PRESENTED BY TEXAS ACADEMY OF FAMILY PHYSICIANS

2024 C. Frank Webber Lectureship and Interim Session

COURSE SYLLABUS

April 12 - 13, 2024
Renaissance Austin Hotel | Austin, Texas

Maximum of 16 *AMA PRA Category 1 Credits™*

Texas Academy of Family Physicians presents:

2024 C. FRANK WEBBER LECTURESHIP

April 12 – 13, 2024 | Renaissance Austin Hotel

Table of Contents

Accreditation

The Texas Academy of Family Physicians is accredited by the ACCME to provide continuing medical education for physicians. TAFP designates this live educational activity for a maximum of 16 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The AAFP has reviewed 2024 C. Frank Webber Lectureship and Interim Session and deemed it acceptable for up to 16 Live AAFP Prescribed credits. Term of Approval is from 4/12/2024 to 4/13/2024. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This course has been designated by TAFP for up to 2 hours of credit in ethics and/or professional responsibility. This conference includes sessions that meet physician CME requirements mandated by the Texas Medical Board for pain management and medical ethics.

Disclosures and Disclaimers

It is the policy of TAFP that all CME planning work group members, speakers, TAFP staff, and joint providers disclose any relevant financial relationships with ineligible companies (i.e., commercial interests). Disclosure documents have been mitigated for actual and potential conflicts of interest. For those who have a conflict of interest, it has been mitigated and resolved prior to confirmation of planning and participation. Only those participants who have no conflict of interest or who agree to an identified mitigation process prior to their participation were involved in the planning and participation in this CME activity. TAFP staff, CME Planning Work Group, and Program Co-chairs (Dale Moquist, MD and Karen Smith, MD) disclosed they have no financial relationships with any ineligible companies or commercial interests.

The views and approaches in this activity are offered solely for educational purposes. TAFP disclaims any and all liability for injury or other damages for all claims which may result from the use of information presented in this activity. Material contained herein may be graphic but is intended for clinical use only.

Friday CME Breakfast

RSV Update: Vaccine and Disease Management

John Midturi, DO

Director, Division of Infectious Disease, Department of Medicine
Baylor Scott & White Health
Temple, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Discuss the burden of respiratory syncytial virus (RSV) infection in adults and list patient risk factors for severe infection and hospitalization.
2. Describe diagnostic approaches to differentiate RSV from other respiratory viral infections in adults.
3. Identify current and emerging approaches to prevent RSV in vulnerable adults.

Speaker Disclosure

Dr. Midturi disclosed he has no financial relationships with any ineligible organizations or commercial interests.

Respiratory Syncytial Virus Update: Focus on Adult Disease

John K. Midturi, DO

April 12, 2024

Disclosure: Dr. Midturi disclosed he has no financial relationships with any ineligible organizations or commercial interests.

1

Objectives

By completing this educational activity, the participant should be better able to:

1. Discuss the burden of respiratory syncytial virus (RSV) infection in adults.
2. List patient risk factors for severe infection and hospitalization.
3. Describe diagnostic approaches to differentiate RSV from other respiratory viral infections in adults.
4. Identify current and emerging approaches to prevent RSV in vulnerable adults.

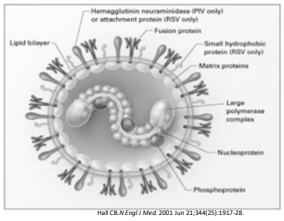
2

Introduction

3

Respiratory Syncytial Virus – Enveloped RNA virus in *Pneumoviridae* Family

- Identified in 1956 in Chimpanzees
  - Originally Chimpanzee Coryza Agent (CCA), then identified in children with clear evidence of neutralizing antibody response to CCA in most school age children.
  - Renamed – Respiratory Syncytial Virus
- RSV-A and RSV-B subgroups
- Infection of the ciliated respiratory epithelium, causing disease of variable severity
- Host response to RSV may be described as overexuberant, inappropriate, or dysregulated



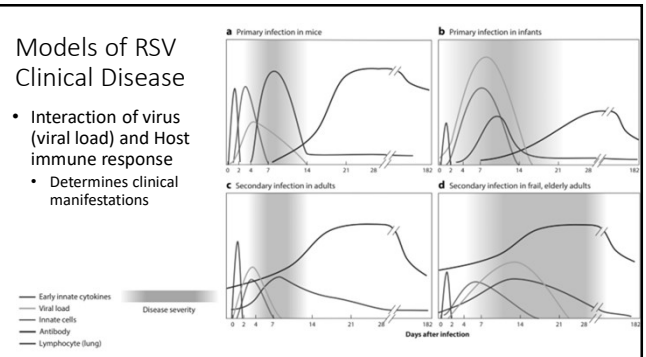
Hall CB. *N Engl J Med.* 2001 Jun 21;344(25):1917-28.

Openshaw. *Annu Rev Immunol.* 2017;35:501.

4

Models of RSV Clinical Disease

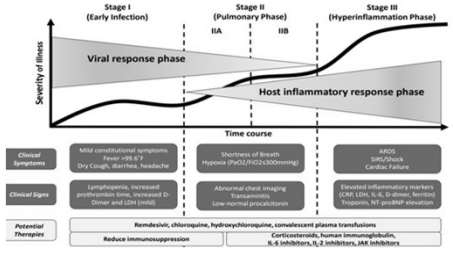
- Interaction of virus (viral load) and Host immune response
  - Determines clinical manifestations



Openshaw. *Annu Rev Immunol.* 2017;35:501.

5

Host – Virus Interaction – Similar to Other Viral Infections

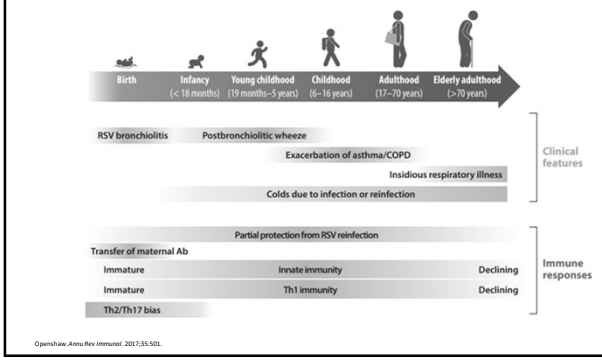


COVID-19 Illness in Native and Immunosuppressed States: A Clinical Therapeutic Staging Proposal. *Journal of Heart and Lung Transplantation.* Hasan k et al doi: 10.1016/j.healun.2020.03.012

6

RSV Epidemiology/Burden of Disease

7

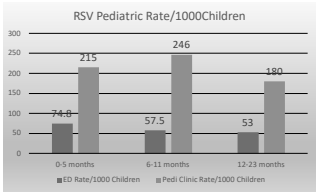


Openshaw. *Annu Rev Immunol.* 2017;35:501.

8

Burden of Pediatric Disease

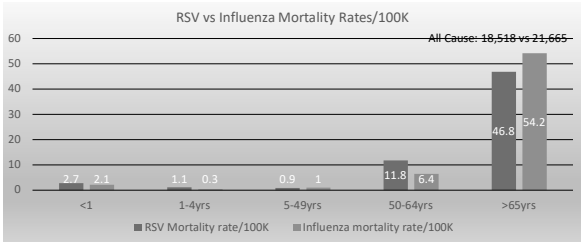
- 2.1 million children younger than 2 years seek medical care as outpatients for RSV infection annually in the United States
  - The majority of these visits occur in the pediatric practice setting
  - Estimated 472,000 visits to the Emergency Department for RSV infection per year
  - Outpatient visits among RSV-infected children exceed the number of outpatient visits attributable to influenza infection by more than twofold



Lively JY, et al. Respiratory Syncytial Virus-Associated Outpatient Visits Among Children Younger Than 24 Months. *J Pediatric Infect Dis Soc.* 2019 Jul 1;8(3):284-286.

9

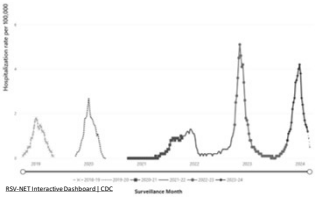
Overall Burden of Disease, 1999-2018



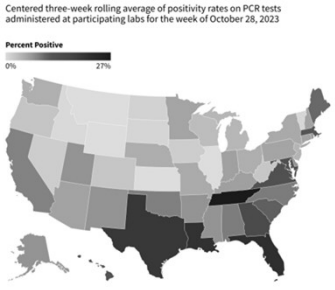
Hansen CL, Chaves SS, Demont C, Viboud C. Mortality Associated With Influenza and Respiratory Syncytial Virus in the US, 1999-2018. *JAMA Netw Open.* 2022;5(2):e220527.

10

RSV: Where and When



RSV-NET Interactive Dashboard | CDC



Five states (AK, AR, DE, RI, and UT) and Washington, DC had insufficient data, while two (MS and NM) administered zero tests. Data includes labs which are participating voluntarily and thus may not be representative of states as a whole.

Source: Centers for Disease Control and Prevention

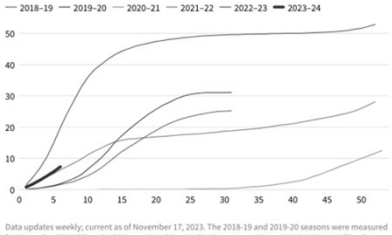
USAFACTS

What is the state of RSV in the United States? (usafacts.org)

11

The 2022-23 RSV season had the highest cumulative rates on record.

National cumulative rates of RSV-associated hospitalizations per 100,000 people over the course of each RSV season, which begins in early October



Data updates weekly; current as of November 17, 2023. The 2018-19 and 2019-20 seasons were measured for 31 weeks. RSV-NET tracks RSV-associated hospitalizations across 58 counties in 12 states. The data does not adjust for "undertesting, differing provider or facility testing practices, and diagnostic test sensitivity."

Source: Centers for Disease Control and Prevention

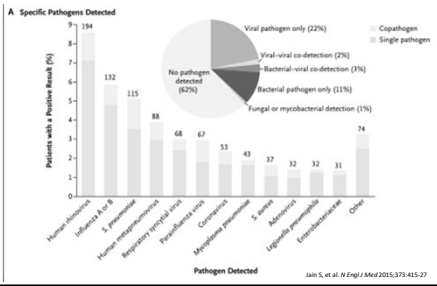
USAFACTS

What is the state of RSV in the United States? (usafacts.org)

12

Etiology of Community Acquired Pneumonia in Adults – Admitted to Hospital

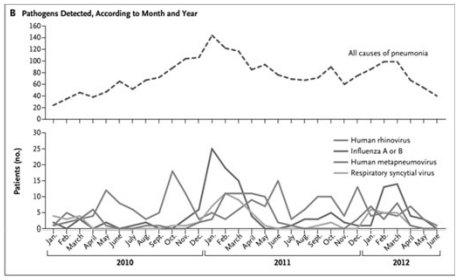
- 2320 Adults with radiographic evidence of pneumonia



Jain S, et al. *N Engl J Med* 2015;373:415-27

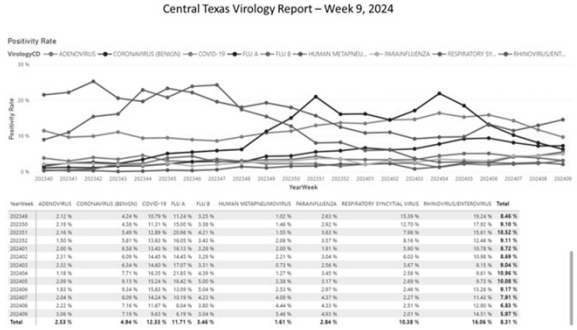
13

Seasonal Trends of CAP Viruses in Adults



Jain S, et al. *N Engl J Med* 2015;373:415-27

14



15

Objective 1

- Discuss the burden of respiratory syncytial virus (RSV) infection in adults
  - Not only a disease of young infants especially premature infants, but also adults over age 60 years
  - If you are thinking about Influenza, then also think RSV
  - Virus and Host response – elderly with declining immune response

16

Risk for Severe Disease

17

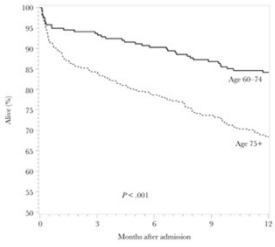
Polling Question #1

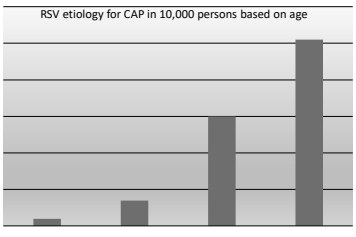
An adult patient is admitted to the hospital with RSV. Which of the following comorbid condition is associated with increased mortality at 12 months?

A. Chronic Obstructive Pulmonary Disease (COPD)
B. Congestive Hearth Failure (CHF)
C. Emphysema
D. Chronic Bronchitis

18

Risk for Severe Disease – Age





Jain S, et al. *N Engl J Med* 2015;373:415-27

Tseng HF, et al. Severe Morbidity and Short- and Mid- to Long-term Mortality in Older Adults Hospitalized with Respiratory Syncytial Virus Infection, *The Journal of Infectious Diseases*, Volume 222, Issue 8, 15 October 2020, Pages 1298–1310

19

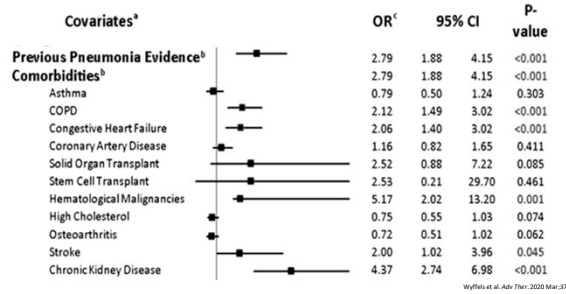
Risk for Severe Disease

- 1795 U.S. Medicare Beneficiary Patients with RSV
- 793 Hospitalized within 1 day; 835 Outpatient (140 – later admitted)
  - ~50% get admitted
- High-risk patients:
  - 180 days before the date of RSV diagnosis
  - Chronic lung disease (including asthma and COPD)
  - Prior pneumonia
  - Congestive heart failure (CHF)
  - Immune compromise

Wyffels et al. *Adv Ther*. 2020 Mar;37(3):1203-1217.

20

Risk for Severe Disease – Co-Morbidities



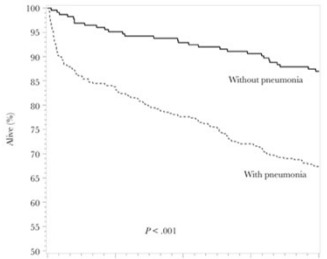
Covariates[a]	OR[c]	95% CI		P-value
Previous Pneumonia Evidence[b]	2.79	1.88	4.15	<0.001
Comorbidities[b]	2.79	1.88	4.15	<0.001
Asthma	0.79	0.50	1.24	0.303
COPD	2.12	1.49	3.02	<0.001
Congestive Heart Failure	2.06	1.40	3.02	<0.001
Coronary Artery Disease	1.16	0.82	1.65	0.411
Solid Organ Transplant	2.52	0.88	7.22	0.085
Stem Cell Transplant	2.53	0.21	29.70	0.461
Hematological Malignancies	5.17	2.02	13.20	0.001
High Cholesterol	0.75	0.55	1.03	0.074
Osteoarthritis	0.72	0.51	1.02	0.062
Stroke	2.00	1.02	3.96	0.045
Chronic Kidney Disease	4.37	2.74	6.98	<0.001

Wyffels et al. *Adv Ther*. 2020 Mar;37(3):1203-1217.

21

Risk for Poor Outcome – Pneumonia

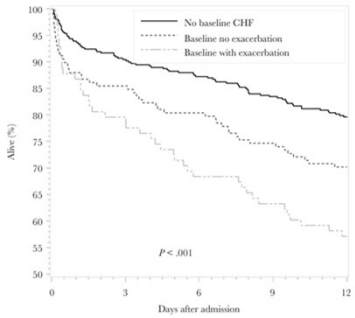
Pneumonia



Tseng HF, et al. *The Journal of Infectious Diseases*, Volume 222, Issue 8, 15 October 2020, Pages 1298–1310

22

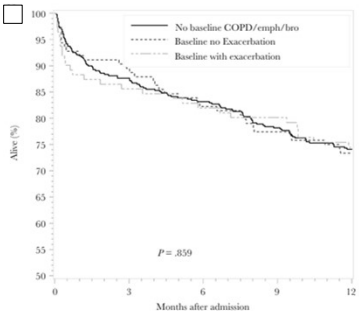
Risk for Poor Outcome – CHF and CHF with Exacerbation



Tseng HF, et al. *The Journal of Infectious Diseases*, Volume 222, Issue 8, 15 October 2020, Pages 1298–1310

23

Risk for Poor Outcome – The Obvious – Not so Obvious



Tseng HF, et al. *The Journal of Infectious Diseases*, Volume 222, Issue 8, 15 October 2020, Pages 1298–1310

24

Objective 2

List patient risk factors for severe infection and hospitalization

- Age
- Previous pneumonia in past 6 months
- COPD
- CHF
- Immunocompromised
  - Organ Transplantation – solid and stem cell
  - Hematologic malignancies
- CKD

Increased risk of mortality

- Pneumonia due to RSV
- CHF diagnosis with/without exacerbation

25

Clinical Manifestation

26

Clinical Symptoms of RSV

- Reinfection is possible
- In adults, viral co-infections less common
- Typically present 5-7 after symptoms
- Starts are upper URI and can progress to acute bronchitis and pneumonia
  - 40% with radiographic evidence of opacity

Symptoms	% of patients
Rhinorrhea/nasal congestion	67–92
Sore throat	20–33
Headache	3
Hoarseness	22–27
Cough	90–97
Sputum	22–67
Dyspnea	11–20
Systemic/constitutional	44–80
Gastrointestinal	0
Signs	
Fever >38°C	20–56
Rales	33–40
Wheezing	6–35
Laboratory findings	
Chest X-ray infiltrates	0–22

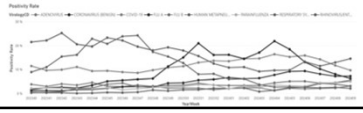
Falsey *Clin Microbiol Rev.* 2000 Jul;13(3):371-84.

27

Limitation of Clinical Diagnosis

- Symptom driven diagnostics are difficult
  - Overlap of symptoms- nonspecific with viral illness
  - Historically not considered adult disease
- Seasons overlap- typically cold season illness
  - Typically tested at same time, usually seen 1-2 months preceding influenza
  - Underestimated

  Starts in southeast and then northeast and then west
- Adults present later in illness



28

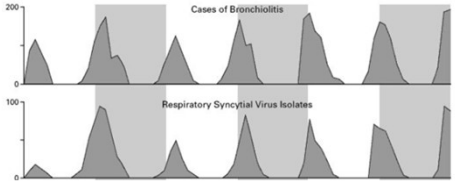
Clinical Characteristics of Illness Due to Influenza or Respiratory Syncytial Virus (RSV)

Characteristic	No. (%) of adults with illness due to RSV (*n* = 177)	Influenza (*n* = 59)	*P*[a]
Sign or symptom			
Fever (temperature, >37.8°C)	50 (28)	43 (73)	<.001
Nasal congestion/rhinorrhea	157 (89)	46 (78)	<.04
Sore throat	102 (58)	32 (54)	.65
Ear pain	35 (20)	3 (5)	<.01
Headache	70 (40)	48 (81)	<.001
Sinus pain	55 (31)	8 (14)	<.01
Cough			
Nonproductive	150 (85)	47 (80)	.36
Productive	92 (52)	14 (24)	<.001
LRT signs/wheezing	28 (16)	5 (9)	.16
Work absence	67 (38)	39 (66)	<.001
Duration of illness, mean days (range)	9.5 (1–20)	6.8 (39–66)	<.001

Hall CB., et al. *Clinical Infectious Diseases*, Volume 33, Issue 6, 15 September 2001, Pages 792–796.

29

Pediatric Cases



Hall CB.*N Engl J Med.* 2001 Jun 21;344(25):1917-28.

30

Difference Between Flu, RSV, COVID-19, and the Common Cold

Common symptoms may include cough, headaches, sneezing, runny nose, and congestion. Different symptoms may include:

Rarely ⊗ Sometimes ⊗⊗ Often

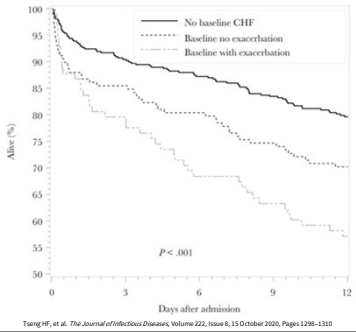
	COLD	FLU	COVID-19	RSV
ACHES	⊗⊗	×××	⊗⊗	●
DIFFICULTY BREATHING	●	●	×××	⊗⊗
FATIGUE	⊗⊗	×××	×××	●
FEVER	●	×××	⊗⊗	⊗⊗
LOSS OF TASTE OR SMELL	●	●	⊗⊗	●
SORE THROAT	×××	⊗⊗	×××	●
WHEEZING	●	●	●	×××

https://www.nfid.org/resource/how-to-tell-the-difference-between-flu-rsv-covid-19-and-the-common-cold/

31

Multisystem Disease

- RSV replicates in respiratory tissue in addition to cardiac tissue
  - Cause inflammation
  - Increase proinflammatory cytokines
- Increase mortality

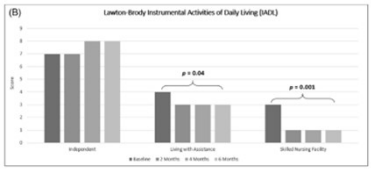


Tseng HF, et al. *The Journal of Infectious Diseases*, Volume 222, Issue 8, 15 October 2020, Pages 1298–1310

32

Complications

- Older adults hospitalized with RSV
  - Acute functional decline may become prolonged.
  - Pre-hospitalization living situation may predict patient outcomes.
- Change in functional status- loss of acute functional
  - 13% all-cause mortality
  - 33% don't return to baseline
  - 14% required higher level of care at 6 months
  - Not unique to RSV



Branche AR, et al. Change in functional status associated with respiratory syncytial virus infection in hospitalized older adults. *Influenza Other Respir Viruses.* 2022 Nov;16(6):1151-1160.

33

Diagnosis

34

Diagnosis

- Adults present later in illness
  - Leads to lower sensitivity with PCR
  - However still better than Antigen or culture
- Nasal specimen or anterior or mid-nasal
  - Molecular test is optimal – In adults
- Antigen test is ok in children given high viral load and earlier in illness
- Consider respiratory panel testing rather than only for 1 etiology

35

Objective 3

- Describe diagnostic approaches to differentiate RSV from other respiratory viral infections in adults.
  - Difficult to differentiate
  - Nasal symptoms and productive cough in adults
    - Molecular based testing for adults – PCR
  - Bronchitis in children
    - Antigen testing ok for Children

36

Treatment

37

Treatment

- Supportive care
  - Antipyretic
  - Oxygen
    - IV fluids
    - COPD
    - Bronchodilators
    - Steroids
    - They don't help with pts without
    - Bacterial complication are rare in community – typically seen more in hospitalized pts
  - Inhaled Ribavirin – approved 1986 – limited use
    - Immunocompromised patients

38

Impact of RSV Disease

- Increase our awareness of potential impact
- Not as benign as previously thought
- Counsel on possible complications
  - Long recovery phase
  - Potential loss of function
  - Increase in mortality in CHF pts

39

What can we do?

- Limited treatment options
- Prevention is key!!!
- Hand Hygiene
- Masking
- Vaccination

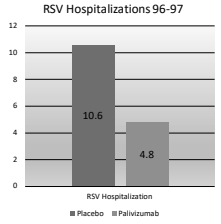
40

RSV Antibody for Children

41

Monoclonal Antibody for Infants

- Guidance from the American Academy of Pediatrics (AAP) for the use of palivizumab prophylaxis against respiratory syncytial virus (RSV) was first published in a policy statement in 1998.
  - Impact-RSV – 1996 to 1997 RSV season. This randomized, placebo-controlled, double-blind trial involved 1502 infants and young children born preterm (at or before 35 weeks' gestation)
    - Absolute reduction of 5.8% in RSV hospitalizations ($P <$ .001)
    - Relative risk reduction of 54.7%

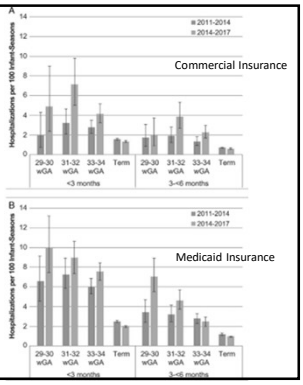


Caserta MT, et al. Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics* (2023) 152 (1): e2023061803.
IMpact-RSV study group. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. *Pediatrics* 1998;102 (3):531–537

42

RSV Risk 2011-2017

- These data were instrumental in the development of the 2014 AAP guidelines.
- Consensus among Committee on Infectious Diseases members was that there was a lack of consistent and robust evidence that would require a change in policy for preterm infants without chronic lung disease.
- Review of publications since 2014 did not support a change in recommendations for palivizumab prophylaxis and continues to endorse the guidance

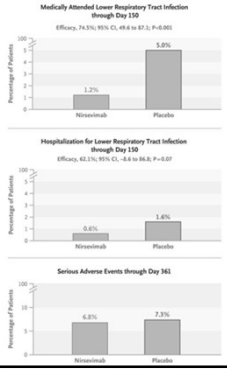


Caserta MT, et al. *Pediatrics* (2023) 152 (1): e2023061803.

43

Nirsevimab

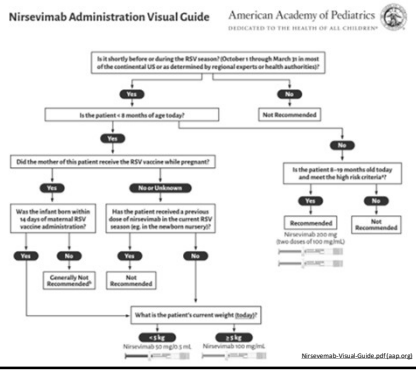
- FDA approved July 2023
- Birth to 24 months
- ½ life – 71 days
- < 8 months born during RSV season
- 74.5% efficacy preventing RSV associated LRTI compared to placebo



LL Hammitt et al. *N Engl J Med* 2022;386:837-846.

44

Nirsevimab



Nirsevimab-Visual-Guide.pdf (aap.org)

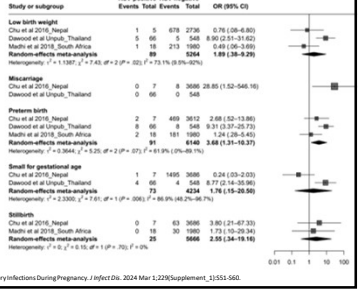
45

Prevention – Vaccination

46

Special Population Consideration – Pregnancy

- Limited data
- First study to summarize evidence among pregnant individuals
- 3.4 % of Acute Respiratory Infections
- Incidence rate 2.1 per 1000 person years
  - Hospitalization – rare
  - No deaths
- No Difference:
  - Stillbirths, miscarriage, lower birth weight, and small for gestation age
- Increase odds of preterm delivery

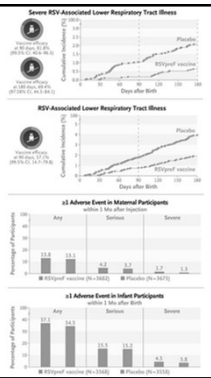


Kenmoe S et al. PROMISE Investigators. Burden of Respiratory Syncytial Virus-Associated Acute Respiratory Infections During Pregnancy. *J Infect Dis.* 2024 Mar 1;229(Supplement_1):S51-S60.

47

Preventing RSV in Children

- Bivalent RSV prefusion F protein
- 7392 women
  - Singleton pregnancy
  - 24 to 36 weeks gestation
- Primary Endpoint:
  - Severe RSV – LRTI
    - 81.8% efficacy at 90 days
    - 69% at 180 days
  - Medically attended RSV-LRTI
    - 57% efficacy at 90 days
  - USA- narrowed to 32-36 weeks gestation
    - Preterm births – 5.7% vs 4.7% (placebo)



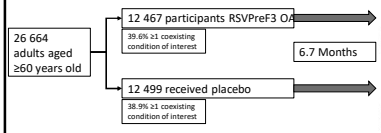
Kampmann B, et al. MATISSE Study Group. *N Engl J Med.* 2023 Apr 20;388(16):1451-1464.

48

Vaccination for Adults

49

RSV Pre F3 (GSK)



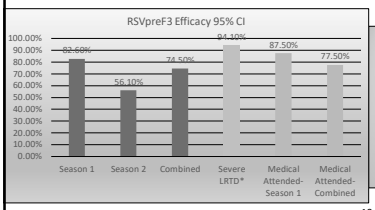
Characteristic	RSVPreF3 OA N = 12 467	Placebo N = 12 499
Mean age (SD), y	69.5 (6.5)	69.6 (6.4)
Age group, n (%)		
60–69 y	6963 (55.9)	6980 (55.8)
70–79 y	4487 (36.0)	4491 (35.9)
≥80 y	1017 (8.2)	1028 (8.2)
Female sex, n (%)	6488 (52.0)	6427 (51.4)
Race, n (%)		
Asian	953 (7.6)	956 (7.6)
Black	1064 (8.5)	1101 (8.8)
White	9887 (79.3)	9932 (79.5)
Other	563 (4.5)	510 (4.1)
Mean BMI (SD), kg/m²	29.1 (6.1)	29.1 (6.0)
Any coexisting medical conditions, n (%)		
≥1 condition	11 929 (95.7)	11 905 (95.2)
Coexisting medical conditions of interest[a], n (%)		
≥1 condition of interest	4937 (39.6)	4864 (38.9)
≥2 conditions of interest	2504 (20.1)	2434 (19.5)
≥3 conditions of interest	805 (6.5)	827 (6.6)
≥1 cardiorespiratory condition of interest	2496 (20.0)	2422 (19.4)
COPD	1131 (9.1)	1113 (8.9)
Asthma	1193 (9.6)	1113 (8.9)
Chronic respiratory/pulmonary disease	2223 (17.8)	2123 (17.0)
Chronic heart failure	398 (3.2)	403 (3.2)
≥1 endocrine and metabolic condition of interest	3200 (25.7)	3236 (25.9)
Diabetes mellitus type 1 or 2	2829 (22.7)	2877 (23.0)
Advanced liver or renal disease	667 (5.4)	676 (5.4)

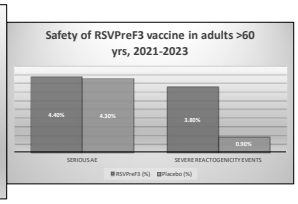
- Recombinant stabilized perfusion F vaccine adjuvanted with AS01E
- 17 countries in Africa, Asia, Australia, Europe, and North America
- Excluded immunocompromised and LTAC, and fewer pts over age 75 yrs
- Primary objective – efficacy of a single dose of RSVPreF3 OA in preventing RSV-Lower Respiratory Tract Disease during 1 RSV season among adults aged ≥60 years

Feldman RG, et al AReSVI-006 Study Group. *Clin Infect Dis.* 2024 Jan 25;78(1):202-209.

