Public Policy & Advocacy Update

Alex Bardakh, MPP, CAE, PLC
Senior Director, Advocacy & Strategic Partnerships
November 8, 2025

1

Learning Objectives

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

- Describe the current legislative environment
- Describe future trends in value-based care models

2

Where we are now:

- Government Shut Down
- House passed CR; Senate rejected it
  - Would only fund government until Nover 21, 2025
- Healthcare things on the table:
  - Telehealth extension
  - Permanent Physician Fee Schedule Pay Fix
  - Prior authorization
- 10-Day Hold on telehealth claims
  - Submit and hope
  - Do in person visits
  - Take a vacation

3

The Big Issues:

Federal vs. State Implications of OBBA

Federal Implications

- Reduced federal Medicaid investment
- Shift of control from CMS to Congress
- Reduced waiver/innovation flexibility
- Benchmarked federal rate caps (e.g. state directed payment limits)
- Pressure on CMS/CMMI to prioritize oversight over experimentation

State Implications

- Immediate budget shortfalls (provider tax caps)
- Rate freezes or cuts to current programs
- Strained Medicaid agency capacity
- Increased scrutiny of long-term care and HCBS programs
- Less flexibility to implement programs

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Whats IN Whats OUT

OBBA

IN-N-OUT BURGER

IN:

- Medicaid cuts
- Physician payment update of 2.5%
- Delay of implementation of nursing home staffing mandate for 10 years

OUT:

- Telehealth Extension
- Prior authorization reform
- Ban on AI regulations

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The Administration - MAHA

- Prevention
- Fraud and Abuse
- Executive Order 10 to 1 on regulations
- Health IT
- Streamline payment models
- Less regulatory comment periods
- Who is working?
- So far not much on PALTC

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Requests for Information

- CMS request focused on deregulation
- Streamline reporting requirements
- Eliminating waste
- Interoperability

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Centers for Medicare & Medicaid Innovation

- All Medicare beneficiaries in value-based care models by 2030
- Not all value-based care models are built equally
- CMMI "reset" focused on prevention, competition, data transparency
- Sunset expiring models
- Complex Care Alliance seeks to influence CMMI on continuing High Need ACOs
- New Wiser Model focused on fraud and abuse

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Latest: Physician Fee Schedule Proposed Rule

The Good

- Implements 2.5% update to physician fee schedule in 2026
- Provides two conversion factors – slightly higher for those participating in alternative payment models
- Permanently removes all restrictions of frequency of medically necessary visits in nursing homes via telehealth
- Expands use of remote patient monitoring codes
- G2211 add-on code paid in assisted living and home care setting
- More flexibility in MSSP ACO program
- No major MIPS changes

The Bad

- Practice expense adjustment for facility-based codes significantly reduced (SNF/NF differential)
- G2211 NOT reimbursed in the nursing homes

*PALTmed jsubmitted comments and thanks to the many PALTmed members who wrote letters as well!

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Other Big Issues

- AI in healthcare
- Vaccines
- Interoperability
- Nursing Home Survey
- Assisted Living
- PBM Reform
- 3-Day Stay Requirement

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What is PALTmed Doing?

- Continue to develop relationships with new Administration and Members of Congress
- Letter to Congressional leadership on our priorities (https://paltmed.org/news-media/paltmed-calls-congressional-leaders-needed-action-paltc-reforms)
- PALTmed statement on ACIP removal of experts
- PALTmed Statement on Medicaid and role of public health agencies
- Grassroots
- Respond to requests for information
- Participate in key coalitions (Advancing Excellence, Moving Forward, LTPAC HIT Collaborative, Coalition on Prior Authorization, Adult Vaccine Access Coalition, Healthcare Liability and Access Coalition)

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Celebrating Victories

- Florida becomes the second state after California to require certified medical director in all nursing homes!
- Texas introduces legislation to require all medical directors to be certified!
- Higher work RVUs for nursing facility codes!
- Permanent addition of nursing home medically necessary visits with no restrictions to the approved telehealth services list!
- CMS agrees to provide information on medical directors!
- Surveyors required to speak with medical directors in the survey process!
- Prior authorization reform bill introduced in Congress!
- Interoperability use cases for Advance Care Planning/Transitions of Care

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What can I do?

- Stay Informed! Read latest newsletter
- Listen to PALTtalk: Advocacy in Action
- Send letters to my representatives using PALTmed templates (https://paltmed.org/grassroots/#/)
- Participate in PALTmed Advocacy Summit
- Liten to Business of Medicine Symposium Recording
- Get involved locally and participate on State Advocacy Committee
- Utilize PALTmed Forum
- Really dive into understanding value-based care models? What affects me the most?

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ADVOCACY SUMMIT

OCTOBER 27-28, 2025

WWW.PALTMED.ORG/SUMMIT

REGISTRATION IS OPEN!

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CASE 1 PRESENTATION
Recurrent Angina Pectoris

HPI:
70 y.o. female LTC resident at one of your facilities has been complaining of left sided chest discomfort and pain over the past several days. She has just recently recovered from a mild COVID-19 (has completed oral nirmatrelvir/ritonavir), now having been off isolation for 3 days. She was hospitalized for Covid 4 years ago.

She has had a history of recurrent chest pain over the past several years, with quite a few ED visits and extensive negative work-up from cardiologists. Similarly to prior occurrences, she noted left-sided chest pain, with no clear associated trigger, often at rest lying in bed, or waking her up from sleep at night. Pain can be fleeting, or lasting just a few minutes, and sometimes up to half an hour.

The chest pain radiates from the left anterior chest to lateral ribcage, with occasional numbness to the lateral aspect of the upper arm. “My neck, shoulder, and thumb also hurt,” she persistently endorses.

The resident had been independent with wheelchair mobility prior to Covid, and she enjoyed self-propelling herself outside for fresh air. There had been no shortness of breath or chest pain with the above activities, even straying into grassy dirt paths with uneven surfaces.

There has been no recent trauma. The only new activity is the post-Covid re-engagement in the rehab gym by therapy team. For the past week, the resident has been doing stationary bike exercises, and she does endorse some SOB and admits that her neck, shoulder, and hands ache after prolonged stationary bike exercises, with occasional chest pain lasting for about 5 minutes.

The patient has a history of depression and panic disorder, and has become quite anxious regarding her undiagnosed recurrent chest pain and uncertain prognosis. “No doctors seem to know what I have, they all ignore me, am I going to die?”

Today, her son and daughter-in-law came to visit and demanded a re-evaluation of her chest pain ASAP. They have done “research” on line, and said: “We want an answer, is this chest pain due to Long-COVID?”

You reviewed the resident’s medical history with her family.

PMH/COMORBIDITIES:
OA, HTN, HLD, DM 2, depression, panic disorder, COVID-19 x 2 (4 yrs ago and now)

VACCINATIONS:
All up-to-date

SOCIAL HISTORY
Her husband passed away a year ago, and her son placed her in LTC

MEDICATIONS:

Amlodipine 5mg daily, Atorvastatin 40mg daily, Metformin 500mg BID, Escitalopram 10mg daily, Clonazepam 0.25 mg BID, Acetaminophen 650mg QID prn

ROS:
Difficult to perform with patient's anxiety and family hovering

PHYSICAL EXAMINATION:

VS: BP 159/85 HR 95 RR 16 Sat 95% RA

GEN: anxious, sitting up in WC
NECK: limited ROM in all planes. You attempted to passively move her head when the patient screamed "My chest, my chest." Patient clutched her left chest, moaning "my thumb hurts."
HEART: tachycardiac
LUNGS: hyperventilating, decreased BS at bases, poor effort
ABD: Soft NT, BS+
BACK: no CVA tenderness
MSK: motor and sensory grossly intact. LEs neg p/c/e. (+) arthritic changes throughout, pain as base of thumbs, worse on left
NEURO: A&O x 4, grossly non focal findings, unable to test reflexes

You proceeded to discuss w Chest Pain Risk Stratifications with family. Cardiac related chest pain unlikely, and patient does not have long covid currently.

"If it is none of the above, what is it? We want an answer NOW!" Her family demanded. "We want her sent to the ED – NOW – or a re-evaluation!"
Given the situation, you decided to call 911 and sent the resident to the nearest ED.
She was sent back to the facility late evening.

The next morning you came in to see the resident. She looked comfortable, although she would complain of left chest pain, arm pain, and thumb pain when asked.
You remember having sent her out for CP about 9 months ago – her first night at LTC!
Upon review, as usual, the discharge packet from ED the previous evening was full of extraneous automated EHR print-outs of post-discharge instructions but no clinical documentations.

<u>QUESTION 1</u>
Assuming the ED work-up was negative for cardiac (otherwise the ED would have kept the resident), what are your top three possible differential diagnoses?
A.???: _____
B.???: _____
C.???: _____

You called the ED requesting clinical notes

EMERGENCY ROOM WORK UP:
EKG: grossly wnl
CTA: neg PE
CXR: neg PNA
XR Lt hand: severe OA at thumb base

XR Lt shoulder: severe OA at the glenohumeral joint
High-sensitivity troponin I assay: 0.010 ng/ml (negative)
CMP, CBC diff, TSH grossly wnl

QUESTION 2
Now that cardiac etiology had been once again ruled out, what would be the next best test to order at the facility that will give clues to what to do next?
Answer: _____

CASE 2 PRESENTATION

Bilateral Arm Itching

A 59-year-old resident is evaluated for a 3-month history of intermittent itching on the forearms. He describes the itch as deep, with a burning or tingling sensation.
Scratching helps somewhat, but topical corticosteroids have not helped.
Cooling the skin soothes the itch. He did not notice a rash until she started scratching.
The itch gets worse after being in the sun, but sun exposure does not cause redness or a rash.

On physical examination, the resident shows evidence of chronic sun damage on sun-exposed skin, including hyperpigmentation and solar lentigines.
A few excoriations are present on the forearms, but no significant dermatitis is observed.
The patient's sensation on the arms and forearms is normal. Deep tendon reflexes are normal in the biceps, triceps, and brachioradialis.

Which of the following is the most likely diagnosis?
A. Brachioradial pruritus
B. Polymorphous light eruption
C. Prurigo nodularis
D. Solar urticaria

What a Pain in the Where?

Heuristic and Cognitive Biases in Diagnosing Neuromusculoskeletal Symptoms in the Geriatric Population

Dominique Vinh, MD, CMD

Chun-ju Wang, DO

MMDA's 32nd ANNUAL CONFERENCE

Sat 11/08/2025

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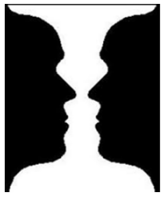

Speaker Disclosures

Dr. Vinh has no relevant financial relationship(s)

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OBJECTIVES

1. Recognize heuristic and cognitive biases in diagnosing clinical symptoms in the geriatric population

2. Identify the elements behind the misattribution of symptoms in the elderly population:
   - Atypical presentation or unawareness of symptoms
   - Cognitive Impairment as barrier to obtaining a history
   - Multiple comorbidities with overlapping symptoms
   - Polypharmacy magnifies cognitive impairment
   - Psychosocial factors contributing to symptomatic manifestation

3. Engaging holistic approach to appropriately address these challenges and to ensure accurate diagnosis and appropriate treatment for this growing segment of the population.

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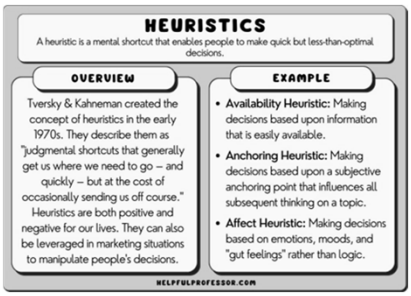
The Pain is Where?



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The Pain is Where?

9:35-10:35 am	**Session #2** – ***Comprehensive Pain Management Workshop*** (1.0) **Dominique Luong Vinh, MD, MBA, CMD**; Adjunct Assistant Professor, Physical Medicine and Rehabilitation, Johns Hopkins School of Medicine Faculty

Will we really be talking about pain management?

Or is this a heuristic assumption based on bounded rationality ?

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Recurrent Angina Pectoris

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The Pain is Where?

CASE PRESENTATION

HPI:

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- She has had a history of recurrent chest pain over the past several years, with quite a few ED visits and extensive negative work-up from cardiologists. Similarly to prior occurrences, she noted left-sided chest pain, with no clear associated trigger, often at rest lying in bed, or waking her up from sleep at night. Pain can be fleeting, or lasting just a few minutes, and sometimes up to half an hour.
- The chest pain radiates from the left anterior chest to lateral ribcage, with occasional numbness to the lateral aspect of the upper arm. "My neck, shoulder, and thumb also hurt," patient persistently endorses.

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The Pain is Where?

CASE PRESENTATION

HPI:

- The resident had been independent with wheelchair mobility prior to Covid, and she enjoyed self-propelling herself outside for fresh air. There had been no shortness of breath or chest pain with the above activities, even straying into grassy dirt paths with uneven surfaces.
- There has been no recent trauma. The only new activity is the post-Covid re-engagement in the rehab gym by therapy team. For the past week, the resident has been doing stationary bike exercises, and she does endorse some SOB and admits that her neck, shoulder, and hands ache after prolonged stationary bike exercises, with an occasional chest pain lasting for about 5 minutes.

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The Pain is Where?

March 04, 2025

COVID-19 Infection Leads to Increased Rates of Chest Pain Six Months to a Year After Infection in Patients, Intermountain Study Finds

CASE PRESENTATION

HPI:

- The patient has a history of depression and panic disorder, and has become quite anxious regarding her undiagnosed recurrent chest pain and uncertain prognosis. "No doctors seem to know what I have, they all ignore me, am I going to die?"
- Today, her son and daughter-in-law came to visit and demanded a re-evaluation of her chest pain ASAP. They have done "research" on line, and said: "We want an answer, is this chest pain due to Long-Covid?"
- You reviewed the resident's medical history with her family.

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The Pain is Where?

CASE PRESENTATION

PMH/COMORBIDITIES:
- OA, HTN, HLD, DM2, depression, panic disorder, COVID-19 x 2 (4 yrs ago and now)

VACCINATIONS:
- All up-to-date

SOCIAL HISTORY
- Her husband passed away a year ago, and her son placed her in LTC

MEDICATIONS:
- Amlodipine 5mg daily, Atorvastatin 40mg daily, Metformin 500mg BID, Escitalopram 10mg daily, Clonazepam 0.25 mg BID, Acetaminophen 650mg QID prn

ROS:
- Difficult to perform with patient's anxiety and family hovering

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CASE PRESENTATION

PHYSICAL EXAMINATION:

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GEN: anxious, sitting up in WC
NECK: limited ROM in all planes. You attempted to passively move her head when the patient screamed "My chest, my chest." Patient clutched her left chest, moaning "my thumb hurts."
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NEURO: A&O x 4, grossly non focal findings, unable to test reflexes

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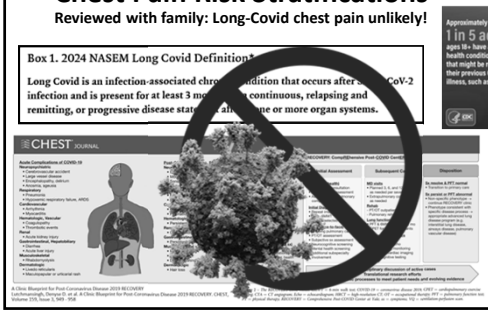
Chest Pain Risk Stratifications

Reviewed with family: Long-Covid chest pain unlikely!



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Chest Pain Risk Stratifications

Reviewed with family: Cardiac related chest pain unlikely!

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The Pain is Where?


CASE PRESENTATION

- "If it is none of the above, what is it? We want an answer NOW!" Her family demanded. "We want her sent to the ED – NOW – for a re-evaluation!"
- Given the situation, you decided to call 911 and sent the resident to the nearest ED.
- She was sent back to the facility from the ED late evening.

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The Pain is Where?

CASE PRESENTATION

- The next morning you came in to see the resident. She looked comfortable, although she would complain of left chest pain, arm pain, and thumb pain when asked. You remember having sent her out for chest pain about 9 months ago – her first night at LTC, for the same symptomatology!
- Upon review, like usual, the discharge packet from ED the previous evening was full of extraneous automated EHR print-outs of post-discharge instructions but no clinical documentations.

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The Pain is Where?

CASE PRESENTATION
- Resident complains of left chest pain (CP), Lt arm pain, and Lt thumb pain
- You called the ED requesting clinical notes

EMERGENCY ROOM WORK UP:
- EKG: grossly wnl – cardiac unlikely
- CTA: neg PE – ruled out as cause of CP
- CXR: neg PNA – ruled out as cause of CP
- XR Lt hand: severe OA at thumb base – possible etiology for Lt thumb pain
- XR Lt shoulder: severe OA at GH joint – possible etiology for Lt shoulder/arm pain
- High-sensitivity troponin I assay: 0.010 ng/ml (negative) – cardiac unlikely
- CMP, CBC diff, TSH grossly wnl – no metabolic contributor to CP

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The Pain is Where?

- **QUESTION 1**

Assuming the ED work-up was negative for cardiac (otherwise they would have kept the resident), what are your top three possible differential diagnoses?

A. ???_____:

B. ???_____:

C. ???_____:

- **QUESTION 2**

Now that cardiac etiology had been once again ruled out, what would be the next best test to order at the facility?

Answer:_____

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BREAKOUT SESSION

Case 1 Discussion

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The Pain is Where?

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A. **Non-cardiac Chest pain:**

B. **Psychosocial:**

C. **Referral/Radiating pain:**

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The Pain is Where?

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Answer:_____

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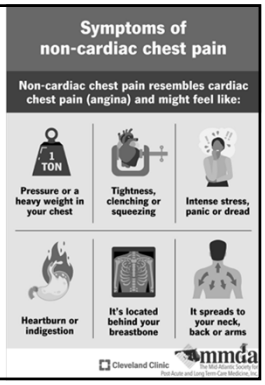
The Pain is Where? Cardiac or Non-cardiac?



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The Pain is Where?

JACC JOURNALS

Sussman WI, Makovitch SA, Merchant SH, Phadke J. Cervical angina: an overlooked source of noncardiac chest pain. Neurohospitalist. 2015 Jan;5(1):22-7.

- Each year, > 7 million patients present to the ED with chest pain
- Most will be admitted for cardiac "rule out"
- Only 15% to 25% will actually have acute coronary syndrome
- The fear of fatally missing an acute coronary syndrome results in non-cardiac causes of chest pain being overlooked.
- Many non-cardiac chest pain remain undiagnosed
- "Atypical chest pain!"

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"Atypical Chest Pain" ≠ Non-anginal Chest Pain

The diagnosis of nonanginal chest pain

Constant J. The diagnosis of nonanginal chest pain. Keio J Med. 1990 Sep;39(3):187-92. doi: 10.2302/kjm.39.187. PMID: 2255129.

Abstract

The term "atypical chest pain" is a waste-basket term that leads physicians to send any patient with chest pain to coronary angiography. In order to avoid this term, we must learn to distinguish atypical angina from nonanginal chest pain before angiography is considered in order to avoid unnecessary invasive procedures. A chest pain is very likely nonanginal if its duration is over 30 minutes or less than 5 seconds, it increases with inspiration, can be brought on with one movement of the trunk or arm, can be brought on by local fingers pressure, or bending forward, or it can be relieved immediately on lying down. There are also many presumptive signs of nonanginal chest pain such as localization with one finger, radiation to the nuchal area, an inframammary primary site, a pain that reaches maximum at the onset, or relief within a few seconds of swallowing food. Cervical root compression pain and esophageal spasm are the greatest mimics of angina since they can both be relieved by nitroglycerin but they have several features which help to rule out angina.

