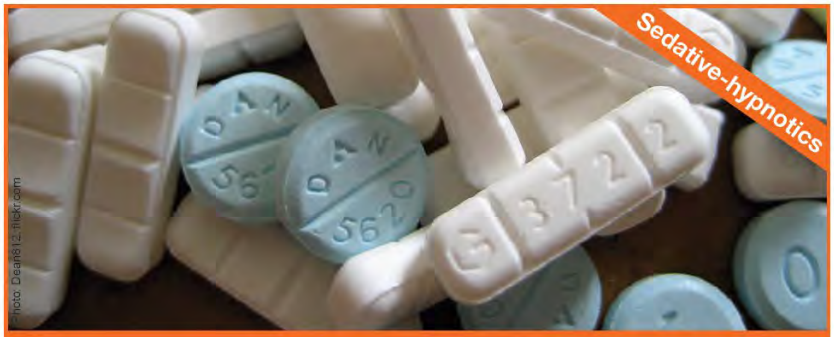
Generally No Taper Needed

- ACE-Is, ARBs, diuretics
- Statins
- Anticholinergics
- NSAIDs and aspirin
- Insulin, sulfonylureas, metformin
- Cholinesterase inhibitors
- OTCs and supplements

www.deprescribing.org
www.deprescribingnetwork.ca

- Deprescribing educational tools for patients and caregivers
- Deprescribing algorithms and videos for clinicians
- Deprescribing patient decision aids
- Non-drug advice

- PPIs, benzodiazepines, Z-drugs, antihyperglycemic agents, antipsychotics, cholinesterase inhibitors/memantine
- Studies: JAMA Intern Med. 2014;174(6):890-898. J Am Geriatr Soc 2018;66:1186–1189



You May Be at Risk

You are taking one of the following sedative-hypnotic medications:

- Alprazolam (Xanax®)
- Bromazepam (Lectopam®)
- Chlorazepate
- Chlordiazepoxide-amitriptyline
- Clidinium-chlordiazepoxide
- Clobazam
- Clonazepam (Rivotril®, Klonopin®)
- Diazepam (Valium®)
- Estazolam
- Flurazepam
- Loprazolam
- Lorazepam (Ativan®)
- Lormetazepam
- Nitrazepam
- Oxazepam (Serax®)
- Quazepam
- Temazepam (Restoril®)
- Triazolam (Halcion®)
- Eszopiclone (Lunesta®)
- Zaleplon (Sonata®)
- Zolpidem (Ambien®, Intermezzo®, Edluar®, Sublinox®, Zolpimist®)
- Zopiclone (Imovane®, Rhovane®)

CIHR IRSC · iugm Institut universitaire de gériatrie de Montréal · Université de Montréal · La Chaire pharmaceutique Michel-Saucier en santé et vieillissement · CaDeN Canadian Deprescribing Network

SO ASK YOURSELF:

YES OR NO?

Have you been taking this sedative-hypnotic drug for a while?	○Y ○N
Are you often tired and groggy during the day?	○Y ○N
Do you ever feel hungover in the morning, even though you have not been drinking?	○Y ○N
Do you ever have problems with your memory or your balance?	○Y ○N

AS YOU AGE

Age-related changes take place in your body and modify the way you process medications. Drugs stay in your body longer and diminished liver function and poor blood flow to your kidneys may increase side effects. The chances you will take more than one medication increases as you age, as does your likelihood of having multiple chronic illnesses.

Unfortunately, this important information is often not passed on to patients who are taking this drug. Please consult your doctor, nurse or pharmacist to discuss this further. Alternative therapies could relieve your anxiety or improve your sleep with fewer side effects and improved quality of life.

www.deprescribingnetwork.ca.

DEPRESCRIBING: REDUCING MEDICATIONS SAFELY TO MEET LIFE'S CHANGES

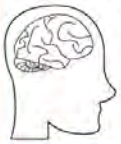
deprescribing.org

FOCUS ON BENZODIAZEPINE RECEPTOR AGONISTS & Z-DRUGS (BZRAs)

As life changes, your medication needs may change as well. Medications that were once good for you, may not be the best choice for you now.