50

RSV Pre F3 – Efficacy and Side Effects





10 cases of Atrial Fibrillation
3/17922 (0.02%) cases of Inflammatory Neurologic events noted in open label study and co-administration study with influenza
1 GBS, 2 acute disseminated encephalomyelitis

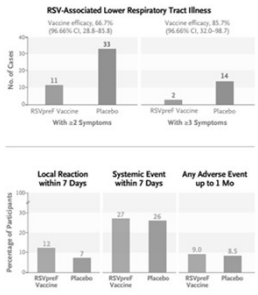
Feldman RG, et al AReSVI-006 Study Group. *Clin Infect Dis.* 2024 Jan 25;78(1):202-209.
*Papi et al. *Engl J Med* 2023;388:595-608

51

RSV Pre F (Pfizer)

- Bivalent Recombinant stabilized PreF vaccine containing equal parts RSV-A and RSV-B proteins
- RSV preF glycoproteins effective against 18-50 yrs
- Ongoing Phase 3 study- completion in 2025
- 34,284 adults – 51% had high risk condition

- Vaccine efficacy against
  - RSV LRTI 2 signs/symptoms – 67 %
  - RSV LRTI > 3 signs – 86%
  - ARI – 62%
  - Local reactions – 12% vs. 7%



10 cases of Atrial Fibrillation, 3 cases of inflammatory neurological events

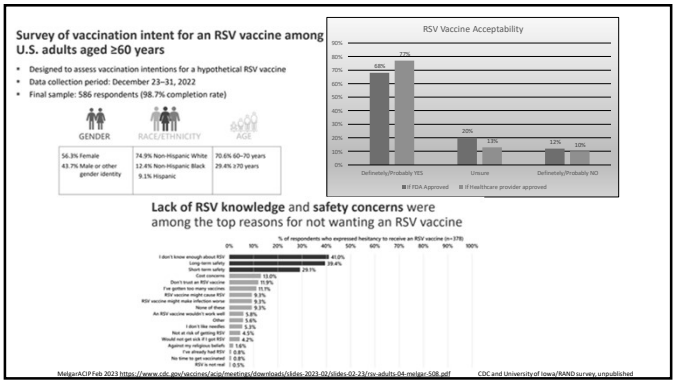
Walsh EE, et al. RENOIR Clinical Trail Group *N Engl J Med.* 2023 Apr 20;388(16):1465-1477.

52

Shared Clinical Decision-Making

- 2 vaccines
  - Approved 2023 by FDA
    - Age >60 yrs with shared decision making
      - Recognizes significant risk for certain populations but not all
        - 20-30K in studies and hopefully will get information as more populations get vaccinated
      - Requiring post-marketing studies to evaluate for AF and inflammatory Neurologic events
      - V-safe monitoring program- self reporting
  - How to?
    - Understand risks
    - Challenge with conversations about all these different vaccines – COVID, Influenza
    - Consider age – each decade of life risk of hospitalization and mortality increases
    - Consider co-morbid condition – CHF, chronic lung disease
    - Consider – DM, CAD, ESRD, chronic liver disease
      - Generalized poorer outcomes with viral infections

53



MelgarACIP Feb 2023 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-23/rsv-adults-04-melgar-508.pdf
CDC and University of Iowa/RAND survey, unpublished

54

Number Needed to Vaccinate Comparison

Number needed to vaccinate (NNV): GSK RSVpreF3

- Derived from cost effectiveness analysis performed by U. Michigan
- Time horizon: one year

Number of vaccinations required to prevent…	Adults aged ≥65 years	Adults aged ≥60 years
1 RSV outpatient visit[a]	84 vaccinations	90 vaccinations
1 RSV hospitalization[b]	1,097 vaccinations	1,348 vaccinations
1 RSV death[c]	21,442 vaccinations	27,284 vaccinations

23

Number needed to vaccinate (NNV): Pfizer RSVpreF

- Derived from cost effectiveness analysis performed by U. Michigan
- Time horizon: one year

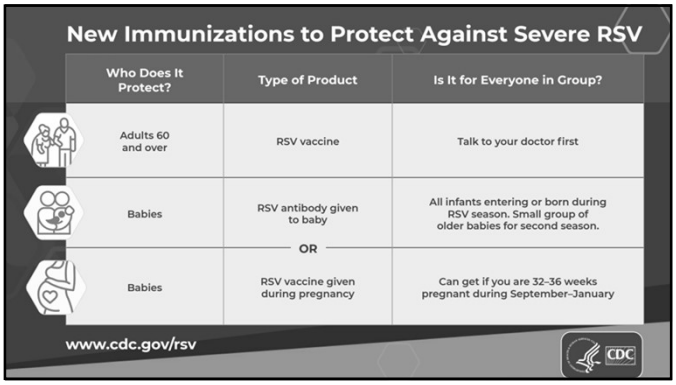
Number of vaccinations required to prevent…	Adults aged ≥65 years	Adults aged ≥60 years
1 RSV outpatient visit[a]	95 vaccinations	103 vaccinations
1 RSV hospitalization[b]	1,275 vaccinations	1,567 vaccinations
1 RSV death[c]	24,927 vaccinations	31,717 vaccinations

33

Limited data to compare the 2 vaccines –
different study designs, populations definitions, on-going
Both have moderate evidence of efficacy

MelgarACIP Feb 2023 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-02/slides-02-23/rsv-adults-04-melgar-508.pdf

55



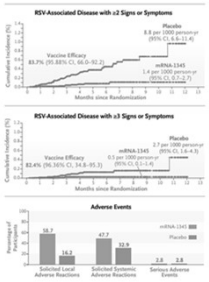
56

Objective 4

- Identify current and emerging approaches to prevent RSV in vulnerable adults.
  - Hand Hygiene
  - Vaccines
    - RSVPre3OA – Adults >60 yrs
    - RSVPreF – Adults >60 yrs and Pregnant women 32-36 gestation
    - Nirsevimab – Infants <8 months of age born during RSV season

57

RSV Vaccine – Pipeline



2023
FDA Approved
-Protein Based
RSV PreF3 OA
RSV PreF

Phase 3
-Nucleic Acid
mRNA

Recombinant Vectors
-pending

Wilson E, et al. ConquerRSV Study Group. *N Engl J Med*. 2023 Dec 14;389(24):2233-2244.

58

Thank You!
Questions?

John Midturi, DO
John.Midturi@BSWHealth.org

59

Notes

Syphilis: Diagnosis to Management in Primary Care

Sandra Guerra, MD, MPH
Chief Medical Officer
Texas Health Action Kind Clinic
Austin, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Review guidelines for syphilis testing based on patients presenting with potential syphilis infection.
2. Interpret tests accurately for an accurate diagnosis and appropriately stage the disease based on the serological and clinical findings.
3. Treat syphilis with evidence-based treatment recommendations while considering the stage of the infection and other coexisting conditions.
4. Appropriately monitor patients after treatment and adequately council patients to help avoid reinfection.

Speaker Disclosure

Dr. Guerra disclosed she has no financial relationships with any ineligible organizations or commercial interests.

The Syphilis Surge

Sandra Guerra, MD, MPH
Texas Health Action
April 2024

1

Speaker Disclosure and Learning Objectives

Speaker Disclosure

Dr. Guerra disclosed she has no financial relationships with any ineligible organizations or commercial interests.

Learning Objectives

By completing this educational activity, the participant should be better able to:

1. Review guidelines for syphilis testing based on patients presenting with potential syphilis infection.
2. Interpret tests accurately for an accurate diagnosis and appropriately stage the disease based on the serological and clinical findings.
3. Treat syphilis with evidence-based treatment recommendations while considering the stage of the infection and other coexisting conditions.
4. Appropriately monitor patients after treatment and adequately council patients to help avoid reinfection.

2

Why is Syphilis Surging?

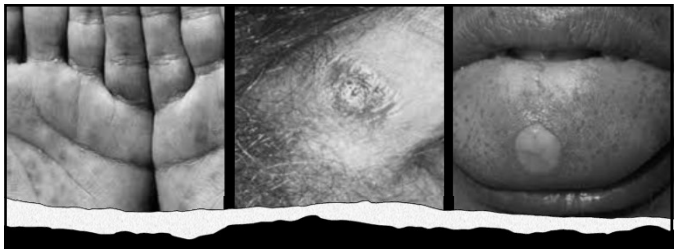
- Experts point to various reasons for the increase, including
  - increases in substance abuse tied to sexual behavior
  - decrease in condom use
  - ongoing social and economic conditions
  - reduction in sexually transmitted infections (STI) services at the state and local level
  - The stigma surrounding STIs can also keep people from seeking care
    - It also can cause issues at the provider level when it comes to talking with people about these issues.
  - Over the past year, there has been a shortage of Bicillin, an antibiotic used to treat syphilis.
  - In addition, last year states lost funding for STD prevention, affecting their ability to respond to syphilis.
  - COVID: stop screening for STI's.

3

Syphilis Surges

- Reported syphilis cases increased 80% in the United States between 2018 and 2022, (from 115,000 to more than 207,000), compounding a decades-long upward trend.
  - More than 3,700 cases of congenital syphilis were documented among newborns in 2022 – more than 10 times the number diagnosed in 2012.
  - Despite comprising 13% of the U.S. population and 14% of live births, Black or African American people represented nearly 32% of all primary and secondary syphilis cases and experienced about 30% of congenital syphilis cases in 2022.
- **HHS Announces Department Actions to Slow Surging Syphilis Epidemic (FOR IMMEDIATE RELEASE January 30, 2024)**
  - Newly established National Syphilis and Congenital Syphilis Syndemic (NSCSS) Federal Task Force.
    - The goal of the HHS Task Force is to avert five percent of congenital syphilis cases by September 2024.

4



Syphilis Images

He who knows Syphilis, knows medicine.
- Sir William Osler

5

- Caused by the bacterium *Treponema pallidum*
- Time between infection and start of first symptom is 10-90 days
- Diagnosed by
  - Dark field microscopy of material taken from a lesion or lymph node
  - Serologic tests (RPR & VDRL)
- Bacteria enter body through minute abrasions in skin
- Transmitted through contact with moist lesions, especially during sexual activity
- Rate of transmission from infected sexual partner is about 30%-60%
- Primary, secondary, and early latent stage account for nearly all transmission
- Syphilis may also be acquired congenitally (at birth)

6

Comparing Stages of Syphilis

Primary Syphilis	Secondary Syphilis
• Single or multiple sores (chancres) • Firm, round, painless; indicates point of bacterial entry • Typically occurs on genital skin and mucosa • May also occur in mouth, hands, or other parts of the body • Chancre heals by itself in 3-6 weeks	• Symptoms are caused by the spread of the bacteria • Fever, sore throat, rash, lymph gland swelling, loss of hair[1] • External genital lesions called condyloma lata • Lesions resolve in 3-12 weeks[2]

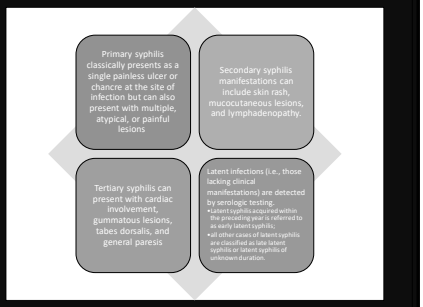
7

Comparing Latent and Tertiary Syphilis

Latent Syphilis	Tertiary Syphilis
• Latent stage can be divided into early and late stages • Mostly asymptomatic and contagious • Early latent stage usually during first year of infection • One-fourth of patients in early latent stage have a relapse (i.e., become symptomatic again) • Relapse is rare in late latent syphilis • May resolve by itself or advance to the tertiary stage[1]	• Occurs in 1/3 of the cases, months or years after latency[1] • Causes walls of major arteries to weaken and balloon out; these aneurysms can rupture and may be fatal • Affects the brain and its coverings to cause paralysis, mental confusion, insomnia, and headaches • Gummas – destructive lesions in skin, bones, and other organs[2]

8

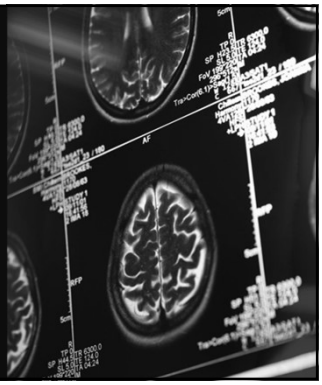
Staging Syphilis



9

Neurologic Involvement

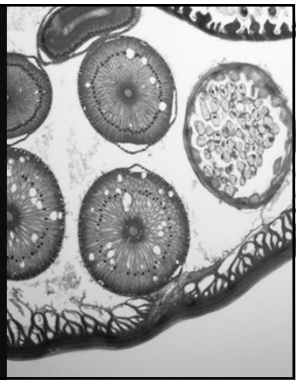
- *T. pallidum* can infect the CNS, which can occur at any stage of syphilis and result in neurosyphilis.
  - Early neurologic clinical manifestations or syphilitic meningitis (e.g., cranial nerve dysfunction, meningitis, meningovascular syphilis, stroke, and acute altered mental status) are usually present within the first few months or years of infection.
  - Late neurologic manifestations (e.g., tabes dorsalis and general paresis) occur 10 to >30 years after infection.



10

Vision and Hearing Impacts

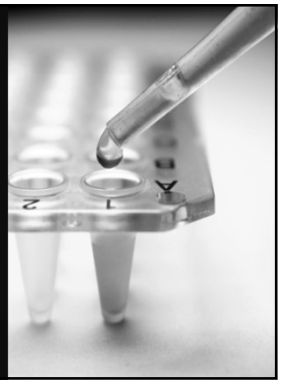
- Infection of the visual system (ocular syphilis) or auditory system (otosyphilis) can occur at any stage of syphilis but is commonly identified during the early stages and can present with or without additional CNS involvement.
- Ocular syphilis often presents as panuveitis but can involve structures in both the anterior and posterior segment of the eye, including conjunctivitis, anterior uveitis, posterior interstitial keratitis, optic neuropathy, and retinal vasculitis.
  - Ocular syphilis can result in permanent vision loss.
- Otosyphilis typically presents with cochleo-vestibular symptoms, including tinnitus, vertigo, and sensorineural hearing loss.
  - Hearing loss can be unilateral or bilateral, have a sudden onset, and progress rapidly.
  - Otosyphilis can result in permanent hearing loss.



11

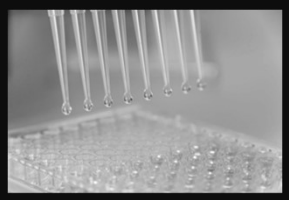
Testing

- A presumptive diagnosis of syphilis requires use of two laboratory serologic tests:
  - a nontreponemal test (i.e., Venereal Disease Research Laboratory [VDRL] or rapid plasma reagin [RPR] test) and
  - a treponemal test (i.e., the *T. pallidum* passive particle agglutination [TP-PA] assay, various EIAs, chemiluminescence immunoassays [CIAs] and immunoblots, or rapid treponemal assays)
- persons with a reactive nontreponemal test should always receive a treponemal test to confirm the syphilis diagnosis (i.e., traditional algorithm).
  - Nontreponemal test antibody titers might correlate with disease activity and are used for monitoring treatment response.
- Further testing with CSF evaluation is warranted for persons with clinical signs of neurosyphilis (e.g., cranial nerve dysfunction, meningitis, stroke, acute or chronic altered mental status, or loss of vibration sense).



12

Titers



- A fourfold change in titer, equivalent to a change of two dilutions (e.g., from 1:16 to 1:4 or from 1:8 to 1:32), is considered necessary for demonstrating a clinically significant difference between two nontreponemal test results obtained by using the same serologic test, preferably from the same manufacturer to avoid variation in results.
- VDRL and RPR are equally valid assays; however, quantitative results from the two tests cannot be compared directly with each other because the methods are different, and RPR titers frequently are slightly higher than VDRL titers.
- False-positive nontreponemal test results can be associated with multiple medical conditions and factors unrelated to syphilis, including other infections (e.g., HIV), autoimmune conditions, vaccinations, injecting drug use, pregnancy, and older age

13

Follow-Up Testing

- The majority of patients who have reactive treponemal tests will have reactive tests for the remainder of their lives, regardless of adequate treatment or disease activity
- Clinical laboratories sometimes screen syphilis serologic samples by using automated treponemal immunoassays, typically by EIA or CIA.
  - This reverse sequence algorithm for syphilis testing can identify persons previously treated for syphilis, those with untreated or incompletely treated syphilis, and those with false-positive results that can occur with a low likelihood of infection.
  - If a second treponemal test is positive (e.g., EIA reactive, RPR nonreactive, TP-PA reactive), persons with a history of previous treatment will require no further management unless sexual history indicates a re-exposure.

14

Bicillin Shortage

- **Reason for the Shortage**
- Pfizer has Bicillin-LA on shortage due to increased demand. Pfizer is allocating resources towards manufacturing adult Bicillin-LA presentations due to increased syphilis infection rates. Once current supplies of the pediatric Bicillin-LA vials are depleted it is unclear when more product will be manufactured. A Dear Healthcare Professional Letter can be found at: https://www.fda.gov/media/169427/download.
- Pfizer is the sole supplier of penicillin G benzathine injection.
- DSHS Statement: There is an ongoing shortage of penicillin G benzathine (Bicillin L-A) estimated to last until at least 2024. This limited supply poses significant challenges to addressing various infectious diseases, especially congenital syphilis. Bicillin L-A is the **only** recommended treatment option for syphilis for women infected or exposed during pregnancy. Thus, healthcare providers should prioritize Bicillin L-A to protect babies exposed to syphilis in utero.

15

Alternatives to Bicillin:

- Temporary Importation of Extencilline, (benzathine benzylpenicillin) Powder and diluent for reconstitution for injection, 1,200,000 units and 2,400,000 units with Foreign, non-U.S. Labeling to Address Supply Shortage
  - Provepharm or its distributor Direct Success is authorized by the FDA to import or distribute Extencilline powder and diluent for reconstitution for injection in the U.S.
  - https://www.cdc.gov/std/dstdp/dcl/2024-january-16-availability_of_extencilline.htm
- The only acceptable alternatives for treating late latent syphilis or syphilis of unknown duration are doxycycline (100 mg orally 2 times/day) or tetracycline (500 mg orally 4 times/day), each for 28 days.

16

Prevention: Doxy PEP

- As CDC and others work quickly to evaluate data to inform clinical guidance on the safe and effective use of post-exposure prophylaxis with doxycycline (also called doxy as PEP) to prevent gonorrhea, chlamydia, and syphilis, we acknowledge there are individuals and clinicians who are already engaged in the off-label use of doxycycline as bacterial STI post-exposure prophylaxis or considering it. As such, we are providing the following considerations to inform those decisions:
- Current efficacy data only applies to gay and bisexual men and transgender women. Studies among heterosexual cis-gender women are ongoing.
- Doxycycline 200 mg administered within 24-72 hours of condomless sex was the regimen evaluated in this study. Other antibiotics should not be considered for PEP.
- In addition to informing patients about the potential STI prevention benefits of doxy as PEP, providers should also counsel patients about potential adverse side effects of doxycycline including phototoxicity, gastrointestinal symptoms, and more rarely esophageal ulceration.
- Providers should continue to screen, test, and treat for bacterial STIs in accordance with CDC's STI Treatment Guidelines and CDC's PrEP for the Prevention of HIV guidelines, even among people who may be using doxycycline as PEP or PrEP.

17

Other Considerations

- All persons who have syphilis should be tested for HIV at the time of diagnosis or treatment.
  - Those persons whose HIV test results are negative should be offered HIV PrEP.
- Clinical and serologic evaluation should be performed at 6 and 12 months after treatment; more frequent evaluation might be prudent if opportunity for follow-up is uncertain or if repeat infection is a clinical concern.
  - Persons who have signs or symptoms that persist or recur and those with at least a fourfold increase in nontreponemal test titer persisting for >2 weeks likely were reinfected or experienced treatment failure.

18

Pregnancy and Syphilis

- All women should be screened serologically for syphilis at the first prenatal care visit, which is mandated by the majority of states.
- Serologic testing should also be performed twice during the third trimester: at 28 weeks' gestation and at delivery for pregnant women who live in communities with high rates of syphilis and for women who have been at risk for syphilis acquisition during pregnancy.
  - Maternal risk factors for syphilis during pregnancy include sex with multiple partners, sex in conjunction with drug use or transactional sex, late entry to prenatal care (i.e., first visit during the second trimester or later) or no prenatal care, methamphetamine or heroin use, incarceration of the woman or her partner, and unstable housing or homelessness
  - Pregnant women seropositive for syphilis should be considered infected unless an adequate treatment history is clearly documented in the medical records and sequential serologic antibody titers have decreased as recommended for the syphilis stage.
- Parenteral penicillin G is the only therapy with documented efficacy for syphilis during pregnancy. Pregnant women with syphilis at any stage who report penicillin allergy should be desensitized and treated with penicillin (see Management of Persons Who Have a History of Penicillin Allergy).
  - For women who have primary, secondary, or early latent syphilis, a second dose of benzathine penicillin G 2.4 million units IM can be administered 1 week after the initial dose

19

Congenital Syphilis

- During 2019, a total of 1,870 cases of congenital syphilis were reported, including 94 stillbirths and 34 infant deaths
  - During 2015–2019, the rate of congenital syphilis increased 291.1% (12.4 to 48.5 per 100,000 live births), which mirrors increases in the rate of primary and secondary syphilis among females aged 15–44 years (a 171.9% increase, from 3.2 to 8.7 per 100,000 females).
- Sonographic signs of fetal or placental syphilis (e.g., hepatomegaly, ascites, hydrops, fetal anemia, or a thickened placenta) indicate a greater risk for fetal treatment failure (*644*); cases accompanied by these signs should be managed in consultation with obstetric specialists.
- All neonates born to mothers who have reactive nontreponemal and treponemal test results should be evaluated with a quantitative nontreponemal serologic test (RPR or VDRL) performed on the neonate's serum because umbilical cord blood can become contaminated with maternal blood and yield a false-positive result,

20

Congenital Syphilis Continued

- All neonates born to women who have reactive nontreponemal serologic tests for syphilis at delivery should be examined thoroughly for evidence of congenital syphilis (e.g., nonimmune hydrops, conjugated or direct hyperbilirubinemia[†] or cholestatic jaundice or cholestasis, hepatosplenomegaly, rhinitis, skin rash, or pseudoparalysis of an extremity).
- Please refer to CDC website on evaluation and treatment and follow up for newborns suspected or confirmed to have congenital syphilis.
- https://www.cdc.gov/std/treatment-guidelines/syphilis.htm

21

Differential and Co-infection Discussion

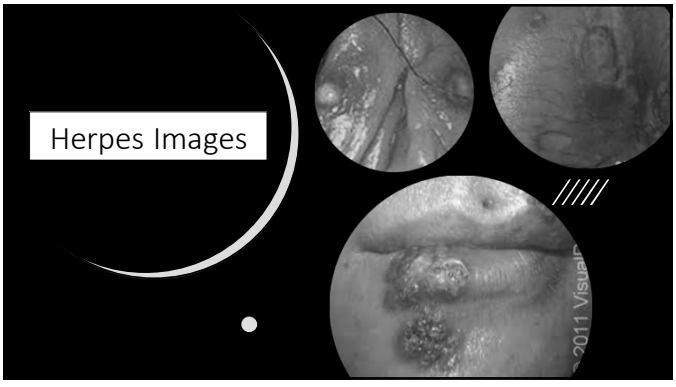
- Genital Herpes
- MPX
- Chancroid
- Lymphogranuloma venereum
- Venereal warts
- Co-infections:
  - Other STI's
  - HIV
  - MPX

22

MPX Images

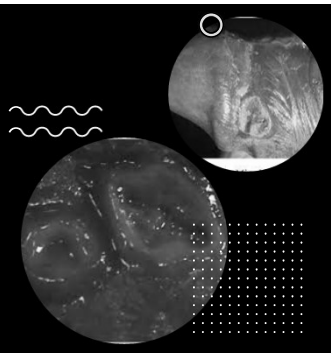
23

Herpes Images



24

Chancroid Images



25

Tell People to Get Tested

- https://youtu.be/Uz8f9L_IeYc

26

Let's see some case examples:

27

A 20-year-old cisgender, male patient presents for their PrEP visit as scheduled. The patient reports no STI symptoms. The patient reports being unaware if any of their partners have been diagnosed with STI's. Per your record, the patient has had 2 bacterial STI's in the last 2 years. The patient is not in a monogamous relationship.

The following tests are indicated EXCEPT:
- HIV
- RPR
- Chlamydia
- Gonorrhea
- MPX

You will likely discuss the following with the patient before they leave EXCEPT:
- PrEP adherence
- Doxy PEP
- PEP
- MPX vaccine
- Lifestyle modification

28

A 27-year-old trans female patient presents for their annual HIV visit. The patient reports compliance with medication and no current symptoms. Their last viral load was undetectable. The patient is sexually active and reports history of a painless ulcer that resolved a month ago on her tongue.

The following tests are indicated EXCEPT:
- HIV viral load
- CD4 count
- RPR
- Herpes IgG & IgM

The following medications are indicated EXCEPT:
- Empiric treatment with Bicillin
- HIV medication refill
- Doxycycline for 28 days
- Doxy PEP

29

A 19-year-old pregnant patient with no history of prenatal care presents in active labor. The patient reports history of rape that led to this pregnancy. The patient was provided PEP in the ER immediately following the rape but they did not follow up or complete the medication. No history of STI's or other partners.

The following is indicated, except:
- Bicillin 2.4 million units
- Stat RPR
- HIV test
- Ultrasound to rule out congenital syphilis

The mother is found to have a reactive RPR with a titer of 1:128. The newborn baby is estimated to be term but weighs less than 5 pounds and is otherwise normal.

The next step is to:
- Draw an RPR on the baby
- Report the baby as a confirmed congenital syphilis baby to the health department
- Notify Child protective services
- Treat the baby with Bicillin immediately.

30

Summary

- Syphilis is surging in the US in 2024
- Congenital syphilis is also surging in 2024
- Doxy PEP is an option for some patients to reduce the risk of syphilis and other STI's
- Bicillin shortage is not ending in 2024, so treatment with Doxy is recommended when possible
- HIV increases usually follow syphilis surges so test patients for both.
- Staging syphilis can be challenging but necessary.
- End stigma of STI's and sexual behaviors to enable patient dialogue and treatment in all patients.

31

Thank you

Sandra.Guerra@texashealthaction.org

32

Notes

Value-Based Care: Family Medicine's Time Has Come!

Clare A. Hawkins, MD, MSc
Texas Chief Medical Officer
Main Street Health Care
Dallas, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Contrast fee for service with capitated care.
2. Decipher differences in accountable care organization (ACO), Medicare Share Savings Program (MSSP), Annual Wellness Visit (AWV), alternative payment models (APM), etc.
3. Appreciate how risk stratification of patients and appropriate visit frequency and use of team-based care all fit very well within Family Medicine.

Speaker Disclosure

Dr. Hawkins disclosed he has no financial relationships with any ineligible organizations or commercial interests.

Value-Based Care: Family Medicine's Time Has Come!

Texas Academy of Family Physicians

Clare Hawkins, MD, MSc
Texas Chief Medical Officer
Main Street Health

1

Speaker Disclosure and Learning Objectives

Disclosure

Dr. Hawkins disclosed he has no financial relationships with any ineligible organizations or commercial interests.

Learning Objectives

By completing this educational activity, the participant should be better able to:

1. Contrast fee for service with capitated care.
2. Decipher differences in accountable care organization (ACO), Medicare Share Savings Program (MSSP), Annual Wellness Visit (AWV), alternative payment models (APM), etc.
3. Appreciate how risk stratification of patients and appropriate visit frequency and use of team-based care all fit very well within Family Medicine.

2

Agenda

1. The Problem
2. What is Value-Based Care?
3. How to Succeed in Value-Based Care?

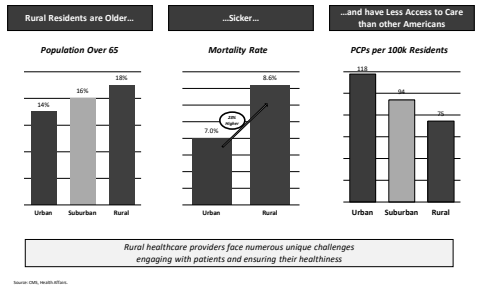
3

The Problem: Our Healthcare System is Broken

US Healthcare is Expensive	2.0x spend per capita *Health consumption expenditures vs. other developed nations*	17% of GDP *Compared to ~9% of GDP at other developed nations*	
US Healthcare has Poor Outcomes	6+ year gap *US life expectancy vs. other developed nations*	5x+ gap *Maternal mortality rate vs. other developed nations*	5.0 HAQ gap *Healthcare access and quality index vs. other developed nations*
Poor Experiences are prevalent in the US Healthcare system	>40% *Physician Burnout Rate*	23M in Debt *Americans owe > $195B in medical debt*	

4

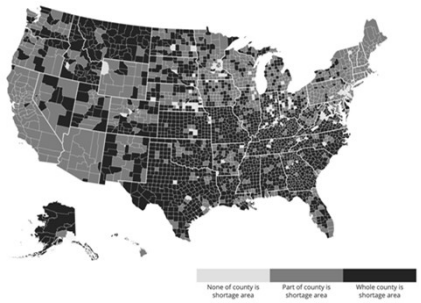
Problems Are Exacerbated in Rural Settings



Source: CMS, Health Affairs.

5

Primary Care Shortage Areas by County



Source: data.HRSA.gov, May 2023.

6

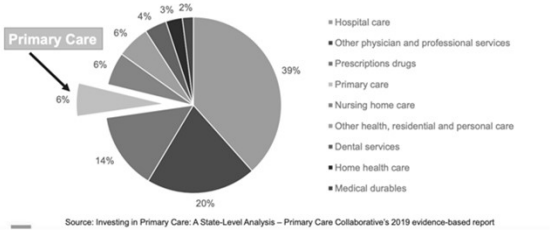
Polling Question

How much of overall U.S. health care spending goes to primary care?