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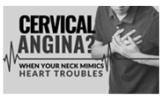
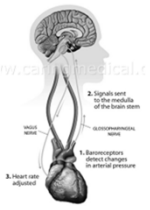
The Pain is Where?



Sussman WI, Makovitch SA, Merchant SH, Phadke J. Cervical angina: an overlooked source of noncardiac chest pain. Neurohospitalist. 2015 Jan;5(1):22-7.

- Non-cardiac chest pain constitute > 50% of all cases of chest pain in the ED
- Of these, **cervical spine disorders represent an unrecognized potential cause of noncardiac chest pain!**
- In one series of 241 patients with C7 radiculopathy undergoing anterior cervical diskectomy, 16% endorse chest pain
- In another series of 706 patients with cervical pathology requiring surgery, 1.4% exhibited symptoms of cervical angina.
- Despite being first described in 1934, cervical angina remains underdiagnosed



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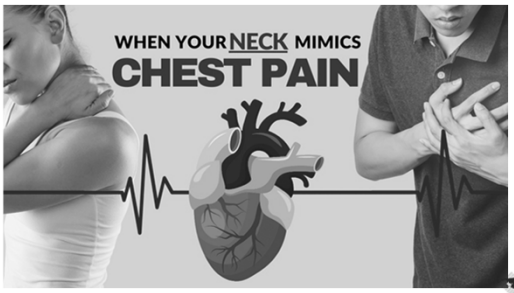
The Pain is Where?



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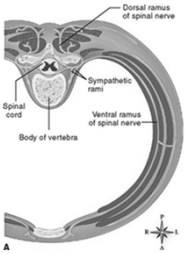
Cervical angina

Cervical and high thoracic radiculopathy can refer to into the chest wall

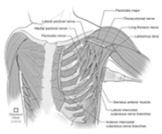


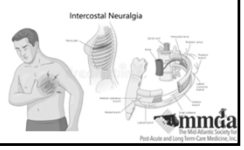
Original Article

Cervical angina: a seemingly still neglected symptom of cervical spine disorder?

H Nakajima*[,1], K Uchida[1], S Kobayashi[1], Y Kokubo[1], T Yayama[1], R Sato[1], T Imakai[1], T Godfrey[1] and H Baba[1]

[1]*Division of Orthopaedics and Rehabilitation Medicine, Department of Surgery, School of Medicine, University of Fukui, Fukui, Japan*





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The Pain is Where?

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Assuming the ED work-up was negative for cardiac (otherwise they would have kept the resident), what are your top three possible differential diagnoses?

A. **Non-cardiac Chest pain:** GI (Esoph Spasm), MSK (costochondritis), Resp (Pleurisy)

B. **Psychosocial:** Panic disorder, Anxiety, Depression

C. **Referral/Radiating pain:** Neuro (radiculopathy, shingles)

- **QUESTION 2**

Now that cardiac etiology had been once again ruled out, what would be the next best test to order at the facility?

Answer:_____

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Now that cardiac etiology had been once again ruled out, what would be the next best test to order at the facility?

Answer: Xray of Cervical Spine (considering EMG/NCS and MRI)

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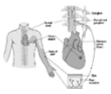
The Pain is Where?



American College of Rheumatology
Empowering Rheumatology Professionals

ABSTRACT NUMBER: 2289

A Cervical Radiculopathy Can Cause Chest Pain

Robert S. Katz[1], Ben J Small[2] and Alexandra Katz Small[1], [1]Rush University Medical Center, Chicago, IL, [2]MacNeal Hospital, Berwyn, IL

Meeting: 2015 ACR/ARHP Annual Meeting

Date of first publication: September 29, 2015

Keywords: Cervical spine and pain

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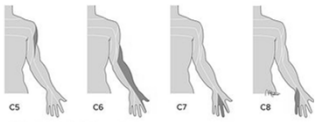
The Pain is Where?

CASE PRESENTATION

- Resident complains of left chest pain (CP), Lt arm pain, and Lt thumb pain

EMERGENCY ROOM WORK UP:

- XR Lt hand: severe OA at thumb base – possible etiology for Lt thumb pain
- XR Lt shoulder: severe OA at GH joint – possible etiology for Lt shoulder/arm pain



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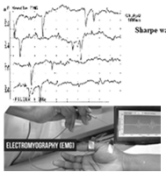
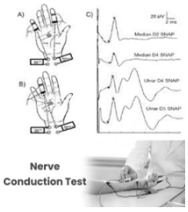
The Pain is Where?

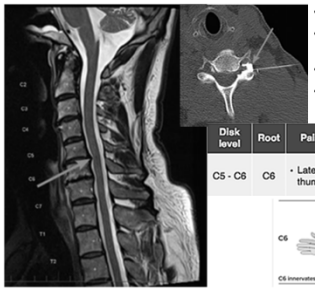




- Active positive waves and fibrillation potentials indicates an active cervical radiculopathy.
- The distribution of nerve conduction study/EMG findings is consistent with a C6 radiculopathy.

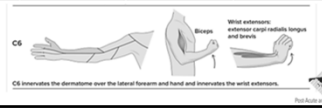
32

The Pain is Where?



- C6 radiculopathy seen on MRI
- The C7 nerve root is the most commonly affected in cervical radiculopathy.
- C6 being the second most common.
- No cord impingement

Disk level	Root	Pain distribution	Weakness	Sensory loss	Reflex loss
C5 - C6	C6	• Lateral forearm, thumb, index finger	• Biceps • Brachioradialis • Wrist extensors	• Thumb and index finger	Biceps reflex



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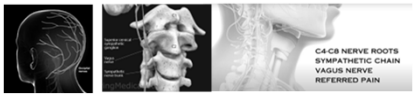
Cervical angina



- First mentioned in 1934
- Prevalence not well-defined due to under-reporting: 1.4% - 9.8%
- Variable clinical presentations, poorly understood mechanisms
  - Chest pain can be sharp, achy, or crushing; paroxysmal or continuous
  - Neck pain, upper arm numbness, and occipital headaches may be present
  - Autonomic manifestations such as dyspnea, dizziness, nausea, sweating, pallor, fatigue, diplopia, and headache
  - Drinking or eating may lessen the pain
  - Epigastric pain can be present
  - SL NTG often relieves the chest pain

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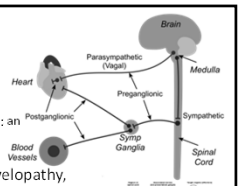
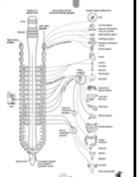
Cervical angina



Sussman WI, Makovitch SA, Merchant SH, Phadke J. Cervical angina: an overlooked source of noncardiac chest pain. Neurohospitalist. 2015 Jan;5(1):22-7.

- Cervical angina etiologies may include cervical myelopathy, spinal cord infarction, spinal cord tumors, herniate disks, and spondyloarthropathies.
- Mechanism of pain is not easily elucidated
  - Sinuvertebral nerves
  - Sympathetic afferent fibers from C8 – T9 dorsal root ganglia
  - In cervical myelopathy, lesions of the dorsal horn or disruption of the ascending cardiac spinothalamic tracts may create the sensation of anginal pain.



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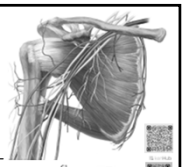
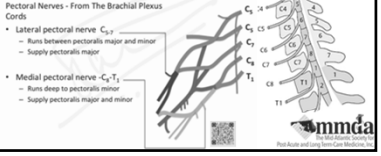
Cervical angina



- C5-T1 form the brachial plexus
  - Medial pectoral nerve (C8, T1) → pectoralis major
  - Lateral pectoral nerve (C6,C7) → pectoralis minor
- Protopathic sensory neurons (heat, cold, pain) result in non-localizing referral pain to the myotomes
- (Epicritic sensation: fine touch, temperature, and pressure)
- Cervical angina distributions
  - 4% C3-4
  - 24% C4-5
  - 35% C5-6
  - 30% C6-7



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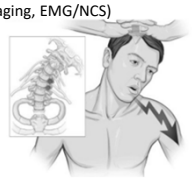
Cervical angina

- **Diagnosing cervical angina**
  - A heightened sense of suspicion:
    - o Recurrent chest pain episodes with multiple negative cardiac work-ups
    - o Known cervical spine disease (i.e.: cervical spine imaging, EMG/NCS)
- **Clinical findings**
  - Chest pain elicited by moving neck or arm
  - Recent lifting, pulling, pushing
  - Pain lasting < 5 sec or > 30 min
  - **Spurling maneuver** may reproduce radicular symptoms
  - XR, CT, or MRI of C-Spine (+) spondylopathy
  - EMG/NCS (+) evidence of radiculopathy



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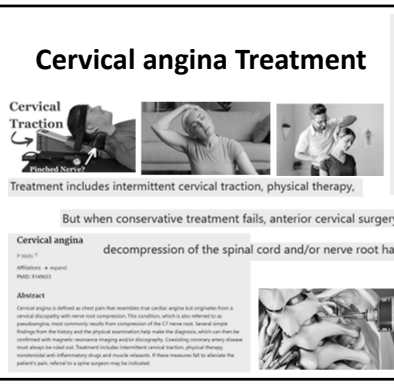
Cervical angina Treatment

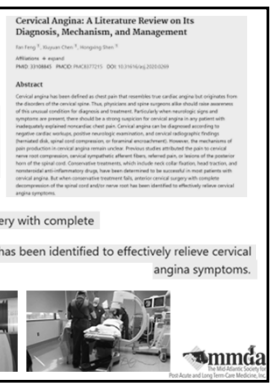
Treatment includes intermittent cervical traction, physical therapy,

But when conservative treatment fails, anterior cervical surgery with complete decompression of the spinal cord and/or nerve root has been identified to effectively relieve cervical angina symptoms.


Cervical angina

Abstract

Cervical angina is defined as chest pain that resembles true cardiac angina but originates from a cervical discopathy with nerve root compression. This condition, which is also referred to as pseudoangina, most commonly results from compression of the C7 nerve root. Several simple findings from the history and the physical examination help make the diagnosis, which can then be confirmed with magnetic resonance imaging and/or discography. Coexisting coronary artery disease must always be ruled out. Treatment includes intermittent cervical traction, physical therapy, nonsteroidal anti-inflammatory drugs and muscle relaxants. If these measures fail to alleviate the patient's pain, referral to a spine surgeon may be indicated.


Cervical Angina: A Literature Review on Its Diagnosis, Mechanism, and Management

Abstract

Cervical angina has been defined as chest pain that resembles true cardiac angina but originates from the disorders of the cervical spine. Thus, physicians and spine surgeons alike should raise awareness of this unusual condition for diagnosis and treatment. Particularly when neurologic signs and symptoms are present, there should be a strong suspicion for cervical angina in any patient with inadequately explained noncardiac chest pain. Cervical angina can be diagnosed according to negative cardiac workups, positive neurologic examination, and cervical radiographic findings (herniated disk, spinal cord compression, or foraminal encroachment). However, the mechanisms of pain production in cervical angina remain unclear. Previous studies attributed the pain to cervical nerve root compression, cervical sympathetic afferent fibers, referred pain, or lesions of the posterior horn of the spinal cord. Conservative treatments, which include neck collar fixation, head traction, and nonsteroidal anti-inflammatory drugs, have been determined to be successful in most patients with cervical angina. But when conservative treatment fails, anterior cervical surgery with complete decompression of the spinal cord and/or nerve root has been identified to effectively relieve cervical angina symptoms.

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LEARNING POINTS CASE 1

- Cervical angina, or pseudoangina pectoris, is a noncardiac syndrome of chest pain that often mimics angina pectoris but is a disease of the spine.
- Diagnosis of cervical angina can be difficult and is often overlooked, although once identified, it can be successfully managed through conservative therapies and/or a variety of surgical interventions.
- Ultimately, cervical angina is an important component of the list of differential diagnoses in noncardiac chest pain.

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CASE 2 PRESENTATION
Bilateral Arm Itching

40

The Itch is What?

- A 59-year-old resident is evaluated for a 3-month history of intermittent itching on the forearms. He describes the itch as deep, with a burning or tingling sensation.
- Scratching helps somewhat, but topical corticosteroids have not helped.
- Cooling the skin soothes the itch. He did not notice a rash until she started scratching.
- The itch gets worse after being in the sun, but sun exposure does not cause redness or a rash.

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The Itch is What?

- On physical examination, the resident shows evidence of chronic sun damage on sun-exposed skin, including hyperpigmentation and solar lentigines.
- A few excoriations are present on the forearms, but no significant dermatitis is observed.
- The patient's sensation on the arms and forearms is normal.
- Deep tendon reflexes are normal in the biceps, triceps, and brachioradialis.

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The Itch is What?

- Which of the following is the most likely diagnosis?
  - A. Brachioradial pruritus
  - B. Polymorphous light eruption
  - C. Prurigo nodularis
  - D. Solar urticaria

43

The Itch is What?

- Which of the following is the most likely diagnosis?
  - **A. Brachioradial pruritus**
  - B. Polymorphous light eruption
  - C. Prurigo nodularis
  - D. Solar urticaria

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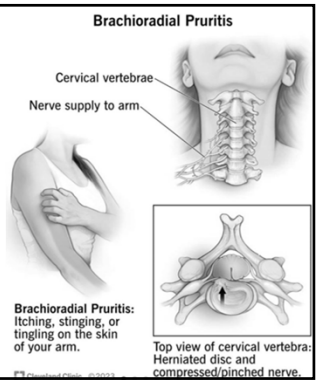
Brachioradial pruritus

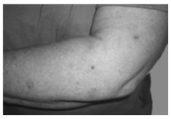
- **Brachioradial pruritus** is a form of **neuropathic itch** that has been linked to abnormalities in the cervical spine.
- Inflammation or irritation of cervical nerves causes recurrent and persistent itching in the upper extremities, usually on the forearms.
- In some cases, around the neck, shoulders, and upper arms.



45

Brachioradial pruritus

- Severe itch in bilateral arms in C5 through C7 dermatomal distribution.
- There are no primary skin findings, and skin biopsy is non-diagnostic.
- The skin may be excoriated, lichenified and hyperpigmented with erythematous papules from repeated scratching.
- MRI of the spine may reveal evidence of osteoarthritis or other structural abnormalities, although radiologic evaluation is not generally recommended.



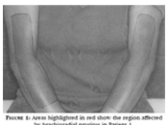


FIGURE 1: Areas highlighted in red show the region affected by brachioradial pruritus in Patient 1.

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Brachioradial pruritus

- Because this is not a histamine-mediated itch, antihistamines and corticosteroids are usually unsuccessful in treating the itch.
- Response to ice or cold packs is very characteristic and helps clinically confirm the diagnosis.
- Topical analgesics offer short-term relief.
- Gabapentin or pregabalin may result in more long-term relief

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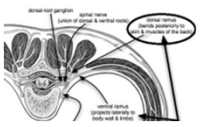
Brachioradial pruritus

- A similar type of neuropathic itch occurs on the mid, medial back, called **notalgia paresthetica**.



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Neuropathic Pruritus

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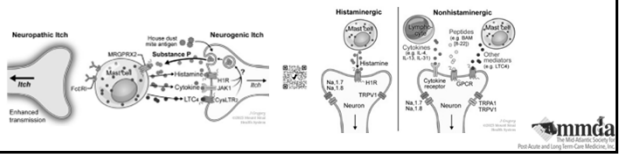
Neuropathic Pruritus

- Sensory neurons can be the source of itch via 2 mechanisms:
  - **Neuropathic itch (non-histaminergic):** when nerve damage directly promotes excessive afferent itch transmission toward the CNS.
  - **Neurogenic itch (histaminergic):** sensory neurons, beyond being a conduit for itch, also can promote neuro-inflammation via the release of substance P, and indirectly trigger the itch via an immune process activation.



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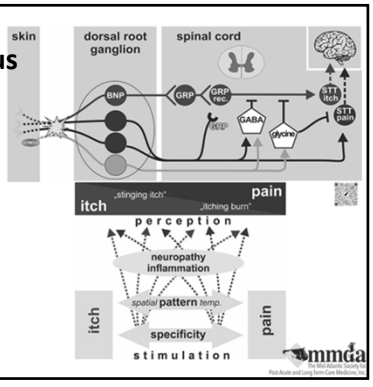
Neuropathic Pruritus

- Pain and pruritic stimuli are processed within the CNS
- **Neuropathic pruritus** may be perceived as partly painful ("stinging itch") and vice versa with neuropathic pain ("itching burn").
- **Peripheral neuropathy** is a common cause of neuropathic pain and itching, ex: postherpetic neuralgia and diabetic neuropathy.



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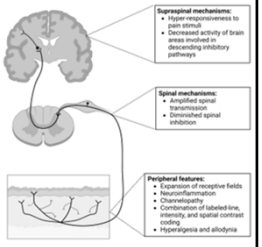
Neuropathic Pruritus

There are currently no US Food and Drug Administration–approved treatments

- **Topical agents:**
  - Capsaicin
  - Intralesional botulinum neurotoxin injections
  - Carbamazepine or oxcarbazepine
  - Pramoxine, lidocaine, prilocaine, and ketamine
- **Systemic agents:**
  - Neuroleptics: gabapentin and pregabalin
  - Antidepressants: sertraline, mirtazapine, and paroxetine
  - Synthetic cannabinoid: dronabinol



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LEARNING POINTS CASE 2

- **Brachioradial pruritus** is a form of neuropathic itch that has been linked to abnormalities in the cervical spine.
- **Neuropathic pruritus** directly (non-histaminergic) results from damage to the nerves. Anormal signalling result in itch. Treatment focuses on addressing nerve dysfunction (gabapentinoids, topical anesthetics, nerve blocks or botox injections).
- **Neurogenic pruritus** indirectly (histaminergic) involves the intact nerves inducing itch mediators such as substance P that activate mast cells to release histamine. Treatment aims to address the inflammation and mediators involved (antihistamines, topical anti-inflammatory creams, and avoiding triggers).

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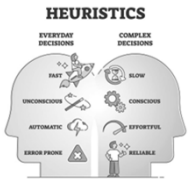
What have we learned today

The neuromusculoskeletal system can mimic many clinical signs and symptoms, and must be considered in the differential diagnoses.



Pain syndromes are diverse in presentation and the premise of pain management does not always evolve around pain medications and opioids.