Deprescribing is a way for health care providers to help you safely cut back on medications.

WHAT ARE BENZODIAZEPINE RECEPTOR AGONISTS & Z-DRUGS?



- Drugs used to treat problems like anxiety or difficulty sleeping
- Examples include:
  - Alprazolam (Xanax®)
  - Bromazepam (Lectopam®)
  - Chlordiazepoxide (Librax®)
  - Clonazepam (Rivotril®)
  - Clorazepate (Tranxene®)
  - Diazepam (Valium®)
  - Flurazepam (Dalmane®)
  - Lorazepam (Ativan®)
  - Nitrazepam (Mogadon®)
  - Oxazepam (Serax®)
  - Temazepam (Restoril®)
  - Triazolam (Halcion®)
  - Zopiclone (Imovane®, Rhovane®)
  - Zolpidem (Sublinox®)

WHY CONSIDER REDUCING OR STOPPING A BZRA BEING USED FOR INSOMNIA?

- BZRAs can cause dependence, memory problems, daytime fatigue, and are linked to dementia and falls
- Many could take them for short periods (up to **4 weeks**) but remain on them for years
- BZRAs are not recommended at all (regardless of duration) in older persons as first line therapy for insomnia
- BZRAs may become less helpful for sleep after only a few weeks

HOW TO SAFELY REDUCE OR STOP A BZRA

- Ask your health care provider to find out if deprescribing is for you; BZRA doses should be reduced slowly with supervision
- Tell your health care provider about the BZRA deprescribing algorithm, available online: http://deprescribing.org/resources/deprescribing-guidelines-algorithms/
- Download the BZRA patient information pamphlet available online: http://deprescribing.org/resources/deprescribing-information-pamphlets/

Ask questions, stay informed and be proactive.

Reference

Pottie K, Thompson W, Davies SJC, Grenier J, Sadowski CA, Welch V, et al. Deprescribing benzodiazepine receptor agonists: an evidence-based clinical practice guideline. *Can Fam Physician*. In press.

Bruyère

6 STEPS TO ENSURE A GOOD NIGHT'S SLEEP

STEP 1 - Start a sleep diary

Familiarize yourself with your baseline sleep profile to help you determine the best strategy to implement.

STEP 2 - Develop good sleep habits

Developing good sleep habits will improve your sleep.

STEP 3 - Dispel myths

Correct any false beliefs you may have concerning sleep.

STEP 4 - Manage daily stress

Various issues have an impact on sleep as you age: medical and psychological issues, medications, lifestyle changes (retirement for example), biological factors, or pain.

STEP 5 - Benefit from good sleep hygiene

Avoid caffeine, nicotine, alcohol and exercises before going to bed. The bedroom should be sleep-inducing: dark, quiet and at a comfortable temperature.

STEP 6 - Taper off sleeping pills

Follow the tapering-off program provided on page 19 under the supervision of your doctor or your pharmacist, if you are currently taking sleeping pills.