A. Less than 5%
B. Between 5-7%
C. Between 7 and 10%
D. More than 10%

7

The Reality of US Spending on Primary Care

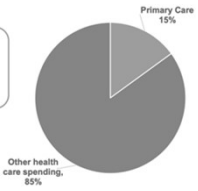


Source: Investing in Primary Care: A State-Level Analysis – Primary Care Collaborative's 2019 evidence-based report

8

International Spending on Primary Care

International spending on primary care is estimated to represent **12-17%** of total spending.



Baillieu R, Kidd M, Phillips R, *et al.* The Primary Care Spend Model: a systems approach to measuring investment in primary care. *BMJ Global Health* 2019;4:e001601.

9

Agenda

1. The Problem
2. **What is Value-Based Care?**
3. How to Succeed in Value-Based Care?

10

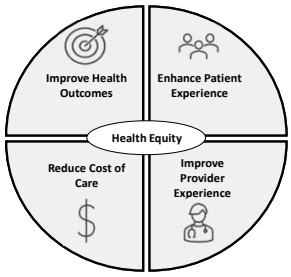
Potential Solution: Value-Based Care

CMS Goals for Healthcare Paradigm Change

- In October 2021, CMMI announced a goal of having every Medicare beneficiary and the majority of Medicaid beneficiaries covered by some type of alterative payment model (APM) by 2030
- CMMI considers an alternative payment model to be any arrangement whereby providers are held accountable for the quality and costs of care, not just paid based on the volume of services they deliver

11

Value-Based Care Focuses on the Quintuple Aim



12

What is Value-based Care?

Fee for Service	Value-Based Care
• Patient care and payment is **based on volume of visits** and number of services provided	✓ Patient care and payment is based on **quality of care for a patient pane**l over quantity of daily visits
• Often **unnecessary spend** for repeated tests and unnecessary care	✓ Care can be **less expensive** for patients because of the coordination of care across the healthcare landscape
• Patient experience is not optimal with most patients wanting more than **15-minute healthcare**	✓ Patient **satisfaction goes up** with an expanded care team and more access to resources and information
• There are **no rewards** for quality of care provided	✓ **Rewards** (and some penalties) for quality of care

13

Fee-for-Service Care

Pros	Cons
Clear payment based on volume of visits	Set reimbursement amounts, regardless of health outcome
No penalties for failed quality initiatives	Unnecessary procedures
Encourages maximum number of patient visits	Denial of care cases
Flexible care structure	Expensive insurance
	More paperwork
	No accountability

Source: carepatron

14

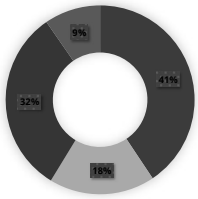
Value-based Care

Pros	Cons
Based on quality of care rather than volume	Increases patient load
Reduced costs	High demands
Patient-centered	Involves efficient data management skills
Increases healthcare quality and outcomes	Relatively new care model
Greater accountability	Expanded care team needs
More informed patients	
Reduced medical errors	

Source: carepatron

15

Types of VBC Arrangements



	Category 1: Fee-for-Service - No Link to Quality & Value
	Category 2: Fee-for-Service - Link to Quality & Value
	Category 3: APMS Built on Fee-for-Service Architecture 3A: Upside Rewards for Appropriate Care 3B: Upside & Downside for Appropriate Care
	Category 4: Population-Based Payment 4A: Condition-Specific Population-Based Payment 4B: Comprehensive Population-Based Payment 4C: Integrated Finance & Delivery Systems
24.5%	Combination of Categories 3B, 4A, 4B & 4C Represents Two-Sided Risk APMs

Based on 64 plans, 4 states, and Traditional Medicare

Source: The Health Care Payment Learning & Action Network

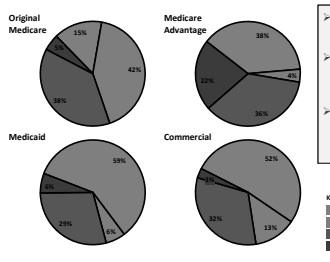
16

The APM Framework

Category 1 FEE-FOR-SERVICE: NO LINK TO QUALITY & VALUE	**Category 2** FEE-FOR-SERVICE: NO LINK TO QUALITY & VALUE	**Category 3** APMS BUILT ON FEE-FOR-SERVICE ARCHITECTURE	**Category 4** POPULATION-BASED PAYMENT
	A **Foundational Payments for Infrastructure & Operations** (e.g., care coordination fees and payments for HIT investments)	A **APMs with Shared Savings** (e.g., shared savings with upside risk only)	A **Condition-Specific Population-Based Payment** (e.g., per member per month payments, payments for specialty services, such as oncology or mental health)
	B **Pay for Reporting** (e.g., bonuses for reporting data or penalties for not reporting data)	B **APMs with shared Savings and Downside Risk** (e.g., episode-based payments for procedures and comprehensive payments with upside and downside risk)	B **Comprehensive Population-Based Payment** (e.g., global budgets or full/percent of premium payments)
	C **Pay-for-Performance** (e.g., bonuses for quality performance)		C **Integrated Finance & Delivery System** (e.g., global budgets or full/percent of premium payments in integrated systems)
		3N Risk Based Payments NOT Linked to Quality	4N Capitated Payments NOT Linked to Quality

17

Value-Based Care is Already Present



- Value-based care penetration is the highest in Medicare beneficiaries
- However, global capitated arrangements still represent a small portion of lives
- For Commercial and Medicaid populations, significant penetration remains in shifting FFS payments to value-based models

CMS Expects 100% of Medicare Beneficiaries to be in VBC Arrangements by 2030

18

Critical Mass of >30% to Get your Attention

High Levels Of Capitation Payments Needed To Shift Primary Care Toward Proactive Team And Nonvisit Care

Basu S, Phillips RS, Song Z, Bitton A, Landon BE. High Levels Of Capitation Payments Needed To Shift Primary Care Toward Proactive Team And Nonvisit Care. Health Aff (Millwood). 2017 Sep 1;36(9):1599-1605. doi: 10.1377/hlthaff.2017.0367. PMID: 28874487.

Exhibit 3 Net surplus per FTE physician per year after shifting to team- and non-visit-based care, by percentage of patients with capitated payment

SOURCE Authors' calculations. NOTES Net surplus per full-time-equivalent (FTE) physician per year is defined in the Notes to Exhibit 2 . The minimum capitation level is the level above which 95 percent of practices would gain revenue by shifting to a team- and non-visit-based primary care delivery strategy. Appendix Exhibit 6 contains a conceptual illustration of the analysis used to determine this level (see Note 18 in text). CI is confidence interval.

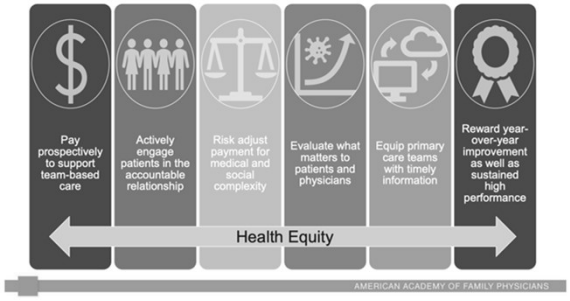
19

Value-Based Care Emphasis

Actively engage patients in the accountable relationship

- Prioritize patient choice
- Rely on primary care services delivered by primary care physicians in a primary care setting when using claims-based methodologies
- Accountability should be at the individual physician level
- Patient attribution/assignment lists should be:
  - communicated on a timely basis
  - up-to-date with demographic and contact info

20



21

Why do we have to worry about specific ICD-10 codes?

Risk adjust payment for medical and social complexity

- Accurately reflect the clinical acuity of the patient
- Consider social risk factors
- Be transparent
- Minimize burden related to risk documentation

22

Hierarchical Condition Categories

- ICD-10 diagnoses are clustered into groupings
- Groupings are called **H**ierarchical **C**ondition **C**ategories, (HCC)
- These grouping have been created to predict future health care costs
- Version 24 = 86 groups
- Version 28 = 115 groups
- Re-weighting to better actually predict costs

- Net reduction in revenue by ~3%
- Phased in over three years 2023, 2024, 2025

23

What Family Physicians Need to Know About the Wave of 2024 HCC Changes

- Family Practice Management
- Nov/Dec 2023

Dr. Venita Magoon
Texas A&M University's Family Medicine Residency in Round Rock, Texas

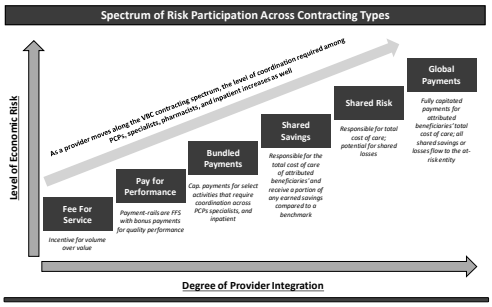
24

Telling the Patient's Story to the Health Plan

- Be **specific**: avoid using symptom codes or unspecified codes when you can use a more specific diagnosis code,
- Try to capture patients' ongoing diagnoses **annually**
- Include codes for **complications and secondary diagnoses** (especially during annual wellness visits)
- Make sure your **documentation** supports the diagnosis codes you use,
- Don't use "history of" diagnosis codes for conditions you're **actively treating**
- Take advantage of diagnosis code **specificity tools** if your EHR has them.

25

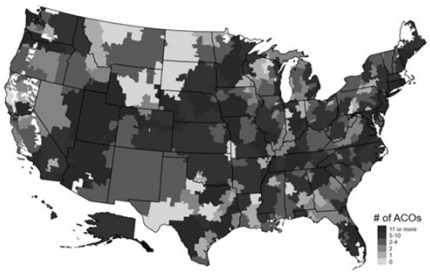
Value-Based Care Can Take a Variety of Forms



26

Geographic Dispersion of ACOs

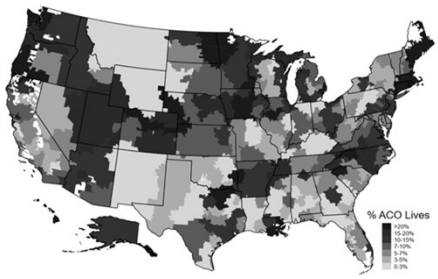
Total number of ACOs by Hospital Referral Region



27

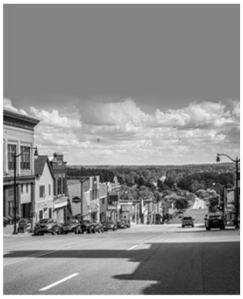
Geographic Dispersion of ACOs

Percent of population in an ACO by Hospital Referral Region



28

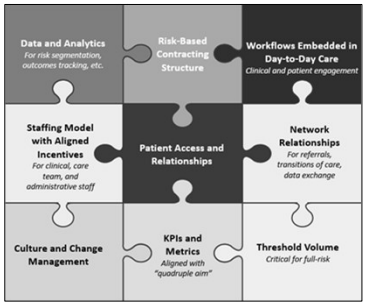
Agenda



1. The Problem
2. What is Value-Based Care?
3. How to Succeed in Value-Based Care?

29

Success in VBC Requires a Variety of Capabilities



30

Collaborative Care Model Drives Success

31

On-Ramp to Value-Based Care

Local Health Navigation: patients benefit from having help identifying the best ways to access care, medications, and specialty services

Appropriate Documentation of Medical Conditions: charting patient's health status during routine visits to identify care coordination needs is a key part of VBC (e.g., quality gaps, HEDIS measures, chronic conditions, risk level, SDOH needs)

Quality Gap Closure: preventive and chronic disease management measure closure at every visit ensures optimal health outcomes

Transitions of Care: Admission/Discharge/Transfer (ADT) notifications help clinicians review admissions with clinic staff and conduct patient outreach to schedule timely follow-up visits

Affordable Access to Care: patients need trusted Medicare advice to ensure they receive all the government-funded subsidies and cost-sharing for which they qualify (e.g., LIS, MSP, dual eligibility)

32

Value-Based Model Design Principles

1. Design with simplicity in mind for both provider and patient
2. Meet patients where they are or prefer to receive care
3. Reduce the burden on clinic providers and staff

33

Contact Information

Clare Hawkins, MD
Regional Chief Medical Officer
Main Street Health
chawkins@mainstreetruralhealth.com

34

Notes

Top 20 POEMS 2023

Rebecca Hayes, MD
Medical Director, Elizabeth Family Medicine
Atrium Health
Charlotte, North Carolina

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Discuss the top 20 research studies for primary care.
2. Discuss POEMS topics clinical relevance, validity, and reported outcomes.
3. Discuss how these research studies have potential to change practice.
4. Discuss POEMS consistent with the principles of the Choosing Wisely campaign.

Speaker Disclosure

Dr. Hayes disclosed she has no financial relationships with any ineligible organizations or commercial interests.

Top 20 POEMS from 2023

Rebecca Hayes, MD, MBA-HM, CPE, FAAFP
Vice Chair of Clinical and Community Operations, Atrium Health
Clinical Associate Professor, Department of Family and Community Medicine, Wake Forest University School of Medicine

1

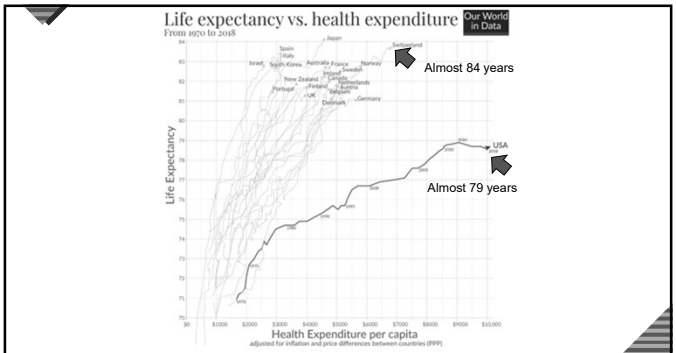
Conflict of Interest Disclosures: None

2

Learning Objectives

- Discuss the top research studies from primary care.
- Discuss POEMS topics clinical relevance, validity, and reported outcomes.
- Discuss how these research studies have potential to change practice.
- Discuss POEMS consistent wit the principles of the Choosing Wisely Campaign.

3



Max Roser (2020) - "Why is life expectancy in the US lower than in other rich countries?" Published online at OurWorldInData.org. Retrieved from: 'https://ourworldindata.org/us-life-expectancy-low' [Online Resource]

4

A lot of care delivered in the US is…

- EXPENSIVE
- DOES NOT CHANGE OUTCOMES – THAT MATTER
- NOT EVIDENCE INFORMED

Why?

- Cultural/societal NEED TO DO SOMETHING

5

Choosing Wisely
An initiative of the ABIM Foundation

Choosing Wisely Canada

- Began in 2012 with 9 US national specialty societies
- Educational campaign about unnecessary health care
- ABIM Foundation ceased maintaining examples on their website in 2023
  - Specialty societies are encouraged to publish individual lists Choosing Wisely | AAFP
  - Choosing Wisely Canada still maintains it's lists Home - Choosing Wisely Canada

6

What is a POEM?

- **P**atient **O**riented **E**vidence that **M**atters
- Is it an outcome that patients care about (will they live longer/better)?
- Is it a common problem for my specialty/discipline?
- If it is valid (high probability of true), would it require a change in practice?

7

POEMS = Patient Oriented Evidence that Matters

- For over 20 years, Top 20 POEMs article published in the *American Family Physician*
- Team made up of experts in family medicine, pharmacology, hospital medicine, and women's health
- Of all the research studies published in 2023, 247 met criteria for validity, relevance, and practice change

The best of the best for 2023 presented today!

8

Where can you get POEMs?

- FREE Weekly "POEM of the Week" podcast
https://www.essentialevidenceplus.com/Home/Podcast
- FREE 4-5 monthly in *American Family Physician*
- $114/year emailed daily to ***Essential Evidence*** subscribers
https://www.essentialevidenceplus.com/Home/Overview


American College of Gastroenterology guideline for evaluating and managing patients with celiac disease

9

Levels of Evidence
Centre for Evidence-Based Medicine, Oxford

- 1a: Systematic reviews of RCT
- 1b: Individual RCT
- 1c: All or none RCT
- 2a: Systematic reviews of cohort studies
- 2b: Individual cohort studies
- 2c: "Outcomes" research
- 3a: Systematic review of case-control studies
- 3b: Individual case-control studies
- 4: Case series
- 5: Expert opinion

10

2023 Themes

- Hypertension
- Colorectal cancer screening
- Depression
- Treatment of ADHD
- Cardiovascular disease
- Cervical cancer screening/treatment
- Children's health
- Infectious disease
- Deprescribing

11

POEMs #1 – #4
What are best practices for treating HTN?

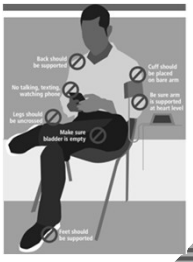
- Does time of day matter? **NO!**
  - Large TIME study found that it didn't matter when patients take their blood pressure medications. LOE = 2b
- Is chlorthalidone better than hydrochlorothiazide? **NO!**
  - No difference in CV outcomes comparing the 2
  - Slightly higher risk of hypokalemia with chlorthalidone. LOE = 1b
- Does continued use of ACEIs or ARBs in stage IV or V CKD worsen outcomes? **NO!**
  - No evidence of harm
  - Possible reduction in need for renal transplant (NNT= 17). LOE = 1b
- Should all elevated BP be treated in hospitalized patients? **NO!**
  - Possible increased risk of adverse events
  - More pronounced in IV vs po meds. LOE = 2b

(*Lancet* 2022;400(10361):1417-1425), (*N Engl J Med* 2022(26):387;2401-2410), (*N Engl J Med* 2022;387(22):2021-2032), (*JAMA Intern Med* 2023;183(7):715-723)

12

POEMs #5 & #6
How should we diagnose & monitor HTN?

- Ambulatory vs clinic readings? **24-hr ambulatory**
  - All-cause and CV mortality greater for 24- hour ambulatory BP monitoring compared to clinic BP readings. LOE = 2b
- Does cuff size matter? **Absolutely!**
  - Too large falsely decreased SBP by 3.6 mmHg
  - Too small cuff falsely increased SBP by 4.8 mmHg. LOE = 1b



(*Lancet* 2023;401(10393):2041-2050), (*JAMA Intern Med* 2023;183(10):1061-1068)

13

13

POEMs #7 – #10
Colorectal Cancer Screening

- When and how should we start screening? **Consider NOT screening pts 45- 49 yo Do NOT use stool DNA, CT, capsule endoscopy, urine or serum screening**
  - ACP guideline, looked at avoiding premature death from CRC
  - Reviewed existing data and made discrepant recommendations
  - Don't screen using Cologuard. LOE = 5
- Colonoscopy vs fecal-based blood testing? **Colonoscopy**
  - Higher rates of participation with colonoscopy
  - More likely to ID advanced neoplasia or large serrated lesions. LOE = 1b
- Rescreening interval? **Probably beyond 10 years**
  - Rates 14+ yrs after initial neg screen only slightly increased
  - Shouldn't be shorter. LOE = 1b
- Older patients with polyps? **Only a few will develop colon cancer**
  - Those 65 + yo with colon polyps on colonoscopy, only 0.2%developed colon cancer.
  - Overuse Alert: Per Canadian AGS Choosing Wisely: Avoid CRCS in asymptomatic pts without FHx or personal hx of CRC and life expectancy < 10 yrs LOE = 1b

Choosing Wisely Canada

(*Ann Intern Med* 2023;176(8):1092-1100), (*Gastroenterology* 2023;165(1):252-266), (*JAMA Intern Med* 2023;183(3):183-190), (*JAMA Intern Med* 2023;183(5):426-434)

14

14

POEM #11
How should we explain depression to our patients?

Adaptation to surroundings is better accepted than disease

- May produce less stigma, more acceptance, and self-efficacy.
- "Chemical imbalance" explanation may decrease self blame, but
  - May reduce hope for recovery
  - Stigmatize them with a disease
  - May be the effect and not the cause. LOE = 1b-

(*Soc Sci Med* 2023;328:115995)

15

15

POEMs #12 & #13
What are the risks of ADHD medications?

- Do ADHD medications increase CV risk? **NO!**
  - Systematic review of 19 studies including all ages
  - No significant association with CVD. LOE = 1a-
- Are ADHD medications associated with subsequent substance abuse? **No**
  - Follow-up data from randomized trial of ADHD treatment
  - Based on self-reported data only, therefore possible reporting bias. LOE = 2b

(*JAMA Network Open* 2022;5(11):e2243597), (*JAMA Psychiatry* 2023;80(9):933-941)

16

16

POEM #14 How should we dose statins?

High-intensity dosing avoids costs and burdens of repeated LDL testing

- Study compared treat-to-target vs high intensity strategies
- Treat-to-target found to be noninferior for reducing adverse events in patients with established CVD
- Great evidence for using high-intensity strategy
  - 20 mg rosuvastatin or 40 mg atorvastatin daily
  - Do not adjust dose based on follow-up LDL levels. LOE = 1b

(*JAMA* 2023;329(13):1078-1087)

17

17

POEM #15
Should we screen children and adolescents for lipid disorders?

Contrary to AAP recommendations – NO

- USPSTF found inadequate evidence on balance of risks and benefits
- No evidence that treatment reduces premature CVD incidence
- Recognized that screening could result in labeling that could lead to unnecessary or harmful testing, treatment, and anxiety.
- Does not address the issue of targeted screening based on FHx. LOE = 2c

(*JAMA* 2023;330(3):253-260)

18

18

POEMs #16 & #17
Cervical cancer screening, surveillance, and treatment

- What method should be used for routine cervical cancer screening? **HPV testing alone**
  - Less than 0.02% of those with biopsy confirmed CIN2+ had + cytology with – HPV
  - Limited benefit for co-testing vs HPV testing alone for routine screening
  - Does not apply to testing for clinical indications. LOE = 2b
- Watchful waiting vs invasive treatment in women 25- 30 yo with CIN2? **Watchful waiting is a reasonable alternative**
  - Majority of CIN2 regresses in women aged 25 to 30 years old except in patients with HPV 16
  - Majority of regression was evident at 12 months. LOE= 1b

(*Prev Med* 2023;166:107364), (*Am J Obstet Gynecol* 2022;227(22):742e1-11)

19

19

POEM #18 Should we screen women older than 70 years old for breast cancer?

No – there is a high risk of overdiagnosis in older women

- Overdiagnosis of breast cancer increases with age
  - 31% for women 70 -74 yo
  - 47% for women 75- 84 yo
  - 51% for women over 85 yo
- No reduction in breast cancer related death. LOE = 2b

(*Ann Intern Med* 2023;176(9):1172-1180)

20

20

POEM #19 Is RSV vaccination in pregnant women safe and effective in reducing severe RSV in their newborns?

Yes! The bivalent RSV vaccine given to women between 24 and 36 wga safely reduces RSV infection in their babies

- Likelihood of severe RSV was significantly lower in the treatment group. NNT = 81
- Likelihood of any RSV requiring medical care was significantly lower in the treatment group. NNT = 58
- Muscle pain was the most common adverse reaction
- No difference in maternal or neonatal outcomes. LOE = 1b-

(*N Engl J Med* 2023;388(16):1451-1464)

21

21

POEM #20 Do PPIs in children increase the risk of serious infections?

Yes – when compared to other medications

- Compared children who received PPIs and those that received H2 blockers or an antacid
- Serious infections included GI, ENT, lower respiratory, kidney/ UTI, nervous system among others
- 48% received a PP and 12% developed a serious infection
- Children using PPIs were 1.34 times more likely to develop a serious infection. LOE = 1b

(*JAMA Pediatr* 2023;177(10):1028-1038)

22

22

POEM #21 Does postexposure doxycycline reduce STI risk?

Yes – in MSM and transgender women with or at risk for HIV (NNT = 5)

- Benefit from single dose of doxycycline 200mg, within 24- 72 hrs after a condomless sexual encounter
- No serious adverse events
- Some concern of increased resistance to doxycycline in treatment group in both gonorrhea and Staph aureus cultures. LOE = 1b-

(*N Engl J Med* 2023;388(14):1296-1306)

23

23

POEM #22 Can we safely remove erroneous PCN allergy labeling in adults and children?

Yes – amoxicillin oral challenge is safe and accessible

- Using an easy decision tool, identified patients at low risk (<5%) of having a true allergy
- Equipped with diphenhydramine elixir and epinephrine to manage anaphylaxis
- Amoxicillin (250mg/ 5ml) 500mg po challenge dose given per protocol
- Only 3% had mild rxn
- 97% had PCN allergy label removed. LOE = 2b

PEN-**FAST** rule
Five or less yrs since the rxn (2pts)
Anaphylaxis or **A**ngioedema or
Severe cutaneous rxn (2pts)
Treatment required for rxn (1pt)
Likelihood of + test: Score = 0: 1%, Score = 1-2: 5%. LOE = 1a

- Protocol
- 10% of challenge dose (50mg or 4.5mg/kg) given – observe for 20 min.
- Remaining 90% of challenge dose (450mg or 40.5mg/kg) given – observe 1 hr.

(*CMAJ Open* 2021;9(2):E394-E399), (*JAMA Intern Med* 2020;180(5):745-752)

24

24

POEM #23 What interventions change clinician behavior for prescribing inappropriate Abx?

Most nudge interventions associated with reduction in inappropriate Abx

- Audit, feedback, reminders, suggested alternative therapies were all successful
- 78% interventions involving feedback showed reduction in overall Abx prescribing
- 83% success rate when targeted to high-prescribing clinicians. LOE = 1a-

(*BMJ Open* 2023;13(1):e062688)

25

POEM #24 Can deprescribing interventions safely reduce polypharmacy in older adults?

Yes

- Extensive deprescribing (Shed-MEDS) intervention by pharmacist or NP targeting older adults discharging from hospital or PAC.
- Led to decrease in overall medication burden with no increase in adverse events. LOE = 1b

Choosing Wisely Canada

Shed-MEDS

- Best Possible Medication History process-review of:
  - medical records
  - pharmacy refill hx
  - Controlled substance monitoring database
  - Patient/ surrogate interview
- Review of medications
- Conversation with patient/surrogate
- Discussion with outpatient prescribers and inpatient team
- Review of recommendations with PAC at transfer

(*JAMA Intern Med* 2023;183(3):223-231)

26

POEM #25 Is intuition accurate when used by PCPs faced with diagnostic uncertainty?

It can be – Lack of concern was correct 98% of the time

- Completed the Gut Feeling Questionnaire
- Reported having gut feeling during 97% of visits
- 75% were reassurance, 22% were alarm
- Alarm correctly predicted serious disease in 12% (PPV 12%)
- Reassurance was correct in 98% (NPV 98%). LOE = 1c

(*J Gen Intern Med* 2022;37(15):3823-3831)

27

POEM #26 Does rounding on discharging patients 1st result in shorter LOS or earlier discharge times?

No

- Compared 2 rounding styles:
  1. Rounding on discharging patients 1st
  2. Usual rounding practice
- 1st group asked to enter dc order as early as possible
- No significant difference in time of placement of dc order, time of actual dc, or LOS
- Perceived increased work and travel between patients and potential harm. LOE = 1b

(*J Hosp Med* 2023 Feb 16. doi: 10.1002/jhm.13060)

28

POEM #27 How long does it take PCPs to provide all recommended care?

26.7 hours!

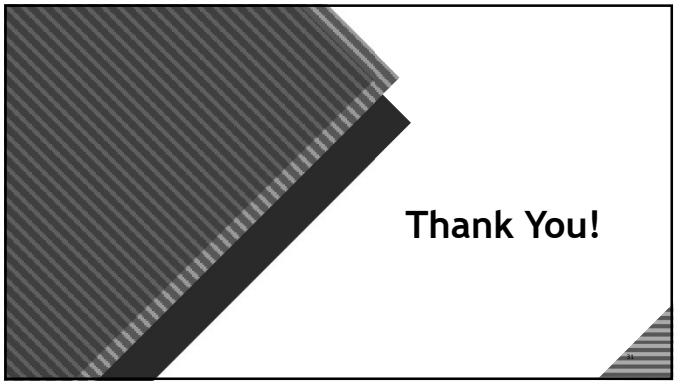
- Conducted theoretical model to estimate time needed according to current guidelines
- Panel of 2500 required:
  - 3.2 hours each day for documentation and inbox management
  - 14.1 hours for preventive care
  - 7.2 hours for chronic disease care
  - 3.2 hours a day for acute care
- Panel of 1500 decreases time by 10.7 hours
- Panel of 3000 increases time by 5.3 hours
- High functioning teams has lower estimates of 9.3 hours. LOE = 5

(*J Gen Intern Med* 2023;38(1):147-155)

29

Deep gratitude to Dave Slawson, MD for passing this opportunity on to me, his leadership, mentorship, and most importantly friendship!

30



31

Notes

Borderline Personality Disorder in Adolescents and Young Adults

Zach Sartor, MD

Family Physician, Waco Family Medicine
Waco, Texas

Lance Kelley, PhD

Deputy Chief Behavioral Health Officer, Waco Family Medicine
Waco, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Review the epidemiology, natural history, and the clinical presentation of borderline personality disorder (BPD).
2. Apply the DSM-5-TR diagnostic criteria to diagnose BPD.
3. Distinguish between BPD and other behavioral disorders, especially common comorbidities.
4. Implement comprehensive behavioral treatment strategies for patients with BPD, including psychological interventions, pharmaceutical treatments, and appropriate involvement of specialists.

Speaker Disclosure

Dr. Sartor and Dr. Kelley disclosed they have no financial relationships with any ineligible organizations or commercial interests.

Borderline Personality Disorder

Lance Kelley, PhD and Zachary Sartor, MD, FAAFP
TAFP C. Frank Webber Lectureship
April 12, 2024

Disclosure: Dr. Sartor and Dr. Kelley disclosed they have no financial relationships with any ineligible organizations or commercial interests.

1

Objectives

1. Review the epidemiology, natural history, and clinical presentation of borderline personality disorder (BPD).
2. Apply the DSM-5-TR diagnostic criteria to diagnose BPD.
3. Distinguish between BPD and other behavioral disorders, specifically common comorbidities.
4. Implement comprehensive behavioral treatment strategies for patients with BPD, including psychological interventions, pharmaceutical treatments, and appropriate involvement of specialists.

2

Personality Disorders

- Enduring and inflexible symptom patterns.
- Two or more of the following domains:
  - Cognition (e.g., perceiving and interpreting self, other people, and events)
  - Affectivity (e.g., intensity, lability, and appropriateness of emotional responses)
  - Interpersonal functioning (ways of responding to interpersonal situations)
  - Impulse control
- Symptoms are not adaptable, differing from cultural expectations.
- Leads to distress or impairment in various life areas.