9:35-10:35 am **Session #2** – ***Comprehensive Pain Management Workshop*** (1.0)
Dominique Luong Vinh, MD, MBA, CMD; Adjunct Assistant Professor, Physical Medicine and Rehabilitation, Johns Hopkins School of Medicine Faculty

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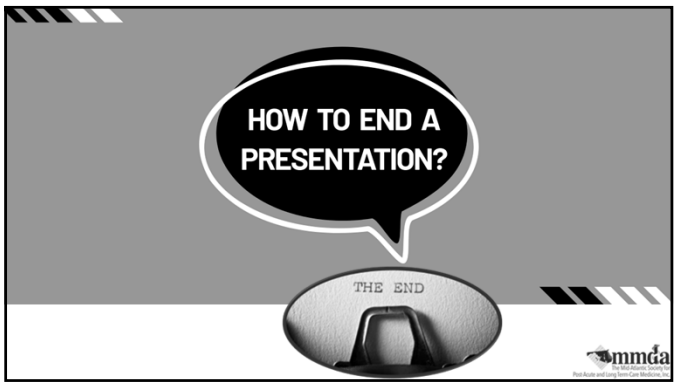

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Office of Health Care Quality
Nursing Home Updates

Heather Reed, Deputy Director, Long Term Care

November 8, 2025

1

Protecting the health and safety of Marylanders across the health care continuum

OHCQ is Maryland's State Survey Agency

- Maryland Department of Health (MDH) has designated OHCQ as Maryland's state survey agency
- On behalf of the Centers for Medicare & Medicaid Services (CMS), OHCQ conducts certification activities and makes recommendations to CMS regarding certification

2

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2

Minimum Standards for Licensure and Certification

- Social Security Act mandates the establishment of federal minimum health and safety standards that providers and suppliers must meet to participate in Medicare and Medicaid
- OHCQ conducts surveys and other activities to determine if a provider is in compliance or not in compliance with the minimum standards required to obtain and maintain State licensure and federal certification

3

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3

Functions of OHCQ

1. **State Licensure:** Issues licenses, authorizing the applicant to operate a certain type of business in the State
2. **Federal Certification:** Recommends certifications to the Centers for Medicare & Medicaid Services (CMS), which allow a facility to participate in and seek reimbursement from the Medicare and Medicaid programs for services provided to beneficiaries

4

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4

Long Term Care Dashboard

5

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5

Long Term Care Provider Resources

6

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6

Long Term Care- FY25 Priorities: Plan to address the Backlog

- **Staffing/Training**
  - Since July 1, 2024 we have hired 30 new LTC surveyors
- **Improve efficiencies**
  - OHCQ has developed and implemented continued training for survey efficiency

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Maryland DEPARTMENT OF HEALTH

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Long Term Care- FY25 Priorities: Plan to address the Backlog

- **MDH subcontract with certified nurse surveyors**
  - OHCQ secured a contract with 2 external agencies to provide SMQT certified Health Facilities Surveyors
  - The contract has resulted in additional surveyors surveying the backlog of complaints

8

Maryland DEPARTMENT OF HEALTH

8

LTC Unit: Program Statistics

Units of Measurement	FY22	FY23	FY24	FY25*
Number of licensed nursing homes	225	225	222	220
Initial surveys	0	0	0	0
Annual full surveys	28	42	47	142
Follow-up surveys (onsite)	41	41	33	44
Follow-up surveys (offsite)	144	54	74	162
Complaints and facility reported incidents (FRI)	4,414	4,692	4,083	4,056
Life safety code surveys	82	132	153	306
Resident fund surveys	59	64	205	205

*FY25 data is preliminary

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Long Term Care Top Ten Deficiencies

Office of Health Care Quality

10

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10

Top 10 Most Frequently LTC Deficiencies cited in FY 25

Tag	Description of Tag
F609	**Reporting of Alleged violations**
F842	**Resident Records**
F812	**Food Procurement, Store/Prepare/Serve- Sanitary**
F610	**Investigate/Prevent/Correct Alleged Violation**
F684	**Quality of Care**
F880	**Infection Prevention & Control**
F657	**Care Plan Timing and Revision**
F656	**Develop/Implement Comprehensive Care Plan**
F689	**Free of Accident Hazards/Supervision/Devices**
F584	**Safe/Clean/Comfortable/Homelike Environment**

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Most Frequently cited IJ Deficiencies FY24 & FY25

- 25 Immediate Jeopardy Citations FY24
  - F689- Free of Accidents Hazards/Supervision/Devices
    - Related to elopements and safe smoking practices
  - F600- Free from Abuse and Neglect
- 27 Immediate Jeopardy Citations FY25
  - F689 and F600

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Maryland DEPARTMENT OF HEALTH

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CFR §483.70(g) Medical director (F841)

Office of Health Care Quality

13

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13

F841- Medical Director

- §483.70(g) Medical director.
- §483.70(g)(1) The facility must designate a physician to serve as medical director.
- §483.70(g)(2) The medical director is responsible for—
- (i) Implementation of resident care policies; and
- (ii) The coordination of medical care in the facility.

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F841- Medical Director- Definition

"Medical director" *refers to* a physician who oversees the medical care and other designated care and services in a health care organization or facility. Under these regulations, the medical director is responsible for coordinating medical care and helping to implement and evaluate resident care policies that reflect current professional standards of practice.

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F841- Medical Director- Responsibilities

The medical director's responsibilities require that he/she be knowledgeable about current professional standards of practice in caring for long term care residents, and about how to coordinate and oversee other practitioners.

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F841- Medical Director- Responsibilities (cont.)

- *Implementation of resident care policies, such as ensuring physicians and other practitioners adhere to facility policies on diagnosing and prescribing medications and intervening with a health care practitioner regarding medical care that is inconsistent with current professional standards of care.*
- Participation in the Quality Assessment and Assurance (QAA) committee or assign a designee to represent him/her.
- Addressing issues related to the coordination of medical care and implementation of resident care policies identified through the facility's quality assessment and assurance committee and other activities.
- *Active involvement in the process of conducting the facility assessment*

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F841- Medical Director- Responsibilities (cont.)

- Administrative decisions including recommending, developing and approving facility policies related to resident care. Resident care includes the resident's physical, mental and psychosocial well-being
- Ensuring the appropriateness and quality of medical care and medically related care
- Assisting in the development of educational programs for facility staff and other professionals
- Working with the facility's clinical team to provide surveillance and develop policies to prevent the potential infection of residents.

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F841- Medical Director- Responsibilities (cont.)

- *Administrative decisions including recommending, developing and approving facility policies related to resident care. Resident care includes the resident's physical, mental and psychosocial well-being*
- Ensuring the appropriateness and quality of medical care and medically related care
- Assisting in the development of educational programs for facility staff and other professionals
- Working with the facility's clinical team to provide surveillance and develop policies to prevent the potential infection of residents.

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F841- Medical Director- Responsibilities (cont.)

- Cooperating with facility staff to establish policies for assuring that the rights of individuals (residents, staff members, and community members) are respected;
- Supporting and promoting person-directed care such as the formation of advance directives, end-of-life care, and provisions that enhance resident decision making, including choice regarding medical care options;
- Identifying performance expectations and facilitating feedback to physicians and other health care practitioners regarding their performance and practices;

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F841- Medical Director- Responsibilities (cont.)

- Discussing and intervening (as appropriate) with a health care practitioner regarding medical care that is inconsistent with current standards of care, *for example, physicians assigning new psychiatric diagnoses and/or prescribing psychotropic medications without following professional standards of practice*
- Assisting in developing systems to monitor the performance of the health care practitioners including mechanisms for communicating and resolving issues related to medical care and ensuring that other licensed practitioners (e.g., nurse practitioners) who may perform physician-delegated tasks act within the regulatory requirements and within the scope of practice as defined by State law.

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F841- Medical Director

What are surveyors looking for?

If a deficiency has been identified regarding a resident's care, also determine if the medical director had knowledge or should have had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current professional standards of practice and failed:

- To get involved or to intercede with other physicians or practitioners to facilitate and/or coordinate medical care; and/or
- To provide guidance for resident care policies.

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F841- Medical Director- Noncompliance

- Designate a physician to serve as medical director; or
- Ensure the medical director fulfilled his/her responsibility for the implementation of resident care policies or the coordination of medical care in the facility.

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F841- Medical Director- Noncompliance Level 4

- The facility's medical director was aware of and did not intervene when a health care practitioner continued over several months to provide inappropriate medical care for infection prevention to a resident that was inconsistent with current professional standards of care. As a result this resident's health continued to decline, and was hospitalized with a severe infection.

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F841- Medical Director- Noncompliance Level 3

- The Director of Nursing repeatedly requested the medical director's assistance in coordinating medical care with attending physicians for residents receiving psychotropic medications. In particular there were several physicians who had a known history of failing to provide justification for continued use of these medications and not attempting a gradual dose reduction for the residents under his/her care. As a result of the medical director's failure to intervene, several residents continued to receive these medications without medical/clinical justification. Due to the continuation of the use of these psychotropic medications, the residents withdrew from activities and from eating in the dining room. This caused decreased appetite and substantial weight loss for several residents. Actual harm, both physical and psychosocial was indicated.

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F841- Medical Director- Noncompliance Level 2

- The medical director, who is responsible for overseeing the medical care in the facility, was made aware of residents newly diagnosed with schizophrenia by their physician and/or other practitioner and their medical records did not contain documentation to support the new diagnoses. The medical director did not review the medical records for these residents nor did he/she discuss the new diagnoses with the residents' physician and/or diagnosing practitioner. This practice resulted in residents being potentially misdiagnosed with schizophrenia and receiving antipsychotic medications. None of the residents experienced harm, but they were at risk for harm by receiving treatment, including antipsychotic medications, when they may not have been clinically indicated

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References

- State Operations Manual (SOM) Appendix PP
- https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984

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Changing Trends in Job Satisfaction and Burnout for Care Aides

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1

INTRODUCTION

- The rapidly aging population and high rates of dementia and chronic disease comorbidities have led to an increased demand for care in long-term care (LTC) homes
- Care aides, also known as personal support workers, orderlies, and nurse assistants, form the vast majority of the point-of care workforce in LTC homes.
- Care aides often report moderate levels of exhaustion and cynicism which are cardinal indicators of burnout
- Burnout among care aides has been linked to heavy workloads, limited resources, and challenges such as managing dementia-related responsive behaviors in residents.

2

INTRODUCTION

- Burnout among care aides result in poor quality of care and quality of life for residents.
- The COVID-19 pandemic intensified existing challenges in the LTC sector and introduced new ones for these vulnerable staff
- Care aides faced widespread significant mental health challenges and physical health issues throughout the pandemic
- It is essential to study trends in burnout for this important staff group

3

GAP

- The ways in which work environments influence changes in quality of work life over time for care aides have been underexplored
- Existing studies often focus on cross-sectional associations between work environments and quality of work life outcomes in LTC staff
- Perceptions of care aides regarding their immediate work environments at the care unit level—as opposed to the broader LTC home or organizational levels—are particularly scarce.
- Research into the nuances of work environments at the care unit level could reveal detailed insights into how immediate work settings impact staff well-being

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PURPOSE

- The study aimed to examine if and how the work environment of care units influenced the longitudinal changes in job satisfaction and burnout among LTC home care aides
- This study reports trends in job satisfaction and burnout among LTC home care aides before the onset of the pandemic.

5

METHODS

- **Study Design:** Retrospective longitudinal study
- **Data Source:** Surveys collected by the Translating Research in Elder Care (TREC)
- **Setting:** Alberta, British Columbia, and Manitoba.
- **Sample:** LTC home care aides
- **Sample size:** 631 care aides from 83 LTC homes

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MEASURES

Job Satisfaction: Michigan Organisational Assessment Questionnaire (MOAQ)-Job Satisfaction Subscale

Burnout: 9-item version of Maslach Burnout Inventory-General Survey (MBI-GS)

Work Environment: 10 scales of the Alberta Context Tool (ACT)

ACT scales: leadership, culture, evaluation (feedback mechanisms), social capital, structural resources, formal interactions, informal interactions, organizational slack in staffing, organizational slack in space, and organizational slack in time

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STATISTICAL ANALYSIS

Study periods: September 2014-May 2015 (T_1), May 2017-December 2017 (T_2), and September 2019-March 2020 (T_3).

Mixed-effects linear regression analysis to examine the association of the outcome with time points, care unit work environment while controlling for other characteristics

Moderation analysis; "time by work environment" interaction

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KEY FINDINGS

Raw Scores of Job Satisfaction and Burnout by Time Point

Variables (Possible Range)	T_1 (September 2014–May 2015)	T_2 (May 2017 –December 2017)	T_3 (September 2019–March 2020)	F Based on Repeated Measures ANOVA (*P*)	Significant Post Hoc Comparison*
	Mean (SD)	Mean (SD)	Mean (SD)		
Job satisfaction (1–5)	4.29 (.58)	4.26 (.63)	4.23 (.62)	3.25 (.043)	T_1 vs T_3
Burnout					
Exhaustion (0–6)	2.51 (1.68)	2.67 (1.65)	2.82 (1.75)	11.59 (<.001)	T_1 vs T_2 T_1 vs T_3
Cynicism (0–6)	2.49 (1.63)	2.74 (1.59)	2.79 (1.64)	10.71 (<.001)	T_1 vs T_2 T_1 vs T_3
Efficacy (0–6)	5.46 (.75)	5.38 (.87)	5.44 (.75)	2.53 (.08)	n/a

n/a, not applicable.
*Bonferroni-adjusted *P* value (.05/3 = .017) was referred to for multiple comparisons.

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KEY FINDINGS

Associations of Job Satisfaction and Burnout (Standardized Z-Scores) With Time Points and Care Unit Work Environment: Regression Coefficients and 95% Confidence Intervals[1]

	Job Satisfaction	Burnout-Exhaustion	Burnout-Cynicism	Burnout-Efficacy
Model 1				
Time point (Ref = T_1)				
T_2	−0.13[3] (−0.21 to −0.05)	0.11[2] (0.03 to 0.19)	0.16[3] (0.07 to 0.26)	−0.12 (−0.22 to 0.00)
T_3	−0.13[3] (−0.22 to −0.05)	0.21[3] (0.12 to 0.29)	0.21[3] (0.11 to 0.31)	−0.05 (−0.15 to 0.05)
Care unit work environment (Ref = Less favorable)				
More favorable	0.16[3] (0.08 to 0.25)	−0.14[3] (−0.23 to −0.05)	−0.08 (−0.18 to 0.01)	0.13[2] (0.03 to 0.23)
Model 2				
Time point (Ref = T_1)				
T_2	−0.17[3] (−0.29 to −0.05)	0.15[2] (0.02 to 0.27)	0.27[3] (0.13 to 0.41)	−0.20[3] (−0.35 to −0.06)
T_3	−0.17[3] (−0.30 to −0.04)	0.31[3] (0.18 to 0.43)	0.28[3] (0.13 to 0.42)	−0.12 (−0.27 to 0.03)
Care unit work environment (Ref = Less favorable)				
More favorable	0.12 (−0.01 to 0.24)	−0.05 (−0.19 to 0.08)	0.03 (−0.12 to 0.17)	0.03 (−0.12 to 0.18)
Interaction between time point and care unit work environment				
T_2 × More favorable	0.07 (−0.10 to 0.24)	−0.07 (−0.24 to 0.10)	−0.19[2] (−0.38 to −0.01)	0.16 (−0.04 to 0.35)
T_3 × More favorable	0.07 (−0.10 to 0.24)	−0.18[2] (−0.35 to −0.01)	−0.13 (−0.32 to 0.06)	0.14 (−0.06 to 0.33)
Average marginal effects of time points by care unit work environment				
For care aides from care units with less favorable work environment				
Time point (Ref = T_1)				
T_2	−0.17[3] (−0.29 to −0.05)	0.15[2] (0.02 to 0.27)	0.27[3] (0.13 to 0.41)	−0.20[3] (−0.35 to −0.06)
T_3	−0.17[3] (−0.30 to −0.04)	0.31[3] (0.18 to 0.43)	0.28[3] (0.13 to 0.42)	−0.12 (−0.27 to 0.03)
For care aides from care units with more favorable work environment				
Time point (Ref = T_1)				
T_2	−0.10 (−0.21 to 0.01)	0.08 (−0.04 to 0.19)	0.08 (−0.05 to 0.2)	−0.05 (−0.18 to 0.08)
T_3	−0.10 (−0.21 to 0.02)	0.13[2] (0.01 to 0.24)	0.15[2] (0.02 to 0.28)	0.02 (−0.12 to 0.15)

[1] T_1: September 2014–May 2015; T_2: May 2017–December 2017; T_3: September 2019–March 2020.
[2] $P < .01$.
[3] $P < .001$.
[4] $P < .05$.

- Statistically significant differences between T_1 and T_2, and between T_1 and T_3 ($P < .01$) in all outcomes except for burnout efficacy.
- **Care aides working in a more favorable environment reported better outcomes, regardless of time points, compared with those working in a less favorable environment**

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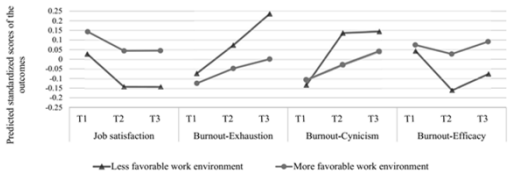
KEY FINDINGS



- The "time by work environment" interaction was statistically significant for burnout-exhaustion and burnout-cynicism
- Care aides working in units with a less favorable work environment showed greater increases in exhaustion from T1 to T3 and in cynicism from T1 to T2, compared to those in more favorable work environments.

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PROPOSED INTERVENTIONS

INFORM: Improving **N**ursing **H**ome **C**are Through **F**eedback **O**n perfo**RM**ance data

Purpose: Designed to increase involvement of care aides in formal team communications about resident care in nursing homes

INFORM was an audit and feedback intervention based on goal setting theory, designed to improve performance.

Components: learning and performance goals for increasing care aide involvement in decisions, creating action plans, defining measures of success, reporting progress and challenges implementing action plans

12

PROPOSED INTERVENTIONS

SCOPE: Safer **C**are for **O**lder **P**ersons in Residential Care **E**nvironments

Purpose: Designed to empower care aides to lead, with coaching support, QI activities that help them to use best evidence in their practice, and secondarily to improve their quality of work life and engagement

SCOPE is based on a modified *Institute for Healthcare Improvement (IHI) Breakthrough Collaborative Series* model that uses the PlanDo-Study-Act (PDSA) approach to improving care

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DISCUSSION

- Longitudinal analysis revealed a concerning trend of worsening job satisfaction and burnout from 2014 to 2020
- Findings align with other longitudinal studies which suggested that employees in unfavourable work environments experienced a statistically significant decline in job satisfaction with increased emotional exhaustion
- Findings suggest that the protective effect of favorable work environments within care units could be long lasting
- There is the need for research into specific work environment factors at the clinical microsystem level to guide the development of targeted interventions

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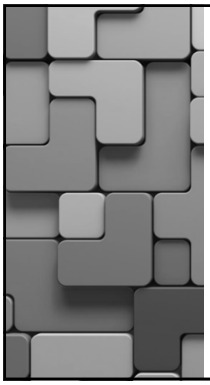

Journal club

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1

Discosures

- I have nothing to disclose

2

Gabapentinoids and Risk for Severe Exacerbation in Chronic Obstructive Pulmonary Disease : A Population-Based Cohort Study.

By Alvi A. Rahman, MSc; Sophie Dell'Aniello, MSc; Erica E.M. Moodie, PhD; Madeleine Durand, MD, MSc; Janie Coulombe, PhD; Jean-François Boivin, MD, ScD; Samy Suissa, PhD; Pierre Ernst, MD, MSc; and Christel Renoux, MD, PhD

(Annals of Internal Medicine, 2024)

3

Background and Rationale

1. Gabapentinoids (gabapentin, pregabalin), are indicated for the treatment of several conditions: epilepsy, neuropathic pain, chronic pain.
2. Despite limited indications, use has surged in Europe and North America for off-label prescribing.
3. Some hypothesize that this may be linked to perception as safer alternative to opioids.