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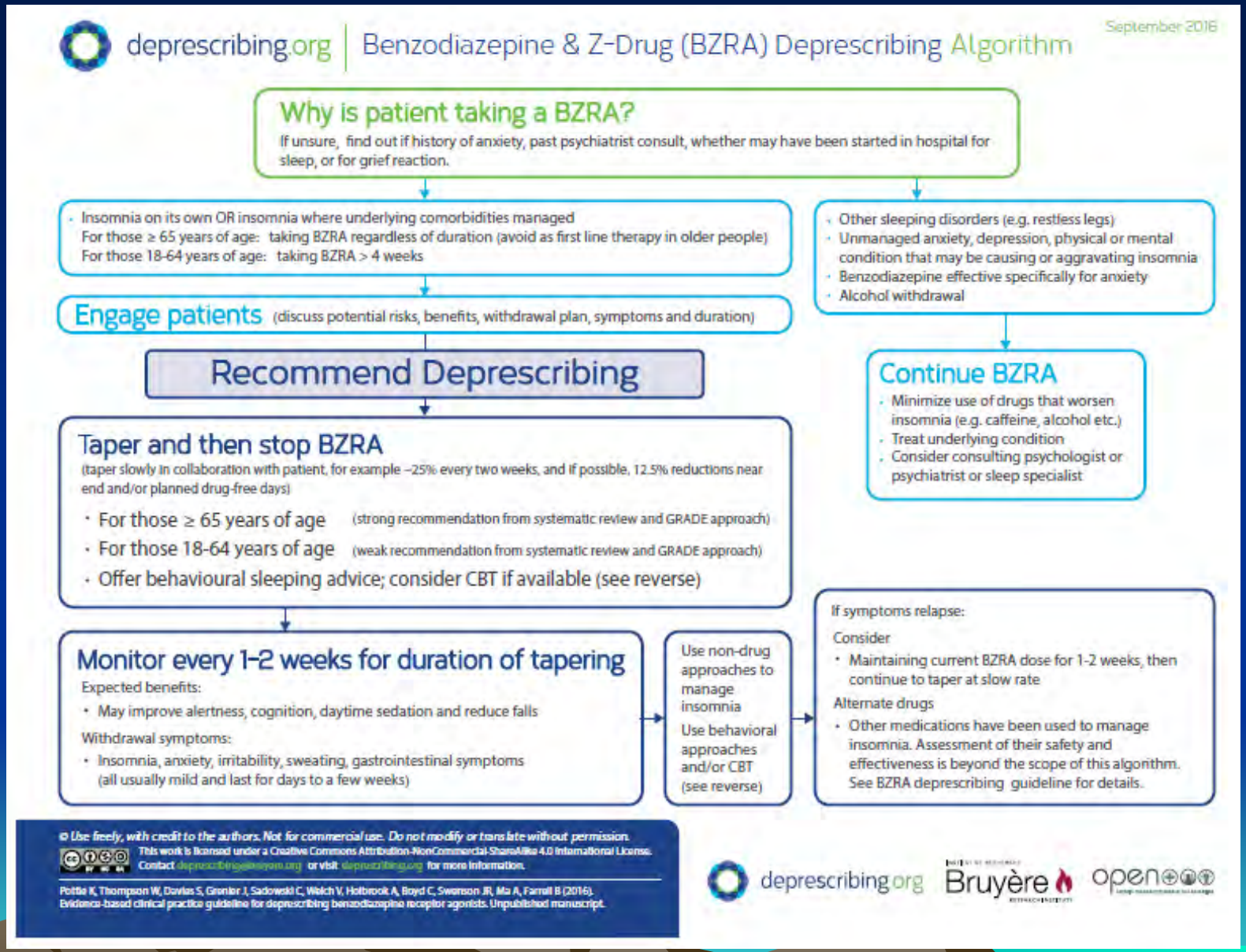
deprescribing.org | Benzodiazepine & Z-Drug (BZRA) Deprescribing Algorithm
September 2016
Why is patient taking a BZRA?
If unsure, find out if history of anxiety, past psychiatrist consult, whether may have been started in hospital for sleep, or for grief reaction.
Insomnia on its own OR insomnia where underlying comorbidities managed
For those ≥ 65 years of age: taking BZRA regardless of duration (avoid as first line therapy in older people)
For those 18-64 years of age: taking BZRA > 4 weeks
Other sleeping disorders (e.g. restless legs)
Unmanaged anxiety, depression, physical or mental condition that may be causing or aggravating insomnia
Benzodiazepine effective specifically for anxiety
Alcohol withdrawal
Engage patients (discuss potential risks, benefits, withdrawal plan, symptoms and duration)
Recommend Deprescribing
Continue BZRA
Minimize use of drugs that worsen insomnia (e.g. caffeine, alcohol etc.)
Treat underlying condition
Consider consulting psychologist or psychiatrist or sleep specialist
Taper and then stop BZRA
(taper slowly in collaboration with patient, for example ~25% every two weeks, and if possible, 12.5% reductions near end and/or planned drug-free days)
For those ≥ 65 years of age (strong recommendation from systematic review and GRADE approach)
For those 18-64 years of age (weak recommendation from systematic review and GRADE approach)
Offer behavioural sleeping advice; consider CBT if available (see reverse)
Monitor every 1-2 weeks for duration of tapering
Expected benefits:
May improve alertness, cognition, daytime sedation and reduce falls
Withdrawal symptoms:
Insomnia, anxiety, irritability, sweating, gastrointestinal symptoms (all usually mild and last for days to a few weeks)
Use non-drug approaches to manage insomnia
Use behavioral approaches and/or CBT (see reverse)
If symptoms relapse:
Consider
Maintaining current BZRA dose for 1-2 weeks, then continue to taper at slow rate
Alternate drugs
Other medications have been used to manage insomnia. Assessment of their safety and effectiveness is beyond the scope of this algorithm. See BZRA deprescribing guideline for details.
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This work is licensed under a Creative Commons Attribution-NonCommercial-ShareAlike 4.0 International License.
Contact deprescribing@ohri.ca or visit deprescribing.org for more information.
Pottie K, Thompson W, Davies S, Grenier J, Sadowski C, Welch V, Holbrook A, Boyd C, Swenson JR, Ma A, Farrell B (2016). Evidence-based clinical practice guideline for deprescribing benzodiazepine receptor agonists. Unpublished manuscript.
deprescribing.org
Bruyère
open