3

Cluster A Odd, eccentric	Cluster B Dramatic, emotional, erratic	Cluster C Anxious, fearful
• Schizoid • Schizotypal • Paranoid	• Borderline • Histrionic • Antisocial • Narcissistic	• Avoidant • Dependent • Obsessive-compulsive

4

What's in a Name: "Borderline"

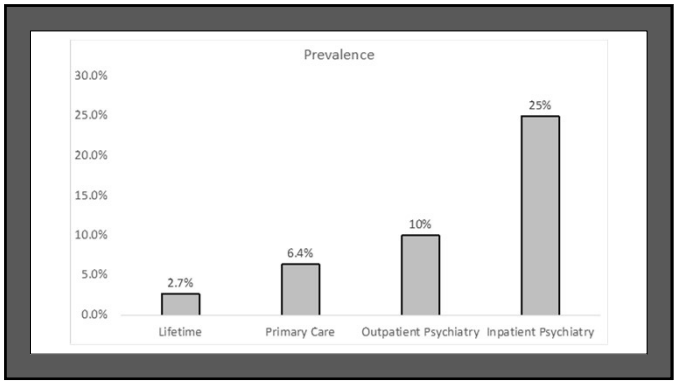
- BPD is characterized by instability in affect regulation, impulse control, interpersonal relationships, and self-image
- The term "borderline" in Borderline Personality Disorder (BPD) originated from the belief that individuals with this condition were on the borderline between neurosis and psychosis
- The concept emerged in the early 20th century, and initially, those with symptoms that did not fit neatly into either the neurotic or psychotic categories were considered to be on the "borderline" between the two

6

Objectives

1. **Review the epidemiology, natural history, and clinical presentation of borderline personality disorder (BPD).**
2. Apply the DSM-5-TR diagnostic criteria to diagnose BPD.
3. Distinguish between BPD and other behavioral disorders, specifically common comorbidities.
4. Implement comprehensive behavioral treatment strategies for patients with BPD, including psychological interventions, pharmaceutical treatments, and appropriate involvement of specialists.

8



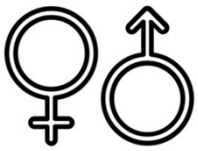
10

In Primary Care **half of patients** with BPD will be undiagnosed and untreated.

11

Sex and Gender-Related Issues

- BPD's prevalence is equal between men and women in community samples
- In clinical settings, the ratio of women to men is 3:1
- Discrepancy reflects women's higher help-seeking in clinical settings
- Men exhibit more externalizing, women more internalizing behaviors



Created by PARDILA from Noun Project

12

Other Factors

- Nearly one-third of patients with borderline personality disorder have been raped or sexually assaulted during adulthood
- Adverse childhood experiences, including physical, sexual, or emotional abuse and neglect, are more common in people with BPD
  - However, not all people diagnosed with BPD have a history of adverse childhood experiences

13

Created by Justin Blake from Noun Project

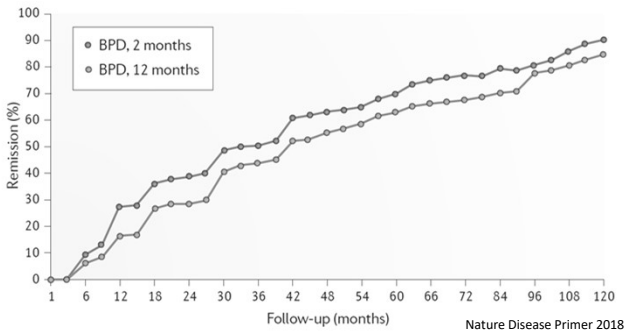
ACEs

14

Adolescent BPD

- Adolescent female study: BPD symptoms associated with impairment in eight domains of psychosocial functioning (including academic achievement, self-perception, social skills, and sexual behavior) between the ages of 14 years and 17 years
- Severity of symptoms higher
- BPD should be recognized and treated in childhood and early adolescence
- Early intervention might prevent BPD chronicity

16

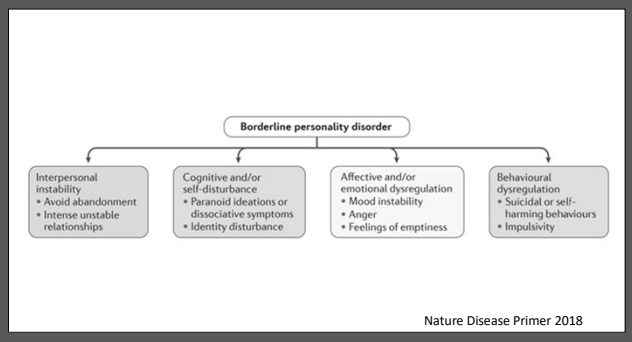


18

Shifts in Symptoms Over Time

- Older patients evidence a shift in symptoms toward more depression, feelings of emptiness, and somatic problems
- Emotional dysregulation, unstable interpersonal relationships, anger, and attachment insecurity typically persist, whereas impulsivity and identity disturbances tend to decrease

19



20

Clinical Presentation: Interpersonal Hypersensitivity

- Interpersonal relationships are best distinguisher of BPD
- Interpersonal events trigger remissions/relapses, self-injurious behaviors, dissociation, suicide, anger, devaluation, abandonment fears
- Although all criteria for BPD are weighted equally for diagnosis, the unstable relationships criterion has the best combined sensitivity and specificity for BPD 2 years later

21

Clinical Presentation: Splitting

- Relationships are rapidly devalued or overvalued
- Example: in one moment the patient can highly appreciate a clinician and then reverse this opinion when an appointment needs to be rescheduled or another perceived rejection occurs

22

POLL #1: What is the prevalence of BPD in the average primary care practice context?

A. 2.7%
B. 6.4%
C. 10%
D. 25%

23

Objectives

1. Review the epidemiology, natural history, and clinical presentation of borderline personality disorder (BPD).
2. **Apply the DSM-5-TR diagnostic criteria to diagnose BPD.**
3. Distinguish between BPD and other behavioral disorders, specifically common comorbidities.
4. Implement comprehensive behavioral treatment strategies for patients with BPD, including psychological interventions, pharmaceutical treatments, and appropriate involvement of specialists.

25

26

DSM—5—TR criteria, must have five or more:

- Frantic efforts to avoid real or imagined abandonment
- A pattern of unstable and intense interpersonal relationships that are characterized by alternating between the extremes of idealization and devaluation
- Markedly and persistently unstable self-image or sense of self (identity disturbance)
- Impulsivity in at least two areas that are potentially self-damaging (for example, spending, sex, substance abuse, reckless driving or binge eating)
- Recurrent suicidal behavior, gestures or threats or self-mutilating behavior
- Affective instability due to a marked reactivity of mood (for example, intense episodic dysphoria, irritability or anxiety usually lasting a few hours and only rarely lasting for more than a few days)
- A chronic feeling of emptiness
- Inappropriate, intense anger or difficulty in controlling anger (for example, frequent displays of temper, constant anger or recurrent physical fights)
- Transient, stress-related paranoid ideation or severe dissociative symptoms

27

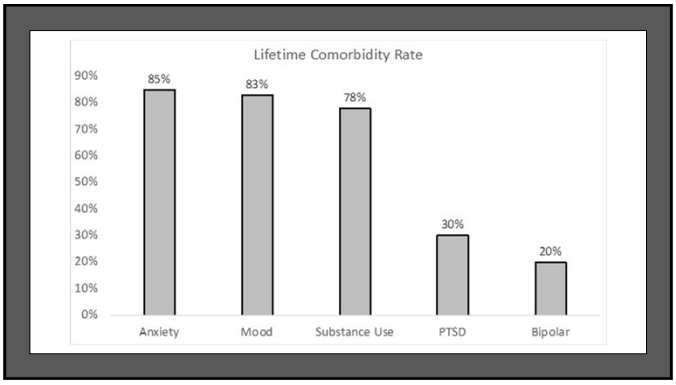
Objectives

1. Review the epidemiology, natural history, and clinical presentation of borderline personality disorder (BPD).
2. Apply the DSM-5-TR diagnostic criteria to diagnose BPD.
3. **Distinguish between BPD and other behavioral disorders, specifically common comorbidities.**
4. Implement comprehensive behavioral treatment strategies for patients with BPD, including psychological interventions, pharmaceutical treatments, and appropriate involvement of specialists.

28

Clinical assessment often occurs during treatment for other behavioral health disorder

29



30

Bipolar Disorder	BPD
Mood episodes last days Mood episodes are less influenced by external events	Rapid, minute-to-minute affective shifts Very sensitive to external stressors

31

Major Depression	BPD
Depressive symptoms last weeks with persistent dysphoria Neurovegetative symptoms may be present (e.g., increased sleep)	Rapid, minute-to-minute affective shifts Lack of neurovegetative symptoms

32

PTSD	BPD
Trauma history Environmental triggers	Trauma history General stress response, broad and across contexts

33

ADHD	BPD
Impulsivity and affective lability Inattentive symptoms	Impulsivity and affective lability Interpersonal focus

34

MacLean Screening Instrument for BPD

1. Have any of your closest relationships been troubled by a lot of arguments or repeated breakups?	Yes___No___
2. Have you deliberately hurt yourself physically (e.g., punched yourself, cut yourself, burned yourself)? How about made a suicide attempt?	Yes___No___
3. Have you had at least two other problems with impulsivity (e.g., eating binges and spending sprees, drinking too much and verbal outbursts)?	Yes___No___
4. Have you been extremely moody?	Yes___No___
5. Have you felt very angry a lot of the time? How about often acted in an angry or sarcastic manner?	Yes___No___
6. Have you often been distrustful of other people?	Yes___No___
7. Have you frequently felt unreal or as if things around you were unreal?	Yes___No___
8. Have you chronically felt empty?	Yes___No___
9. Have you often felt that you had no idea of who you are or that you have no identity?	Yes___No___
10. Have you made desperate efforts to avoid feeling abandoned or being abandoned (e.g., repeatedly called someone to reassure yourself that he or she still cared, begged them not to leave you, clung to them physically)?	Yes___No___

35

Diagnostics:
Interview and Self-Report

36

- Do you often wonder who you really are?
- Do you sometimes feel that another person appears in you that does not fit you?
- Do your feelings toward other people quickly change into opposite extremes (e.g., from love and admiration to hate and disappointment)?
- Do you often feel angry?
- Do you often feel empty?
- Have you been extremely moody?
- Have you ever deliberately hurt yourself (e.g., cut or burned yourself)?

37

POLL #2: What is the rate of comorbid BPD and substance use disorders?

A. 10%
B. 20%
C. 78%
D. 84%

38

POLL #3: What is the rate of comorbid BPD and anxiety disorders?

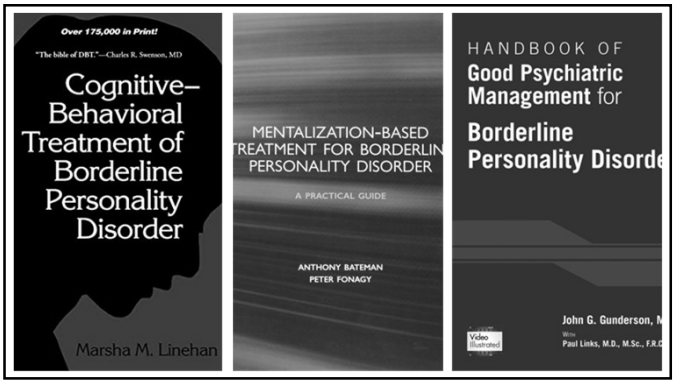
A. 10%
B. 20%
C. 78%
D. 84%

39

Objectives

1. Review the epidemiology, natural history, and clinical presentation of borderline personality disorder (BPD).
2. Apply the DSM-5-TR diagnostic criteria to diagnose BPD.
3. Distinguish between BPD and other behavioral disorders, specifically common comorbidities.
4. **Implement comprehensive behavioral treatment strategies for patients with BPD, including psychological interventions, pharmaceutical treatments, and appropriate involvement of specialists.**

41



42

Type of Psychotherapy	Frequency of Treatment	Summary
Dialectical Behavior Therapy (DBT)	1-hour individual, 2-hour group (24 hours per day, 7 days per week availability), and 2-hour therapist consultation (>5 hours per week).	Combines individual and group sessions focused on skill-building for self-harm and emotion regulation. Therapists are directive and validating.
Mentalization-Based Treatment (MBT)	1-hour individual, 2-hour group, and 1-hour therapist consultation (4 hours per week).	Individuals and group components using a developmental model; emphasizes that patients consider the effects of the self on others and vice versa; therapists are active, curious, and validating.
General ('good') Psychiatric Management (GPM)	Weekly treatment, with the flexibility regarding treatment duration and intensity.	Individual case-management-orientated therapy focusing on situational stressors and social adaptation; therapists are active, directive, and challenging.

43

The GPM Approach

- Education is essential – even if initially ignored by the patient
- Medical Model – what are the symptoms
- Non-specific factors
  - Listening, unconditional positive regard, safe space, concern
- Relationship issues are primary
- Situational challenges can produce meaningful change
  - Reduce the level stress so that the patient is less reactive
- Pragmatism
  - Every patient is different; "forego theory if it isn't working"

44

GPM—Principle #1
Be Active NOT Reactive

- Patients with BPD need more structure
  - All empirically supported psychotherapies for BPD instruct the clinician to be active
- The clinician is the "container" (model cautiousness, thoughtfulness)
- Disclose the diagnosis
  - Some clinicians may not because of fear or stigma but delays intervention
  - Consider reading the criteria together

45

GPM—Principle #2
Psychoeducation

- Psychoeducation
- Providing information for patients and loved ones to better understand and cope with a disorder can improve BPD symptoms
- Medical analogy: A patient with diabetes learns to recognize signs of complications and self-manage their symptoms, and seek help from doctors

46

GPM—Principle #3
Getting a Life

- Work Before Love
  - For Adolescents: School Before Dating
  - This is recognizing the impact of interpersonal hypersensitivity
- Advises that patients work first, and once they develop a more independent source of self-direction and identity, they are likely to be more stable in the context of relationships.

47

GPM—Principle #4
Suicidality and Self-Harm Prevention

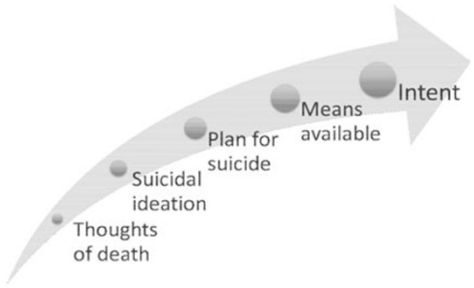
- Suicidal behavior is part of diagnostic criteria
- Significant risk: 3-10% lifetime risk
  - 50x more than the general population
  - 80% engage in suicidal behavior
  - Average number of attempts is 3-4
- 75% engage self-harm
- Suicidal acts are AMBIVALENT (particularly for BPD)
- Don't ignore it! Always assess the risk.

48

Self-Harm:
Differentiating Key Constructs

- **Morbid ideation** (morbid ruminations)
  - No personal agency
- **Suicidal ideation**
  - Personal agency
- **Self-harm or Non-suicidal self-injury**
  - Underlying reason is emotion regulation or something other than death (Simon & Hales, 2012)

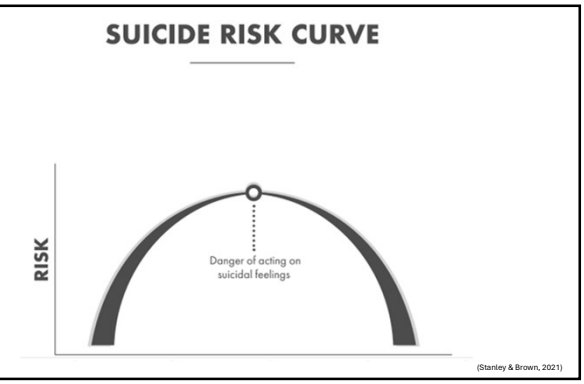
49



50

There is no evidence to support use of "no harm" contracts

51



52

Safety Planning Intervention Steps

Review Suicide Risk Curve

Offer Rationale for Safety Planning

Describe Collaborative Process of Safety Planning

Complete Safety Plan Steps

Review Use of the Safety Plan

53

Safety Plan

Step 1. Warning Signs
Step 2. Internal Coping Strategies
Step 3. People/Settings that provide distraction
Step 4. People Who I Can Ask for Help
Step 5. Who I Can Contact During Crisis
Step 6. Making the Environment Safe

54

GPM—Principle #5
Conservative Psychopharmacology

55

GPM—Principle #6 Coordination of Care

- Endorses group therapy and family input for broader support
- Promotes group involvement for substance issues and general support
- Advocates family involvement and clinician collaboration for cohesive care
- Naturally increased for adolescents' balance between connectedness and autonomy

56

FAMILY NEA BPD
education - skills - support
CONNECTIONS™

https://www.borderlinepersonalitydisorder.org/family-connections-programs/

57

Recommended Approaches for Primary Care: Patient-Clinician Relationship

- Reduce Stigma: Avoid preconceptions such as viewing patients with BPD as intentionally difficult or untreatable
- Collaboration among all treating clinicians: Open communication and agreement on a consistent approach with all clinicians to avoid splitting (e.g., one clinician is "all good," another "all bad")
- Manage patients with clear boundaries, regular visits, and additional psychiatric support
- Clinicians can avoid excessive familiarity by setting clear boundaries at the first visit and not responding to a patient's attempts to interact outside of established clinical encounters.
- Physicians should set firm limits on manipulative behaviors without judgment or anger
- Steer patient discussions towards current issues, not past experiences.

58

POLL #4: Which of the following are best practices for preventing suicide?

A. Consider the use of a no harm contract
B. Help the patient identify internal coping strategies
C. Developing a safety plan collaboratively with the patient
D. Both B & C

59

POLL #5: A patient has panic disorder and BPD. Which of the following medications might you recommend in addition to psychotherapy?

A. Sertraline
B. Escitalopram
C. Medications would not be effective
D. Either A or B

60

References (1)

- Mendez-Miller M, Naccarato J, Radico JA. Borderline Personality Disorder. *American Family Physician*. 2022;105(2):156-161. https://www.aafp.org/pubs/afp/issues/2022/0200/p156.html
- Gunderson JG, Herpertz SC, Skodol AE, Torgersen S, Zanarini MC. Borderline personality disorder. *Nature Reviews Disease Primers*. 2018;4(4):18029. doi: https://doi.org/10.1038/nrdp.2018.29
- American Psychiatric Association. (2022). *Diagnostic and Statistical Manual of Mental Disorders-Text Revision (5th ed.)*. Arlington, VA: American Psychiatric Publishing
- Tate AE, Sahlin H, Liu S, et al. Borderline personality disorder: associations with psychiatric disorders, somatic illnesses, trauma, and adverse behaviors. *Mol Psychiatry*. 2022;27(5):2514-2521. doi:10.1038/s41380-022-01503-z
- Porter C, Palmier-Claus J, Branitsky A, et al. Childhood adversity and borderline personality disorder: a meta-analysis. *Acta Psychiatr Scand*. 2020;141(1):6-20. doi:10.1111/acps.13118
- Stepp SD, Lazarus SA, Byrd AL. A systematic review of risk factors prospectively associated with borderline personality disorder: taking stock and moving forward. *Personal Disord*. 2016;7(4):316-323. doi:10.1037/per0000186
- Tomko RL, Trull TJ, Wood PK, Sher KJ. Characteristics of borderline personality disorder in a community sample: comorbidity, treatment utilization, and general functioning. *J Pers Disord*. 2014;28(5):734-750. doi:10.1521/pedi_2012_26_093

61

References (2)

- National Comorbidity Survey. www.hcp.med.harvard.edu. Accessed December 12, 2023. https://www.hcp.med.harvard.edu/ncs/replication.php
- Volkert J, Gablonski TC, Rabung S. Prevalence of personality disorders in the general adult
- population in Western countries: systematic review and meta-analysis. *Br J Psychiatry*. 2018;213(6): 709-715. doi:10.1192/bjp.2018.202
- Kessler RC, Petukhova M, Sampson NA, et al. Twelve-month and lifetime prevalence and lifetime morbid risk of anxiety and mood disorders in the United States. *Int J Methods Psychiatr Res.* 2012;21 (3):169-184. doi:10.1002/mpr.1359
- Steel Z, Marnane C, Iranpour C, et al. The global prevalence of common mental disorders: a systematic review and meta-analysis 1980-2013. *Int J Epidemiol*. 2014;43(2):476-493.
- Leichsenring F. Development and first results of the Borderline Personality Inventory: a self-report instrument for assessing borderline personality organization. *J Pers Assess*. 1999;73(1):45-63. doi:10.1207/S15327752JPA730104

62

MacLean Screening Instrument for BPD

1. Have any of your closest relationships been troubled by a lot of arguments or repeated breakups? Yes____No____

2. Have you deliberately hurt yourself physically (e.g., punched yourself, cut yourself, burned yourself)? How about made a suicide attempt? Yes____No____

3. Have you had at least two other problems with impulsivity (e.g., eating binges and spending sprees, drinking too much and verbal outbursts)? Yes____No____

4. Have you been extremely moody? Yes____No____

5. Have you felt very angry a lot of the time? How about often acted in an angry or sarcastic manner? Yes____No____

6. Have you often been distrustful of other people? Yes____No____

7. Have you frequently felt unreal or as if things around you were unreal? Yes____No____

8. Have you chronically felt empty? Yes____No____

9. Have you often felt that you had no idea of who you are or that you have no identity? Yes____No____

10. Have you made desperate efforts to avoid feeling abandoned or being abandoned (e.g., repeatedly called someone to reassure yourself that he or she still cared, begged them not to leave you, clung to them physically)? Yes____No____

Notes

Pain Management and Opioids: Balancing Risks and Benefits

Clare A. Hawkins, MD, MSc

Texas Chief Medical Officer
Main Street Health Care
Dallas, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Describe the pathophysiology of pain as it relates to the concepts of pain management.
2. Accurately assess patients in pain and develop a safe and effective pain treatment plan.
3. Identify evidence-based non-opioid options for the treatment of pain.
4. Identify the risks and benefits of opioid therapy and manage ongoing opioid therapy.
5. Recognize behaviors that may be associated with opioid use disorder.

Speaker Disclosure

Dr. Hawkins disclosed he has no financial relationships with any ineligible organizations or commercial interests.

Supporter Disclosure

Presented by the California Academy of Family Physicians (CAFP), a member of the CO*RE Collaborative, nine interdisciplinary organizations working together to improve pain management and prevent adverse outcomes.

This activity is supported by an independent educational grant from the Opioid Analgesics REMS Program Companies (RPC). Please see this page for a listing of REMS Program Companies. This activity is intended to be fully compliant with the Opioid Analgesic REMS education requirements issued by the U.S. Food and Drug Administration.

Striking a Balance

Understanding Pain Management and Opioids

A Case-Based Curriculum

PRESENTED BY CO*RE

1

PRESENTING FACULTY

TAFP

- ABFM Certified in Hospitalist Medicine and Palliative Care
- Past TAFP President
- Current TAFP Alternate Delegate to AAFP
- VP of Harris County Medical Society

FACULTY ADVISORY PANEL

- **Michael Cheshire, DO, FACOI, FACP**, West Virginia University School of Medicine
- **Katherine Galluzzi, DO**, Philadelphia College of Osteopathic Medicine
- **Anita Karnik, MD**, University of Arizona College of Medicine
- **Barbara St. Marie, PhD, AGPCNP, FAANP, FAAN**, University of Iowa
- **Arianna Sampson Campbell, PA-C**, Marshall Medical Center
- **Joseph Shega, MD**, Vitas Healthcare

None of the Faculty, Advisors, Reviewers, or Planners have relevant financial relationships with ineligible companies.

2

THE CO*RE COLLABORATIVE

This course does not advocate for or against the use of opioids.

We intend to help clinicians manage pain without putting vulnerable patients at risk for misuse or opioid use disorder. The goal is to keep our patients, our communities, and ourselves SAFE.

AAPA American Academy of PAs · California Academy of Family Physicians Strong Medicine for California · AANP American Association of Nurse Practitioners · AAOS American Academy of Orthopaedic Surgeons · AOA American Osteopathic Association · American Society of Addiction Medicine ASAM · aahpm American Academy of Hospice and Palliative Medicine · IPMA · American Academy of Family Physicians Strong Medicine for America · NPHF

3

ACKNOWLEDGMENTS

Presented by California Academy of Family Physicians, a member of the CO*RE Collaborative, ten interdisciplinary organizations working together to improve pain management and prevent adverse outcomes. For more information about CO*RE, visit http://core-rems.org/.

This activity is supported by an independent educational grant from the Opioid Analgesics REMS Program Companies (RPC). This activity is intended to be fully compliant with the Opioid Analgesic (OA) REMS education requirements issued by the U.S. Food and Drug Administration. For more information about the Opioid Analgesics REMS, visit https://opioidanalgesicrems.com/RpcUI/products.u.

This course is based on the FDA Education Blueprint (Sept. 2018) and existing guidelines, including the 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain.

Scan the QR code to go to the FDA OA REMS Blueprint

4

MATE ACT AND STATE REQUIREMENTS

MATE Act

As of June 27, 2023, DEA registrants are to have completed a total of at least 8 hours of training on treatment and management of patients with opioid or other substance use disorders. This activity meets the criteria outlined by SAMHSA to count toward this training requirement.

State Requirements

This course also meets many states' requirements for pain education.

5

TODAY'S CASES

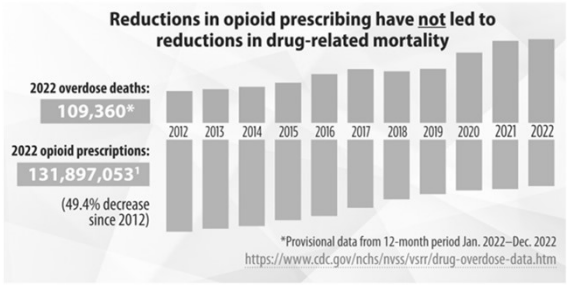
45 y/o male, diabetic peripheral neuropathy

30 y/o female, MVA 10 years ago, self medicating, pregnant

70 y/o male, prostate cancer, metastatic to bones progressing despite antitumor treatment

6

Reductions in opioid prescribing have not led to reductions in drug-related mortality

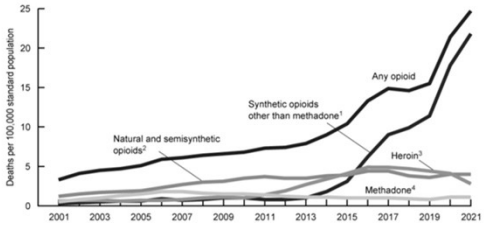


Source: https://www.ama-assn.org/system/files/ama-overdose-epidemic-report.pdf

7

OPIOID OVERDOSE DEATHS BY TYPE OF OPIOID

Figure 4. Age-adjusted rate of drug overdose deaths involving opioids, by type of opioid: US, 2001-2021



Source: https://www.cdc.gov/nchs/images/databriefs/451-500/db457-fig4.png

8

BY THE END OF THIS SESSION, YOU WILL BE BETTER ABLE TO:

EVALUATE
↓
DIAGNOSE
↓
TREAT/ EDUCATE
↓
MANAGE/ MONITOR

1. Describe the pathophysiology of pain as it relates to the concepts of pain management.
2. Accurately assess patients in pain.
3. Develop a safe and effective pain treatment plan.
4. Identify evidence-based non-opioid options for the treatment of pain.
5. Identify the risks and benefits of opioid therapy.
6. Manage ongoing opioid therapy.
7. Recognize behaviors that may be associated with opioid use disorder.

9

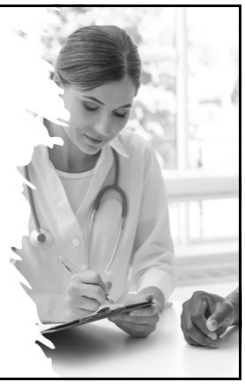
EVALUATE

Diabetic peripheral neuropathy

Self medicates, Pregnant

Prostate cancer metastatic to bones

MULTI-DIMENSIONAL EVALUATION OF A PATIENT WITH PAIN



10

HOW WOULD YOU APPROACH PATIENTS?

1. Ask permission: "Is it okay if I ask you about alcohol or drugs?"
2. Reframe approach to avoid use of stigmatizing terms:

TERMS TO AVOID	PREFERRED TERM
~~*Addiction*~~	**Substance use disorder (SUD) or opioid use disorder (OUD) [from the *DSM-5-TR*®]**
~~*Drug seeking aberrant/problematic behavior*~~	**Using medication not as prescribed**
~~*Addict/user*~~	**Person with a SUD or OUD**
~~*Dirty urine/failing a drug test*~~	**Testing positive on a urine drug screen**
~~*Abuse or habit*~~	**Misuse or "use other than prescribed"**
~~*Substance Abuse*~~	**Substance use**

Source: https://nida.nih.gov/research-topics/addiction-science/words-matter-preferred-language-talking-about-addiction

11

HISTORY OF PRESENT ILLNESS

*Scan to view CO*RE Tools*

PRE-SCREENERS COLLECTED IN ADVANCE (PHQ-2/9, BPI)

DESCRIPTION OF PAIN

WHAT RELIEVES THE PAIN?

WHAT CAUSES OR INCREASES THE PAIN?

PATIENT'S LEVEL OF PAIN AND THE EFFECT ON PHYSICAL, EMOTIONAL, AND PSYCHOSOCIAL FUNCTION (e.g., PEG, BPI, MPI)

Source: Hogans, B., Barreveld, A. (Eds.). *Pain Care Essentials*, NY, NY: Oxford Univ. Press.2020.