4

Concerns

Propensity to cause CNS depression leading to sedation and respiratory depression reported in animal and human studies.

49 case reports submitted to FDA showed severe breathing difficulties in patient using gabapentinoids

Particular concern in patients with COPD

5

COPD exacerbations

- Severe exacerbations are indicators of rapid disease progression and are associated with poor prognosis.

6

Pain and COPD

- 85% patients with COPD have 1 or more pain related diagnosis
- 27% neuropathic pain
- 70% using 1 or more prescription medication

7

Preventive measures

In 2016, Health Canada warned of potential serious breathing problems, recommend updated product information

In 2019, FDA released warning about breathing problems, especially for patients with respiratory factors

8

Study objective

- Aim: to assess whether gabapentinoid use is associated with increased risk of severe COPD exacerbation.
- Approved or off-label indication of gabapentinoids

9

Methods

- Time-conditional propensity score-matched, new-user cohort design

10

Data source

3 computerized health care databases from Quebec province in Canada

Information on demographics, medical services, dispensed outpatient prescriptions on all residents convered in the Public Prescription Insurance Plan (includes all individuals >65, welfare recipients, all residends without private insurance) = 43% of population

Records of all hospitalizations are available

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Inclusion criteria

- Age 55 +
- Receiving 3 or more prescriptions for respiratory drug (LAMA, LABA, combination LAMA-LABA, or LAMA-inhaled corticosteroid on at least 2 dates within a year between 1994 and 2015

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Exclusion criteria

- Diagnosis of asthma during hospitalization
- Prescription of nedocromil, ketotifen, cromolyn, antileukotrienes
- Receiving gabapentinoids prior to cohort entry

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Methods

- Patient followed until date of outcome, death, end of prescription drug coverage, or end of study period (31 Dec 2015)
- Generated time-based exposure sets including comparator individuals who were not exposed to gabapentinoids up to that time point, had the same indication, age (+ or – 1 year), sex, calendar time of base cohort entry (+ or – 1 year), had a physician visit in prior 3 months
- Matched each gabapentinoid treatment initiator 1:1 without replacement on TCPS to a comparator with the closest TCPS in the exposure set
- Cohort entry: date of gabapentinoid initiation or same time in the matched nonusers

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Methods

- Estimated TCPS using conditional logistic regression, including comorbid conditions measured any time before the date of matched exposure set: HTN, HLD, CAD, heart failure, stroke or TIA, DM, CKD, liver disease, cancer, OSA, dementia, anxiety, OCD, mood disorder, schizophrenia, schizotypal or delusional disorder, drug misuse, alcohol misuse.
- Also included hospitalizations for pneumonia, moderate-severe COPD exacerbations, number of bronchodilators used in 1 year prior to cohort entry.

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Outcome

- Primary: severe COPD exacerbation: first hospitalization with an admission for COPD or primary diagnosis of COPD at follow up or death due to COPD exacerbation
- Secondary: moderate or severe exacerbation and respiratory failure. Moderate: prescription for oral prednisone.

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Statistical analysis

- Descriptive statistics, comparing patients initiating gabapentinoid therapy with TCPS-matched comparator using standardized mean differences
- Poisson distribution for crude incidence rates and 95% CIs
- Cox proportional hazards models for hazard ratio and 95% CIs

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Statistical analysis

Secondary analyses and 6 sensitivity analyses:

1. varied the grace period between successive prescriptions to 15 and 30 days.
2. repeated the primary analysis, limiting the follow-up to 1 year.
3. analysis using an intention-to-treat exposure definition with the maximum follow-up limited to 1 year.
4. excluded patients with cancer before or at cohort entry, who may be prescribed gabapentinoids or other pain medications for palliative care.
5. inverse probability of censoring weights to further account for potential informative censoring by discontinuation of study medication therapy and for competing risk fordeath from other causes. Also censored patients who used benzodiazepines or opioids during follow-up
6. computed an E-value to assess the robustness of findings to potential residual confounding.

Post hoc analysis: repeated the primary analysis including neuropathic pain and other chronic pain in the TCPS for the epilepsy subcohort, and other chronic pain for the neuropathic pain subcohort

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Results, main findings

- Base cohort of 156803 patients with COPD, including:
1. 356 gabapentinoid treatment initiators with epilepsy
2. 9411 with neuropathic pain
3. 3737 with other chronic pain
4. Matched to equal numbers of nonusers
- Before TCPS matching, gabapentinoid users were sicker than nonusers (comorbidities, overall health, had higher medication use across indications)
- After matching, characteristics were balanced except for CKD in patients with epilepsy

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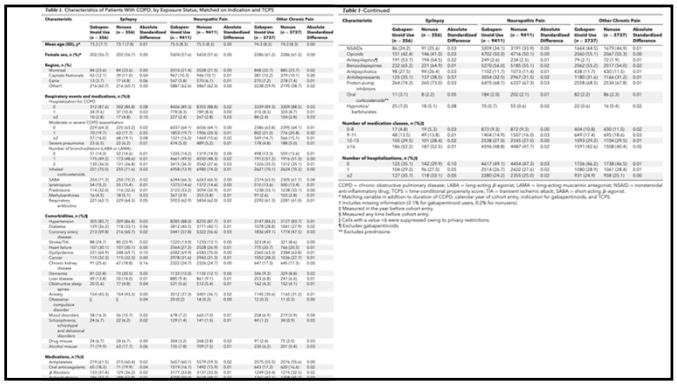

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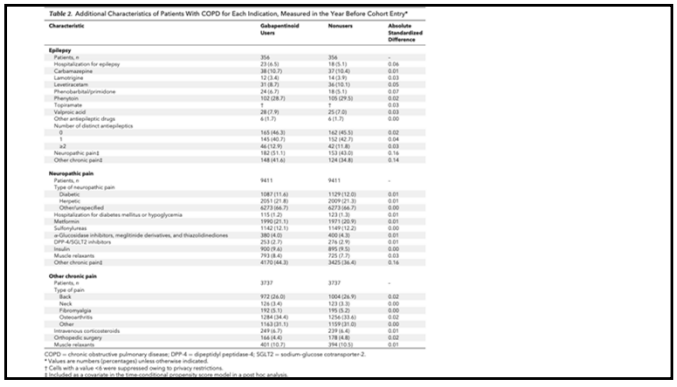

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Results, main findings

Mean follow up time:

1. Patients with epilepsy: 1.5 years, gabapentinoid treatment duration: 0.6 years
2. Patients with neuropathic pain: 1.6 years, gabapentinoid treatment duration 0.5 years
3. Patients with other chronic pain: 1.6 years, gabapentinoid treatment duration 0.5 years

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Results, main findings

Gabapentinoid use was associated with increased risk for severe COPD exacerbation across all indications:

Table 3. Adjusted HRs for Severe COPD Exacerbation Associated With the Use of Gabapentinoids, by Indication and Overall

Exposure	Patients, *n*	Events, *n*	Person- Years, *n*	Incidence Rate (95% CI)*	Adjusted HR (95% CI)†
Epilepsy					
Nonuse	356	90	838	10.7 (8.7-13.2)	1.00 (Reference)
Gabapentinoid use	356	46	205	22.4 (16.8-29.9)	1.58 (1.08-2.30)
Neuropathic pain					
Nonuse	9411	2142	24 645	8.7 (8.3-9.1)	1.00 (Reference)
Gabapentinoid use	9411	712	4646	15.3 (14.2-16.5)	1.35 (1.24-1.48)
Other chronic pain					
Nonuse	3737	756	10 298	7.3 (6.8-7.9)	1.00 (Reference)
Gabapentinoid use	3737	258	1842	14.0 (12.4-15.8)	1.49 (1.27-1.73)
Overall cohort					
Nonuse	13 504	2988	35 780	8.3 (8.0-8.6)	1.00 (Reference)
Gabapentinoid use	13 504	1016	6693	15.1 (14.2-16.1)	1.39 (1.29-1.50)

COPD = chronic obstructive pulmonary disease; HR = hazard ratio.
* Per 100 persons per year.
†After matching on duration of COPD, indication for gabapentinoids, age, sex, calendar year of cohort entry, and time-conditional propensity score.

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Results

The cumulative incidence curves diverged shortly after gabapentinoid treatment initiation.

Peak increase in risk after 6 months of continuous use (suppl figure 1)

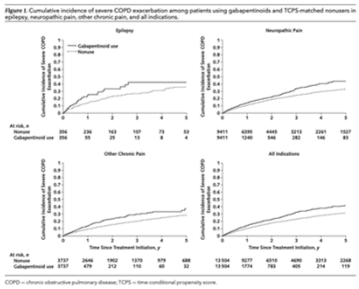

Figure 1. Cumulative incidence of severe COPD exacerbation among patients using gabapentinoids and TCPS-matched nonusers in epilepsy, neuropathic pain, other chronic pain, and all indications.

COPD = chronic obstructive pulmonary disease; TCPS = time-conditional propensity score.

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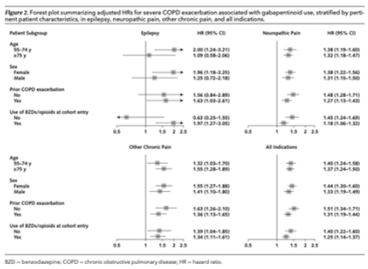
Results

In stratified analyses, estimates in patients with epilepsy had uncertainty

In patients with neuropathic/other pain risk observed regardless od age, sex, number of prior COPD exacerbations, prior use of ICS, number of respiratory meds, opioid or BZD use at entry.



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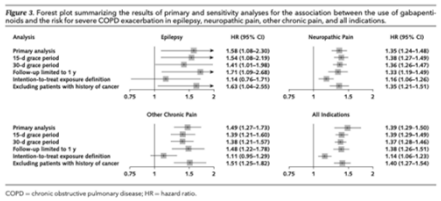
Subgroup analysis

Results consistent with primary analysis



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Subgroup analysis

- Risk of severe exacerbation similar in gabapentin or pregabalin
- Association still present in patients with undocumented indication
- Compared with NSAIDs, gabapentinoids remains associated with risk for severe exacerbation
- Gabapentinoids also associated with increased risk for moderate-severe exacerbation and respiratory failure

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Discussion – strengths

- Large sample, multiple indications
- Matched exposed and unexposed patients on indication, COPD duration, age, sex, calendar time and TCPS

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Limitations

- Definition of COPD: use of medications, due to limited validity of ICD codes
- Possible misclassification of asthma among prescribed LABA-ICS
- More likely to capture age>65 because covered by insurance for prescription medications
- Data on outpatient visits to ED not available
- Lack of information on previous or current smoking
- Could not exclude patients with pain in the subcohort of patients with epilepsy
- Opioid/BZD use is another potential confounder, but was well balanced between groups
- Race and ethnicity not available – possible residual confounding

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Clinical implications

- Need for caution when prescribing gabapentinoids to COPD patients, especially those with additional risk factors (polypharmacy, older age, renal impairment, concurrent CNS depressants).

30

Summary and recommendations

- Gabapentinoids are associated with increased risk of severe COPD exacerbation, and prescribers should carefully weigh risks and benefits in this population.

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32

PointClickCare

Use of AI in Nursing Homes

Steven Buslovich, MD, CMD, MS
Chief Medical Officer, Senior Care

Hussien Ballout, MD,
backed by PointClickCare

1

Learning Objectives

1. **Identify core principles about the use of AI in health care.**
2. **Apply AI to produce accurate, real-time data and use it to identify QI opportunities, monitor patients, assess and address risks, and ensure accurate reimbursement that align with value-based care.**
3. **Understand how AI tools may intensify or promote structural inequities and racial biases and how to overcome these.**
4. **Use AI is a way that fosters public trust, protects resident privacy/rights, and aligns with applicable values, regulations, and laws.**

2

2

Fun Fact:

The term 'artificial intelligence' was coined in 1956 — the same year the first power lawn mower hit the market. Progress comes in all forms!

3

What is Artificial Intelligence?

Definition: The simulation of human intelligence processes by machines.

Core Domains:
- Machine Learning (ML)
- Natural Language Processing (NLP)
- Large Language Models (LLMs)
- Predictive Analytics

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Brief History of AI

- 1950s: Birth of AI – Alan Turing proposes the Turing Test
- 1980s: Expert Systems – Rule-based decision aids in medicine
- 2000s: Machine Learning Boom – Data-driven predictive models
- 2010s: Deep Learning Era – Neural networks mimic human brain function
- 2020s: Generative AI – ChatGPT, medical note summarization, and more

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Fun Fact:

The first AI program to diagnose illness was written in 1972 — it took 8 minutes to process one patient.

6

AI in Healthcare Today

Applications

- Clinical Documentation: Ambient scribing, structured note generation
- Predictive Analytics: Readmission risk, pressure injury prevention, Coding, Compliance
- Medication Management: Polypharmacy alerts, deprescribing assistance
- Workflow Optimization: Task prioritization, communication
- Resident Monitoring: Falls, sleep, cognitive changes

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Common Myths About AI

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Myth #1: AI will replace clinicians

Reality: It reduces cognitive load and documentation burden.

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Beyond Myths: The Leaders Pushing AI Forward

- IBM's CEO, Arvind Krishna, reported that while AI has replaced **several hundred HR roles**, the company has simultaneously increased hiring in areas like **programming and sales** that require **human judgment and creativity**.
- Salesforce has reallocated **500 employees to data-centric roles** due to **AI handling routine customer support tasks**.
- Nvidia CEO Jensen Huang **emphasized that individuals risk job loss** not to AI directly, but to peers who adeptly **utilize AI tools**.

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The Real Story of AI in Action

When AI is introduced, many feared it would lead to sweeping job losses. But here's what actually unfolded:

- 🔥 **The so-called "freed up" resources?**
- 🔥 **The "extra capacity"?**
- 🔥 **And those "redundant" roles?**

AI didn't replace people

The true risk isn't being replaced by AI—it's being left behind by those who know how to use it.

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Myth #2 AI is error-free

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Myth #2 AI is error-free

Reality: It learns from our biases and data gaps

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Myth #3 AI is too expensive for PALTC

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Myth #3 AI is too expensive for PALTC

Reality: Cloud-based tools are lowering the cost barrirer

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Think of AI Like Your Favorite Intern

16

AI in Post-Acute & Long-Term Care

Applications:

- Chronic Condition Management: Predicting exacerbations
- Staffing Optimization: Scheduling to reduce burnout
- Quality Improvement: Trend analysis from MDS and EHR data
- Resident Safety: Fall detection, behavioral monitoring
- Education: Clinical decision support & just-in-time learning

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Responsible & Ethical AI Use

Principles:

- Transparency: Know when AI is assisting
- Bias Mitigation: Reflect diverse populations
- Privacy & Security: HIPAA-compliant design
- Clinical Oversight: AI augments, not replaces, human judgment

AI should extend the clinician's empathy, not erode it.

18

18

Accountable AI & Privacy

”It takes many good deeds to build a good reputation, and only one bad one to lose it”

- Benjamin Franklin

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Accountable Artificial Intelligence and Privacy

- High Stakes in Healthcare
- Principles of Trust, Transparency, and Care Collaboration
- Reliable Partner

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Care Collaboration

AI can be applied within existing clinical workflows:

- To augment and inform care throughout the patient journey
- To support EHR systems (PointClickCare and partners); and
- To improve care collaboration through the same data set that spans the continuum of care.

Value-Based Care

- AI enables risk-bearing entities to improve
- compliance with contractual obligations associated with VBC
- providing proper risk identification
- achieve better outcomes.

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Efficiency & Empowerment

- AI helps deliver on the promise to help clinicians make appropriate care decisions at the right time for the highest-needs patients.
- AI supports risk assessments with the goal of improving clinical outcomes through predictive models, more efficient extraction of chart data, and bi-directional learning between human and technology, reducing administrative burden and enhancing care quality.

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Trust & Transparency

- AI often requires large data sets that may include PHI.
- We need to remain dedicated to responsible AI practices, including rigorous testing and adherence to ethical standards and guidance created by credible third-party associations
- PointClickCare selects, adapts and integrates AI technologies using a cross-functional approach involving clinical experts, applied scientists, product development, designers and engineers to ensure solutions meet all expectations of our customers and industry best practices.
- Peer-reviewed research validates PointClickCare's approach, due diligence and effectiveness of its AI model to empower clinical care teams and non-clinical staff. An example is the Predictive Return to Hospital (pRTH) model

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JAMDA 26 (2024) 105288

ELSEVIER

JAMDA

journal homepage: www.jamda.com

Original Study

Development of a Predictive Hospitalization Model for Skilled Nursing Facility Patients

Ben Kandel PhD [a,*], Cheryl Field MSN, RN [a], Jasmeet Kaur MS [a], Dean Slawson BS [a], Joseph G. Ouslander MD [b]

[a] PointClickCare Technologies Inc., Mississauga, ON, Canada
[b] Schmidt College of Medicine, Florida Atlantic University, Boca Raton, FL, USA

ABSTRACT

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24

Mismatch Between Capabilities and Expectations

- AI often marked by hype that doesn't reflect it's capabilities
- AI can make confident, but wrong predictions
- When users discover limitations (i.e., hallucinations in chatbots), it can feel as a betrayal of trust

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Accountability

Lack of accountability creates legal and ethical challenges:

- When AI causes harm, who bears the responsibility?

26

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The Road Ahead

Next-Gen Applications

- Personalized Care Plans
- Multimodal AI (EHR, voice, image data)
- Clinical governance for safe deployment

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Your Role

- Embrace AI as a clinical partner
- Contribute data responsibly
- Stay curious and engaged

How to Get Started
- Identify pain points (documentation, meds)
- Pilot AI tools in low-risk workflows
- Train teams on responsible use
- Partner with vendors for integration

AI won't replace clinicians – but clinicians who use AI will replace those who don't

28

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What can we do as leaders?

New Mandate for AI Transformation

29

How can leaders be successful in this transformation…

- Elevating your mindset
- See AI as a partner, not a threat
- Foster curiosity over fear
- Encourage experimentation over perfection
- Make space for reflection, learning, and growth

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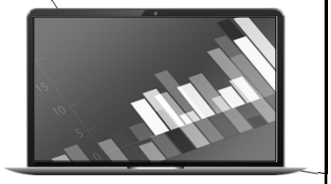
Practical Scenarios Using Copilot

- Demonstrate drafting constructive feedback with AI assistance.
- Show how AI can summarize leadership meetings quickly.
- Explore brainstorming techniques for development plans using AI.
- Prepare strategic narratives efficiently with AI tools.



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Where in your leadership do you consistently find yourself operating in the weeds—where AI could help you rise above and focus on higher-impact work?