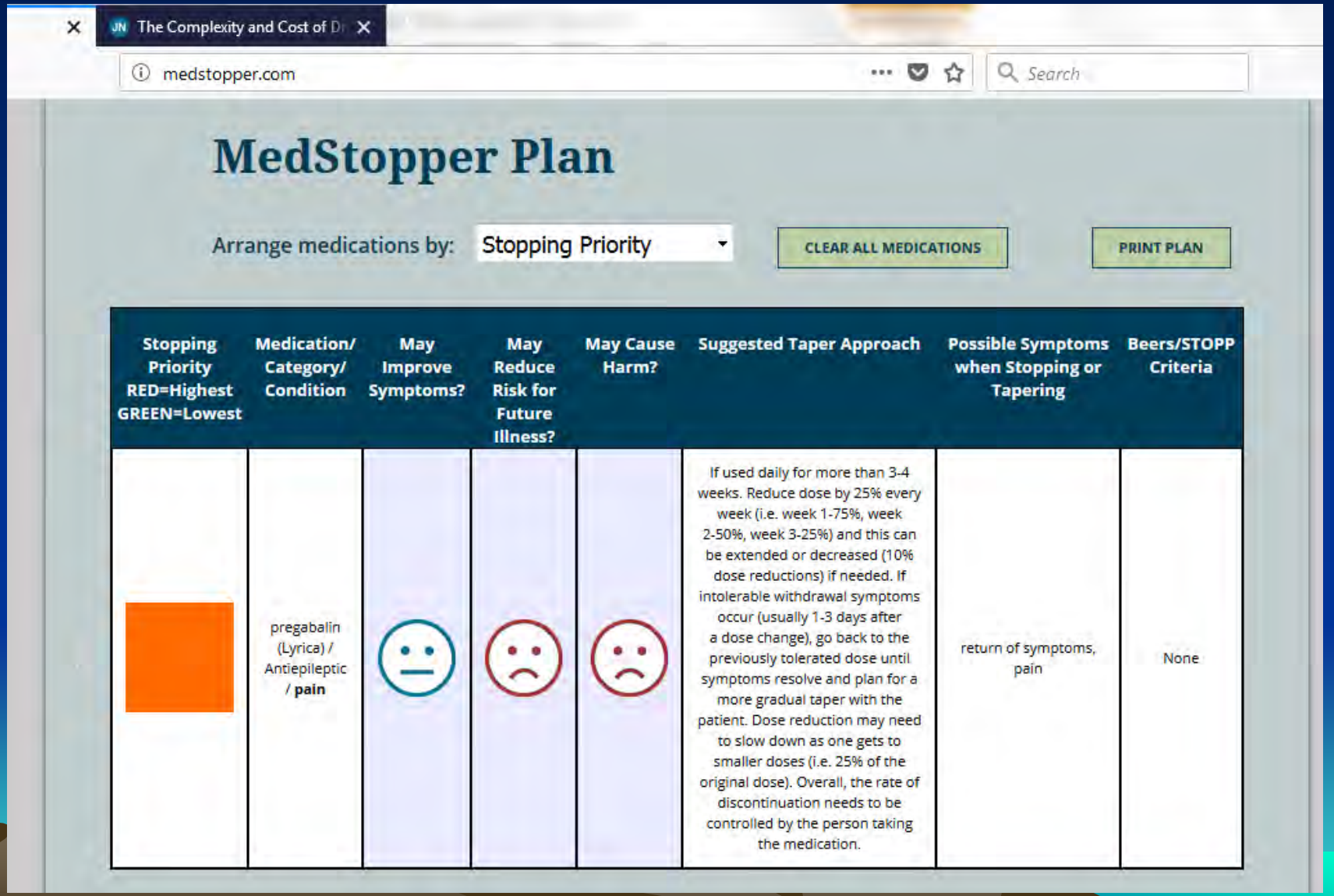
US Deprescribing Research Network (USDeN)