13

MEDICAL AND TREATMENT HISTORY

Frank

RELEVANT ILLNESSES

NONPHARMACOLOGIC STRATEGIES AND EFFECTIVENESS

PHARMACOLOGIC STRATEGIES AND EFFECTIVENESS

If past or current opioid use:

- Query your state's Prescription Drug Monitoring Program (PDMP) to confirm patient report
- Contact past clinicians and obtain prior medical records
- For opioids currently prescribed, note the opioid, dose, regimen, and duration
- Determine whether the patient is opioid-tolerant

BARRIERS TO PREVIOUS TREATMENT STRATEGIES

14

OBTAIN A COMPLETE PSYCHOSOCIAL HISTORY

PSYCHOLOGICAL HISTORY

Screen for:

- Mental health diagnoses, depression, anxiety, PTSD, current treatments (using *PHQ-2, PHQ-9, GAD-7*, etc.)
  Depression and anxiety can be predictors of chronic pain
- Alcohol, tobacco, and other drug use
- History of Adverse Childhood Experiences (ACEs) using *ACE Questionnaire*
- Family history of substance use disorder and psychiatric disorders

*Scan to view CO*RE Tools*

SOCIAL DETERMINANTS OF HEALTH (SDOH)

SDOH relate to pain in terms of

- Economic stability
- Education access & quality
- Health care access & quality
- Neighborhood & built environment
- Social & community context

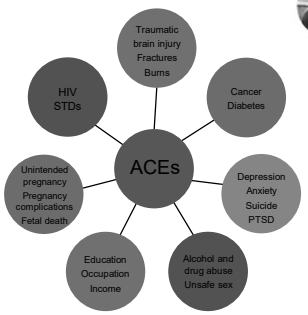
Source/QR code: https://health.gov/healthypeople/priority-areas/social-determinants-health:

15

ADVERSE CHILDHOOD EXPERIENCES (ACEs)

A shift in focus…

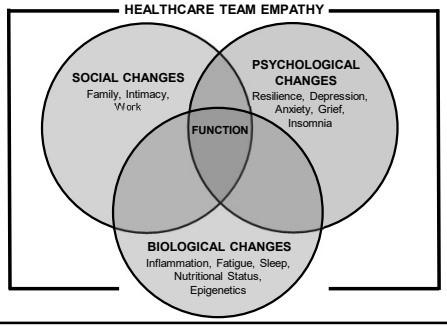
from
"What's wrong with this patient?"
to
"What has this patient experienced?"



Scan to view ACEs questionnaire

16

THE EXPERIENCE OF PAIN: A BIOPSYCHOSOCIAL MODEL



17

PHYSICAL EXAM AND ASSESSMENT

Seek objective data → Conduct physical exam and evaluate for pain → Order diagnostic or confirmatory tests

General: vital signs, appearance, and pain behaviors

Neurologic exam

Musculoskeletal exam
- Inspection
- Gait and posture
- Range of motion
- Palpation
- Percussion
- Auscultation
- Provocative maneuvers

Cutaneous or trophic findings

Source: Hogans, B., Barreveld, A. (Eds.). Pain Care Essentials, NY, NY: Oxford Univ. Press. 2020.

18

EVALUATION: FRANK

- 45 y/o male
- Diabetic peripheral neuropathy
- Pain is gradually worsening and is most bothersome at night
- No other aggravating or alleviating factors

Comorbidities
- Diabetes, Obesity, Depression

Psychosocial
- ACE Questionnaire for Adults: 5/10 positive responses

Physical Exam/Diagnostics
- Sensation/motor:
  - Loss of protective sensation in feet bilaterally.
  - No motor deficits noted with muscle strength 5/5 bilaterally
- BPI = 9

Previous Therapies
- Attempts at improved glycemic control, HgbA1c improved from 9% to 7.5% with addition of GLP-1 agonist to metformin
- Amitriptyline for pain & depression, but switched to fluoxetine due to weight gain
- Remote history of prescription drug use; experimented with prescription pills in adolescence.

19

EVALUATION: SUSAN

- 30 y/o female
- MVA 10 yrs ago
- No one believed her, so self medicating for chronic nonspecific back pain
- Pregnant

Psychosocial
- Depression, anxiety, ACES, suicidal?
- Screen for Intimate Partner Violence
- Family support? Community support?
- Screen for SDOH
- Emphasize that she is as important in the care process as the infant

Physical Exam/Diagnostics
- Clinically significant findings for pain?
- Consider the physiologic changes as pregnancy progresses
- Draw inflammatory markers?

Medications Used
- Self medicates with nonprescribed oxycodone and acetaminophen; she takes 6-10/day every day

20

EVALUATION: RALPH

- 70 y/o male
- Prostate cancer metastatic to pelvis and lumbar spine
- Progressing despite treatment

Comorbidities
- Type 2 DM with peripheral neuropathy
- Insomnia
- Vietnam veteran with history of PTSD and anxiety

Psychosocial
- Retired engineer
- Moved in with his daughter and teenage grandchildren
- Desires to avoid hospitalization as long as possible, if not entirely
- Moderate alcohol use, father was an alcoholic

Previous Therapies
- NSAIDs
- Gabapentin
- Muscle relaxant
- Palliative radiation therapy

Ongoing discomfort

21

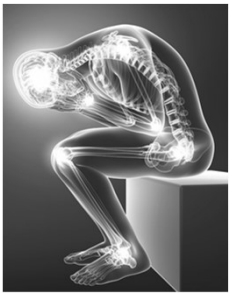
EVALUATION: RALPH (cont.)

Physical Exam/Diagnostics
- Hips full ROM but some discomfort reported and concomitant facial grimacing
- Tenderness lumbar spine deep palpation no muscle spasm noted and full ROM
- Overall slow gait but appears a little uncomfortable and reports discomfort
- Worst pain 9/10, best 4/10, average 7/10, right now 8/10
- Mild interference with mood, walking, relationship with others
- Moderate interference sleep and enjoyment of life

22

DIAGNOSE

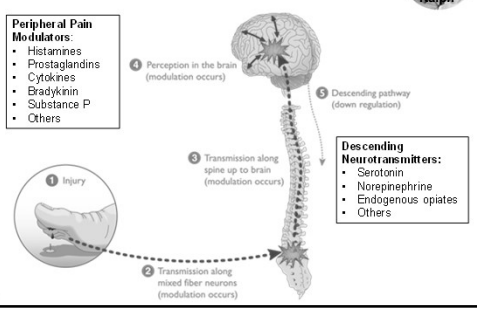
BIOLOGY AND TYPES OF PAIN



23

THE NEUROMECHANISMS OF PAIN

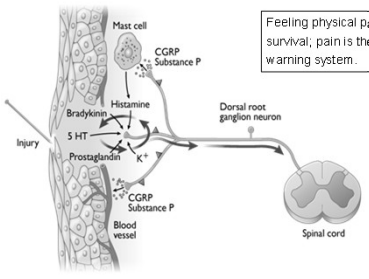
Peripheral Pain Modulators:
- Histamines
- Prostaglandins
- Cytokines
- Bradykinin
- Substance P
- Others



Descending Neurotransmitters:
- Serotonin
- Norepinephrine
- Endogenous opiates
- Others

24

MEDIATORS OF PERIPHERAL NOCICEPTION



Feeling physical pain is vital for survival; pain is the body's early warning system.

With thanks to Allan Basbaum and David Julius, University of California, San Francisco

25

PAIN

"An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage."

—IASP (July 2020)

ACUTE	CHRONIC
• Acute pain duration of < 1 month	• Lasting 3 months or longer
• Sudden onset, self-limiting	• Generally steady-state or worsening
• Ideally resolves with healing	• Persists beyond normal healing period
• Triggered by tissue damage and inflammation	• Serves no value
• Has protective value	• Peripheral and central sensitization
• Inflammatory mediation	
• **Subacute**, pain that continues for 1-3 months, can become chronic	

26

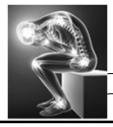
TYPES OF PAIN

NOCICEPTIVE / INFLAMMATORY	NOCIPLASTIC	NEUROPATHIC	MIXED TYPES (NOCICEPTIVE / NEUROPATHIC)
Pain in response to an injury or stimuli; *typically* acute	Pain that arises from altered nociceptive function; *typically* chronic	Pain that develops when the nervous system is damaged; chronic	Primary injury and secondary effects
Post-operative pain, sports injuries, arthritis, sickle cell disease, mechanical low back pain	Fibromyalgia, irritable bowel syndrome, nonspecific low back pain	Post-herpetic neuralgia, trigeminal neuralgia, distal polyneuropathy, CRPS, neuropathic low back pain	

27

TYPES OF PAIN (cont.)

	Self medicating, pregnant	Diabetic peripheral neuropathy	Prostate cancer metastatic to bones
NOCICEPTIVE / INFLAMMATORY	Pain in response to an injury or stimuli; *typically* acute		
NOCIPLASTIC		Pain that arises from altered nociceptive function; *typically* chronic	
NEUROPATHIC			Pain that develops when the nervous system is damaged; chronic
MIXED TYPES (NOCICEPTIVE / NEUROPATHIC)			Primary injury and secondary effects
	Post-operative pain, sports injuries, arthritis, sickle cell disease, mechanical low back pain	Fibromyalgia, irritable bowel syndrome, nonspecific low back pain	Post-herpetic neuralgia, trigeminal neuralgia, distal polyneuropathy, CRPS, neuropathic low back pain



28

TREAT

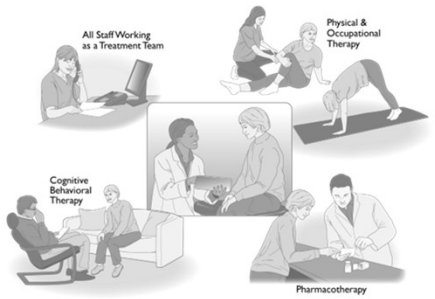
CREATING THE PAIN TREATMENT PLAN

29

HOW IS PAIN MANAGED?

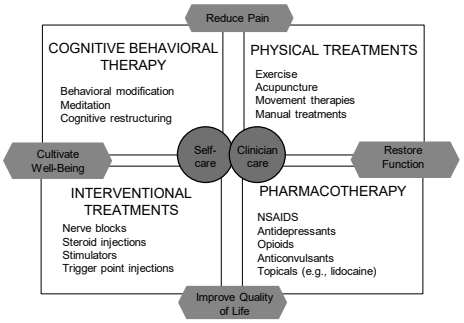
30

COMPONENTS OF A MULTIMODAL TREATMENT PLAN FOR PAIN



31

PAIN MANAGEMENT GOALS AND TREATMENT OPTIONS: A MULTIMODAL APPROACH



32

EVIDENCE-BASED NONPHARMACOLOGIC TREATMENTS

- Tai Chi
- Yoga
- CBT and ACT
- Acupuncture
- PT/OT/aquatic

- Mindfulness meditation
- OMT
- Massage therapy
- Chiropractic
- Neuromodulation or surgical approaches (in some situations)

What treatment would most likely engage each patient?

Possibly: weight loss program

No acupuncture

Physical therapy, OMT, massage

CBT-cognitive behavioral therapy; ACT-acceptance commitment therapy; OMT-osteopathic manipulative therapy

Source: https://effectivehealthcare.ahrq.gov/products/noninvasive-nonpharm-pain-update/research

33

PHARMACOLOGIC TREATMENTS BY TYPE OF PAIN

Continue *Effective* Nonpharmacologic Options First

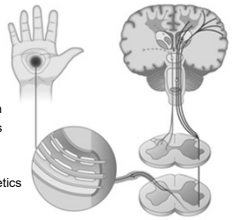
		 
NOCICEPTIVE / INFLAMMATORY	**NOCIPLASTIC**	**NEUROPATHIC**
IR opioids Nerve blocks NSAIDs Topicals and patches	Anticholinergic Anticonvulsants TCAs and SNRIs Other serotonin agents **No Opioids***	Anticonvulsants IR and ER/LA opioids Gabapentinoids Nerve blocks TCAs and SNRIs Transdermal opioids

*Assumes no OUD; if patient has OUD, opioid agonist treatment may be appropriate.

34

POTENTIAL SITES OF ACTION FOR ANALGESIC AGENTS

Peripherally Mediated Pain:
- Acetaminophen
- Anticonvulsants
- NSAIDs
- Opioids
- Topical anesthetics



Centrally Mediated Pain:
- Alpha-2 agonists
- Anticonvulsants
- Ca^{+} channel antagonists
- NMDA RAs
- Opioids
- TCA/SNRI antidepressants

Most commonly, pain conditions are a combination of peripherally and centrally mediated processes

35

DRUG CHARACTERISTICS TO CONSIDER BEFORE PRESCRIBING

Route of administration	Mechanism of action	Strength	Dosing interval
Key instructions (indications, uses, contraindications)	Specific drug interactions	Formulation	Product-specific safety concerns
Specific information about product conversions, if available	ER/LA: Use **only** in opioid tolerant patients		Relative potency to morphine (MME)

Opioid product information available at https://opioidanalgesicrems.com/products.html
- **Immediate Release (IR)**: rapid onset of analgesia, relatively short duration of effect
- **Extended Release/Long-Acting (ER/LA)**: potentially longer onset of action, longer duration of effect; formulation allows for QD or BID dosing; less frequent dosing.

36

WHEN TO CONSIDER A THERAPEUTIC TRIAL OF IR OPIOID

Patient has failed to adequately respond to non-opioid and nonpharmacological interventions

Patient has moderate to severe nociceptive or neuropathic pain

Potential benefits are likely to outweigh risks

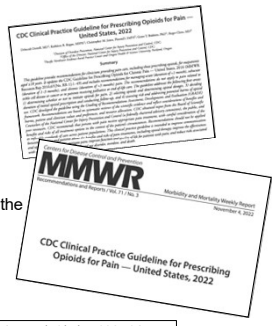
CDC Guideline recommendations **do not apply** to pain related to **sickle cell disease** or **cancer** or to patients receiving **palliative or end-of-life care** (separate guidelines apply to some). There are **differences in benefits, risks,** and expected outcomes for these patients compared to other patients with chronic pain.

Sources: 2022 CDC Guideline: https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm.
Department of Veterans Affairs, Department of Defense & VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain. 2017.

37

2022 CDC GUIDELINE

- Clinician recommendations for patients aged ≥18 years
- Summary of current research
- Flexible; encourages patient-centered decision making
- Emphasizes the importance of the individual & clinical judgement
- This is a clinical tool, not a law, regulation or policy



https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm

38

RISKS VERSUS BENEFITS OF PRESCRIBED OPIOIDS

POTENTIAL RISKS

- Life-threatening respiratory depression/overdose, death
- SUD/OUD (assess using ORT-OUD or other validated tool)
- Diversion
- Inadvertent exposure to family and pets
- Interactions with other meds and substances
- Neonatal abstinence syndrome
- Physiologic dependence and withdrawal

POTENTIAL BENEFITS

- Analgesia
- Option for patients with contraindications for non-opioid analgesics
- Relieves suffering
- May improve function and quality of life

39

ASSESS RISK FOR OPIOID USE DISORDER

TOOLS FOR PATIENTS CONSIDERED FOR OPIOID THERAPY
ORT-OUD Opioid Risk Tool
SOAPP® Screener and Opioid Assessment for Patients with Pain
DIRE Diagnosis, Intractability, Risk, and Efficacy score

TOOLS FOR SUBSTANCE USE DISORDER
CAGE-AID Cut down, Annoyed, Guilty, Eye-Opener tool, Adapted to Include Drugs
TAPS Tobacco, Alcohol, Prescription Medication and Other Substances
DAST Drug Abuse Screening Test
CTQ Childhood Trauma Questionnaire
ACEs Adverse Childhood Experiences

GENETIC TESTING FOR OUD RISK
Genetic variants associated with OUD can be used as part of the risk assessment

*Scan to view CO*RE Tools*

40

A CLOSER LOOK AT THE ORT-OUD

Mark each box that applies	YES	NO
Family history of substance abuse		
Alcohol	1	0
Illegal drugs	1	0
Rx drugs	1	0
Personal history of substance abuse		
Alcohol	1	0
Illegal drugs	1	0
Rx drugs	1	0
Age between 16-45 years	1	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	1	0
Depression	1	0
Scoring totals	4	

Substance use disorder history does not prohibit treatment with opioids but may require additional monitoring and expert consultation or referral.

Scoring:

- **≤ 2: low risk**
- **≥ 3: high risk**

Scan to view ORT-OUD Video

Source: Cheatle, M., Compton, P.A., et al. J Pain 2019; Jan 26.

41

PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

Frank's PDMP: Sporadic short courses of opioids from ED & Urgent Care providers

A NON-PUNITIVE APPROACH TO PRESCRIBING ANALGESIC AGENTS

- Check when initiating opioid therapy, regularly when continuing therapy
- Improves patient communication, education, and safety
  - Confirm PDMP information with patient; do not dismiss from care
  - Identify drugs that increase overdose risk when taken together
  - Provide potentially life-saving information and interventions (safety concerns, provide naloxone)
- Discuss safety concerns with other clinicians
- Lowers rates of prescription opioid-related hospitalization and ED visits
- Most PDMPs allow you to appoint a delegate

Multiple prescriptions from different clinicians is most predictive of opioid misuse.

Source: https://www.cdc.gov/opioids/healthcare-professionals/pdmps.html

43

CATEGORIZATION OF OPIOIDS

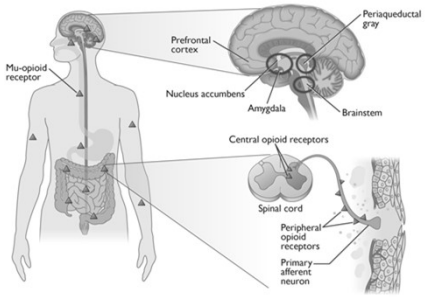
Scan to view DEA Drug Scheduling

NATURALLY OCCURRING OPIATES	SEMI-SYNTHETIC OPIOIDS	SYNTHETIC OPIOIDS
Codeine	Buprenorphine	Alfentanil
Morphine	Hydrocodone	Fentanyl
	Hydromorphone	Methadone
	Oxycodone	Remifentanil
	Oxymorphone	Tapentadol
		Tramadol
AGONISTS	**PARTIAL AGONISTS**	**ANTAGONISTS**
Codeine	Buprenorphine	Naloxone
Methadone	Nalbuphine	Nalmefene
Morphine		Methylnaltrexone*
Oxycodone		Naloxogel*

*These represent PAMORA: peripherally-acting mu opioid receptor antagonist

44

OPIOID RECEPTOR LOCATIONS



45

OPIOID SIDE EFFECTS AND ADVERSE EVENTS

SIDE EFFECTS	ADVERSE EVENTS
Respiratory depression	Death
GI effects: dry mouth, nausea/vomiting, **opioid-induced constipation** (most common; mitigate!)	Addiction
Myoclonus (twitching or jerking)	Overdose
Sedation, cognitive impairment	Hospitalization
Sweating, miosis, urinary retention	Disability or permanent damage
Allergic reactions	Falls or fractures
Hypogonadism	Opioid-induced hyperalgesia
Tolerance, physical dependence	

Prescribers should report serious AEs and medication errors to the FDA: https://www.fda.gov/media/76299/download or 1-800-FDA-1088

46

OPIOID-INDUCED RESPIRATORY DEPRESSION

MORE LIKELY TO OCCUR:	HOW TO REDUCE RISK:
• In older, cachectic, or debilitated patients	• Ensure proper dosing and titration
• If given concomitantly with other drugs that depress respiration (such as benzodiazepines*)	• **Do not overestimate** dose when converting dosage from another opioid product – Can result in fatal overdose with first dose
• In patients who are opioid-naïve or have just had a dose increase	• Avoid co-prescribing benzodiazepines*
• In patients with conditions causing respiratory compromise (e.g., obstructive sleep apnea)	• Instruct patients to swallow tablets/capsules whole – Dose from cut, crushed, dissolved, or chewed tablets/capsules may be fatal, particularly in opioid-naïve individuals
• In patients with organ dysfunction	

*Greatest risk of respiratory depression

47

DRUG INTERACTIONS COMMON TO OPIOIDS

Other CNS Depressants
- Increased risk of respiratory depression, hypotension, profound sedation, or coma
- Reduce initial dose

Partial Agonists* or Mixed Agonist/Antagonists†
- Use caution with full opioid agonist
- May reduce analgesic effect and/or precipitate withdrawal

Skeletal Muscle Relaxants
- Concurrent use may enhance neuromuscular blocking action and increase respiratory depression

Anticholinergic Medication
- Concurrent use increases risk of urinary retention and severe constipation
- May lead to paralytic ileus

*Buprenorphine; †Pentazocine, nalbuphine, butorphanol

48

FOR SAFER USE: KNOW DRUG INTERACTIONS, PHARMACODYNAMICS, PHARMACOKINETICS

CNS depressants can potentiate sedation and respiratory depression
(e.g., benzodiazepines, gabapentin)

Some ER/LA products rapidly release opioid (dose dump) when exposed to alcohol
Some drug levels may increase without dose dumping

Opioid use w/ MAOIs may increase respiratory depression
Certain opioids with MAOIs can cause serotonin syndrome (e.g., tramadol)

Opioid use can reduce efficacy of diuretics
Inducing release of antidiuretic hormone

Many opioids can prolong QTc interval, check the PI; methadone requires extra caution

Drugs that inhibit or induce CYP enzymes can increase or lower blood levels of some opioids

49

OPIOIDS AND CYP450 ENZYME INTERACTIONS

Metabolism of several commonly used opioids occurs through the cytochrome P450 system

Be aware of potential inhibitors (e.g., macrolides, azole antifungals) and inducers (e.g., carbamazepine)

Genetic and phenotypic variations in patient response to certain opioids

Refer to product-specific information in the drug package insert before prescribing

Source: https://dailymed.nlm.nih.gov/dailymed/index.cfm

50

TRANSDERMAL/TRANSMUCOSAL DOSAGE FORMS

⚠ Do not cut, damage, chew, or swallow

Prepare skin: clip (not shave) hair and wash area with water	Rotate location of application	Do not apply buccal film products if film is cut, damaged, or changed in any way—use the entire film
Note that metal foil backings are not safe for use in MRIs	Monitor patients with fever for signs or symptoms of increased opioid exposure	
Note that exertion or exposure to external heat can lead to fatal overdose		

51

SPECIAL POPULATION CONSIDERATIONS: *OLDER ADULTS*

RISK FOR RESPIRATORY DEPRESSION

- Age-related changes in distribution, metabolism, excretion; absorption less affected

ACTIONS

- Monitor
  - Initiation and titration
  - Concomitant medications (polypharmacy)
  - Falls risk, cognitive change, psychosocial status
- Reduce starting dose to 1/3 to 1/2 the usual dosage in debilitated, non-opioid-tolerant patients
- Start low, go slow, but GO
- Routinely initiate a bowel regimen
- Patient and caregiver reliability/risk of diversion

Sources: American Geriatrics Society Panel on the Pharmacological Management of Persistent Pain in Older Persons. J Am Geriatr Soc. 2009;57:1331-46, Chou R, et al. J Pain. 2009;10:113-30.

52

SPECIAL POPULATION CONSIDERATIONS: *WOMEN OF CHILDBEARING POTENTIAL*

Neonatal abstinence syndrome is a potential risk

GIVEN THIS POTENTIAL RISK, CLINICIANS SHOULD:

- Discuss family planning, contraceptives, breastfeeding plans with patients
- Counsel women of childbearing potential about risks and benefits of opioid therapy during pregnancy and after delivery
- Encourage minimal/no opioid use during pregnancy, unless potential benefits outweigh risks to fetus
- Consider referring to a qualified clinician who will ensure appropriate treatment for the baby

Perform universal screening to avoid neonatal opioid withdrawal syndrome (NOWS)

****For women using opioids daily, ACOG recommends buprenorphine or methadone****

ACOG-American College of Obstetricians and Gynecologists.
Sources: Chou R, et al. J Pain. 2009;10:113-30; ACOG Committee on Obstetric Practice, August 2017

53

SPECIAL POPULATION CONSIDERATIONS: *PEDIATRICS*

Scan to view AAP resources

- **HANDLE WITH CARE: JUDICIOUS AND LOW-DOSE USE OF IR FOR BRIEF THERAPY**
- **THE SAFETY AND EFFECTIVENESS OF MOST OPIOIDS ARE UNESTABLISHED**
  - Pediatric analgesic trials pose challenges
  - Transdermal fentanyl approved in children ≥2 years
  - Oxycodone ER dosing changes for children ≥11 years
- **ER/LA OPIOID INDICATIONS ARE PRIMARILY LIFE-LIMITING CONDITIONS**
- **WHEN PRESCRIBING ER/LA OPIOIDS TO CHILDREN:**
  - Consult pediatric palliative care team or pediatric pain specialist or refer to a specialized multidisciplinary pain clinic
- **ADOLESCENTS ages 12-21: Identify and treat for OUD *(use SBIRT)***

Scan to view SBIRT resource

SBIRT-Screening, Brief Intervention, Referral to Treatment.
Sources: Berde CB, et al. *Pediatrics*. 2012;129:354-364; Gregoire MC, et al. Pain Res Manag 2013;18:47-50; Mc Donnell C. Pain Res Manag. 2011;16:93-98; Slater ME, et al. Pain Med. 2010;11:207-14.
https://publications.aap.org/pediatrics/article/138/1/e20161210/52573/Substance-Use-Screening-Brief-Intervention-and
https://www.aap.org/en/patient-care/substance-use-and-prevention/resources-to-address-the-opioid-epidemic/

54

OTHER POPULATIONS NEEDING SPECIAL TREATMENT CONSIDERATIONS

Persons with…

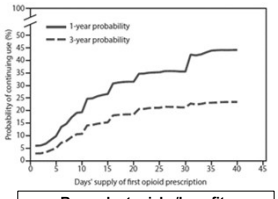
- Sleep disorders or sleep-disordered breathing (sleep apnea)
- Obesity
- Dementia/nonverbal patients
- Renal/hepatic impairment
- Psychiatric disorders
- Life-limiting illness
- Substance use disorder

55

INITIATING IR OPIOIDS

- Prescribe the ***lowest* effective dose** for the ***shortest* period of time** based on the individual patient's condition
- Always include dosing instructions and daily maximum
- Be aware of interindividual variability of response
- **Have patient provider agreement (PPA), baseline urine drug test (UDT), and informed consent in place**
- Co-prescribe naloxone and stimulant laxative

1- and 3-year probabilities of continued opioid use, by days' supply of first Rx



Re-evaluate risks/benefits within 1–4 weeks (could be as soon as 3–5 days)

Source: https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm

56

TREATMENT PLAN: FRANK

- 45 y/o male
- Increased pain from diabetic peripheral neuropathy

Previous Therapies
- Attempts at improved glycemic control by PCP, HgbA1c improved from 9% to 7.5% with addition of GLP-1 agonist to metformin
- Amitriptyline for pain and depression, but was switched to fluoxetine due to weight gain

Treatment Plan
- Weight loss program?
- Consider duloxetine or gabapentin?
- Opioid?

57

TREATMENT PLAN: SUSAN

- 30 y/o female
- MVA 10 yrs ago
- Self medicating for chronic nonspecific back pain
- Pregnant

Treatment Plan
- Establish therapeutic relations
- Conduct conversations
- Promote honest exchange of information
- Provide age- and education- appropriate educational materials
- DO NOT terminate patient from practice
- Ensure access to naloxone
- Offer treatment:
  Initiate treatment or refer. Medications for Opioid Use Disorder (MOUD) are GOLD STANDARD treatment in pregnancy.

58

TREATMENT PLAN: RALPH

- 70 y/o male
- Widely metastatic prostate cancer involving pelvis and lumbar spine

Treatment Plan
- Physical therapy at outpatient center
- Osteopathic manipulative therapy (OMT)
- Massage
- Switch NSAIDS to steroids
- ORT 2-3 depending if put anxiety/PTSD as psychiatric condition
- Initiate short acting morphine 5mg as needed, inadequate control, increase to 10mg every 3-4 hours as needed

59

EDUCATE

EDUCATING PATIENTS AND CAREGIVERS

60

INFORMED CONSENT

When initiating a pain treatment plan, confirm patient understanding of informed consent to establish:

- ANALGESIC AND FUNCTIONAL GOALS OF TREATMENT
- EXPECTATIONS
- POTENTIAL RISKS
- ALTERNATIVES
- PATIENT'S UNDERSTANDING
- PATIENT'S DECISION

61

PATIENT PROVIDER AGREEMENT (PPA)

Reinforce Expectations For Appropriate And Safe Opioid Use

- Clarify treatment plans & goals
- One prescriber
- Consider one pharmacy
- Safeguards
  - Do not store in medicine cabinet
  - Keep medication safe
  - Do not share or sell
- Instructions for disposal when no longer needed
- Prescriber notification for any event resulting in a pain medication prescription
- Follow-up plan
- Monitoring
  - Random urine drug test (UDT) & pill counts
- Refill procedure
- Identify behaviors indicating need for discontinuation
- Exit strategy
- Signed by both

62

COUNSEL ON OPIOIDS

Proper Use
- Take opioid as prescribed
- If a dose is missed: do not take extra, contact HCP
- Use least amount of medication necessary for shortest time
- Notify HCP if pain is uncontrolled
- Long-term opioid use: avoid abrupt discontinuation, taper safely to avoid withdrawal symptoms

Side Effects & Safety
- Go over all side effects (see previous section)
- Inform HCP of ALL side effects
- Inform HCP of other meds/supplements taken
- Use caution when operating heavy machinery and driving

Scan to view Patient Counseling Guide

Storage
- Note how many pills are in each prescription
- Keep track of dosage and refills
- Make sure everyone in the home knows meds are tracked
- Keep meds in a safe place (locked cabinet or box)
- Store away from children, family, visitors, and pets
- Extra precautions needed with adolescents in the home

Sources: https://www.accessdata.fda.gov/drugsatfda_docs/rems/opioid_Analgesic_2018_09_18_Patient_Counseling_Guide.pdf & McDonald E, Kennedy-Hendrick A, McGinty E, Shields W, Barry C, Gielen A. Pediatrics. 2017;139(3):e20162161

63

COUNSEL ON OPIOIDS (cont.)

WARNINGS (Safe Administration)	WHAT TO WATCH FOR (Safety Concerns)
• Never break, chew, crush, or snort an opioid tablet/capsule • Never cut or tear patches or buccal films • If patient cannot swallow, determine if appropriate to sprinkle contents on applesauce or administer via feeding tube • Use of CNS depressants or alcohol with opioids can cause overdose	• Cravings • Being unable to fulfill work/family obligations • Nodding off • Taking more than prescribed • Sedation, cognitive impairment • Falls and fractures • Never share medications with others

64

OPIOID-INDUCED RESPIRATORY DEPRESSION

Distribute, dispense, or prescribe naloxone to patient or caregiver. Teach proper administration.