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By 2030, AI may save U.S. healthcare up to **$150 Billion** annually

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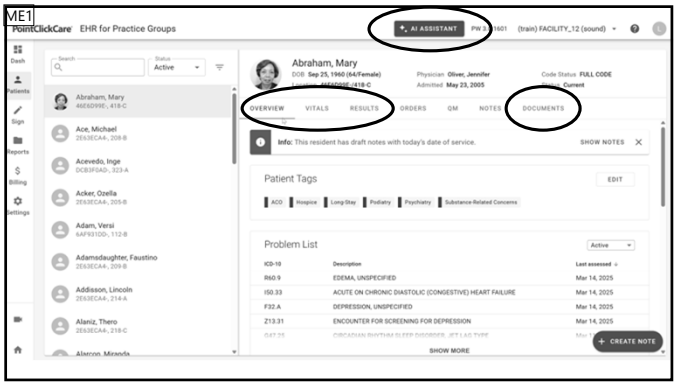
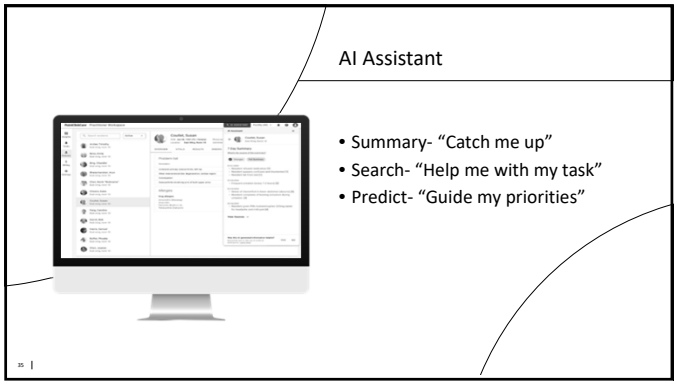
ME1


PointClickCare EHR for Practice Groups
AI ASSISTANT
(train) FACILITY_12 (sound)
Abraham, Mary
OVERVIEW
VITALS
RESULTS
ORDERS
QM
NOTES
DOCUMENTS
Info: This resident has draft notes with today's date of service.
SHOW NOTES
Patient Tags
EDIT
Problem List
CREATE NOTE
SHOW MORE

34


AI Assistant
• Summary- “Catch me up”
• Search- “Help me with my task”
• Predict- “Guide my priorities”
35

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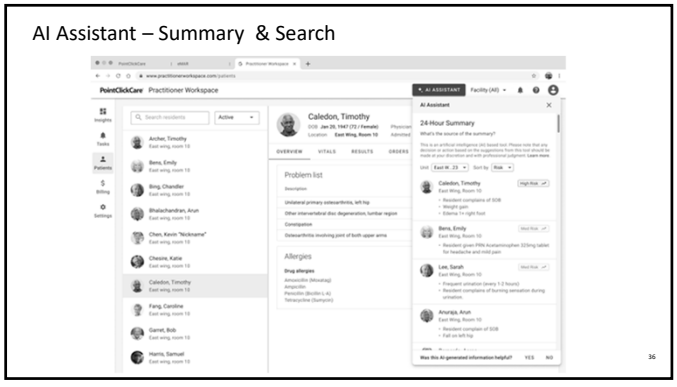
AI Assistant – Summary & Search
PointClickCare Practitioner Workspace
AI ASSISTANT
Caledon, Timothy
24-Hour Summary
Problem list
Allergies
36

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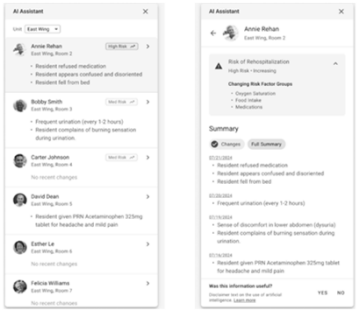
Slide 34

ME1 [@Anthony Laflen] Added slides- will work on the content and delivery.
Maggie Emerson, 2025-01-10T05:41:19.742

AI Assistant – Predict



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SNF Stay Summary Notification

Collaborative Partner of

Promotes faster evaluation, stabilization, admission or return to SNF

A summarized view of the SNF stay and transfer data including:

- SNF admission date, time and diagnoses
- Facility and practitioner name
- Emergency contacts
- Resuscitation preferences
- Last 14 days of administered medications, dosages, dates, and times
- Transfer insights from the SNF EHR, informed by our proprietary **Reason for Transfer AI Model**

38

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ED Optimization

Collaborative Partner of

American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

Improve ED Point of Care Decisions

Enable faster, more informed and collaborative care with real-time, information integrated into their workflow.

Enhance Care Delivery for High-Priority Populations

Provide patient-centered, quality of care for high-risk, complex and vulnerable patients driving utilization or requiring other care coordination.

Improve ED Efficiency, Throughput, and Outcomes

Real-time notifications and actionable clinical insights help improve responsiveness and patient outcomes.

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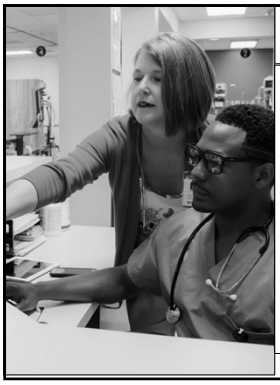

Top Insights Delivered to the ED

1. Patterns of High ED Utilization
2. Mental and Behavioral Health Events
3. Substance Use Disorder or Overdose Events
4. History of Violence/Safety and Security Events
5. Recent Post-Acute Discharge or Transfer from SNF
6. Acute Readmission Risk
7. Social Determinants: Housing insecurity
8. Traveling Patients
9. Documented Individual Care Plans
10. PDMP data

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Epic Trackboard Integration

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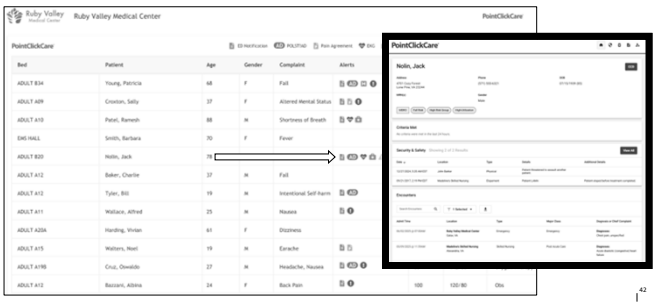
Smart on FHIR Trackboard View



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Closing Thoughts

- AI represents the next wave of clinical transformation in PALTC
- It's not about replacing compassion – it's about amplifying it through data
- Ask yourself, what kind of leader of Tomorrow do you want to be?

43

43

Thank you!

44

Legal Implications of Artificial Intelligence ("AI") In Healthcare

1

March 11, 2025

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1

"It Cannot Be Reasoned With!!!..."

The Terminator
Dir: James Cameron

Orion Pictures

1984

2

Overview of Presentation – How AI Will Impact Provision of Health Care and Legal Implications

1. Impact on Patients' Bill of Rights
2. Ethical Considerations
3. HIPAA compliance and data security
4. Delivery of Bedside care
5. Risk management and Patient Care
6. Current legislative landscape

3

Patients' Bill of Rights – Every Patient Has the Right to…

- Receive considerate, respectful and compassionate care.
- Receive emergency care
- Obtain their medical records
- Right to privacy of their medical records
- Right to informed consent
- Right to refuse treatment
- Right to refuse to take part in research
- Right to receive and question itemized bills for medical services.

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THE LIGHT COLLECTIVE

"In an era where AI is reshaping the healthcare landscape, it is imperative that patient rights are not only protected, but also championed."

– Andrea Downing, co-founder of The Light Collective

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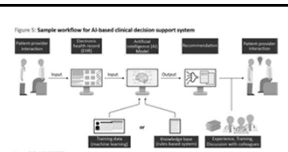

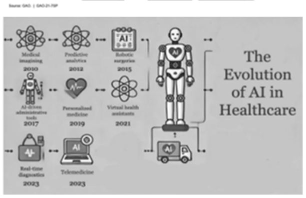

AI Evolution in Healthcare

6

The Deloitte AI Report

Transforming health care with artificial intelligence

7

The Deloitte AI Report

- In January … v healthcare organizatio… ve when adopting A…
- The Deloit… urvey asked 60 healthc… considerat… Well over 70 percent of… spect of implement… ory compliance… r is being left behind…

Transforming health care with artificial intelligence

8

Patients Bill of Rights

- Only 50 p… focused … a crucial c… while the… ed on equita… n fewer (45… educatio… Deloitte f…

Transforming health care with artificial intelligence

9

Survey Results for AI

- November 2023 report from Deloitte showed that 53 percent of all healthcare consumers think AI can improve access to healthcare, and 46 percent said it could potentially improve healthcare affordability.
- Among those who have used AI before, those numbers are even higher – 69 and 63, percent respectively.

10

Patients Bill of Rights

- Patient trust in AI is already 50/50 at best. An October 2023 report from Propeller Insights found that 49 percent of patients were comfortable with their healthcare provider using AI in the healthcare setting, while 51 percent were not.
- Relatedly, a study in May 2023 found that trust in AI chatbots is around 50 percent

11

Patients Bill of Rights and AI – What Consumers Want?

- **Transparency**: Healthcare consumers need transparency when AI is being used. Four in five healthcare consumers told Deloitte that it's important or *extremely* important that their healthcare provider let them know when they are using AI for their healthcare needs.

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Light Collective – Seven (7) AI Patient Rights Protections

1. **The right to patient-led governance**, or the idea that patients are involved in the "design, policymaking, and development of rules that govern AI"
2. **Independent duty to patients**. This could be AI's version of the Hippocratic Oath doctors must take when treating patients. Right now, AI is not guided by such principles of first doing no harm toward patients. To achieve that end, the Light Collaborative said there needs to be a fiduciary incentive plus diverse patient representation guiding healthcare's AI design and use
3. **Right To Transparency**: (Spanning three domains):
   - Patients being informed of how and why their data is being used in generative or predicative models
   - Patients being informed when medical guidance, education, or communication is based on an AI algorithm rather than direct human impact
   - Patients having access to the evidence of AI efficacy in their care

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Light Collective – Seven (7) AI Patient Rights Protections (Cont.)

4. Right to AI self-determination, meaning that AI needs to be used and developed in a way that lets patients make informed decisions about their own care. That means letting patients opt out or appeal AI-generated medical decisions
5. Right to identity privacy and security. This means ensuring patients understand any cyber risks in using AI or contributing their data to generative or predictive AI. AI should also be free of risk for scams or medical mis-or dis-information. Patients also have the right to disclosures of cyber events related to AI use.

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Light Collective – Seven (7) AI Patient Rights Protections

6. **Right of action**, meaning patients have a right to *legally enforceable action* should they experience a harm related to AI use
7. **Right to a shared benefit from AI**. This means diverse patient communities must "equitably share in the benefits created as a result of health IT." This entails creating protections from commodifying the date contributed to AI algorithms and sharing resources and funding with patient communities.

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Patients Bill of Rights – AI and Remote Monitoring (RPM)

- Artificial Intelligence will also enable Remote Patient Monitoring and raises Surveillance concerns.
- In 2021, it was reported that approximately 54 million Americans are over the age of 65. Consequently, with healthcare budgets on the rise – health care organizations such as nursing homes are searching for ways to increase efficiency and reduce costs.
- **Remote Patient Monitoring (RPM)** – which involves using connected electronic devices to record personal health and medical data in one location that a provider can review in a different location. Coupled with AI, RPM devices help in clinical decision-making by analyzing vital health data points and generating alerts. AI RPM aims for better health outcomes and reduced costs through early detection of adverse health events and prioritizing hospitalization.

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Overall Concerns including with AI RPM and Surveillance

- As these advancements are made particularly in the are of remote patient monitoring and being able to use AI in ways which seem promising from efficiency and cost-reducing standpoints, there are clear concerns that are raised and need to be enforced and remembered from a patients' rights standpoint.
- Many patients, particularly in nursing homes may not be comfortable with remote patient monitoring or surveillance, or feeling like they are being watched a la The Truman Show.
- Many older patients would prefer to know they are being monitored and managed by a human, rather than a machine. This is an important comfort consideration as machines are not nearly at the point where they are fully trusted, particularly in the older generation.
- Privacy concerns are also clearly evident and can lead to lawsuits if proper precautions are not put into place in this regard. We will discuss this further in our HIPAA section, but these points are important to remember for Patients' Bill of Rights.

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Ethical Challenges of Using AI In Healthcare Include:

- Safety and Liability – While AI has the potential to reshape healthcare operations by making them safer and more reliable, AI can be prone to errors and determining liability can be complex due to multiple parties involved in creating these applications
- Patient privacy – AI systems rely on vast amounts of data, raising concerns about how patient information is collected, stored, and used
- Informed Consent – Healthcare providers should inform patients about the use of AI in their care. Patients should additionally have the right to consent or opt out if they are uncomfortable with AI involvement in their diagnosis or treatment.

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Ethical Considerations continued

Data Ownership – Determining who owns and controls healthcare data used by AI systems can be an ethical issue with competing interests among healthcare providers, application developers and data aggregators

Data Bias and Fairness – Data used to train AI algorithms may result in biased healthcare decisions. This can lead to ethical dilemmas where AI systems possibly perpetuate or exacerbate disparities in healthcare outcomes among different demographic groups

Transparency and Accountability – Healthcare professionals and patients need to understand how AI systems make decisions. Promoting transparency in AI algorithms and ensuring that developers and providers are accountable for their decisions is essential to building trust in AI systems

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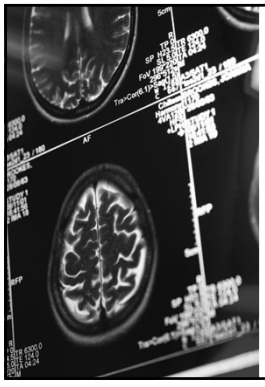

Ethical Considerations – Equitable Access

- AI algorithms can be influenced by biases present in healthcare data. In addition to well-known study biases like blinding and sampling, also need to identify implicit and explicit biases in the healthcare system. Large-scale data used to train AI systems may be impacted by these biases.
- -Clinical decision-making can be influenced by factors like clinical trial eligibility requirements and implicit biases present in real-world treatment decisions, which can affect the predictions given by AI.

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Ethical Considerations –Equitable Access

- AI can lead to healthcare inequities through biased data collection, algorithm development, a lack of diversity in training data, transparency, and research teams, requiring efforts to address biases and promote equitable outcomes
- Particularly with regard to demographic traits like sex and ethnicity, there is growing recognition of the detrimental effects of model bias. Studies have also revealed poorer implementation rates for specific diseases in rural areas, racial and ethnic minority groups, those without insurance or with inadequate insurance, as well as individuals with lower education and income.

22

Ethical Considerations and Liability

- Hippocratic Oath: Doctors and Nurses have a duty – including a Hippocratic Oath – governing treatment of patients and governing duties of confidentiality that are sacrosanct.
- But what happens when machine judgment and diagnoses replace that of humans?

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Medical Malpractice Liability Issues

- Human Doctor is liable for the injuries incurred by the patient. In such circumstances, medical negligence law would apply.
- Courts have yet to consider liability for medical negligence in the case of autonomous AI. With machine learning, the ability of AI to operate as a medical practitioner is becoming increasingly more of a reality. In its current state it is not clear how civil liability should apply to AI and who would be liable. This is because of the ongoing debate regarding what type of liability should apply and that it would be the doctor (or hospital or nursing home), AI creator, software designer using the AI that should be liable. The issue with this is that AI is not a legal person, and cannot, therefore, be directly liable for the acts of negligence!

24

Artificial Intelligence in Healthcare: Managing Risk of Malpractice

25

Who's he gonna sue????

26

Ethical Considerations and Liability continued

- Is AI A Product or Service? Product liability is probably not an accurate categorization either, as the autonomous decision-making of the product can blur the link between the AI's manufacturer and the product itself. Indeed, it would not always be clear who would be responsible for the "defective" product, in particular, whether it would be the legal person who developed the algorithm, or the legal person who provided the data or trained the data, as different entities may have contributed to the end result.
- Moreover, an undesired outcome from the use of AI **may** not be attributable to the AI as such but to how it was used, for instance if it was used in situations where it would not be adequate.
- This illustrates how there is no current single liability approach for AI, suggesting that modern concepts of liability should evolve to encompass autonomous technology and ensure accountability.
- **Practice Tip: Speak with your Broker about AI – related coverage**

27

Ethical Considerations re: Substituting Human Judgment

"Can smart machines outthink us, or are certain elements of human judgment indispensable in deciding some of the most important things in life?"

– Michael Sandel, Political Philosopher

28

What if AI Becomes a Determiner of Capacity of Patient?

When high-stake decisions are made about an individual's life, such as whether to withdraw care or move forward with a high-risk procedure, traditionally, a responsible party is accountable for ultimate decision (with input and advice from physicians)

In modern medical systems, when patient autonomy is overridden due to lack of capacity, the decision is made by a treating physician, often with consultation and input from psychiatry consultants specializing in capacity assessments, service chiefs, and hospital ethics committees. This can also involve Court oversight in the Guardianship process.

However, if a decision were to be made by an AI algorithm, it is less clear how to improve the system should a bad outcome occur. If AI algorithms are ever to be involved, it is essential that guidelines be established regarding when and how a physician may overrule an algorithm.

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Ethical Considerations re: Substituting Human Judgment

- According to participants in studies, AI cannot replace the judgment of HCPs, and the human dimension of care is fundamental. The results from another empirical study follow the idea that AI systems **should not be autonomous**; decisions and monitoring should remain the tasks of a human being.
- Moreover, the **patient should must be involved in the decision-making process independent of the involvement of AI in care**.
- It seems that citizens would react negatively *if AI were used alone in health care*, without staff assistance, indicating a lack of trustworthiness despite the acknowledged benefits – this may be where to draw the line

30

HIPAA Compliance and Data Security

- AI systems rely completely on the input of data – so the machine can learn and be useful. In healthcare systems, that data consists of highly sensitive private medical information.
- As one can imagine, there are significant legal risks associated with giving an algorithm access to patients' private health information. It's quite problematic as it not only exposes personal information to potential security threats associated with online data but can also violate the personal autonomy of patients.
- For example, there have been references in the past to public-private partnerships for implementing machine learning that have resulted in poor protection of privacy

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HIPAA Compliance and Data Security

Gathering private data without patient consent infringes on personal autonomy.

Data being processed will potentially include

(all of which are considered special categories of data, subject to a higher level of data protection of the subjects, including limitations on the grounds for processing such data).

From a legal perspective, there should be safeguards to ensure that the data processed for training AI models respects patients' privacy rights, including assuring proper data subjects' consent when required and applying adequate safeguards

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Regulatory Compliance: A focus on HIPAA

- AI's increasing role in healthcare, attention to HIPAA compliance becomes essential. **HIPAA**, or the Health Insurance Portability and Accountability Act, sets the standard for safeguarding medical information in the United States. It ensures the confidentiality, integrity, and availability of all electronic protected health information (ePHI) that a covered entity creates, receives, maintains, or transmits. As AI applications often involve handling sensitive health data, they must adhere to these regulations.
- Implementing AI while also ensuring HIPAA compliance can be challenging. AI applications require vast amounts of data for training, which may include sensitive health information. Ensuring this data is adequately de-identified to protect patient privacy, while still useful for AI, is a complex task.
- The dynamic and evolving nature of AI technology can make it difficult to maintain ongoing compliance. As such, healthcare organizations need to be vigilant in their compliance efforts and work closely with AI developers to ensure that all applications meet HIPAA standards.

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The Role of AI: De-Identifying Sensitive Health Data

AI has a pivotal role in managing sensitive health data, particularly in de-identification. De-identification refers to the process of removing or obscuring personally identifiable information from data sets, ensuring individuals cannot be identified from the data used. This process is crucial in maintaining HIPAA compliance, as it enables the use of patient data for AI applications without breaching privacy regulations.

AI can automate and improve this process by applying sophisticated algorithms that can recognize and replace identifiable information, thus reducing the chance of human error. For instance, natural language processing (NLP) algorithms can scan electronic health records and anonymize sensitive information. This not only increases the speed and accuracy of the process but also allows for the utilization of larger and more complex data sets, improving the performance of AI models.