- https://deprescribingresearch.org/
- Links to Canadian, Australian, and UK deprescribing tools
- Links to articles discussing deprescribing and potentially inappropriate medications
- Webinars for researchers and clinicians

MedStopper.Com

- Provides guidance for deprescribing with risk/benefit for each drug
- Medications can be arranged by either stopping priority or by condition
- For some medications/indications, just below the faces, there are CALC and NNT links for more information.
- Includes suggested tapering approach if applicable
- If the medication is listed in either the Beers or STOPP criteria, click the details button and the specific criteria form these tools will be provided in a popup

MEDSTOPPER.COM



MedStopper Plan

Arrange medications by: Stopping Priority

CLEAR ALL MEDICATIONS

PRINT PLAN

Stopping Priority RED=Highest GREEN=Lowest	Medication/ Category/ Condition	May Improve Symptoms?	May Reduce Risk for Future Illness?	May Cause Harm?	Suggested Taper Approach	Possible Symptoms when Stopping or Tapering	Beers/STOPP Criteria
	pregabalin (Lyrica) / Antiepileptic / **pain**	😐	☹	☹	If used daily for more than 3-4 weeks. Reduce dose by 25% every week (i.e. week 1-75%, week 2-50%, week 3-25%) and this can be extended or decreased (10% dose reductions) if needed. If intolerable withdrawal symptoms occur (usually 1-3 days after a dose change), go back to the previously tolerated dose until symptoms resolve and plan for a more gradual taper with the patient. Dose reduction may need to slow down as one gets to smaller doses (i.e. 25% of the original dose). Overall, the rate of discontinuation needs to be controlled by the person taking the medication.	return of symptoms, pain	None

TaperMD (taperMD.com)

- Medication Therapy Management and Drug Review Tool (for a fee)
  - ✓Dashboard with EHR integration with PointClickCare
  - ✓Tracking and exporting of reports related to patient progress, recommendations, and monitoring plan
- Deprescribing resources: guidelines, algorithms, guides for many drugs (free)
- Taper guidance, withdrawal symptoms and monitoring guidance for many drugs (free)

MedSafer https://www.medsafer.org/

- Deprescribing software integrated with PointClickCare in Canada

ORIGINAL RESEARCH

MedSafer to Support Deprescribing for Residents of Long-Term Care: a Mixed-Methods Study

Giulia-Anna Perri, MD[1*], Émilie Bortolussi-Courval, CPN[2*], Christopher D. Brinton, BSc[1], Anna Berall, RN[1], Anna Theresa Santiago, MPH, MSc[1], Mareiz Morcos, RPh, PharmD, PMP[4], Todd C. Lee, MD, MPH[2,3], Emily G. McDonald, MD, MSc[2,3]

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[*]These authors contributed equally to this paper

https://doi.org/10.5770/cgj.25.545

JAMA Internal Medicine | Original Investigation | LESS IS MORE

The MedSafer Study—Electronic Decision Support for Deprescribing in Hospitalized Older Adults

A Cluster Randomized Clinical Trial

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https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2788297; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9156423/

Example Deprescribing

89 y/o man with dementia and atrial fibrillation

Deprescribing Considerations for Each Drug

- ✓ Is the patient receiving a benefit from the drug?
- ✓ Do the harm(s) outweigh the benefit?
- ✓ Are the patient's symptoms stable?
- ✓ Is the purpose of the drug preventive or treatment?
- ✓ Will withdrawal symptoms or disease recurrence occur if the drug is stopped?
- ✓ Is tapering required?
- ✓ How should the patient be monitored?