If not immediately recognized and treated, may lead to respiratory arrest and death

More likely to occur in opioid-naïve patients during initiation or after dose increase

Instruct patients/family members to:
- Screen for shallow or slowed breathing
- Deliver NALOXONE
- **CALL 911**

Instructions may differ if patient is on hospice or near end of life

Greatest risk: when co-prescribed with a benzodiazepine

65

SIGNS OF ACCIDENTAL OPIOID POISONING

- Person cannot be aroused or is unable to talk
- Any trouble with breathing, heavy snoring is warning sign
- Gurgling noises coming from mouth or throat
- Body is limp, seems lifeless; face is pale, clammy
- Fingernails or lips turn blue/purple
- Slow, unusual heartbeat or stopped heartbeat

CALL 911 & Administer Naloxone

66

NALOXONE OPTIONS

- Available as auto-injector, intramuscular injection, or nasal spray
- Cost and insurance coverage vary
- Make use of tutorial videos or live demonstration to educate patient/family/caregiver on proper administration
- Store at room temperature

Naloxone vials Narcan nasal spray Evzio (auto-injector)

Trade names are used for identification purposes only and do not imply endorsement.

Source: FDA Information About Naloxone and Nalmefene

67

WHERE AND HOW TO DISPOSE OF UNUSED OPIOIDS

Authorized Collection Sites
- Use the DEA disposal locator website to find sites near you (QR code to right) or search Google Maps for "drug disposal nearby"

Scan to view disposal locator

Options
- Check with local pharmacy for disposal options
- Flush
  - Fold patch in half so sticky sides meet, then flush
- Trash (mix with noxious element like kitty litter or compost)

Mail-Back Packages
- Obtain from authorized collectors

Sources: FDA. Where and How to Dispose of Unused Medicines. https://www.fda.gov/consumers/consumer-updates/where-and-how-dispose-unused-medicines; EPA. How to Dispose of Medicines Properly. https://archive.epa.gov/region02/capp/web/pdf/pcpflyer.pdf

68

MANAGE

MANAGING PATIENTS ON OPIOID ANALGESICS

69

PERIODIC, CONTINUAL ASSESSMENT

Re-evaluate risks/benefits:

- *Upon initiation or dose escalation:* within 1–4 weeks (could be as soon as 3–5 days)
- *Ongoing:* every 1–3 months
- If benefits do not outweigh harms, optimize other therapies and work to taper and discontinue

- Is the patient making progress toward functional goals?
- Reassess to identify the underlying source of pain
- Reset goals if required or indicated; develop reasonable expectations
- Ask if patient is willing to engage with other modalities
- Monitor for breakthrough pain or comorbid conditions that may arise
- Review adverse events/side effects at each visit
  - Evaluate bowel function
  - Screen for endocrine function as needed
  - Implement opioid rotation, as indicated

70

PERIODIC, CONTINUAL ASSESSMENT (cont.)

MONITOR FOR SAFETY

- Check Prescription Drug Monitoring Program (PDMP)
- Use urine drug testing (UDT)
- Reassess risk of substance use disorder (SUD) and/or OUD
- Monitor adherence to the treatment plan
  - Medication reconciliation
  - Evaluate for nonadherence

CONSIDERATIONS FOR TREATMENT MODIFICATION

- Continue IR
- Taper and discontinue (when opioid therapy is no longer necessary)
- Transition to ER/LA

71

URINE DRUG TESTING (UDT)

- Urine testing is done **FOR** the patient, not **TO** the patient (not punitive)
- Helps to identify drug misuse
- Assists in assessing and documenting adherence

Scan to view Urine Drug Screen Video

CLINICAL CONSIDERATIONS

- Recommend UDT before first prescription (baseline), then intermittently, depending on clinical judgment and state regulations
- Document time and date of last dose taken
- Be aware of possible false positives or negatives
- Clarify unexpected results with the lab before confronting patient to rule out poor specimen or error

73

SCREENING VERSUS CONFIRMATORY UDTs

	SCREENING (Office-based)	CONFIRMATORY (Send to lab)
Analysis technique	Immunoassay	GC-MS or HPLC
Sensitivity (power to detect a class of drugs)	Low or none when testing for semi-synthetic or synthetic opioids	High
Specificity (power to detect an individual drug)	Varies (can result in false positives or false negatives)	High
Turnaround	Rapid	Slow
Cost/Other	Lower cost; intended for a drug-free population; may not be useful in pain medicine	Higher cost; legally defensible results

GC-MS = gas chromatograph-mass spectrometry; HPLC = high-performance liquid chromatography

75

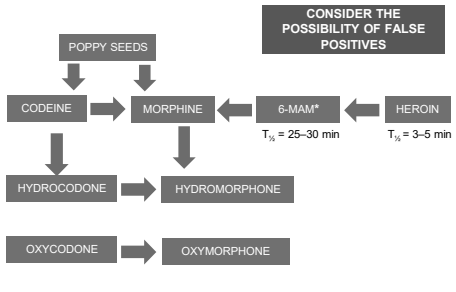
WINDOWS OF SPECIFIC DRUG DETECTION

Drug	How soon after taking drug will there be a positive drug test?	How long after taking drug will there continue to be a positive drug test?
Cannabis/ Tetrahydrocannabinol (THC)	1–3 hours	1–7 days (can be up to 1 month if long-term use)
Crack (cocaine)	2–6 hours	2–3 days
Heroin (opiates)	2–6 hours	1–3 days
Speed/uppers (amphetamine, methamphetamine)	4–6 hours	2–3 days
Angel dust/PCP	4–6 hours	7–14 days
Ecstasy	2–7 hours	2–4 days
Benzodiazepine	2–7 hours	1–4 days
Barbiturates	2–4 hours	1–3 weeks
Methadone	3–8 hours	1–3 days (up to 2 weeks)
Tricyclic antidepressants	8–12 hours	2–7 days
Oxycodone	1–3 hours	1–2 days

Source: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/DrugsofAbuseTests/ucm125722.htm

76

EXAMPLES OF OPIOID METABOLISM



*6-MAM = 6-Monoacetylmorphine

77

PATIENT PROVIDER AGREEMENT (PPA) NONADHERENCE

Behavior outside the boundaries of agreed-on treatment plan

Unsanctioned dose escalations or other noncompliance with therapy on 1 or 2 occasions	Multiple dose escalations or other noncompliance with therapy despite warnings
Unapproved use of the drug to treat another symptom	Prescription forgery
Openly acquiring similar drugs from other medical sources	Obtaining prescription drugs from nonmedical sources

Any of the above behaviors merits further inquiry: proceed with caution

78

CONSIDERATIONS FOR RE-EVALUATING OPIOID USE

THERAPEUTIC GOALS ARE ACHIEVED	INTOLERABLE AND UNMANAGEABLE AEs	NO PROGRESS TOWARD THERAPEUTIC GOALS	RISKS OUTWEIGH BENEFITS

MISUSE BEHAVIORS

- One or two episodes of increasing dose without prescriber knowledge
- Sharing medications
- Unapproved opioid use to treat another symptom (e.g., insomnia)
- Use of illicit drugs or unprescribed opioids
- Repeatedly obtaining opioids from multiple outside sources
- Prescription forgery
- Multiple episodes of prescription loss
- Diversion

Even at prescribed doses, opioids carry the risk of misuse, opioid use disorder, overdose, and death

*Scan to view CO*RE Tools*

79

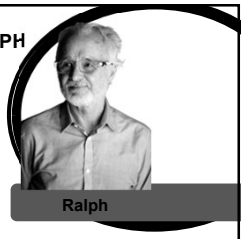
RE-EVALUATION & NEXT STEPS: FRANK

- Adherent to treatment plan
- Lost 20 lbs.
- Neuropathic pain still bad
- UDT and PDMP consistent with prescribed medications
- OUD risk:
  - Initial ORT = 4
  - COMM® = 0

Changes to Treatment Plan
- Began opioid trial
- Mu reversal agent prescribed

80

RE-EVALUATION & NEXT STEPS: RALPH



- Was using the 10mg about 8 times a day, so we scheduled it with it being SA
- Still having breakthrough pain and incident pain with scheduled 20mg every 6 hours and as needed (total daily dose 80mg)
- Seems to use extra prn when anxious

Changes to Treatment Plan
- Change from short-acting to long-acting: start the LA morphine 30mg every 12 hours to see if get a better steady state and less need breakthrough
- Keep prn 10mg SA
- Initiate duloxetine to help with neuropathic pain, anxiety, mood
- Need to schedule senna for OIC
- Decrease steroids to lowest dose possible
- Educate about opioids in house with granddaughter
- Naloxone script

81

PATIENT-CENTERED APPROACH TO TAPERING

No single approach is appropriate for all patients

- Discontinue through a taper schedule
- If OUD suspected:
  - Begin treatment: Medications for Opioid Use Disorder (MOUD)
  - Consider referral to an addiction or OUD specialist if appropriate
- Consider rotation to partial agonist (e.g., buprenorphine)
- May use a range of approaches, from a slow 10% dose reduction per week to a more rapid 25%–50% reduction every few days
- To minimize withdrawal symptoms in patients physically dependent on opioids, consider medications to assist with withdrawal (clonidine, NSAIDs, antiemetics, antidiarrheal agents)

Source: https://pubmed.ncbi.nlm.nih.gov/37356051/

82

TRANSITIONING FROM IR TO ER/LA OPIOID OPTIONS

PRIMARY REASONS	OTHER POTENTIAL REASONS
• Maintain stable blood levels (steady state plasma)	• Patient desire or need to try a new formulation
• Longer duration of action	• Cost or insurance issues
• Multiple IR doses needed to achieve effective analgesia	• Adherence issues
• Poor analgesic efficacy despite dose titration	• Change in clinical status requiring an opioid with different pharmacokinetics
• Less sleep disruption	• Problematic drug-drug interactions

83

CONSIDERATIONS FOR CHANGE FROM IR TO ER/LA OPIOIDS

DRUG SELECTION IS CRITICAL

Some ER/LA opioids or dosage forms are only recommended for opioid tolerant patients (ER/LA in opioid-naïve patients is controversial)

- ANY strength of transdermal fentanyl
- Certain strengths/doses of other ER/LA products (check drug prescribing information)
- Consider transition to buprenorphine (patch, film)

MONITOR PATIENTS CLOSELY FOR RESPIRATORY DEPRESSION

- Especially within 24–72 hours of initiating therapy and increasing dosage

INDIVIDUALIZE DOSAGE BY TITRATION BASED ON EFFICACY, TOLERABILITY, AND PRESENCE OF ADVERSE EVENTS

- Check ER/LA opioid product PI for minimum titration intervals
- Supplement with IR analgesics (opioid and non-opioid) if pain is not controlled during titration

Sources: Chou R, et al. J Pain. 2009;10:113-130; FDA. Education Blueprint Healthcare Providers Involved in the Treatment and Monitoring of Patients with Pain 09/2018. https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf; https://pubmed.ncbi.nlm.nih.gov/31917418/; https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/IB_1497_Provider_RxChronicPain.pdf

84

EMERGENCE OF OPIOID-INDUCED HYPERALGESIA

- An increased sensitivity to pain
- Usually occurs at high MME dosages and over long periods of time
- A physiological phenomenon that can happen to anyone
- Consider this explanation if:
  - Pain increases despite dose increases
  - Pain appears in new locations
  - Patient becomes more sensitive to painful stimuli
  - Patient is not improving in the absence of underlying cause or disease progression

Source: Yi P, Pryzbylkowski P. Opioid induced hyperalgesia. Pain Medicine 2015; 16: S32-S36

85

OPIOID TOLERANCE

If opioid tolerant, still use caution at higher doses

Patients considered opioid tolerant are taking at least:

- 60 mg oral morphine/day
- 30 mg oral oxycodone/day
- 8 mg oral hydromorphone/day
- 25 mg oral oxymorphone/day
- An equianalgesic dose of another opioid

IMPORTANT

FOR 1 WEEK OR LONGER

Also use caution when rotating a patient

Transdermal fentanyl is restricted to opioid tolerant individuals.

Source: The Opioid Analgesics Risk Evaluation & Mitigation Strategy product search, https://opioidanalgesicrems.com/products.html

86

OPIOID TOLERANCE VERSUS PHYSICAL DEPENDENCE

TOLERANCE

- Occurs when increased dose is needed to maintain the functional status no longer achieved by current dose
- Remember CNS and respiratory depression can develop with dose increase

PHYSICAL DEPENDENCE

- Occurs when an individual only functions normally in the presence of the substance
- Abrupt discontinuation or dosage decrease causes uncomfortable symptoms of withdrawal

Both **tolerance** and **physical dependence** are physiological adaptations to chronic opioid exposure and **DO NOT** equal addiction or opioid use disorder

87

OPIOID ROTATION

DEFINITION

A change from an existing opioid regimen to another opioid with the goal of improving therapeutic outcomes or to avoid AEs attributed to the existing drug

RATIONALE

Used when differences in pharmacologic or other effects make it likely that a switch will improve outcomes

- Effectiveness and AEs of different mu-opioids vary among patients
- Patient tolerant to first opioid might have improved analgesia from second opioid at a dose lower than calculated from an equianalgesic dosing table (EDT)

Sources: Fine PG, et al. J Pain Symptom Manage. 2009;38:418-425; Knotkova H, et al. J Pain Symptom Manage. 2009;38:426-439; Pasternak GW. Neuropharmacol. 2004;47(suppl 1):312-323.

89

EQUIANALGESIC DOSING TABLES (EDTs)

Many different versions:

- Published
- Online calculators
- Smartphone apps

Vary in terms of:

- Equianalgesic values
- Whether ranges are used

Which opioids are included: May or may not include transdermal opioids, rapid-onset fentanyl, ER/LA opioids, or opioid agonist-antagonists

90

START WITH AN EDT FOR ADULTS

	EQUIANALGESIC DOSE		USUAL STARTING DOSE	
DRUG	SC/IV	PO	PARENTERAL	PO
Morphine	10 mg	30 mg	2.5–5 mg SC/IV q3–4hr (1.25–2.5 mg)	5–15 mg q3–4hr (IR or oral solution) (2.5–7.5 mg)
Oxycodone	NA	20 mg	NA	5–10 mg q3–4hr (2.5 mg)
Hydrocodone	NA	30 mg	NA	5 mg q3–4hr (2.5 mg)
Hydromorphone	1.5 mg	7.5 mg	0.2–0.6 mg SC/IV q2–3hr (0.2 mg)	1–2 mg q3–4hr (0.5–1 mg)

91

MU-OPIOID RECEPTORS AND INCOMPLETE CROSS TOLERANCE

MU-OPIOIDS BIND TO MU RECEPTORS

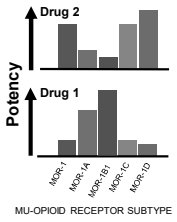
MANY MU RECEPTOR SUBTYPES

Mu-opioids produce **subtly different** pharmacologic responses based on distinct activation profiles of mu receptor subtypes

MAY HELP EXPLAIN:

Interpatient variability in response to mu-opioids

Incomplete cross tolerance among mu-opioids



92

GUIDELINES FOR OPIOID ROTATION

Calculate equianalgesic dose of new opioid from EDT

REDUCE CALCULATED EQUIANALGESIC DOSE BY 25%–50%*

SELECT % REDUCTION BASED ON CLINICAL JUDGMENT

CLOSER TO 50% REDUCTION	CLOSER TO 25% REDUCTION
IF PATIENT…	IF PATIENT…
• Is receiving a relatively high dose of current opioid regimen	• Does not have these characteristics
• **Is an older adult** or medically frail	• Is changing route of administration

*75%–90% reduction for methadone

93

GUIDELINES FOR OPIOID ROTATION (cont.)

IF SWITCHING TO **METHADONE**:

- Do **not** give methadone to opioid-naïve patients
- Standard equianalgesic dosing tables are less helpful in opioid rotation to methadone
- For opioid tolerant patients, methadone doses should **not** exceed 30–40 mg/day upon rotation
  - Consider inpatient monitoring; EKG monitoring controversial

IF SWITCHING TO **BUPRENORPHINE**:	IF SWITCHING TO **TRANSDERMAL FENTANYL**:
Consider cross-taper with buccal film or transdermal patch; see guidelines for switch to higher dose	Calculate dose conversion based on equianalgesic dose ratios included in the drug package insert

SOURCES: https://pubmed.ncbi.nlm.nih.gov/31917418/; https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/IB_1497_Provider_BupChronicPain.pdf https://accpjournals.onlinelibrary.wiley.com/doi/full/10.1002/phar.2676; CDC 2022 Guideline for Prescribing Opioids for Pain, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4078896/

95

GUIDELINES FOR OPIOID ROTATION: SUMMARY

Practice Example! **Transition an 80 y/o patient from morphine 180 mg/day to oxycodone**

VALUES FROM EDT*	PATIENT OPIOID VALUES	SOLVE FOR X	AUTOMATICALLY REDUCE DOSE
Value of current opioid / Value of new opioid	24-hr dose of current opioid X amount of new opioid	Equianalgesic 24-hr dose of new opioid	By 25%–50%†
30 mg / 20 mg (Conversion factor)	180 mg / X (Solve for X)	Equianalgesic 24-hr dose of new opioid X 120 mg (Equianalgesic dose)	By 25%–50%† (Reduce dose) 60 – 90 mg (NEW DOSE)

96

GUIDELINES FOR OPIOID ROTATION: SUMMARY

VALUES FROM EDT*	PATIENT OPIOID VALUES	SOLVE FOR X	AUTOMATICALLY REDUCE DOSE
Value of current opioid / Value of new opioid	24-hr dose of current opioid X amount of new opioid	Equianalgesic 24-hr dose of new opioid	By 25%–50%†

Frequently assess initial response	Titrate dose of new opioid to optimize outcomes	Calculate supplemental rescue dose used for titration at 5%–15% of total daily dose‡

* If switching to transdermal fentanyl, use equianalgesic dose ratios provided in PI.
† If switching to methadone, reduce dose by 75%–90%.
‡ If oral transmucosal fentanyl used as rescue, begin at lowest dose irrespective of baseline opioid.

97

BREAKTHROUGH PAIN (BTP)

PATIENTS ON STABLE ATC OPIOIDS MAY EXPERIENCE BTP

- Due to disease progression or a new or unrelated pain
  - Target cause or precipitating factors
- Dose for BTP: Using an **IR, 5%–15%** of total daily opioid dose, administered at an appropriate interval
- **Never use ER/LA for BTP**

CONSIDER OPTIMIZING

- PRN IR opioid trial based on analysis of benefit versus risk
  - There is a risk for problematic drug-related behaviors
  - High-risk: Add only in conjunction with frequent monitoring and follow-up
  - Low-risk: Add with routine follow-up and monitoring
- Consider non-opioid drug therapies and nonpharmacologic treatments

ATC=around the clock

98

ABUSE-DETERRENT FORMULATION (ADF) OPIOIDS

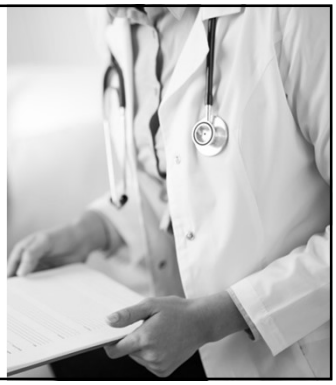
Drug formulations designed to discourage misuse

- An ER/LA opioid with properties to meaningfully deter misuse (less likely to be crushed, injected, or snorted)
- Consider as one part of an overall strategy
- Mixed evidence on the impact of ADF on misuse
- Overdose is still possible if taken orally in excessive amounts
- These products are expensive with no generic equivalents

99

CONSULTING A PAIN SPECIALIST

- Appropriate when you feel you cannot provide the level of care needed
- First ensure you have a reliable specialist to refer to
- To find a pain specialist in your area:
  - Consult with state boards
  - Consult with colleagues
  - Use online resources
  - Consult payment source
- Prior to referral, contact the specialist and ask what is needed for referral



100

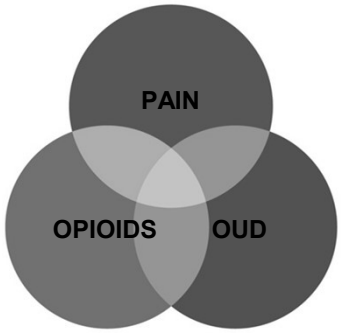
Adequately **DOCUMENT** all patient interactions, assessments, test results, treatment plans, and expectations.

101

MONITOR

RESPOND TO OPIOID USE DISORDER

102



103

WHAT IS ADDICTION?

Practical Definition:

Addiction is the continued use of drugs or activities, despite knowledge of continued **harm** to oneself or others.

Official ASAM Definition:

Addiction is a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences. Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases.

104

OPIOID USE DISORDER: DSM-5-TR CRITERIA

Be alert to these factors in patients on long-term opioid therapy

1. Taking larger amounts and/or for longer periods than intended
2. Persistent desire or inability to cut down or control use
3. Increased time spent obtaining, using, or recovering
4. Craving/compulsion to use opioids
5. Role failure at work, home, school
6. Social or interpersonal problems
7. Reducing social, work, recreational activity
8. Physical hazards
9. Physical or psychological harm

10. Tolerance ❖
11. Withdrawal ❖

❖ **Not valid if opioid is taken as prescribed**

2–3 = mild
4–5 = moderate
≥6 = severe

SOURCE: APA. Diagnostic and Statistical Manual of Mental Disorders (DSM-5-TR). 2022

105

WORDS MATTER – *PEOPLE MATTER*

Physical dependence or tolerance — Doesn't necessarily equal — OUD/ addiction — Doesn't necessarily equal — Aberrant/ problematic behavior

106

HOW TO IDENTIFY RISK FOR MY PATIENTS

10%–26% of patients on chronic opioid therapy (COT) for chronic noncancer pain (CNCP) may develop OUD

What to look for:

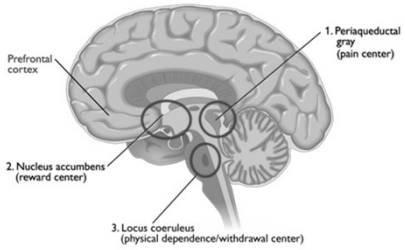
- High dosages
- Prolonged use
- Low hedonic tone
- Mental health disorders
- Past history of substance use disorder

Clinical judgment is key.

SOURCES: Chou R, et al. Ann Intern Med. 2015;162:276-286. Kaye, AD. Pain Physician 2017 Feb: 20(2S):S93-S109.

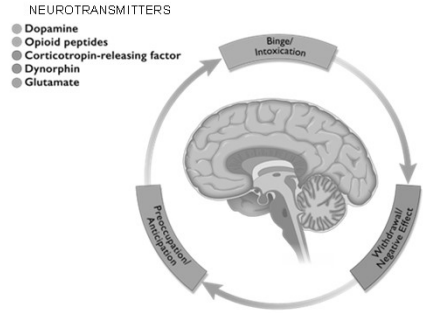
107

OPIOID RECEPTORS IN THE BRAIN: RELATIONSHIP TO ANALGESIA, OUD, AND WITHDRAWAL



108

THE CYCLE OF SUBSTANCE USE DISORDER



109

MEDICATION FOR OPIOID USE DISORDER (MOUD)

- Important and evidence-based medication that saves lives
- You can start from your office, as an outpatient
- Patients with OUD have decreased mortality when treated – *you can save a life!*

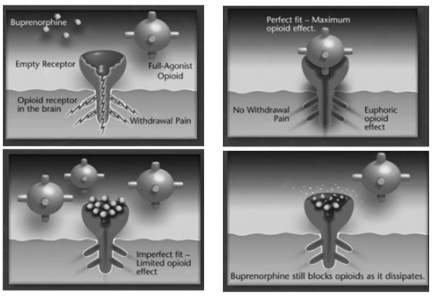
There are three medication options:

1. Buprenorphine (Schedule III)
2. Methadone (Schedule II)
3. Naltrexone (not a controlled substance)

Are we just replacing one drug with another?
Myth or fact?

110

HOW BUPRENORPHINE WORKS



Source: https://www.naabt.org/education/images/Receptors_HiRes.jpg, https://pubmed.ncbi.nlm.nih.gov/16547090/

111

BUPRENORPHINE

- Most commonly prescribed pharmacotherapy for treatment of OUD
- Good efficacy and safety profile
- "Plateau effect" for respiratory depression
- Congress eliminated the X-waiver requirement to prescribe Bup
- All DEA-licensed HCPs can prescribe without patient number caps
- Long-acting injectable and sublingual form indicated to treat opioid withdrawal and craving

FDA-approved buprenorphine products for pain:

- Butrans: 7-day transdermal patch
- Belbuca: buccal mucosal film; BID dosing

Source: https://pubmed.ncbi.nlm.nih.gov/16547090/

112

AVOID OTHER SUBSTANCES THAT COULD CONTRIBUTE TO AN ACCIDENTAL OVERDOSE

- Benzodiazepines (BZDs), sedatives, muscle relaxants; they are CNS depressants
- More than 30% of opioid overdoses involve benzodiazepines (BZDs)
- Evaluate for SUD to support recovery efforts for all substances

Source: NIDA. Takaki H, et al. Am Journal Addictions. 2019;1-8.

113

USE A WHOLE-PERSON APPROACH WHEN TREATING A PATIENT WITH OUD FOR PAIN

- Must address *both* pain and opioid use disorder
- Remember that untreated pain is a trigger for return to use
- Avoid other potentially problematic medications
- Consider a multimodal pain program, including non-pharma options
- Avoid stigmatizing patients who are on long-term opioids for pain

- Consider buprenorphine for both pain and OUD
- Enlist patient's family/caregivers to secure and dispense opioids
- Recommend an active recovery program
- Remember to use PDMP
- Use screening methods (UDT, pill counts, PPA) to identify challenges and initiate discussion

Source: Bailey J, et al. Pain Med 2010;11:1803-1818.

114

RESOURCES TO HELP YOU TREAT OR TO REFER:

TREATMENT SUPPORT	REFERRAL SUPPORT
SAMHSA – Training Materials & Resources	**ASAM** – Physician Finder
NIDA – Treatment Resources	**SAMHSA** – Find Treatment
PCSS – Providers Clinical Support System	**AAAP** – Specialist Finder

115

IN SUMMARY

- There is a place for opioids, but use caution
- Use multimodal therapies as part of the pain management care plan
- Screen for OUD risk with a validated instrument
- Continually reassess patients using opioids
- Patient and family/caregiver education is essential
- If you suspect OUD, begin treatment

116

OPTIMIZING PATIENT CARE THROUGH TELEHEATH

- Series of four short videos
- Help clinicians conduct successful telehealth patient visits
- Available online **https://learningipma.org**

117

MAKE SURE your participation is counted.

Become an official "FDA Blueprint Completer" by answering the post-test questions!

Please complete your post-test

This education counts toward the MATE Act hours needed to renew your DEA License and your feedback is critical to improving future education.

118

THANK YOU!

WWW.CORE-REMS.ORG

FULL LIST OF SOURCES AVAILABLE UPON REQUEST

119

Opioid Analgesic
Risk Evaluation and Mitigation Strategy (REMS)
List of Participant Companies

The REMS Program Companies (RPC) include:

Abhai, LLC
ACI Healthcare Limited / Novitium Pharma LLC
Alvogen, Inc.
Amneal Pharmaceuticals LLC
ANI Pharmaceuticals, Inc.
Apotex Inc.
Ascent Pharmaceuticals, Inc.
Athena Bioscience, LLC
Aurolife Pharma LLC
Avanthi, Inc.
Aveva Drug Delivery Systems, Inc.
Cerovene, Inc.
Cipher Pharmaceuticals Inc.
Collegium Pharmaceutical, Inc.
Dr. Reddy's Laboratories, Inc.
Elite Laboratories, Inc.
Endo Pharmaceuticals Inc.
Epic Pharma, LLC
Fosun Pharma USA Inc.
Genus Lifesciences Inc.
Granules Pharmaceuticals Inc.
Hikma Pharmaceuticals USA Inc.
Ingenus Pharmaceuticals NJ, LLC.
Ipca Laboratories Ltd.
Jerome Stevens Pharmaceuticals, Inc.
Kindeva Drug Delivery L.P.
Kowa Pharmaceuticals
KVK-Tech, Inc.
Lannett Company, Inc.
LGM Pharma Solutions, LLC
Lupin Pharmaceuticals Inc. / Novel Laboratories, Inc.
Macleods Pharmaceuticals Limited
Mallinckrodt LLC
Megalith Pharmaceuticals Inc.
Micro Labs USA Inc.
Mikart, Inc.
Nortec Development Associates, Inc.
Nostrum Laboratories, Inc.
Nuvo Pharmaceuticals, Inc.

Osmotica Pharmaceutical US, LLC
Padagis US LLC
Pharmaceutical Associates, Inc.
Protega Pharmaceuticals Inc.
Purdue Pharma L.P.
Quagen Pharmaceuticals LLC
Rhodes Pharmaceuticals L.P.
Rising Pharma
Rubicon Research Private Limited
Sandoz, Inc.
Strides Pharma Global Pte. Limited
Sun Pharmaceuticals Industries Inc.
Teva Pharmaceuticals USA, Inc.
ThePharmaNetwork, LLC
Tris Pharma, Inc.
Unichem Laboratories Limited
Upsher-Smith Laboratories, LLC
Validus Pharmaceuticals LLC
Viatris
Virtus Pharmaceuticals, LLC
VistaPharm, LLC
WES Pharma Inc
Wockhardt Bio AG
Wraser Pharmaceuticals, LLC
Zevra Therapeutics, Inc.
Zydus Pharmaceuticals (USA) Inc.
Zyla Life Sciences

Notes

Medicare Wellness Visits

Lesca Hadley, MD
Geriatric Medicine Physician
Methodist Charlton Medical Center
Dallas, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Distinguish between the 'Welcome to Medicare' visit and an Annual Wellness Visit.
2. Plan preventive services consistent with the 'Welcome to Medicare' visit and the annual wellness visit for eligible patients.
3. Identify services covered by these visits.

Speaker Disclosure

Dr. Hadley disclosed she has no financial relationships with any ineligible organizations or commercial interests.

Medicare Wellness Visits

Lesca Hadley MD, MBA, AGSF, FAAFP
Director of Geriatrics
Methodist Charlton, Dallas, Texas

1

Speaker Disclosure

Dr. Hadley disclosed she has no financial relationships with any ineligible organizations or commercial interests.

2

Polling Question #1

Are you caring for Medicare patients?

A. Yes
B. No

4

Objectives

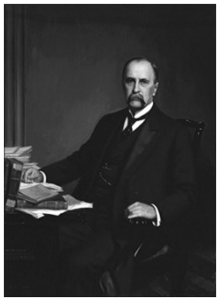
By the end of this session, learners will be better able to:

1. Distinguish between the "Welcome to Medicare" visit and an Annual Wellness Visit.
2. Plan preventive services consistent with the 'Welcome to Medicare" visit and the annual wellness visit for eligible patients.
3. Identify services covered by these visits.