However, the use of AI in de-identification also poses some challenges from a regulatory perspective. This includes the issue of 're-identification', where de-identified data can be combined with other pieces of information to identify individuals, which we will explore in a section to follow

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Navigating Responsibility: The Sentience Question

As AI applications become more complex and autonomous, the question of who is ultimately responsible for maintaining HIPAA compliance arises.

The sentience of AI, or its capacity to make decisions, is often at the center of this issue. On one hand, AI tools are just that—tools. They are designed and programmed by humans, and thus any non-compliance could be seen as a failure on the part of the humans who programmed them.

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Navigating Responsibility: The Sentience Question

However, AI's potential for self-learning and decision-making complicates this perspective. If an AI model, for example, incorrectly de-identifies information or accesses more information than necessary for its task, who is held accountable? The developers who created the AI? The healthcare professionals who use it? Or the AI tool itself? This is a gray area in current regulations.

As AI continues to advance, clear guidelines regarding the allocation of responsibility in the context of AI and HIPAA compliance will be crucial to navigate these challenges. This will involve ongoing dialogue and collaboration between healthcare professionals, AI developers, and regulatory bodies.

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Understanding Responsibility: The Developer's Role

- Developers play a vital role in ensuring the HIPAA compliance of AI tools in healthcare. From the conception of an AI tool to its deployment, developers must consider the application's interaction with sensitive health data and take steps to ensure the information is handled in a HIPAA-compliant manner. This includes adequately de-identifying data sets used for training AI models and ensuring the models themselves do not access more information than necessary.
- In addition to technical measures, developers also need to consider the broader ethical implications of their work. They should engage in ongoing dialogues with healthcare providers and regulatory bodies to stay abreast of changing regulations and ethical standards in the industry.
- In cases where AI tools learn and adapt over time, developers also need to take into account how this evolution might impact HIPAA compliance and design safeguards accordingly. In essence, developers must not only focus on creating AI tools that enhance healthcare outcomes but also ensure that these tools respect and protect patient privacy.

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The Doctor's Perspective: Change in Regulatory Concerns

- Incorporation of AI into practice also changes the landscape of regulatory concerns. Doctors and other healthcare professionals must now consider not only their own interactions with patient data but also how the AI tools they use handle this information. For them, understanding the basics of how AI works and its implications for patient privacy becomes crucial in maintaining HIPAA compliance. They need to be aware of the source and nature of the data that AI tools use and the safeguards in place to protect this data.
- Healthcare professionals also play a critical role in ensuring these tools are used responsibly and in a manner consistent with patient privacy rights. This includes obtaining necessary patient consents and maintaining transparency about the use of AI in patient care. Training and ongoing education are crucial in this regard, as healthcare professionals need to stay informed about the latest advancements in AI and their potential privacy implications.
- In the end, maintaining HIPAA compliance in the age of AI is a shared responsibility that requires concerted efforts from all stakeholders, including healthcare professionals.

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Potential Concerns in AI and HIPAA Compliance

- While AI has immense potential in healthcare, its use also raises several concerns related to HIPAA compliance. A significant concern is data security. AI applications require substantial amounts of data, often including sensitive health information, raising the potential for data breaches. Therefore, robust security measures are necessary to protect this data.

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Potential Concerns in AI and HIPAA Compliance

Another issue is the risk of 're-identification' of de-identified patient data used in AI development. This can happen when anonymized data is combined with other data, possibly leading to the identification of individuals, which is a violation of HIPAA. Additionally, many AI tools are designed to learn and adapt over time, which can make it challenging to maintain ongoing compliance.

As these tools change, they may begin to access more data or use data differently, potentially breaching HIPAA regulations. Another concern is the lack of clarity around responsibility for HIPAA compliance in the context of AI. As AI tools become more autonomous, it can be unclear who should be held accountable for non-compliance: the developer, the healthcare provider, or the AI tool itself.

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Staying Compliant: Navigating Healthcare Advancements

In a rapidly evolving field like AI in healthcare, staying HIPAA compliant requires continuous effort and adaptation. Healthcare organizations need to work closely with AI developers to understand the functioning of AI tools and to ensure they meet HIPAA standards. Regularly updating policies and procedures, implementing robust security measures, and monitoring AI tools for potential compliance issues are essential strategies.

Training healthcare professionals to understand the implications of AI for patient privacy is another critical step. In this way, they can use AI tools responsibly and maintain transparency with patients about how their data is being used. Moreover, healthcare organizations should participate in the ongoing dialogue about AI and HIPAA, contributing their perspective to the development of regulations that address the unique challenges posed by AI.

Efforts should be made to stay informed about the latest advancements in AI and their potential privacy implications. Navigating the complexities of HIPAA compliance in the age of AI is undoubtedly challenging, but with collaboration, vigilance, and a commitment to patient privacy, it is certainly achievable.

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The Path Forward

HIPAA, along with the General Data Protection Regulation (GDPR) impose strict regulations on the protection of patient data. Organizations that fail to comply with these regulations can face substantial fines.

The case of a hospital facing penalties for non-compliance with HIPAA regulations underscores the need for a robust cybersecurity framework

The AI system, though designed to improve patient care, becomes a vulnerability if not forfeited with robust cybersecurity measures. The incidents highlight the urgent need for future healthcare leaders to integrate AI and cybersecurity seamlessly.

While facing the challenges posed by AI and cybersecurity, a clarion call goes out to future healthcare leaders who possess the vision, knowledge and determination to drive positive change. These leaders must champion the integration of AI while maintaining an unwavering commitment to the community.

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AI in Medicine: Long-Term Care

- -Use of AI has been steadily increasing at Nursing Homes, as nursing homes look to use the technology to improve efficiencies in a wide variety of areas, from clinical outcomes to back-office work
- -From clinical decision support, to looking to improve staff engagement and the resident experience, to assessing risk for falls and pressure ulcers, to having robots serve food and clean, AI-powered tools are making their way into every facet of nursing home operations.

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AI in Medicine: Nursing Homes – Advocacy for its use

- Majd Alwan, who is Chief strategy and growth officer for Thrivewell – a company that's focus is in "Innovative Senior Living IT Services," is one of the stronger advocates for use of AI in Nursing Homes
- Majd Alwan is one of the many who believes that AI's assistance with clinical decision-making will mean improvements in the accuracy and power of diagnosing and treating disease, in turn leading to better clinical outcomes and more time spent with patients
- Pressure ulcers, wound management, hypertension, congestive heart failure (CHF) and diabetes – some of the more common conditions in nursing homes can be potentially better managed with assistance of AI tools

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AI in Medicine: Nursing Homes – Advocacy for its use

- Predicting and diagnosing pressure ulcers – a condition often missed on darker skins due to being difficult to visually detect in early stages of development is one example cited by Alwan.
- "All the nurse needs to do now is connect a camera to a computer and take a picture of the patient's back, and it will identify exactly where the pressure points are…You are preventing a pressure ulcer from developing into stage one, and maybe even stage two pressure ulcer, which would be much, much harder and costlier to treat." – Alwan

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AI in Medicine: Nursing Homes – Advocacy for its use

- AI-enabled tools are also similarly being used to manage CHF patients. For CHF patients, a simple weight and blood pressure check can now alert the clinical staff to modifications in crucial medications.
- Lasix removes excess fluid and treats CHF as well as kidney disorders and liver disease, but its use requires tedious monitoring of patients. With AI's guidance, this process can be less laborious and even more accurate

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AI in Medicine: Nursing Homes – Advocacy for its use

- "If the system sees a sudden change in the patient's weight, the system may ask them if they're taking their Lasix, and if they're not, it may give them an education about the importance of medication and taking their Lasix. If they complain, it may ask them why they're not taking their medication, and if they say 'The frequency of the nightly bathroom visits is disrupting my sleep,' then the clinician may come back and give them recommendations to change the schedule of taking their Lasix." – Majd Alwan

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AI in Care: Risk Assessment and Patient Care

- In a Mayo Clinic Cardiology study, AI successfully identified people at risk of left ventricular dysfunction, which is the medical name for a weak heart pump, even though the individuals had no noticeable symptoms.
- "We have an AI model that can incidentally say 'Hey you've got a lot of coronary artery calcium, and you're at high risk for a heart attack or a stroke in five or 10 years." – Bhavik Patel, Chief Intelligence Officer at Mayo Clinic in Arizona
- As discussed, AI has many capabilities in patient care, including even answering patients' questions. In a study of a social media forum, most people asking healthcare preferred responses from an AI-powered chatbot over those from physicians, ranking the chatbot's answers higher in quality and empathy.

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AI in Care Potential Negatives

- The debate about incorporating AI into healthcare raises controversy in the workforce. With the intent to make AI a fundamental pillar in healthcare, several drawbacks and difficulties have been put into consideration. Some of those we have already discussed include: relevant data accessibility, concern for clinical implementation and ethical dilemmas between AI and patients
- The current capabilities of AI are far from perfected. The most popular AI platform, ChatGPT, has been proven to have a lack of authenticity regarding references used in medical articles. The ChatGPT generated 30 short medical papers, each with at least 3 references. Overall, of 115 references found in those medical articles, 47% were fabricated, 46% were authentic but inaccurate, and only 7% of them were authentic and accurately analyzed the information.
- This shows a very legitimate concern for using AI in the medical world provided its current accuracy

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AI in Care: Other Concerns

- Beyond privacy, the accountability for misdiagnosis of AI is also an issue, as we have noted. AI's have been touted by supporters as more accurate than physicians in their diagnoses. However, there is a danger to trusting AI implicitly.
- For instance, a cardiologist who defaults to AI in their diagnosis when they are uncertain, that would be making a rational choice. But, if the AI misdiagnoses the patient and creates a worse situation, it is hard to pin the blame on the cardiologist. To overcome these obstacles, several approaches like developing ethical governance, model explainability, and ethical auditing are possible solutions which have been recommended to maximize fairness, accountability and transparency.

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AI in Care: The Liability Issue

- As touched on earlier, it is clear that the increasing use of AI in medicine will lead to legal challenges regarding medical negligence. Since the use of AI involves multiple actors, consisting of manufacturer, hospitals, physicians, etc. the issue of who is liable for issues caused by AI is wide-open.
- There have been multiple solutions discussed to solve this complicated issue. For example, giving AI personhood has been discussed as a possible solution, so that harmed patients could directly sue AI devices. There is also the suggestion of a common enterprise model, which encloses manufacturers, physicians and hospitals, which would be a shift from the individualistic concept of responsibility toward a more distributed one

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Current Legislative Landscape

- Video – Legal Issues surrounding AI in General:
- https://www.wsj.com/video/series/tech-news-briefing/ais-thorniest-issues-will-be-addressed-in-court/648D0ED8-65B4-4623-A0D4-E892BA076C3F
- **Like any other emerging innovation, AI in healthcare also comes with its own risks and requires regulatory controls. Most of the regulations revolve around Software as a Medical Device (SaMD) and are regulated under digital health products. So, we will take a look at some of these regulations, some issues they may present and where to go from here.**

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Current Legislative Landscape: Jurisdictional Issue

- As AI is still in its early stages of growth, many jurisdictions still lack specific regulations for the use of AI-enabled tools by various actors. Of those that do have regulations, the next challenge lies within the lack of clarity and the many differences across different jurisdictions.
- This inconsistency means the protections of health and safety may be lacking in some circumstances. Additionally, the license for AI providers to operate in a market is often highly dependent on local officials whose discretion can change quickly. This variability creates an uncertain regulatory environment that generally impedes investment and the scale-up of AI technology

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Current Legislative Landscape: What, if anything, is in Place Right Now

FDA

- Currently, there are no specific regulatory pathways for AI-based technologies in the USA, but the Food and Drug Administration (FDA) evaluates them under the existing regulatory framework for medical devices.

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Current Legislative Landscape: What, if anything, is in Place Right Now

- The FDA issues an AI based Action Plan in January 2021, which outlined the following five actions based on the total product life cycle (TPLC) approach for the oversight of AI:
  1. Specific regulatory framework with the issuance of draft guidance on "Predetermined Change Control Plan"
  2. Good machine learning practices
  3. Patient-centric approach, including the transparency of devices to users;
  4. Methods for the elimination of algorithm bias and algorithm improvement;
  5. Real-world performance monitoring pilots

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Expanding on FDA Action Plan

- The first action, a "Predetermined Change Control Plan" – is expected to be a framework for modification of AI and would include the type of anticipated modifications, and the associated methods used to implement those changes in a controlled manner that would mitigate the risks to patients, known as the "algorithm change protocol" (ACP).
- The second action of "Good Machine Learning Practices" refers to good software engineering practices or quality system practices that include the following features:
  1. High relevance of available data to the clinical problem and current clinical practice;
  2. Consistency in data collection that does not deviate from the intended use;
  3. Planned modification pathway;
  4. Appropriate boundaries in the datasets used for training, tuning and testing the AI algorithms;
  5. Transparency of the AI algorithms and their output for users

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Current Legislative Landscape: What is in Place Right Now

- Recognizing the need to develop frameworks that are as equally flexible as AI's adaptability and constant evolution, instead of a static, one-time certification model, the FDA has focused on AI developers with its precertification program to assess an organization's performance for high-quality software design, testing and monitoring.
- By collaborating with and trusting AI companies to uphold certification standards, FDA can also regulate AI changes and modification as developers are expected to be transparent and update the administration when necessary. FDA has also been updating its catalogue of AI medical devices as new innovations appear.
- The National Academy of Medicine has also recognized and identified areas in which AI can be deployed in an ethical, equitable and transparent manner

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Moving forward and Considerations for Regulations to be put in Place

- WHO publication outlines six areas for regulation of AI for health:
  1. To foster trust, the publication stresses the importance of transparency and documentation, such as through documenting the entire product lifecycle and tracking development processes;
  2. For risk management, issues like "intended use," "continuous learning," human interventions, training models and cybersecurity threats must all be comprehensively addressed, with models made as simple as possible
  3. Externally validating data and being clear about the intended use of AI helps assure safety and facilitate regulation

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WHO Publication Six areas for Regulation Continued

4. A commitment to data quality, such as through rigorously evaluating systems pre-release, is vital to ensuring systems do not amplify biases and errors
5. The challenges posed by important, complex regulations – such as the General Data Protection Regulation (GDPR) in Europe and the Health Insurance Portability and Accountability Act (HIPAA) in the USA – are addressed with an emphasis on understanding the scope of jurisdiction and consent requirements, in service of privacy and data protection
6. Fostering collaboration between regulatory bodies, patients, healthcare professionals, industry representatives, and government partners, can help ensure products and services stay compliant with regulation throughout their lifecycles

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Wrapping Up

- It is necessary to note that the current regulations and regulations to be put in place still may not suffice as AI-based technologies are capable of working autonomously, adapting their algorithms, and improving their performance over time based on the new real-world data that they have encountered.
- With promising capabilities and enormous potential, many healthcare organizations are likely to jump at the opportunity to incorporate AI, considering the ability to increase efficiency and reduce costs.
- However, there are important ramifications and considerations that cannot be forgotten as AI becomes increasingly utilized. The importance of the patient cannot be forgotten – whether it be protecting them, their data, or their ability to identify liability for an act of negligence, these will be big issues to watch moving forward.
- The answers are still open, but one thing is for certain, the machines have arrived on the scene and are here to stay – and will be a prominent part of healthcare moving forward –
- The question for us humans, is how will we adapt and what will we do to optimize living and working with AI at our fingertips?

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Questions???

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LATEST CMS UPDATES & GUIDANCE

MID-ATLANTIC SOCIETY OF POST-ACUTE & LTC MEDICINE

1

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2

AGENDA

Part I – *Overview of Key Areas: MDS Impact*

Barbara Bates, MSN, DNS-MT, RAC-CT, QCP-MT

Questions and Answers

Moderator: Dr. Ziad K. Mirza

Co-Moderator:

Dr. Fatima Naqvi

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TRAINING OBJECTIVES

1. Discuss the 2025 updates to the survey process and how they may impact on the practice and care of the resident
2. Identify strategies to prioritize implement & monitor changes
3. Describe the Minimum Data Set (MDS) assessment tool and the need for accuracy
4. Highlight the MDS sections key to the Medical Team and their supporting documentation

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TRAINING OBJECTIVES

5. Discuss provider orders and clarify timing of orders for use in determining active diagnoses
6. Identify common deficiencies that occur due to lack of specific provider documentation
7. Describe what we must know about the Preadmission Screening and Resident Review (PASRR)

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CMS REGULATORY CHANGE 2025

F627 & F628 – Transfer, Admission, Discharge and Discharge Documentation

- Assessment for self care or need for caregiver
- Discharge organized, communicated, well thought out
- Policy & Procedure allows resident return following hospitalization and therapeutic leave
- Against Medical Advice (AMA) policy is reviewed, aligns with current guidance
- Staff educated/understand what AMA means

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F758 & F605 – UNNECESSARY USE OF PSYCHOTROPICS & CHEMICAL RESTRAINT

Merged with F tags and removed F758 Unnecessary Use of Psychotropics

F757 Revised and reorganized to include guidance for unnecessary medications excluding psychotropics

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F605 – UNNECESSARY USE OF PSYCHOTROPICS/CHEMICAL RESTRAINTS

- Not required to treat resident's medical symptoms
- Used as last resort
- Documentation that facility attempted interventions have been deemed clinically contraindicated or unsuccessful
- Residents have right to be informed & participate in their treatment

  -Notification before initiating or increasing, right to participate, right to accept or decline the medication

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F605 – UNNECESSARY USE OF PSYCHOTROPICS (CONTINUED)

- Facility must ensure each resident's drug regimen must be free from unnecessary drugs
- Unnecessary medication definition:
  - Excessive doses – including duplicate drug therapy
  - Excessive duration
  - Without adequate monitoring
  - Without adequate indications for use
  - Presence of adverse consequences which indicate should be reduced or discontinued
  - Any combination of reasons noted

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F605 – UNNECESSARY USE OF PSYCHOTROPICS(CONTINUED)

- New order or increasing psychotropic medication – must address in medical record non-pharmacological approaches used prior
- Document assessment of relative benefits & risks, preferences and goals for treatment
- Admitted with psychotropic without clearly documented indication
  - Prescribing provider & IDT should determine if med justified by conducting comprehensive medical & psychiatric evaluation

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F605 – UNNECESSARY USE OF PSYCHOTROPICS(CONTINUED)

- Psychotropics switched from one type to another – rationale for change should be reflected in medical record
- Documented verbal consent is sufficient, but documentation must cover everything reviewed verbally
- Mental Disorders should be diagnosed, using evidence –based criteria, such as the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), and documented in resident's record.
- Resident/Resident Representative must be informed of benefits, risks & alternatives for medications – including black box warnings in advance to initiation or increase

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INSUFFICIENT DOCUMENTATION

- Schizophrenia or other diagnoses only mentions as indication in MD orders – no supporting documentation
- Practitioner's note or transfer summary from previous provider stating hx of Schizophrenia or other diagnosis without supporting documentation confirming the dx with previous practitioner or family – facility failed to provide evidence of comprehensive evaluation after admission by a practitioner
- Note of Schizophrenia or other diagnosis in EMR without supporting documentation which populated throughout EMR
- Note of Schizophrenia or other diagnosis in EMR by a nurse without supporting documentation by a practitioner