Deprescribing Process

- 1. Review medications for opportunities to deprescribe. You identify simvastatin 40 mg and omeprazole 20 mg daily.
  - ✓Statin indication: primary prevention of CV events, no stroke history
  - ✓PPI indication: GERD, patient currently asymptomatic
- 2. Consider life expectancy and using eprognosis

Deprescribing Process

Mitchell Index

- Population: Nursing home adults aged 65 and older
- Outcome: 6 month survival
- Scroll to the bottom for more detailed information

Risk calculators cannot predict the future for any one individual. Risk calculators give an estimate of how many people with similar risk factors will live and die, but they cannot identify who will live and who will die.

Thank you so much for your time today.

Results Based on Score:
Your total score is **13.7**

Six Month Mortality

Points	Risk of 6 month mortality
1.0 - 6.4	7%
6.5 - 7.9	10%
8.0 - 8.9	13%
9.0 - 9.7	14%
9.8 - 10.5	17%
10.6 - 11.5	20%
11.6 - 12.5	23%
12.6 - 14.0	28%
14.1 - 16.1	34 - 43%
> 16.1	49 - 62%

Finish

- The index was developed and internally validated in 218,088 nursing home residents (49% of subjects were between 80 and 90 years, 23% were male, 84% were white).
- The index was externally validated in 606 nursing home residents with advanced dementia in 21 nursing homes in Boston, Massachusetts between 2007 and 2009 (39% were 85 and younger, 82% female)
- Discrimination: This risk calculator sorts patients who died from patients who lived correctly 67% of the time (c-statistic, 95% CI, 0.62-0.72).

- Calibration: There is no evidence of poor calibration with a Hosmer-Lemeshow goodness-of-fit test.
- Citation: Mitchell SL, Miller SC, Teno JM, Kiely DK, Davis RB, Shaffer ML. Prediction of 6-Month Survival of Nursing Home Residents With Advanced Dementia Using ADEPT vs Hospice Eligibility Guidelines. JAMA. 2010;304(17):1929-1935. doi:10.1001/jama.2010.1572. (https://www.ncbi.nlm.nih.gov/pubmed/21045099)