5

Affordable Care Act of 2010 created the Medicare annual wellness visit to provide patients with comprehensive preventive care services at no cost.

9



"Let me congratulate you on the choice of calling which offers a combination of intellectual and moral interests found in no other profession."
– Sir William Olser

10

Polling Question #2

Are you providing? (Choose all that apply)

- Welcome to Medicare Visits/ Initial Preventative Physical Exam
- Initial Annual Medicare Visits
- Subsequent Annual Medicare Visits

11

Fraction of Eligible Patients receiving AWVs

- 15.6 percent of eligible patients received an AWV through 2014.
- Rates are lower among practices caring for underserved populations, such as racial minorities, rural residents, or those dually enrolled in Medicaid.
- Visits concentrated in ACOs and among certain PCPs and regions of the country, suggesting the decision to perform an AWV was primarily driven by practice factors

Trends in Use of the US Medicare Annual Wellness Visit, 2011-2014 | Health Care Economics, Insurance, Payment | JAMA | JAMA Network

12

Polling Question #3

What are your barriers to AWV and IPPEs? (Choose all that apply)

- Documentation burden
- Time constraints
- Not supported by EHR
- Not familiar with requirements for visits
- Complexity of patients makes other problems the priority
- Other

13

Benefits

- Patient
  - Creation of a personalized prevention plan
  - Personalized health advice that identifies risk factors and suggests referrals or programs to address them
- Provider
  - Addresses pay-for-performance quality measure gaps
  - Generates greater revenue with associated preventive services and same-day problem-oriented charges
  - Reports risk-adjusted diagnoses for Medicare Advantage beneficiaries

14

The AAFP's Position on AWVs

The AAFP supports this preventive coverage as it provides an opportunity to deliver, document, and bill for the service. Implementing the service allows physicians to invest in patient-centered, team-based care while promoting quality and cost-effective care.

15

16

Initial Preventative Physical Exam

Welcome to Medicare

17

12 Months of Starting Medicare Part B Coverage

18

Patients pay nothing if provider accepts assignment

19

per lifetime

20

Review the Patient's Medical and Social History

21

Minimum History

- Past medical
- Surgical history
- Current medications
- Supplements
- Family history
- Diet
- Physical activities
- Social activities and engagement
- Alcohol
- Tobacco
- Illegal drug use
- Other substance use

22

Review the Patient's Potential Depression Risk Factors

23

Depression History

- Current or past experiences with depression
- Other mood disorders

24

Select from various standardized screening tools designed for this purpose and recognized by national professional medical organizations

- Beck Depression Inventory
- Center for Epidemiologic Studies Depression Scale
- EQ-5D
- Hamilton Depression Rating Scale
- Montgomery-Åsberg Depression Rating Scale
- Social Problem-Solving Inventory-Revised
- Beck Hopelessness Scale
- Quick Inventory of Depressive Symptomatology-Self-Report (QIDS-SR)
- Reminiscence Functions Scale
- Short Form Health Survey
- Social Adjustment Scale-Self Report
- Social Functioning Questionnaire
- Patient Health Questionnaire

25

Screening Specific to the Older Population

- Geriatric Depression Scale
  - Self administered
  - 15 question short version and 30 question long version both validated
  - May use with cognitive impairment
  - Many languages available in public Domain on internet
  - www.web.stanford.edu/~yesavage/GDS.html
- Life Satisfaction Index
  - Designed to measure well being and life satisfaction
  - Used with permission

26

Review the Patient's Functional Ability and Safety Level

27

Use direct patient observation, appropriate screening questions, or standardized questionnaires recognized by national professional medical organizations to review, at a minimum

- Ability to perform activities of daily living (ADLs)
  - Bathing, Dressing, Toileting, Transferring, Continence, Feeding
  - adl_tool.pdf (stanford.edu)
- Fall risk
  - Resource Algorithm for Fall Risk Screening, Assessment, and Intervention (cdc.gov)
  - Brochure - Stay Independent_I (cdc.gov)
- Home and community safety, including driving when appropriate

28

Additional Requirements

- Hearing impairment
- Hearing Handicap Inventory For Adults.pdf (ummhealth.org)

Recommendation Summary

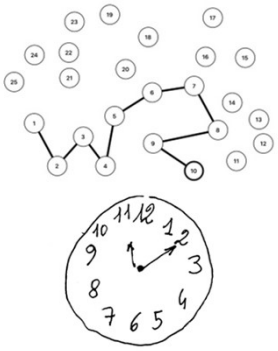
Population	Recommendation	Grade
Asymptomatic adults 50 years or older	The US Preventive Services Task Force (USPSTF) concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for hearing loss in older adults. See the Practice Considerations section for additional information regarding the I statement.	I

- Home and community safety, including driving when appropriate

29

Evaluating Driving

- Physical Examination
- Motor and Sensory Function
- Vision
- Hearing
- Cognitive Function
- Trail Making Test A
- Clock Drawing



30

Additional Tools for Driving Assessment

- American Automobile Association
- AARP
- American Geriatrics Society
- National Highway Traffic Safety Administration
- Texas Department of Public Safety reporting
  - Texas Medical Evaluation Process for Driver Licensing | Department of Public Safety
  - **MAB@dps.texas.gov**

31

"Sometimes, the best thing we can do for our patients is to tell them what the best behavior is and then negotiate something they can live with."
– Nancy Dickey

32

Simple Exam

- Height
- Weight
- Body mass index or waist circumference
- Blood pressure
- Visual acuity screen
- Other factors deemed appropriate based on medical and social history and current clinical standards

33

Balance and Gait Assessment

- Timed Up & Go
  - TUG_Test-print.pdf (cdc.gov)
- 30-Second Chair Stand
  - Assessment 30-second Chair Stand (cdc.gov)
- 4-Stage Balance Test
  - 4-Stage_Balance_Test-print.pdf (cdc.gov)

- STEADI - Older Adult Fall Prevention | CDC

34

End of Life Planning

- End-of-life planning
- Medical Advanced Directives
- Psychiatric Advanced Directives
- Texas Forms | NRC PAD (nrc-pad.org)
- How to Make an Advance Directive - Disability Rights Texas (disabilityrightstx.org)

www.samhsa.gov/sites/default/files/practical-guide-psychiatric-advance-directives.pdf

35

Psychiatric Advance Directive

- Legal document for person's preferences for future mental health treatment
- Allows appointment of a health proxy
- Drafted when a person is well enough to consider preferences
- Used when a person becomes unable to make decisions during a mental health crisis.

36

Psychiatric Advance Directive

- 3 Treatment decisions
  - Psychotropic medications you do or do not want
  - Electroconvulsive treatment (ECT)
  - In an emergency, treatment options for sedation
- Can resume participating directly in decisions about care when competent

37

Review Current Opioid Prescriptions

- Review any potential opioid use disorder risk factors
  - National Institute on Drug Abuse has screening and assessment tools.
    - nida.nih.gov/nidamed-medical-health-professionals/screening-tools-resources/chart-screening-tools
  - Implementing Drug and Alcohol Screening in Primary Care
    - www.alcoholdrugscreening.simmersion.com
- Evaluate pain severity and current treatment plan
- Provide information about non-opioid treatment options
- Refer to a specialist, as appropriate

38

Educate, Counsel, and Refer Based on Previous Components

39

"Success is not the key to happiness. Happiness is the key to success. If you love what you are doing, you will be successful." – Albert Schweitzer

40

Educate, Counsel, and Refer for Other Preventive Services

- Include a brief written plan
- Once-in-a-lifetime screening electrocardiogram (ECG), as appropriate
- Appropriate screenings and other covered preventative services
  - MLN006559 – Medicare Preventive Services (cms.gov)
  - www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html#ALC_MISUSE

41

Diagnosis for Encounter

- Report a diagnosis code when submitting IPPE claims
  - No requirements for a specific IPPE diagnosis code
  - May choose any diagnosis code consistent with the patient's exam
- G0402 Code for IPPE

42

Billing

- Part B covers an IPPE by qualified provider
  - Physician
  - Qualified non-physician practitioner
  - Physician assistant, nurse practitioner, or certified clinical nurse specialist
- With an IPPE and a significant, separately identifiable, medically necessary evaluation and management (E/M) service
  - Additional CPT code (99202–99205, 99211–99215) with modifier 25. Must be medically necessary and reasonable to treat the patient's illness or injury

43

Use these HCPCS Codes to File IPPE and Routine 12 Lead EKG

- **G0402**
  - Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment
- **G0403**
  - Performed as a screening for the IPPE with interpretation and report
- **G0404**
  - Tracing only, without interpretation and report, performed as a screening for the IPPE
- **G0405**
  - Interpretation and report only, performed as a screening for the IPPE
- **G0468***
  - FQHC visit, IPPE or AWV; FQHC visit that includes an IPPE or AWV and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving an IPPE or AWV

44

1st Annual Wellness Visit

45

Minimum Health Risk Assessment

- Demographic data
- Health status self-assessment
  - Frailty
  - Physical Functioning
- Psychosocial risks
  - Depression, life satisfaction, stress, anger, loneliness or social isolation, pain, suicidality, and fatigue

46

Minimum Health Risk Assessment

- Behavioral risks
  - Tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual health, motor vehicle safety, and home safety
- Activities of daily living (ADLs)
- Balance or fall risks
- Instrumental ADLs
  - Including using the phone, housekeeping, laundry, transportation, shopping, managing medications, and handling finances

47

Update the Patient's Medical and Family History Minimum Requirements

- Medical events of the patient's parents, siblings, and children, including hereditary conditions
- Past medical and surgical history
- Medications, supplements, and other substances

48

Additional Requirements

- Update all current providers and suppliers list
- Measure
  - Weight or waist circumference and blood pressure
- Other routine measurements deemed appropriate based on medical and family history

49

Detect Cognitive Impairments

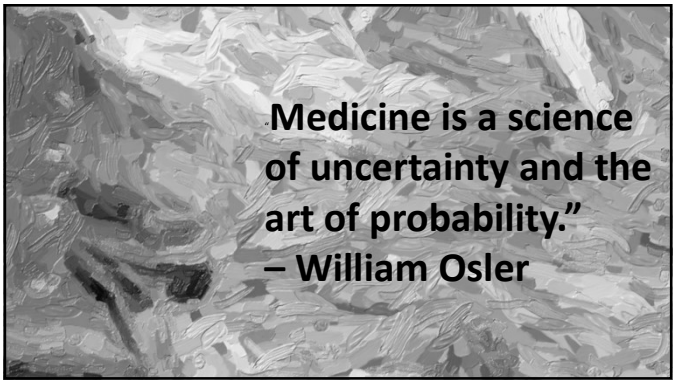
- Direct observation or reported observations from the patient and caregivers
- Brief cognitive tests
  - Mini-Cog
    - www.mini-cog.com
    - Sensitivity reported 76-99% and specificity 83-93%
  - SLUMS test
    - www.slu.edu/medicine/internal-medicine/geriatric-medicine/aging-successfully/pdfs/english-canada.pdf
    - Sensitivity 98-100% and specificity 98-100%
  - www.nia.nih.gov/health/health-care-professionals-information/alzheimers-and-related-dementias-resources

50

Update the Patient's Written Screening Schedule

- United States Preventive Services Task Force
- Advisory Committee on Immunization Practices (ACIP) recommendations
- Patient's Health Risk Assessment
- Health status
- Screening history
- Age-**appropriate** preventative services covered

51



52

Update the Patient's List of Risk Factors and Conditions

- Provide recommendations for primary, secondary, or tertiary interventions or report they are occurring
- Mental health screening and current conditions

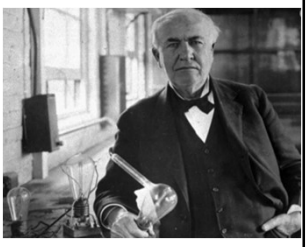
53

Provide personalized health advice and appropriate referrals to health education or preventive counseling services or programs

- Community-based lifestyle interventions to reduce health risks and promote self-management and wellness
  - Fall prevention
  - Nutrition
  - Physical activity
  - Tobacco-use cessation
  - Social engagement
  - Weight loss

54

"The doctor of the future will give no medicine but will interest his patients in the care of the human frame, in diet and in the cause and prevention of disease."
- Thomas Edison



55

Provide Advance Care Planning Services at the Patient's Discretion

- Advance directive elements
  - Caregiver identification
  - Living will
  - Instruction directive
  - Psychiatric advance directive
  - Health care power of attorney
- No limitations on number of times the patient can revisit the ACP during the year, but cost sharing applies outside the AWV.

56

Screen for Potential Substance Use Disorders

- Review the patient's potential risk factors
- As appropriate, refer for treatment
- National Institute on Drug Abuse has screening and assessment tools
  - www.nida.nih.gov/nidamed-medical-health-professionals/screening-tools-resources/chart-screening-tools
- Implementing Drug and Alcohol Screening in Primary Care
  - www.alcoholdrugscreening.simmersion.com

57

2024: Social Determinants of Health Risk Assessment

- Optional Social Determinants of Health Risk Assessment
- Must follow standardized, evidence-based practices and ensure communication aligns with the patient's educational, developmental, and health literacy level, as well as being culturally and linguistically appropriate
- A Review of Tools to Screen for Social Determinants of Health in the United States: A Practice Brief - PMC (nih.gov)
- The AHC Health-Related Social Needs Screening Tool (cms.gov)
- www.prapare.org
- Short Patient (Print) Social Needs Screening Tool (aafp.org)

58

Diagnosis

- Report a diagnosis code when submitting AWV claims
- No specific diagnosis is required
- Choose any diagnosis code consistent with the patient's exam

59

Part B Covers an AWV Performed By

- Physicians
- Qualified non-physician practitioner
- Physician assistant
- Nurse practitioner
- Certified clinical nurse specialist
- Medical professional
  - Health educator, registered dietitian, nutrition professional, or other licensed practitioner or a team of medical professionals directly supervised by a physician

60

AWV and a Significant, Separately Identifiable, Medically Necessary Evaluation and Management (E/M) Service

- Report the additional CPT code (99202–99205, 99211–99215) with modifier 25
- Portion of the visit must be medically necessary and reasonable to treat the patient's illness or injury

61

Optional Advanced Care Planning Coding

- **99497**
  - Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate
- **99498**
  - Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (List separately in addition to code for primary procedure)

62

Diagnosis for Advanced Care Planning Claim

- Choose any diagnosis code consistent with a patient's exam

63

Billing for Advanced Care Planning

- Part B ACP coinsurance and deductible is waived once a year
  - Provided on the same day as the covered AWV
  - Provided by the same provider as the covered AWV
  - Billed with modifier 33 (Preventive Service)
  - Billed on the same claim as the AWV

64

Billing for Advanced Care Planning

- AWV billed with ACP for exceeding the once-per-year limit, deductible and coinsurance is billed.
- No limits on the number of times ACP can be reported for a certain patient in a certain period. Document changes in the patient's health status or wishes about their end-of-life care.

65

"Wherever the art of medicine is loved, there is also a love for humanity."
– Hippocrates

66

Beginning July 1, 2024 Billing Optional Social Determinants of Health in AWV

- **G0136**
  - Administration of a standardized, evidence-based social determinants of health risk assessment tool, 5-15 minutes
- **Diagnosis**
  - Report a diagnosis code when submitting an SDOH Risk Assessment claim as an optional AWV element
  - No requirements to use a specific SDOH Risk Assessment diagnosis code
  - Choose any diagnosis code consistent with a patient's exam.

67

Billing Optional Social Determinants of Health in AWV

- Waive both the Part B SDOH Risk Assessment coinsurance and deductible
  - Provided on the same day on same claim as the covered AWV
  - Provided by the same provider as the covered AWV
  - Billed with modifier 33 (Preventive Service)
- If exceeding the once-per-year limit, the deductible and coinsurance are applied. Deductible and coinsurance are applied with the SDOH Risk Assessment outside the covered AWV

68

Subsequent Annual Wellness Visits

69

Perform a Health Risk Assessment

- Staff or the patient can update the Health Risk Assessment before or during the AWV
- Update the patient's medical and family history
- Establish a current providers and suppliers list
- Simple Exam as AWV
- Detect any cognitive impairments
- Update the patient's written appropriate screening schedule

70

Additional Components

- Update the patient's list of risk factors and conditions
- As necessary, provide and update patient's personalized health advice and appropriate referrals to health education or preventive counseling services or programs
- Provide advance care planning services at the patient's discretion

71

The aim of medicine is to prevent disease and prolong life; the ideal of medicine is to eliminate the need of a physician."
– William J. Mayo

72

Review Current Opioid Prescriptions

- Review any potential Opioid Use Disorders risk factors
- Evaluate pain severity and current treatment plan
- Provide information about non-opioid treatment options
- Refer to a specialist, as appropriate

73

Coding

- G0438 or G0439 once in a 12-month period. Cannot bill within 12 months of a previous G0402
- **G0438**
  - Annual wellness visit; initial visit
- **G0439**
  - Annual wellness visit, subsequent visit
- **G0468***
  - FQHC visit, IPPE or AWV; a FQHC visit that includes an initial preventive physical examination or annual wellness visit and includes a typical bundle of Medicare-covered services that would be furnished per diem to a patient receiving an IPPE or AWV

74

Preparing Eligible Patients for their AWV Needed Information from Patients

- Medical records, including immunization records
- Detailed family health history
- Full list of medications and supplements
- Full list of current providers and suppliers involved in their care
  - Personal care
  - Adult day care
  - Home-delivered meals
  - Behavioral health specialists

75

Systematic Approach to Annual Wellness Visits

- Manage patient expectations
- Develop scheduling protocols
- Do pre-visit planning
- Verify eligibility
- Pre-visit questionnaires
- Define the encounter
- Determine responsibilities of staff
- Plan for efficient follow up care based on patient responses

76

AAFP Information for Patients


A word to our patients about
MEDICARE ANNUAL WELLNESS VISITS

Medicare pays for a single wellness visit once a year to identify health risks and help you to reduce them.

Medicare Annual Wellness Visit
What Patients Need to Know

1. What is the Medicare Annual Wellness Visit?
The Medicare Annual Wellness Visit (AWV) is a way for our practice to keep you as healthy as possible. Our practice helps you develop or update a personalized prevention

4. Is the AWV the same an annual physical exam?
No. The AWV does not replace a complete head-to-toe physical exam.

77

G2211 CPT Code Began January 1, 2024 $16.05

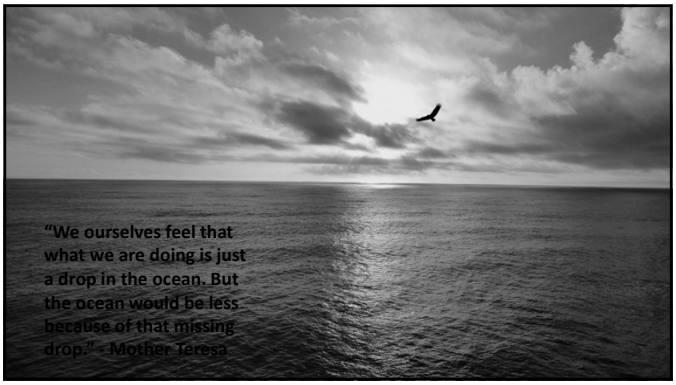
- Way to report the extra time, effort, and associated practice expense involved with caring for Medicare patients across the continuum of healthcare.
- *Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (**Add-on code**, list separately in addition to office/outpatient evaluation and management visit, new or established)*

78

G2211 Considerations

- Expected to provide longitudinal care to the patient
  - Urgent care, consultants, second opinions, etc. should not bill G2211
- Primary care physicians and specialists may bill this add-on code
- Bill in conjunction with an office or other outpatient (E/M) service
- May be billed with telehealth services
- Do not bill when the E/M service is reported with modifier 25
- Do not bill when chronic/complex conditions are documented but not considered or addressed
- No specific documentation guidelines from the CMS

79



80

Is IPPE the same as a yearly physical?

No. The IPPE is not a routine physical that some patients may get periodically from their physician or other qualified non-physician practitioner. The IPPE is an introduction to Medicare and covered benefits, and it focuses on health promotion, disease prevention, and detection to help patients stay well.

81

Is an AWV the same as a Routine Physical Exam?

Routine physical is an exam performed without relationship to treatment or diagnosis for a specific illness, symptom, complaint, or injury.
Medicare does not cover routine physical exams, but the IPPE, AWV, or other Medicare benefits cover some routine physical elements
Patients pay 100% out of pocket for routine physical exams.

82

If a patient enrolled in Medicare in 2023, can they get a IPPE in 2024 if it was not performed in 2023?

A patient who hasn't had an IPPV and whose Part B enrollment began in 2023 can get an IPPE in 2024 if it's within 12 months of the patient's Part B enrollment effective date.

83

Does the deductible, coinsurance, or copayment apply for the IPPE?

No. The coinsurance, copayment, and Part B deductible are waived for the IPPV (HCPCS code G0402). Neither is waived for the screening ECG (HCPCS codes G0403, G0404, or G0405).

84

Does the deductible, coinsurance, or copayment apply for the AWV?

No. The coinsurance, copayment, and Part B deductible are waived for the AWV.

85

Who is eligible for an AWV?

An AWV for all patients who've had Medicare coverage for longer than 12 months is covered after their first Part B eligibility date and who did not have an IPPE or AWV within those past 12 months. **Medicare covers only 1 IPPE per patient per lifetime and 1 additional AWV every 12 months after the date of the patient's last AWV or IPPE.**

86

Are clinical lab tests part of the IPPV or AWV?

No. The IPPE and AWV do not include clinical lab tests, but you may make appropriate referrals for these tests as part of the IPPE or AWV.

87

Are other services covered on the same date as a Medicare Wellness Visit?

- Bill for them separately using modifier 25 appended to the appropriate evaluation and management (E/M) code
- Patient's deductible and coinsurance or copayment would apply for these other services
- Explain to patients why you recommend these services and what they are likely to cost

88

Can I bill an AWV and EKG on the same date of service?

Generally, you may provide other medically necessary services on the same date as an AWV. The deductible and coinsurance applies for these and other medically necessary and reasonable services.

89

How do I know if a patient received an AWV from another provider in the past?

Different options exist for accessing AWV eligibility information depending on where you practice. Check eligibility to find when a patient is eligible for the next preventive service.

90

Key Points

- The Medicare annual wellness visit (AWV) and the initial preventive physical examination (IPPE) provide a number of benefits to patients and physicians, but many physicians still do not provide them.
- Medicare wellness visits can help physicians address care gaps and report quality measures important in pay-for-performance systems.
- When billed correctly and delivered efficiently along with other covered Medicare preventive services, AWVs can boost practice revenue.
- Medicare Wellness Visits: Reassessing Their Value to Your Patients and Your Practice | AAFP

91

"Cure sometimes, treat often, comfort always."-

- Hippocrates

92

Additional References

- MLN6775421 – Medicare Wellness Visits (cms.gov)
- Get Paid with the Annual Wellness Visit | AAFP
- Medicare Annual Wellness Visits Made Easier | AAFP
- Medicare 101: Navigating the Rules for Coverage and Benefits in Clinical Practice | AAFP
- Medicare Wellness Visits: Reassessing Their Value to Your Patients and Your Practice | AAFP
- Trends in Use of the US Medicare Annual Wellness Visit, 2011-2014 | Health Care Economics, Insurance, Payment | JAMA | JAMA Network

93

Notes

Deciphering Genomic Tests

Julie Reardon, MD

Family Medicine and Integrative Medicine Physician
Lake Travis Integrative Medicine
Austin, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Discuss the difference between genetic diseases and Genomic SNPS and how SNPS can help guide medical care.
2. Utilize cardiac related genomics to determine what interventions might best benefit patients.
3. Discuss the etiology of macular degeneration by looking at its genomics and how this can guide supplements.
4. Be comfortable with some of the ethical, emotional and legal issues regarding the field of genomics.

Speaker Disclosure

Dr. Reardon disclosed she has no financial relationships with any ineligible organizations or commercial interests.

DECIPHERING GENOMIC TESTS:

NAVIGATING SNP'S IN FAMILY MEDICINE PRACTICE

Julie Reardon, MD

1

Julie Reardon, MD

Diplomate, American Board of Family Medicine
Board Certified, American Board of Integrative Medicine
Fellow, Arizona Center for Integrative Medicine
Institute for Functional Medicine Certified Practitioner
AAFP, TAFP
(I have no disclosures.)

Lake Travis Integrative Medicine

2

Objectives:

TRANSLATION OF COMPLEX INFORMATION

Genomics vs. Genetics

Cardiac Related Genomics

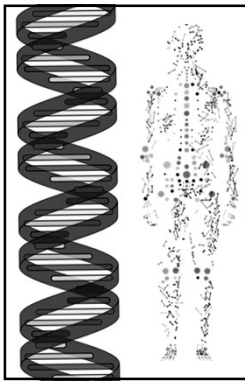
Macular Degeneration Related

Genomics

Challenges

Conclusion

3



Genomics for Primary Care

- Better understanding of the science
- Medication and Supplement safety
- Tool for patient story/lifestyle changes

5

Genetic "Diseases" Tend to be Fairly Large Genetic Events

- Duplications of chromosomes (Trisomy 21)
- Nucleotide repeats of pieces of chromosomes (Huntington's = CAG repeat of 36 -100 times vs. normal 10 – 35 times)
- Deletions (Turner's syndrome is partial or missing X chromosome)

SOMETIMES HOWEVER CAN BE DUE TO GENOMIC EVENT:

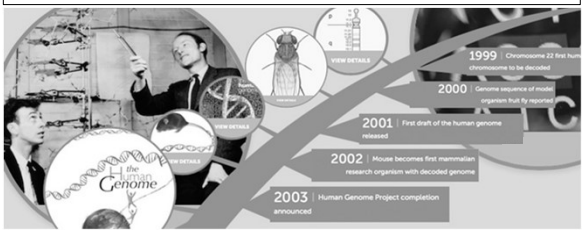
- Single Nucleotide Genomic Variants (Over 30 of the 60 forms of Tay-Sachs)

6

BRCA

7

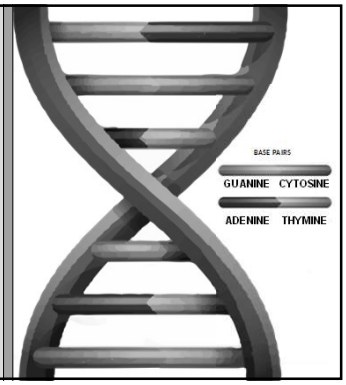
1953 – DNA Helix
2003 – Genome Sequencing
2024 – YOUR DNA IS USEFUL AND CAN HELP YOU OPTIMIZE HEALTH



8

Looking Deeper into DNA

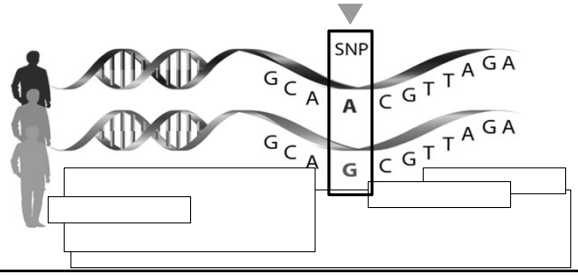
- The building blocks of the DNA "base pairs".
- These building blocks are represented by letters G, C, A & T
- You have about ~3 billion of these letters in YOUR DNA.



9

SNP

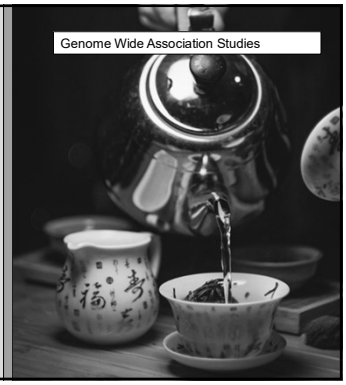
SINGLE NUCLEOTIDE POLYMORPHISM:
A change in one nucleotide within a stretch of DNA or within a gene



10

GWAS:

- As of 2019-10-14, the GWAS Catalog contains 7,796 publications and 159,202 associations. GWAS Catalog data is currently mapped to Genome Assembly GRCh38.p12 and dbSNP Build 151.
- Low Penetrance Markers
- Search to help us understand Complex/ Chronic Diseases
  - Diabetes
  - Inflammatory Bowel Disease
  - Coronary Artery Disease



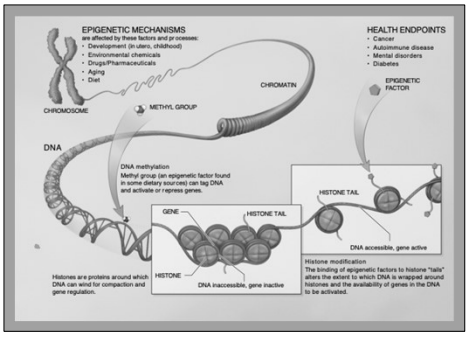
11

"EPIGENETICians"

Family Physicians

- The study of how DNA dynamically interacts with the environment.
- How our DNA activates and expresses.
- Environmental impact on our genes and our future descendants.
- Nature AND Nurture dancing together

12



Slide adapted from commonfund.nih.gov with permission from National Institutes of Health

13

Cardiac Related Genomics:

Utilize cardiac related genomics to determine what interventions might best benefit patients.

15

Cardiovascular

- 9p21/ CDKN2A/2B
- 4q25/ PITX2 (Afib risk and stroke)
- APOE
- MTHFR
- COMT
- CYP2c19
- SLC01B1

16

MTHFR

homocysteine levels:

- CV risk factor
- 5,10-methylenetetrahydrofolate reductase
- We all have the enzyme...

THE ON-OFF SWITCH FLIPPED A BILLION TIMES PER SECOND IN YOUR BODY

Plays a role in:

- Embryonic development
- Detoxification/ Transsulfuration
- Genomic imprinting
- Preservation and Repair of Chromosome Stability/ Genetic repair
- Regulation of Enzyme Production/ Krebs cycle

17

Environment on methylation

AGOUTI METHYLATED MICE

Pregnant mice fed diet with choline, folic acid, betaine, and b12 vs. normal mouse diet.