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F658 & F841 – PROFESSIONAL STANDARDS & MEDICAL DIRECTOR

- Clarification that the medical director is responsible for intervening when medical care is inconsistent with current accepted standards of care
- Participation in the Quality Assessment and Assurance (QAA) committee or assign a designee to represent him/her (F868 – QAA committee)
- Clarification regarding the Medical Director's responsibilities related to implementing resident care policies (specifically about prescribing antipsychotics)
- Action items for F658
  - Educate medical directors and all prescribers

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F641 – ACCURACY/COORDINATION/CERTIFICATION

- Guidance added to investigate if there was sufficient documentation to support a medical condition identified, especially related to a diagnosis of schizophrenia
- Surveyors not questioning practitioner's medical judgement, they are evaluating whether the medical record contains supporting documentation for the diagnosis to verify the accuracy of the resident assessment

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F697 – PAIN MANAGEMENT

- Revised guidance- added definition for acute, chronic, and subacute pain definitions to align with CDC
- Opioid treatment for pain needs to be appropriately assessed and individualized for reach resident
- Clinicians may consider prescribing immediate-release opioids instead of extended-release & long –acting opioids
- Provided resources from AMDA, JAMA, CDC, NIH, etc. related to opioid treatment
- Emphasizes resident rights to be informed about risks and benefits of proposed treatment

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F697 – PAIN MANAGEMENT (CONTINUED)

- Review updates to guidance with Medical Director and with prescribers and consultant pharmacist
- Review/update policies & procedures related to pain medication
- Consider developing or implementing routine audits to determine if facility is following their own policies for pain management

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KEY IMPACT OF MEDICAL DOCUMENTATION ON THE MINIMUM DATA SET (MDS) ASSESSMENT

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MINIMUM DATA SET (MDS) ASSESSMENT

- Standardized tool used in nursing homes to evaluate resident's health, function status and care needs
- Ensures compliance with Medicare & Medicaid requirements

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MINIMUM DATA SET (MDS) ASSESSMENT (CONTINUED)

Overview of MDS Assessment

- Mandated for all residents in nursing home
- Designed to collect essential information about resident's medical conditions, functional capabilities & psychosocial needs
- Critical component of the Resident Assessment Instrument (RAI), which includes MDS, Care Area Assessments (CAAs) and Resident Utilization Guidelines
- Provides standardized method for assessing residents, which helps to ensure care plans are tailored to their specific needs

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MINIMUM DATA SET (MDS) ASSESSMENT (CONTINUED)

Purpose and Importance

- Care Planning- information gathered through the MDS used to develop, review & revise individualized care plans for residents
- Required to submit MDS assessments electronically to the federal MDS repository as part of the participation in Medicare & Medicaid programs
- Ensures facilities meet federal standards for resident care & quality monitoring

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MDS SECTIONS-IMPACTED BY MD ORDERS/DOCUMENTATION/TEAM COMMUNICATION

- Section B – Hearing, Speech & Vision
- Section C – Cognitive Pattern (BIMS) (Delirium)
- Section D – Mood Interview
- Section E – Behaviors (rejection of care, wandering)
- Section GG – Functional Abilities
- Section H – Indwelling Catheter, Ostomy – incontinence (type)
- Section I – Active Diagnosis

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MDS SECTIONS-IMPACTED BY MD ORDERS/DOCUMENTATION/TEAM COMMUNICATION (CONTINUED)

- Section J – Pain Management, Shortness of Breath, Falls, Surgery
- Section K – Swallow Disorder, Weight Loss/Gain, Nutritional Approaches
- Section L – Oral/Dental Status
- Section M – Sin Conditions, Pressure Ulcers, Arterial Wounds, Vascular Wounds, Diabetic wounds, etc.
- Section N – Medications (injections, insulin, high risk drug classes, antipsychotic meds, drug regimen review & f/u, etc.)

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MDS SECTIONS-IMPACTED BY MD ORDERS/DOCUMENTATION/TEAM COMMUNICATION (CONTINUED)

- Section O – Special Treatments, Procedures, Programs (cancer treatment, respiratory treatment, IV meds, transfusions, dialysis, oxygen, vaccines, therapies, etc.)
- Section Q – Resident Participation and Discharge Planning
- Section V – Care Area Assessment Investigations
- Comprehensive Care Planning

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Active Diagnosis & MD Documentation

Active Diagnoses in the last 7 days - Check all that apply

Diagnoses listed in parentheses are provided as examples and should not be considered as all-inclusive lists

Cancer

☐ I0100. **Cancer** (with or without metastasis)

Heart/Circulation

☐ I0200. **Anemia** (e.g., aplastic, iron-deficiency, pernicious, and sickle cell)
☐ I0300. **Cardiac Dysrhythmia** (e.g., atrial fibrillation, flutter, and tachycardias)
☐ I0400. **Coronary Artery Disease (CAD)** (e.g., angina, myocardial infarction, and atherosclerotic heart disease (ASHD))
☐ I0500. **Deep Venous Thrombosis (DVT), Pulmonary Embolus (PE), or Pulmonary Thrombo-Embolism (PTE)**
☐ I0600. **Heart Failure** (e.g., congestive heart failure (CHF) and pulmonary edema)
☐ I0700. **Hypertension**
☐ I0800. **Orthostatic Hypotension**
☐ I0900. **Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD)**

Gastrointestinal

☐ I1100. **Cirrhosis**
☐ I1200. **Gastroesophageal Reflux Disease (GERD) or Ulcer** (e.g., esophageal, gastric, and peptic ulcers)
☐ I1300. **Ulcerative Colitis, Crohn's Disease, or Inflammatory Bowel Disease**

Genitourinary

☐ I1400. **Benign Prostatic Hyperplasia (BPH)**
☐ I1500. **Renal Insufficiency, Renal Failure, or End-Stage Renal Disease (ESRD)**
☐ I1550. **Neurogenic Bladder**
☐ I1600. **Obstructive Uropathy**

Infections

☐ I1700. **Multidrug-Resistant Organism (MDRO)**
☐ I2000. **Pneumonia**
☐ I2100. **Septicemia**
☐ I2200. **Tuberculosis**
☐ I2300. **Urinary Tract Infection (UTI) (LAST 30 DAYS)**
☐ I2400. **Viral Hepatitis** (e.g., Hepatitis A, B, C, D, and E)
☐ I2500. **Wound Infection** (other than foot)

Metabolic

☐ I2900. **Diabetes Mellitus (DM)** (e.g., diabetic retinopathy, nephropathy, and neuropathy)
☐ I3100. **Hyponatremia**
☐ I3200. **Hyperkalemia**
☐ I3300. **Hypogonadism** (e.g., hypercholesterolemia)
☐ I3400. **Thyroid Disorder** (e.g., hypothyroidism, hyperthyroidism, and Hashimoto's thyroiditis)

Musculoskeletal

☐ I3700. **Arthritis** (e.g., degenerative joint disease (DJD), osteoarthritis, and rheumatoid arthritis (RA))
☐ I3800. **Osteoporosis**
☐ I3900. **Hip Fracture** - any hip fracture that has a relationship to current status, treatments, monitoring (e.g., sub-capital fractures, and fractures of the trochanter and femoral neck)
☐ I4000. **Other Fracture**

Neurological

☐ I4200. **Alzheimer's Disease**
☐ I4300. **Aphasia**
☐ I4400. **Hemi/Quad Palsy**
☐ I4500. **Cerebrovascular Accident (CVA), Transient Ischemic Attack (TIA), or Stroke**
☐ I4800. **Non-Alzheimer's Dementia** (e.g. Lewy body dementia, vascular or multi-infarct dementia, mixed dementia, frontotemporal dementia such as Pick's disease, and dementia related to stroke, Parkinson's or Creutzfeldt-Jakob diseases)

Neurological Diagnoses continued on next page

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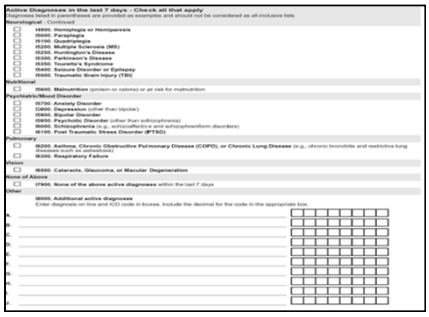
Active Diagnosis & MD Documentation



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ACTIVE DIAGNOSIS & MD DOCUMENTATION

Definitions:

Active Diagnoses: Physician-**documented diagnoses** in the **last 60 days** that has direct relationship to the resident current functional status, cognitive status, mood or behavior, medical treatments, nursing monitoring or risk of death **during the 7 day look back period.**

Functional Limitations: Loss of range of motion, contractures, muscle weakness, fatigue, decreased ability to perform ADLs, paresis or paralysis.

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ACTIVE DIAGNOSIS & MD DOCUMENTATION *(CONTINUED)*

2-step look back process used during Section I – Active Diagnosis

- Diagnosis Identification (1st step) **60–day look back period**
- Diagnosis Status: Active or Inactive (2nd step) is **7 day look back period**, except for I2300 UTI, which does not use 7 day look back period
- Require physician-documented diagnosis (or PA, NP, or CNS) in last 60 days
- Sources for physician diagnoses – progress notes, recent history and physical, transfer documents, discharge summaries, diagnosis problem list, and other resources as available
- Only diagnosis confirmed by physician can be entered in section

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ACTIVE DIAGNOSIS & MD DOCUMENTATION *(CONTINUED)*

- Determine whether diagnoses are **active**
- Active diagnoses are diagnoses that have a direct relationship to resident's current functional, cognitive, or behavior status, medical treatments, nursing monitoring, or risk of death, **during the 7 day look back period**
- **Do not include conditions that have been resolved, do not affect the resident's current status, or do not drive the resident's plan of care during the 7 day look back period, as these are considered inactive diagnoses**

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MDS ERRORS – POTENTIALLY IMPACTED BY MD DOCUMENTATION

- Primary Diagnosis/Active Diagnoses (PDPM)
- UTI (QM)
- Recent Surgery Requiring SNF Care (PDPM)
- High-risk medications & indications for use
- Isolation (PDPM)
- Vaccinations (QM)

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MDS ERRORS – POTENTIALLY IMPACTED BY MD DOCUMENTATION (CONTINUED)

- Drug Regimen Reviews
- GDR – contraindicated – lacks clear documentation/rationale
- Respiratory Failure – lack of diagnosis
- CVA & Sequelae – often missing impact of functional limitations, neurological or cognition status

30

PREADMISSION SCREENING & ADMISSION REVIEW (PASRR)

- All individuals admitted to a Medicaid certified SNF, regardless of payment source – MUST have Level I PASRR to rule out possible mental illness (MI), intellectual disability (ID), developmental disability (DD) or related conditions
- Suspected or have MI or ID/DD or related conditions – not to be admitted unless approved through Level II PASRR determination
- Residents covered by LEVEL II PASRR process may require certain care & services provided by nursing home and/or specialized services provided by the State

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PREADMISSION SCREENING & ADMISSION REVIEW (PASRR) *(CONTINUED)*

- A resident with MI or ID/DD must have a Resident Review (RR) conducted when there is a significant change in the resident's physical or mental condition
- Significant Change in Status assessment is completed for a resident with MI or ID/DD, the nursing home is required to notify the State mental health authority, intellectual disability or developmental disability authority in order to notify them of the resident's change in status

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PREADMISSION SCREENING & ADMISSION REVIEW (PASRR) *(CONTINUED)*

- Referral for Level II resident review evaluation is required for individuals previously identified by PASARR to have a mental disorder, intellectual disability, or a related condition who experience a significant change

33

PREADMISSION SCREENING & ADMISSION REVIEW (PASRR) *(CONTINUED)*

- Examples of notification changes:
- Resident who demonstrates increased behavioral, psychiatric, or mood-related symptoms
- Resident with behavioral, psychiatric, or mood-related symptoms that have not responded to ongoing treatment
- Resident who experiences an improved medical condition—such that the residents' plan of care or placement recommendations may require modifications

34

PREADMISSION SCREENING & ADMISSION REVIEW (PASRR) *(CONTINUED)*

- Resident whose significant change is physical, but has behavioral, psychiatric, or mood-related symptoms, or cognitive abilities, that may influence adjustment to an altered pattern of daily living
- Resident whose condition or treatment is or will be significantly different than described in the resident's most recent PASARR Level II evaluation and determination

35

QUESTIONS

36

AGENDA

Part II – *Overview of Key Areas: Nursing Role*

Melissa "Missy" Mansfield, BSN, MS, RN; Regional Vice President, Complete Care MidAtlantic

Questions and Answers

Moderator: Dr. Ziad K. Mirza

Co-Moderator: Dr. Fatima Naqvi

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COLLABORATION

- **Interdisciplinary alignment is essential** – nursing must coordinate with MDS, pharmacy partners, and providers to ensure assessments, care plans, and documentation reflect the resident’s true clinical status.
- **Shared accountability** – regular interdisciplinary communication builds a unified understanding of CMS expectations and promotes a culture of compliance and quality.
- **Improved resident outcomes** – joint decision-making fosters proactive care, timely interventions, and stronger Quality Measure performance.

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F605- RIGHT TO BE FREE FROM CHEMICAL RESTRAINTS

When a new psychotropic medication has been prescribed or dose has been increased:

- ❑ Document non-pharmacological approaches used prior to administering the medication.
- ❑ Document informed consent: resident/ family/ representative must be informed of risks, benefits, and alternatives for the medication.

When a resident is admitted with a psychotropic medication without a clearly documented indication:

- ❑Prescribing practitioner and IDT should determine if continuing the medication is justified.
- ❑Coordinate a comprehensive medical and psychiatric evaluation.
- ❑Explore prior medical records and elicit feedback from responsible party/ family regarding previous diagnoses.

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F627 & 628 – TRANSFER & DISCHARGE

Combines guidance from F622-626 & F-660-661 under two new tags: F-627 and F-628

- ❑Document that facility staff has assessed the resident's ability to care for themselves at home, and if they cannot, that there are interventions in place to ensure their safety at home.
  - ❑Medication Administration
  - ❑Wound Care/ Treatments
  - ❑Mobility
- ❑Must allow residents to return to the facility following hospitalization or therapeutic leave.

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F 641 ACCURACY OF ASSESSMENTS & F 658 PROFESSIONAL STANDARDS

Added language regarding accuracy of documentation and MDS coding, specifically for schizophrenia.

- ❑ Ensure supporting documentation is present in medical record.
  - ✓ Proper diagnosis
  - ✓ Nursing notes with supportive documentation by attending physician, psych providers, etc.
- ❑ Collaborate with prescribers on the documentation requirements for psychotropic medications.
- ❑ Educate nursing staff on the documentation requirements when psychotropic medications are newly prescribed, increased, or changed.

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F697 – PAIN MANAGEMENT

- ❑ Document individualized assessment and treatment plan for each resident.
- ❑ Document non-pharmacological interventions attempted prior to administration of pain medication.
- ❑ Document effectiveness of medication regimen and inform physician of same.
- ❑ Consider referral to pain specialist.
- ❑ Collaborate with consultant pharmacist to reduce polypharmacy.

Definitions Added
"Acute Pain" refers to pain that is usually sudden in onset and time-limited with a duration of less than 1 month and is often caused by injury, trauma, or medical treatments such as surgery.
"Chronic Pain" refers to pain that typically lasts greater than 3 months and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause.
"Subacute Pain" refers to pain that has been present for 1-3 months.

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F757 – DRUG REGIMEN IS FREE FROM UNNECESSARY DRUGS CONT'D.

- ❑ **Right to be informed** - document informed consent: resident/ family/ representative must be informed of risks, benefits, and alternatives for the medication. Resident/ family/ representative have the right to accept or decline.
- ❑ **Dose and duration** - based on a variety of factors, including the resident's diagnoses, signs and symptoms, current condition, age, coexisting medication regimen, review of lab and other test results.
- ❑ **Monitoring** - monitoring and accurate documentation of the resident's response to any treatment (such as, lab results, vital signs, progress notes, behavior flow sheets, medication administration records, and the consultant pharmacist's drug regimen review) is essential to evaluate the ongoing effectiveness, benefits, as well as risks of medication therapy.

Gather input from the IDT about the resident, including the resident's preferences and goals.

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F757 – DRUG REGIMEN IS FREE FROM UNNECESSARY DRUGS

- ❑ Medical record should include documentation of comprehensive assessment and rationale for chosen treatment options.
- ❑ Ensure that the initiation or change in a medication is not:
  - ❑ Due to a medical condition or problem (e.g., pain, fluid or electrolyte imbalance, infection, obstipation, medication side effect or polypharmacy) that can be expected to improve or resolve as the underlying condition is treated, or the offending medication(s) are discontinued;
  - ❑ Due to environmental stressors alone, that can be addressed to improve the symptoms; or
  - ❑ Due to psychological stressors alone, that can be expected to improve or resolve as the situation is addressed.

Circumstances that warrant evaluation of a resident's underlying medical condition and medication(s) include:

- ➢ *Admission or re-admission: Some residents may be admitted to the facility on medications that were started in the hospital or the community without a clear, documented indication for why the medication was begun or should be continued. The prescribing practitioner and the IDT should subsequently determine if continuing the medication is justified by conducting a comprehensive evaluation*
- ➢ *A new or worsening change in condition/status*
- ➢ *An irregularity identified in the pharmacist's medication regimen review.*
- ➢ *New medication order as an emergency measure – When a resident is experiencing an acute medical problem or emergency and the acute phase has stabilized, the staff and prescriber should consider whether medications are still indicated.*

45

F880 – INFECTION PREVENTION AND CONTROL

Enhanced Barrier Precautions (EBP) – an infection control intervention designed to reduce transmission of MDROs that employs targeted gown and glove use during *high contact* resident care activities.

MDRO Colonization / Infection – Contact precautions are used for residents infected or colonized with MDROs in the following situations:

- Presence of acute diarrhea, draining wounds or other sites of secretions or excretions that are unable to be covered or contained;
- Co-infection with another organism for which Contact Precautions is recommended (e.g., norovirus);
- For a limited time, as determined in consultation with public health authorities, on units or in facilities during the investigation of a suspected or confirmed MDRO outbreak; and when otherwise directed by public health authorities.

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F880 – INFECTION PREVENTION AND CONTROL (CONTINUED)

Facilities should:

- Ensure proper documentation of pertinent diagnoses and infection control interventions.
- Provide staff education and perform frequent rounds to determine compliance.
- Consult with IDT to determine length and duration of treatment.

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F887 – COVID-19 IMMUNIZATION

When COVID-19 vaccine is available to the facility, each resident and staff member is *offered* the COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized.

❑ The resident's medical record should include documentation that indicates:

- ✓ *That the resident/ representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine; and*
- ✓ *Each dose of COVID-19 vaccine administered to the resident, or*
- ✓ *If the resident did not receive the COVID-19 vaccine due to medical contraindications or refusal.*

❑ The facility maintains documentation related to staff COVID-19 vaccination that includes:

- ✓ *That staff were provided education regarding the benefits and potential risks associated with COVID-19 vaccine; and*
- ✓ *Staff were offered the COVID-19 vaccine or information on obtaining COVID-19 vaccine; and*
- ✓ *The COVID-19 vaccine status of staff.*

Medical Director may provide standing orders for annual COVID-19 immunization of facility residents and staff.