Deprescribing Process

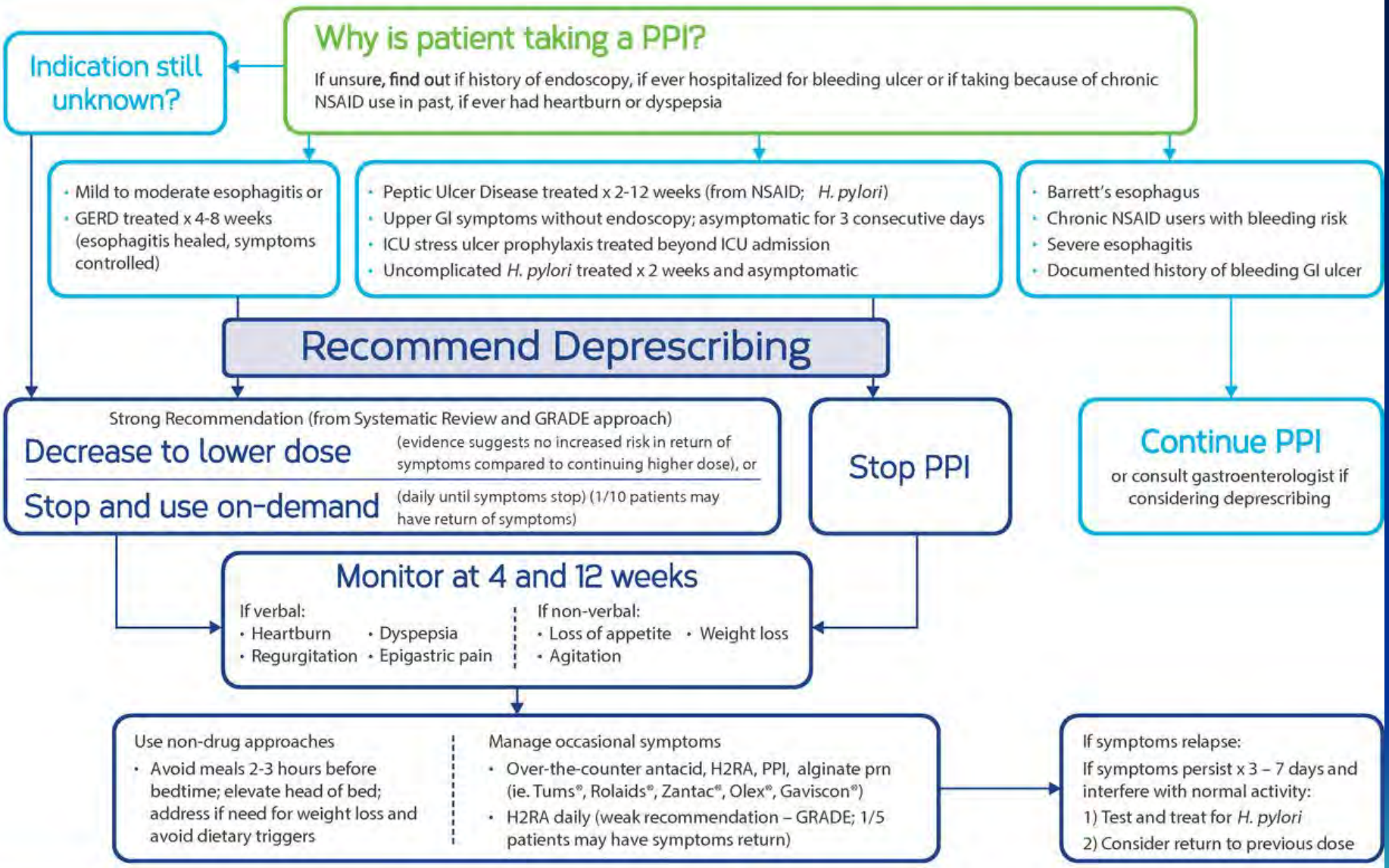
- 3. Consider benefits
  - ✓ Less pill burden, less muscle pain, less GI side effects, less DDIs, lower risk of C. diff/PNA/Mg and B12 deficiency
- Consider risks
  - ✓ Return of GI symptoms; potential increased GI bleed risk if patient is taking a DOAC or ASA
  - ✓ CV events—3 retrospective studies of older adults show ↑ CV risk 2-5 yrs after discontinuation, no increased risk if at end of life
- 4. Do the meds need tapered?
  - ✓ PPI: ideally, yes
  - ✓ Statin: no

Deprescribing Process

- 5. Discontinue simvastatin
- 6. Consider omeprazole taper https://tapermd.com/tapering-resources/proton-pump-inhibitors/
  - ✓ Reduce dose by 50% every 1-2 weeks. Once at 25% of the original dose and no withdrawal symptoms have been seen, stop the drug
  - ✓ If any withdrawal symptoms occur, go back to approximately 75% of the previously tolerated dose
- 7. Construct and document a follow-up plan
  - ✓ Monitor for CV events?: no
  - ✓ Monitor for side effect (GI/muscle pain) resolution: yes
  - ✓ Monitor for return of GERD/heartburn: yes

Figure 1 | Proton Pump Inhibitor (PPI) Deprescribing Algorithm

September 2016



Farrell B, Pottie K, Thompson W, Boghossian T, Pizzola L, Rashid FJ, et al. Deprescribing proton pump inhibitors. Evidence-based clinical practice guideline. *Can Fam Physician* 2017;63:354-64 (Eng), e253-65 (Fr).

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THANK YOU!
QUESTIONS?

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