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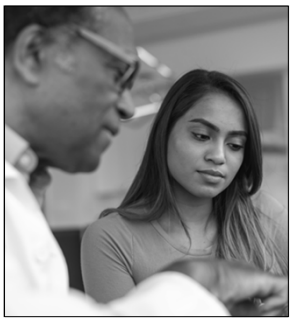

F 841 – RESPONSIBILITIES OF THE MEDICAL DIRECTOR

- Ensure your Medical Director is aware of and involved in:
  - ✓ Confirming adherence to properly diagnosing and prescribing medications.
  - ✓ Assisting with development and refinement of facility assessment.
  - ✓ Administrative decisions including recommending, developing, and approving facility policies related to residents' care.
  - ✓ Intervening when medical care is inconsistent with current accepted standards of care.
  - ✓ Active participation with QAPI committee.

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Part II – *F605 and Chemical Restraints*

Psychotropic Medication and Deprescribing:

Dr. Naveen Maddineni

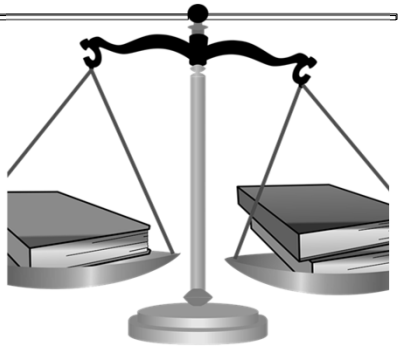
Questions and Answers

Moderator: Dr. Ziad K. Mirza

Co-Moderator: Dr. Fatima Naqvi

50

BALANCING THE SCALES: ANTIPSYCHOTIC USE & DEPRESCRIBING IN NURSING HOME PATIENTS – A RISK-BENEFIT APPROACH



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TRAINING OBJECTIVES

1.Describe the April 28, 2025, revisions to CMS SOM Appendix PP, that focus on the updated definition and regulatory expectations for F605 and the Right to Be Free from Chemical Restraints.
2.Identify the risk benefit of antipsychotics and how to effectively deprescribe.
3.List the indications for antipsychotic medication use.
4.Differentiate between appropriate and inappropriate use of psychotropic medications in long-term care, based on resident diagnosis, documentation, and the presence of medical symptoms.

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TRAINING OBJECTIVES

5. Apply evidence-based strategies and interdisciplinary practices to reduce the use of chemical restraints, including pharmacist-led medication reviews and nonpharmacological interventions.
6. Demonstrate proper documentation standards required to justify the clinical use of psychotropic medications under F605, including assessment, rationale, monitoring, and time limitations.
7. Explain the medical director's role in overseeing psychotropic medication use, discharge planning, documentation, and quality assurance.

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RESIDENT RIGHTS REGULATORY SECTION: §483.10 RIGHT TO BE FREE FROM CHEMICAL RESTRAINTS (F-605)

CMS has revised regulations and guidance regarding chemical restraints and unnecessary psychotropic medications

- The regulations and guidance for the unnecessary use of psychotropics, originally found in F-758, have been incorporated into F-605
- Expectation that residents who have not previously used psychotropic drugs are not prescribed these drugs unless it is necessary to treat a specific condition and not for purposes of discipline or staff convenience
- The guidance regarding "convenience" has been revised to include situations when medications are used to cause symptoms consistent with sedation and/or require less effort by facility staff to meet the resident's needs

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PRESCRIBING

There must be adequate documentation of the indication for the psychotropic medication including:

- A documented clinical rationale
- Assessment of resident's condition
- Therapeutic goals
- Documentation that the facility has attempted behavioral (i.e., nonpharmacological interventions) and that these interventions have been deemed clinically contraindicated or unsuccessful prior to prescribing psychotropic medications.

55

RIGHT TO BE FULLY INFORMED

Informed Consent:

- Must be obtained prior to initiating or increasing a psychotropic medication
- Resident or Responsible Party (RP) must be informed of risks, benefits and alternatives and this must be documented.
- Resident or RP have right to accept or decline the initiation or increase

56

MONITORING

Monitoring for Efficacy and Adverse Consequences

- Providers should monitor and document the resident's response to treatment using:
  - Lab results
  - Behavior records
  - Progress notes
  - EMAR
  - Pharmacy Consultant Drug Regimen Reviews (DRRs)

57

PERIODIC REVIEW

- Periodic medication regimen reviews must be completed to determine the continued need for the medication
- Gradual Dose Reduction should be trialed documented success or failure
- PRN orders for psychotropic drugs are limited to 14 days.
  - If provider believes it is appropriate for the PRN order to be extended beyond 14 days, he/she should document their rationale and indicate the duration for the PRN order.
  - PRN orders for antipsychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of the medication.

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COMMON INDICATIONS FOR ANTIPSYCHOTIC USE

The various common diagnosis are:

1. Schizophrenia
2. Schizoaffective disorder
3. Bipolar Disorder
4. Major depressive disorder with Psychotic features
5. Tourette's syndrome
6. Huntington's disease
7. Delusional disorder
8. Severe Dementia with Psychosis
9. Delirium

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RECOGNITION

- How do we identify individuals who may have acute problematic behavior and altered mental function?
- Behavior is a symptom, like others. Unlike many other symptoms or condition changes, problematic behavior often affects other patients and staff. Often produces a sense of alarm and urgency to stop the symptom ASAP
- Professional approach is important to assess behavioral symptoms and altered mental function in much the same way as other symptoms

60

DELIRIUM AND PSYCHOSIS

- Symptoms of acute psychosis unlikely to respond adequately to nonpharmacological interventions alone
- All patients with delirium and psychosis should also receive environmental and supportive interventions at least until mental function stabilizes or begins to improve

61

WANDERING AND SLEEP DISTURBANCES

- Medical and pharmacologic options to address wandering are limited
- May be helped by addressing underlying causes; for example,
  - Reduce does of medications causing motor restlessness mistaken for agitation
  - Treat psychosis that leads a patient to wander into others' rooms to try to find nonexistent person

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AGITATED BEHAVIOR

Possible causes:

- Exacerbation of underlying psychotic disorder (e.g., depression with psychosis)
- New onset of delirium
- Adverse reaction to medications that were added recently to address similar symptoms

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BEHAVIORAL AND PSYCHOLOGICAL SYMPTOMS (BPSD)

- Consider and address medical (e.g., pain, delirium), psychiatric and environmental causes
- Consider nonpharmacological interventions to address nonspecific behavioral and psychological symptoms related to dementia before using medications

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MEDICATION FOR BPSD

- No “magic bullets”
- No medication class demonstrated to have consistent, predictable benefits
- No established ways to predict who will respond or have long term benefits
- Even apparently successful medication interventions require re-evaluation
  - May need to be changed or discontinued, depending on subsequent results

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RISKS WITH ANTIPSYCHOTIC USE

- Even when they are used appropriately there are risks
- When prescribed inappropriately the risks will generally outweigh the benefits of the medications
- Increased rates of stroke and death in older adults with dementia
- Sedation
- Postural Hypotension
- Extrapyramidal side effects
- Metabolic side effects (Weight gain, DM, HLD, etc.)

66

BARRIERS OR FACILITATORS WHEN ATTEMPTING TO DEPRESCRIBE PSYCHOTROPIC DRUG

67

OBJECTIVES

- The objective of this presentation is to discuss which factors nursing home general practitioners and nursing home staff experience as barriers or facilitators when attempting to deprescribe psychotropic drugs in nursing home residents.

68

BACKGROUND

- Behavioral and psychological symptoms of dementia are frequently experienced in the nursing home setting and place a substantial burden on patients, relatives and nursing home staff.
- This is the case despite their effects being limited, and there being a risk of side effects and adverse events for the patient.
- Reports show that up to 90% of older persons with dementia experience one or more symptom(s) of BPSD with the course of the disease.

69

BACKGROUND

- Anxiety
- Agitation
- Hallucinations
- Depression
- Apathy

70

BARRIERS OR FACILITATORS

1. Operationality and routines
2. Lack of resources and qualifications
3. Patient-related outcomes
4. Policies
5. Collaboration

71

COGNITIVELY HEALTHY PATIENT

- Face to face consultation
- Risk vs benefits weighed
- Common decision made

72

PATIENT WITH COGNITIVE IMPAIRMENT

- Physician has the main responsibility for Prescribing
- Additional people are involved in the process
- Licensed prescribers
- Nurse assistants
- Patient relatives
- Legal guardians

73

OPERATIONALITY AND ROUTINES

- Routines and systematic procedures for reviewing psychotropic drugs in nursing homes served as a facilitator to discontinuing or reducing inappropriate use
- Reports of pharmacists' recommendations could provide nursing home staff and general practitioners with a tool for change

74

LACK OF RESOURCES AND QUALIFICATIONS

- Staff reports lack of time needed to enable the use of Non-pharmacological treatments
- Education of the relatives was required to ensure their support in the deprescribing process
- Lack of time for the General practitioner to perform a thorough drug review

75

LACK OF RESOURCES AND QUALIFICATIONS

- General Practitioners and Nursing home staff lack the qualifications necessary to enable deprescribing
- Lack of possible alternatives
- Staff's lack of knowledge concerning the side effects of antipsychotics

76

PATIENT-RELATED OUTCOMES

- Concerns of worsening of the symptoms if deprescribed
- Nursing home staff and relatives saw that it will negatively impact the patient quality of life

77

POLICIES

- National regulations
- Rating systems for Nursing homes

78

COLLABORATION

- Collaboration, communication, and the acknowledgement of the valuable contributions made by the different professionals deeply influence the deprescribing process
- Pharmacists' recommendations
- Nursing staff input

79

COLLABORATION

- Need for more educational opportunities for General practitioners and nursing home staff
- More nursing home staff
- More time with the patients

80

IMPLICATIONS AND FUTURE RESEARCH

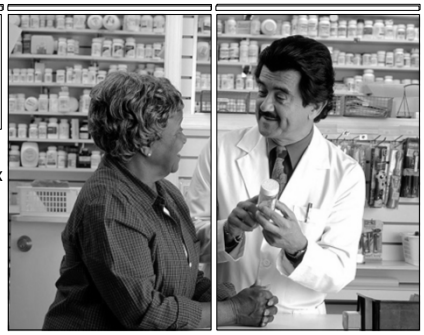
- There is general belief in the effectiveness of psychotropic drugs for managing behavioral and psychological symptoms
- Document the frequency and severity of the behavior using a standardized assessment tool
- Relatives perspective

81

ROLE OF CONSULTANT PHARMACIST

Ensuring Compliance with CMS SOM Appendix PP – F605 (Chemical Restraints/Unnecessary Psychotropics)

Naudine Mokhtari, PharmD



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OVERVIEW: CMS APPENDIX PP AND F605

- SOM Appendix PP is guidance to surveyors in long-term care settings; updated guidance became effective April 28, 2025
- F605 now F tag for "Freedom from chemical restraints/unnecessary psychotropic medications" (guidance formerly under F758 now consolidated under F605)
- Key regulatory requirements under 42 CFR §483.45(d) & (e); medications must be clinically indicated, lowest effective dose, monitored, periodic re-evaluation, gradual dose reduction(GDR) unless contraindicated, informed consent, nonpharmacologic interventions first

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KEY RISK AREAS FOR NON-COMPLIANCE

- Use of psychotropic meds for staff convenience or discipline rather than clinical need = chemical restraint
- Lack of documentation of indication, monitoring, GDR attempts
- Inadequate use of documentation of non-drug interventions
- Poor staff education and awareness
- Surveyor may expect justification, audit records, track trends in psychotropic use
- Risk of high severity citations if sedation or harm is evident and not addressed

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CONSULTANT PHARMACIST: CORE ROLES & MECHANISMS

- **Monthly Medication Regimen Review (MRR)/Drug Regimen Review**:
  - Consultant pharmacist reviews each resident's full chart, lab data, diagnoses, medication list, interactions, duplications, appropriateness. This is a regulatory expectation
- **Psychotropic review & GDR oversight**:
  - Flag psychotropic use, ensure nonpharmacologic first, ensure GDR attempts documented, ensure PRN orders are appropriate, duration limited, and rationale documented

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CONSULTANT PHARMACIST: CORE ROLES & MECHANISMS

(continued)

- **Education & training:**
  - Educate nursing, medical, therapy staff on behavioral interventions, informed consent, adverse effects of psychotropics, documentation expectations
- **Policy, procedure and audit support:**
  - Help craft and review facility policies on psychotropic use, consent, monitoring, GDR, perform audits of psychotropic prescribing trends and compliance

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CONSULTANT PHARMACIST: CORE ROLES & MECHANISMS

(Continued)

- **Participation in QAPI/QA Committees:**
  - Integrate medication compliance into quality improvement projects; provide reports & metrics
- **Consultation & intervention with prescribers**:
  - Communicate directly with attending physicians or medical director about recommendations, requiring rationale or acceptance/refusal documentation

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HOW CONSULTANT PHARMACISTS SUPPORT F605 COMPLIANCE

- **Medication Reviews Ensure Clinical Justification** – Monthly Drug Regimen Reviews help verify that every psychotropic medication has a documented, valid clinical indication – core F605 requirement
- **GDR Monitoring Prevents Chemical Restraint Use** – Pharmacists flag cases where GDR hasn't been attempted or documented, ensuring the facility doesn't default to long-term psychotropic use without clinical need

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HOW CONSULTANT PHARMACISTS SUPPORT F605 COMPLIANCE (CONTINUED)

- **Audit Trails Support Survey Readiness** – Pharmacist reports and interventions create a clear paper trail of oversight, which surveyors can review during audits – supporting compliance documentation
- **Education Reduces Inappropriate Prescribing** – Staff and prescriber education by pharmacists helps reduce misuse, especially when medications are being used for convenience or behavioral control (red flag under F605)
- **Policy Development and QA Involvement** – Pharmacists contribute to facility policies on psychotropic medication use, help set protocols for documentation and GDR and often participates in Quality Assurance & Performance Improvement (QAPI) initiatives – all of which surveyors expect to see

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OUTCOMES OF EFFECTIVE COLLABORATION

- **Reduced survey citations** (F-605, F-757, F-758, F-759, F-760) – fewer financial penalties and reputational risk
- **Stronger survey readiness** through accurate documentation, drug regimen review notes, and QAPI tracking
- **Demonstrated medical director oversight** that surveyors look for
- **Fewer unnecessary medications** – lower pill burden and reduced polypharmacy
- **Decreased adverse drug events (ADEs)** such as falls, delirium, over-sedation, or hospital transfers
- **Improved resident function and quality of life** (mobility, alertness, mood)
- **Safer psychotropic prescribing** with appropriate indications, monitoring, and gradual dose reductions (GDR)

90

QUESTIONS

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MEDICAL DIRECTOR ROLE

Dr. Ziad K. Mirza

SOM REV. 231; ISSUED: (07-09-25)

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MEDICAL DIRECTOR F-TAG RESPONSIBILITY CROSSWALK

CMS State Operations Manual – Appendix PP

The key regulatory responsibilities of medical directors in long-term care facilities, based on CMS Appendix PP.

93

F841 MEDICAL DIRECTOR (§483.70(G))

F841 is the cornerstone of the medical director's role:

1. Ensure care policies are clinically sound and consistently applied
2. Coordination with attending physicians is essential especially when resolving conflicts or ensuring continuity of care

Oversee implementation of resident care policies.

Coordinate medical care across the facility.

Supervise attending physicians and ensure compliance.

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F839 LICENSURE (§483.70(E))

- Ensures medical director is legally qualified to practice in the state
- Facilities must maintain documentation of licensure and verify that the medical director meets all professional standards

Ensure medical director holds a valid state license.

Verify credentials and qualifications.

95

F867 QAPI PARTICIPATION (§483.75(G)(2)(II))

- Play a vital role in QAPI
- Your clinical expertise helps:
  1. Identify patterns in care delivery
  2. Guide the facility in implementing evidence-based improvements

Active member of the Quality Assurance & Performance Improvement committee.

Review clinical trends and outcomes.

Recommend corrective actions.

96

F867
QAPI PARTICIPATION
(§483.75(G)(2)(II))

- Play a vital role in QAPI
- Your clinical expertise helps:
  1. Identify patterns in care delivery
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Active member of the Quality Assurance & Performance Improvement committee.

Review clinical trends and outcomes.

Recommend corrective actions.

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F881
INFECTION CONTROL
(§483.80(C))

- Role includes:
  1. Guiding infection control practices
  2. Ensuring antibiotic use is justified and monitored
- Helps prevent resistance and protects vulnerable residents

Support Antibiotic Stewardship Program.

Collaborate with Infection Preventionist.

Ensure compliance with CDC guidelines.

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F842
MEDICAL RECORDS
(§483.70(H))

- Must ensure that clinical documentation is:
  1. Complete
  2. Timely
  3. Secure
- Supports care continuity and legal compliance

Ensure accuracy and confidentiality of medical records.

Support documentation standards.

99

F656 CARE PLANNING (§483.21(B)(1))

- Care plans must be:
  1. Individualized
  2. Updated as residents' conditions change
- Input ensures medical interventions align with resident goals and clinical best practices

Oversee development and revision of care plans.

Ensure plans reflect resident needs and medical conditions.

100

F842 MEDICAL RECORDS (§483.70(H))

- Must ensure clinical documentation is:
  1. Complete
  2. Timely
  3. Secure
- Supports care continuity and legal compliance

Ensure accuracy and confidentiality of medical records.

Support documentation standards.

101

F580 NOTIFICATION OF CHANGES (§483.10(G)(14))

Must ensure significant changes in a resident's status are promptly communicated to all relevant parties, including families and care teams

Ensure timely communication of changes in resident condition.

Coordinate with physicians and families.

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F553
RESIDENT PARTICIPATION
(§483.10(C)(2))

- Residents have right to participate in their care decisions
- Your role includes facilitating informed consent and honoring their choices, even when they differ from clinical recommendations

Support resident involvement in medical decisions.

Respect autonomy and preferences.

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F757
PSYCHOTROPIC MEDICATIONS
(§483.45(D))

- Psychotropic medications must be used judiciously
- Must document clinical justification and support efforts to reduce or discontinue use when appropriate

Monitor use and ensure justification.

Support gradual dose reduction (GDR) protocols.

104

BEHAVIORAL HEALTH
(§483.40(D))

- Behavioral health is a growing focus in long-term care
- Must ensure that residents receive appropriate:
  1. Assessments
  2. Interventions
- Staff is trained to manage behavioral symptoms

Coordinate with behavioral health professionals.

Ensure appropriate care for residents with mental health needs.

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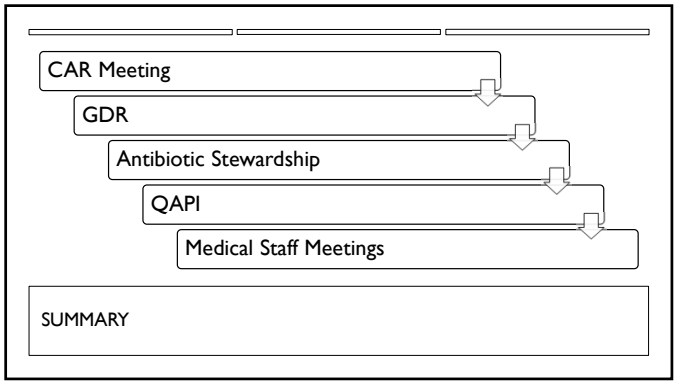
CAR Meeting
GDR
Antibiotic Stewardship
QAPI
Medical Staff Meetings
SUMMARY

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