- Licked pups
- Higher stress response
- More methyl tags

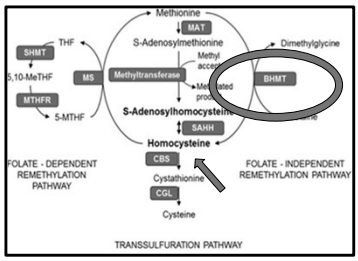
https://www.nature.com/articles/news030728-12 and https://mcb.asm.org/content/23/15/5293

18

Multiple Enzymes: Not Just One SNP

3 different pathways to clear homocysteine:

- Folate/methylfolate and B12
- Choline dependent
- B6 dependent



Barroso M, Handy DE, Castro R, The Link Between Hyperhomocysteinemia and Hypomethylation, The Link Between Hyperhomocysteinemia and Hypomethylation: Implications for Cardiovascular Disease,Implications for Cardiovascular Disease. Journal of Inborn Errors of Metabolism and Screening. 2017;5:2326409817698934. doi:10.1177/2326409817698934

20

Medical Intervention Impacting Methylation Pathway

- Seizure meds
- Fenofibrate meds are de-methylators
- Niacin de-methylates
- Cancer therapies
- Methotrexate

21

COMT

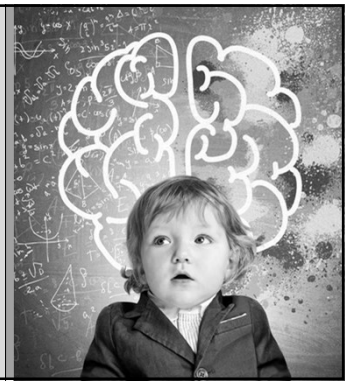
Catecholamine Transferase (COMT)

- High Adrenaline and Norepinephrine triggers the release of the stress hormone cortisol

22

COMT Variant Often Found in High Achievers

- 2 Copies associated improved memory retrieval and better cognitive processing



23

COMT:

INCREASES STRESS AND RISK OF ACUTE CORONARY SYNDROME

- Increased risk of having heart attack under stress 1.7x risk with two copies
- Individuals with variants and elevated homocysteine levels have an additional increased risk (2.94x)

24

APOE

Impact on lipids

- e2/e2 genotype is associated with increased triglycerides and reduced total cholesterol,
- e4/e3 and e4/e4 genotypes are associated with increased total cholesterol, triglycerides and LDL cholesterol
- Carriers of an e4 allele are at 42% higher risk for CHD

25

APOE

Lifestyle response

Statin Response

- e2/e2 or e2/e3 genotype, extremely low-fat diets can increase small dense LDL levels=moderate fat restriction(respond well to statins)
- e4/e3 or e4/e4 genotype, on the other hand=very low-fat dietary restrictions(statins less effective)

26

9P21

Heart Attack Gene: association with atherosclerosis: Vitamin K2

- CDKN2A/2B
- Cyclin dependent kinase inhibitor impact arterial calcification and stiffness
- Increased risk of premature heart disease and abdominal aneurysms

27

PIX2

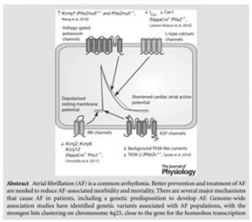
Atrial fibrillation risk

Stroke risk

(used to be called 4q25)

Paired Like Homeodomain 2

PITX2-dependent gene regulation in atrial fibrillation and rhythm control



28

Pharmacogenomics Defined

Pharmacogenomics uses information about a person's genetic makeup, or genome, to choose the drugs and drug doses that are likely to work best for that particular person.

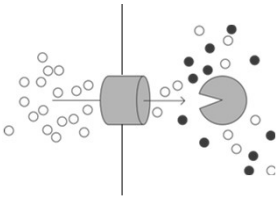
National Institutes of Health
National Human Genome Research Institute

29

A Pharmacogenomic Example:

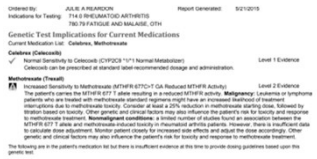
STATIN TOLERABILITY: SLCO1B1

- SLCO1B1=rs4149056
  - Codes for the OATP1B protein (organic anion transporting polypeptide) that takes up statins into the liver. *Non-coding allele* is the variant.
- One copy of C allele gives 4.5x risk of statin induced myopathy
  - Particularly with the hepatically metabolized statins like simvastatin and lovastatin.



30

PHARMACOGENOMIC REPORT EXAMPLE



31

MTHFR	1298A>C AC 677C>T CT	No Increased Risk of Hyperhomocysteinemia	The patient's MTHFR activity is reduced. However, this change is not associated with increased total plasma homocysteine levels.
OPRM1	A118G A/A	Normal OPRM1 Function	Consistent with a normal OPRM1 receptor signaling efficiency induced by exogenous opioids. This is associated with a good analgesia following standard opioid doses and a poor response to naltrexone.
SLCO1B1	521T>C T/C	Decreased Function	Consistent with a decreased SLCO1B1 transporter function. The patient's risk for statin-induced myopathy is intermediate.
UGT2B15	*1/*2	Intermediate Metabolizer	Consistent with a moderately decreased UGT2B15 glucuronidation function. Potential risk for side effects with drug substrates.

Current Patient Medications

Wellbutrin, Sertraline, Crestor

⚠ **Crestor** *Rosuvastatin*	**Increased Myopathy Risk (SLCO1B1: Decreased Function)** The reduced SLCO1B1 function may result in elevated rosuvastatin plasma levels. Because the risk of myopathy increases in patients with high statin plasma levels, the use of high rosuvastatin doses in this patient should be avoided. If rosuvastatin is used in this patient, a closer monitoring of serum creatine kinase and liver function is recommended. Other myopathy predisposing factors include advanced age (≥65), uncontrolled hypothyroidism, renal impairment, comedications, and female gender.	INFORMATIVE
⚠ **Sertraline** *Zoloft®*	**Possible Reduced Response to Sertraline (CYP2C19: Ultra-Rapid Metabolizer)** Sertraline can be prescribed at standard label-recommended dosage and administration. If patient does not respond to recommended maintenance dosing, consider an alternative medication.	INFORMATIVE
✓ **Wellbutrin** *Bupropion*	**Good Response to Bupropion for Smoking Cessation (ANKK1: Unaltered DRD2 function)** Smoking Cessation: The patient's genotype result is associated with a positive response with bupropion treatment.	INFORMATIVE

32

About Cytochrome P450 Enzymes

33

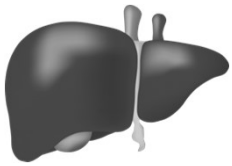
CYP1A2

- Coffee fast and slow metabolizer
- If slow metabolizer higher cardiac risk
- If fast metabolizer… Mild to moderate intake decreased MI and HTN risk

34

Cytochrome P450s (CYP):

- Enzymes that metabolize drugs, toxins, endogenous products in the liver.
- There are several isoforms within the CYP that medications use to be broken down.
  - *CYP2C19* – clopidogrel, amitriptyline, SSRI's*
  - *CYP3A4 – NSAIDs*
  - *CYP2D6* – codeine, paroxetine*



35

CYP2C19

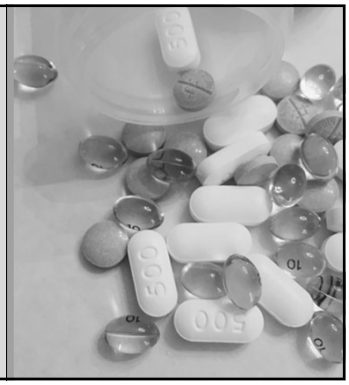
clopidogrel

- Poor metabolizers (loss of CYP2C19 activity) have 2X the risk of having a subsequent adverse cardiac event while receiving treatment with clopidogrel after a myocardial infarction4.
- Ultra-rapid metabolizers (increased CYP2C19 activity) have a reduced risk of major adverse cardiac events while being treated with clopidogrel but are at an increased risk of bleeding.

36

CYP2C19

- Best known for its role in the metabolism of proton pump inhibitors, phenytoin, diazepam, carisoprodol, and clopidogrel.
- Variants in CYP2C19 can cause clopidogrel failure and dangerous variations in phenytoin.



37

Cytochrome P450 (CYP):

Ultra Rapid Metabolizer
- *Lower plasma concentration will increase probability of therapy failure.*
- *Associated with increase function.*

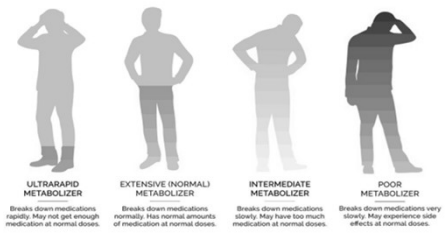
Extensive Metabolizer
- *Normal Metabolism*
- *Associated with normal function.*

Intermediate Metabolizer
- *Reduced metabolism compared to extensive metabolizer*
- *Associated with decreased function.*

Poor Metabolizer
- *Higher plasma concentration that can increase probability of side effects.*
- *Associated with non-functional.*

38

HOW GENETICS CAN AFFECT MEDICATION BLOOD LEVELS



*Phenotype frequency is based on internal Assurex Health data of over 100,000 tested patients.

39

Each Designation has Multiple SNPs

EXAMPLE: CYP2C19

SNP ID	Risk Allele	Allele Name	Function
rs4244285	A	CYP2C19 ***2**	Non-functional
rs4986893	A	CYP2C19 ***3**	Non-functional
rs28399504	G	CYP2C19 ***4**	Decreased
rs12248560	T	CYP2C19 ***17**	Increased
	No Variants Above	CYP2C19 ***1**	Normal/ wildtype

40

Determining Phenotype Metabolism

BASED ON COMBINATION OF ALLELES

Phenotype	Examples of Diplotype	Implications for prodrugsa
Ultra rapid Metabolizer	*17/*17, *1/*17	Lower plasma concentration will increase probability of therapy failure.
Extensive Metabolizer	*1/*1	Normal metabolism
Intermediate Metabolizer	*1/*2, *1/*3, *2/*17	Reduced metabolism compared to extensive metabolizer.
Poor Metabolizer	*2/*2, *2/*3, *3/*3	Higher plasma concentration that can increase probability of side effects.

41

Ethnicity and CYP2C19

- The prevalence of the *2 and *3 alleles vary by ethnicity.
- Percentage of one copy of variant allele carried by ethnicity:

CYP2C19*2:
- Caucasians 25%
- Blacks 30%
- Asians 40-50%

CYP2C19*3:
- Caucasians <1%
- Blacks <1%
- Asians 7%

42

MACULAR DEGENERATION

- USE GENOMICS TO UNDERSTAND DISEASES BETTER
- USE GENOMICS TO DECODE MULTFACTORIAL PREVENTION

44

CFH Y402H

Complement Factor H

vitamin D :)

vitamin A :(

CHROMOSOME 1

COMPLEMENT CASCADE

45

ARMS2/HTRA

CHROMOSOME 10

Age-related Maculopathy Susceptibility Protein2

High Temperature Requirement Factor A1

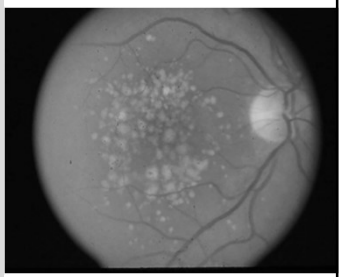


Image source: Joan Kahn, "The ABC's of Drusen", 2020.
Accessed via https://www.ohsu.edu/casey-eye-institute/abcs-drusen

46

AREDS VITAMINS:

- Vitamin C(ascorbic acid) 500 mg
- Vitamin E 400 international units (IU)
- Lutein 10 mg
- Zeaxanthin 2 mg
- Zinc (as zinc oxide) 80 mg
- Copper (as cupric oxide) 2 mg

AREDS 2 (Age-Related Eye Disease Study 2

47

Think Before You Spit

- CDC
- Use as clinical support DECISION TOOL
- Evolving Data
- Clinician Competence
- GINA

CDC Blog, Genomics and Precision Health, Direct to Consumer Genetic Testing: Think Before you Spit, 2018 Posted on April 18, 2017 by Muin J Khoury, Director, Office of Public Health Genomics, Centers for Disease Control and Prevention
https://blogs.cdc.gov/genomics/2017/04/18/direct-to-consumer-2/

Hayden E. 2016 The flip side of person genomics: When a mutation doesn't spell disease. Nature 20986

JAMA 10/3/18 Companies Tout Psychiatric Pharmacogenomic Testing, But is it Ready for a Store Near You

49

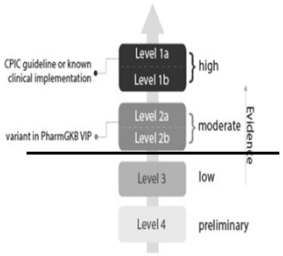
Clinical Pharmacogenetics Implementation Consortium (CPIC)

An international consortium of individual volunteers and a small dedicated staff who are interested in facilitating use of pharmacogenetic tests for patient care… translate into actionable prescribing decisions for affected drugs.

CPIC
Clinical Pharmacogenetics Implementation Consortium

50

Levels of Scientific Evidence



- Level 1A
- Level 1B
- Level 2A
- Level 2B
- Level 3
- Level 4

51

Who gets testing?

- Chronic disease
- Family history
- Positive biomarkers
- Medical mystery patients
- Data Driven

52

Integrating Genomics into Your Practice?

53

Evaluation of a Genomic Tool

A	Analytical validity Is the test sensitive and specific?
C	Clinical validity Is the test not only scientifically valid but predictive of patient outcome? • (harder evolving predictive value regarding polygenic traits)
C	Clinical utility: Does the test help guide a healthcare provider /improve care/ economic utililty/personal utility?
E	Ethical, legal, social issues

Reference website from CDC
https://www.cdc.gov/genomics/gtesting/index.htm#EGAPP
Evaluation of Genomic Applications in Practice and Prevention
(EGAPP™)

54

55

LIVE IT Philosophy

Lake Travis Integrative Medicine

drjulie@laketravisintegrative.com

56

Polling Questions:

Lake Travis Integrative Medicine

drjulie@laketravisintegrative.com

57

POLLING Question 1

Genomics can help Family Physicians understand metabolism of medications such as

A. Statins
B. Blood thinners like clopidogrel
C. Proton Pump Inhibitors
D. All of the Above

58

POLLING Question 2

As of 2024, everyone should get a full genomic analysis for best patient care.

A. True
B. False

59

POLLING Question 3

COMT variant has implications for

A. Handling stress
B. Dopamine metabolism
C. Cardiovascular risk
D. All of the Above

60

POLLING Question 4

Genomic SNP analysis of ARMS2/HTRA and CFHY402H can help us understand why antioxidants can slow Macular Degeneration.

A. True
B. False

61

POLLING Question 5

The MTHFR gene variant is very rare and diagnostic of heart disease.

A. True
B. False

62

MTHFR

Ganguly, P et al. Role of homocysteine in the development of cardiovascular disease. *Nutr J* 2015: 14:6.

Frosst P, Blom HJ, Milos R, et al. A candidate genetic risk factor for vascular disease: a common mutation in methylenetetrahydrofolate reductase. *Nature Genetics*. 1995;10(1):111-113. doi:10.1038/ng0595-111

Hazra A, Kraft P, Lazarus R, et al. Genome-wide significant predictors of metabolites in the one-carbon metabolism pathway. *Hum Mol Genet*. 2009;18(23):4677-4687. doi:10.1093/hmg/ddp428

Li W-X, Dai S-X, Zheng J-J, Liu J-Q, Huang J-F. Homocysteine Metabolism Gene Polymorphisms (MTHFR C677T, MTHFR A1298C, MTR A2756G and MTRR A66G) Jointly Elevate the Risk of Folate Deficiency. *Nutrients*. 2015;7(8):6670-6687. doi:10.3390/nu7085303

Liew S-C, Gupta ED. Methylenetetrahydrofolate reductase (MTHFR) C677T polymorphism: epidemiology, metabolism and the associated diseases. *Eur J Med Genet*. 2015;58(1):1-10. doi:10.1016/j.ejmg.2014.10.004

63

COMT

Gellekink H, Muntjewerff J-W, Vermeulen SHHM, Hermus ARMM, Blom HJ, den Heijer M. Catechol-O-methyltransferase genotype is associated with plasma total homocysteine levels and may increase venous thrombosis risk. *Thromb Haemost*. 2007;98(6):1226-1231.

Voutilainen S, Tuomainen T-P, Korhonen M, et al. Functional COMT Val158Met Polymorphism, Risk of Acute Coronary Events and Serum Homocysteine: The Kuopio Ischaemic Heart Disease Risk Factor Study. *PLOS ONE*. 2007;2(1):e181. doi:10.1371/journal.pone.0000181

APOE

Xu M, Zhao J, Zhang Y, et al. Apolipoprotein E Gene Variants and Risk of Coronary Heart Disease: A Meta-Analysis. *Biomed Res Int*. 2016;2016. doi:10.1155/2016/3912175

Babenko VN, Afonnikov DA, Ignatieva EV, Klimov AV, Gusev FE, Rogaev EI. Haplotype analysis of APOE intragenic SNPs. *BMC Neurosci*. 2018;19(Suppl 1). doi:10.1186/s12868-018-0413-4

64

APOE

Kaufman CS, Morris JK, Vidoni ED, Burns JM, Billinger SA. Apoprotein E4 moderates the association between vascular risk factors and brain pathology *Alzheimer Dis Assoc Disorder* 2021. Jul-Sept: 35(3);223-229

9p21

Heart attack gene: Holdt LM, Teupser D. Recent studies of the human chromosome 9p21 locus, which is associated with atherosclerosis in human populations. *Arterioscler Thromb Vasc Biol*. 2012;32(2):196-206.

Knapen MHJ, Braam LAJLM, Drummen NE, Bekers O, Hoeks APG, Vermeer C. Menaquinone-7 supplementation improves arterial stiffness in healthy postmenopausal women. A double-blind randomised clinical trial. *Thromb Haemost*. 2015;113(5):1135-1144. doi:10.1160/TH14-08-0675

Niemiec P, Gorczynska-Kosiorz S, Iwanicki T, et al. The rs10757278 Polymorphism of the 9p21.3 Locus Is Associated with Premature Coronary Artery Disease in Polish Patients. *Genet Test Mol Biomarkers*. 2012;16(9):1080-1085. doi:10.1089/gtmb.2012.0046

65

PIX2

Martin RIR, Babaei MS, Choy M-K, et al. Genetic variants associated with risk of atrial fibrillation regulate expression of PITX2, CAV1, MYOZ1, C9orf3 and FANCC. *J Mol Cell Cardiol.* 2015;85:207-214. doi:10.1016/j.yjmcc.2015.06.005

Syeda F, Kirchhof P, Fabritz L. PITX2-dependent gene regulation in atrial fibrillation and rhythm control. *The Journal of Physiology*. 2017;595(12):4019-4026. doi:10.1113/JP273123

CYP2c19

Sibbing D et al. Cytochrome 2C19*17 allelic variant, platelet aggregation, bleeding events, and stent thrombosis in clopidogrel-treated patients with coronary stent placement. *Circulation*. 2010; 121: 512-518. .

66

SLC01B1

Group TSC. SLCO1B1 Variants and Statin-Induced Myopathy — A Genomewide Study. *New England Journal of Medicine*. 2008;359(8):789-799. Doi:10.1056/NEJMoa0801936

CYP1A2

Thorn CF, Aklillu E, McDonagh EM, Klein TE, Altman RB. PharmGKB summary: caffeine pathway. *Pharmacogenet Genomics*. 2012;22(5):389-395. doi:10.1097/FPC.0b013e3283505d5e

67

CFHY402

Sharma, Neel Kamal, Amod Gupta, Sudesh Prabhakar, Ramandeep Singh, Suresh Kumar Sharma, Wei Chen, and Akshay Anand. "Association between CFH Y402H Polymorphism and Age-Related Macular Degeneration in North Indian Cohort." *PLOS ONE* 8, no. 7 (July 29, 2013): e70193. https://doi.org/10.1371/journal.pone.0070193.

Munch IC, Toft U, Linneberg A, Larsen M. Precursors of age-related macular degeneration: associations with vitamin A and interaction with CFHY402H in the Inter99 Eye Study. *Acta Ophthalmol*. 2016;94(7):657-662. doi:10.1111/aos.13198

ARMS/HTRA

Tang NP, Zhou B, Wang B, Yu RB. HTRA1 promoter polymorphism and risk of age-related macular degeneration: a meta-analysis. *Ann Epidemiol*. 2009;19(10):740-745. doi:10.1016/j.annepidem.2009.03.002

Micklisch, S., Lin, Y., Jacob, S. *et al*. Age-related macular degeneration associated polymorphism rs10490924 in *ARMS2* results in deficiency of a complement activator. *J Neuroinflammation* 14, 4 (2017). https://doi.org/10.1186/s12974-016-0776-3

68

Notes

Risk Assessment and Treatment for Transient Ischemic Attacks (TIA)

Grant C. Fowler, MD

Professor and Chair, Department of Family and Community Medicine
TCU Burnett School of Medicine
Chief of Primary Service, JPS Health Network
Fort Worth, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Recognize various risk factors of TIA.
2. Apply risk stratification, rapid assessment, and diagnostic imaging techniques to guide the treatment plan and manage patients with TIA.
3. Discuss the risks and benefits of pharmacologic and nonpharmacologic interventions, and other measures to prevent TIA and stroke.

Speaker Disclosure

Dr. Fowler disclosed he has no financial relationships with any ineligible organizations or commercial interests.

Risk Assessment and Treatment for Transient Ischemic Attacks (TIA)

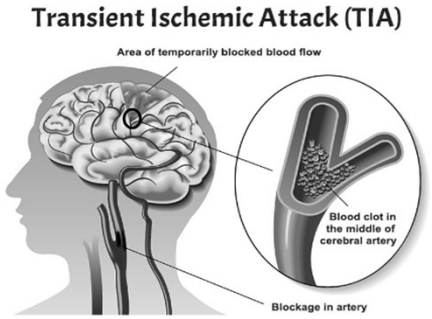
Grant C. Fowler, MD
Professor and Chair, Department of Family and Community Medicine
TCU Burnett School of Medicine
Chief of Primary Service, JPS Health Network
Fort Worth, Texas

1

Speaker Disclosure

Dr. Fowler disclosed he has no financial relationships with any ineligible organizations or commercial interests.

2



3

Transient Ischemic Attack (Risk Assessment and Treatment)

4

TAFP C. Frank Webber Lectureship
April 13, 2024

5

Presentation Objectives

- Compare old vs. new definition of TIA
- Risk factors
- Differential diagnosis
- Risk stratification
- Work-up and treatment
- Risk reduction for strokes (and CV events)

6

Presentation Objectives

- Discuss the need for aggressive treatment in certain populations.

7

Facts

- Approximately 240, 000 TIAs per year in U.S.
- 1 in 3 who have TIA will eventually have a stroke
- Half of these occur within a year

8

Facts

- In general, with very few exceptions, patients with TIA and those with ischemic stroke should be treated the same in terms of secondary prevention

Stroke 52:7 AHA/ ASA 2021 Guidelines for Prevention of Stroke

9

Facts

- BP control, a healthy diet, regular physical activity, and smoking cessation can prevent the overwhelming majority of strokes

Stroke 52:7 AHA/ ASA 2021 Guidelines for Prevention of Stroke

10

Facts

- "In fact, 5 factors — BP, diet, physical inactivity, smoking, and abdominal obesity — accounted for 82% and 90% of the population-attributable risk (PAR) for ischemic and hemorrhagic stroke in the INTERSTROKE study."

Stroke 52:7 AHA/ ASA 2021 Guidelines for Prevention of Stroke

11

12

Old School Definition TIA (Time-based)

- Sudden onset of a focal neurologic symptom and/or sign lasting less than 24 hours and caused by reversible cerebral ischemia
- Problems with this definition?

13

Problems with Old School Definition TIA

- Approximately 50% of patients with time-based TIA syndromes (<24 hours in duration) have ischemic lesions by MRI or other imaging

14

Problems with Old School Definition TIA

- Even when focal transient neurologic symptoms last less than an hour, permanent tissue injury can occur (i.e., infarction)

15

16

New School Definition TIA

- Transient episode of neurologic dysfunction caused by focal brain, spinal cord, or retinal (CNS) ischemia, without acute infarction

17

Ischemic Stroke

- Ischemic stroke is an infarction of central nervous system tissue

18

Risk Factors for TIA

- Family history of stroke or TIA
- Age > 55 years
- Males > females
- HTN
- Diabetes
- Tobacco
- Sickle cell disease

19

Risk Factors for TIA

- Prior TIA
- Ethnicity
- Physical inactivity
- Hyperlipidemia

20

TIA Risk Stratification-ABCD^2 Score

- Age
- Blood pressure
- Clinical features
- Duration of symptoms
- Diabetes

21

Problems with ABCD^2 Score

- 1 in 5 patients with low ABCD^2 score (<4) will have treatable vascular pathology such as:
- Atrial fibrillation
- Significant, symptomatic internal carotid (or large intracranial) artery stenosis

22

Problems with ABCD^2 Score

- Score not always predictive of risk of stroke (as seen in subsequent studies)
- Miscalculation errors can result in poor clinical decisions using ABCD^2 score cut-off

23

ABCD^2 Score Still Drives Treatment

- Age (≥60 years = 1 point)
- Blood pressure elevated at first assessment after TIA (systolic ≥140 mmHg or diastolic ≥90 mmHg = 1 point)
- Clinical features (unilateral weakness = 2 points; isolated speech disturbance = 1 point; other = 0 points)
- Duration of TIA symptoms (≥60 minutes = 2 points; 10 to 59 minutes = 1 point; <10 minutes = 0 points)
- Diabetes (present = 1 point)

24

Differential Diagnosis (Most Common Alternatives)

- Seizure
- Migraine with aura
- Syncope

25

Differential Diagnosis (Less Common)

- Metabolic: hypoglycemia, electrolyte abnormalities or hepatic, renal, or pulmonary encephalopathies (can produce temporary aberrations in behavior and movement)
- Peripheral nerve or nerve root compression neuropathies (transient paresthesia and numbness)
- Vestibulopathy (e.g., transient episodic dizziness)
- Transient global amnesia
- Cerebral amyloid angiopathy

26

Workup

- Labs (CMP, CBC, platelets, TSH, A1c, glucose, lipids, INR, ?UDS?)
- O_2 sat
- ECG
- CT, CTA, MRI
- Carotid ultrasound (usually not digital subtraction angiography which can cause stroke 0.3 to 3%)
- Echo (Transthoracic [bubble] versus Transesophageal)
- ?Holter monitor? In cryptogenic stroke

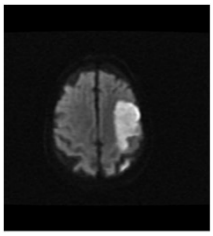
27

Diffusion Weighted MRI

- Uses diffusion of water molecules to generate contrast
- Highly cellular tissues or cellular swelling inhibit Brownian motion
- Especially useful for tumor characterization and noting cerebral ischemia

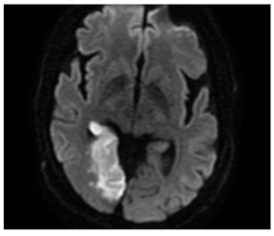
28

Infarct: Left Middle Cerebral



29

Infarct: Right Posterior Cerebral

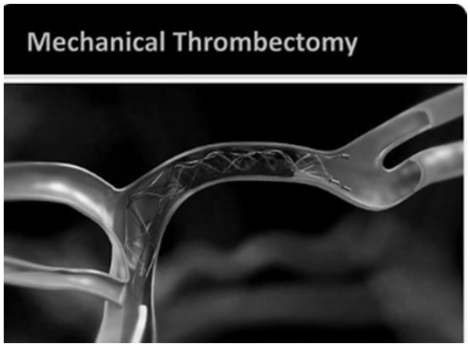


30

Minor Stroke

- No persistent disabling neurologic deficit

31



32

Disabling Stroke

- Thrombolytic therapy can be administered up to 4.5 hours after symptom onset
- Mechanical thrombectomy (interventional radiology) can be administered up to 24 hours after symptom onset

33

Thrombolytic Therapy

- Consider for persistent neurologic deficit which is potentially disabling, even if it has improved

34

Thrombolytic Therapy (Exclusion Criteria, Imaging and BP)

- Intracranial hemorrhage (CT or MRI)
- Persistent elevated BP (unresponsive to treatment and SBP>=185, DBP >=110 mmHg)

35

Thrombolytic Therapy (Hematologic)

- Warfarin or heparin (INR >1.7, PT >15 sec, PTT >40 sec)
- Current DOAC use (with evidence of anticoag on lab)
- Therapeutic dose LMWH (not DVT prophylactic doses)
- Platelet count < 100,000 /mm^3
- Active internal bleeding

36

Thrombolytic Therapy (Exclusion for Hypoglycemia)

- Serum glucose <50 mg/dL (with clinical improvement after dextrose)

37

Thrombolytic Therapy (Exclusion by History)

- Ischemic stroke or severe head trauma in previous 3 months
- Previous intracranial hemorrhage
- Intra-axial intracranial neoplasm
- GI malignancy
- GI hemorrhage within 21 days

38

Thrombolytic Therapy (Exclusion by History)

- Intracranial or intraspinal surgery in last 3 months
- Likely infective endocarditis
- Stroke associated with aortic arch dissection

39

Treatment of Low-Risk TIA or Ischemic Stroke >= Moderate Severity

- Early aspirin therapy (162-325 mg)
- Low Risk TIA ($ABCD^2$< 4) or Ischemic Stroke >= Moderate Severity (NIHSS score is >5)

40

Treatment of High-Risk TIA, Minor Ischemic Stroke

- Dual antiplatelet therapy (DAPT is aspirin 162-325 mg load, then 50 to 100 mg/d; clopidogrel 300 to 600 mg load, then 75 mg/d [alternative aspirin plus ticagrelor])
- High Risk TIA ($ABCD^2$>=4) or Ischemic Stroke < Moderate Severity (NIHSS score <=5)

41

Treatment of High-Risk TIA, Minor Ischemic Stroke

- DAPT (aspirin 162-325 mg load, then 50 to 100 mg/d; clopidogrel 300 to 600 mg load, then 75 mg/d [alternative aspirin plus ticagrelor])
- Stroke due to large artery atherosclerosis (stenosis 70 to 99%)

42

Treatment of High-Risk TIA, Minor Ischemic Stroke

- Duration important: DAPT for 21 days for High-Risk TIA ($ABCD^2$>=4) or Ischemic Stroke Moderate Severity (NIHSS score <=5)
- DAPT can be extended to 90 days for stroke due to large artery atherosclerosis (stenosis 70 to 99%)

43

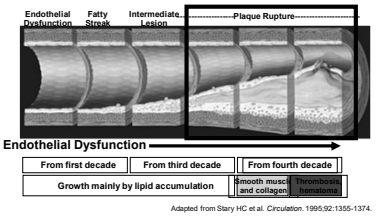
Polling Question #1

If you've had a stroke, survive and die within next 6 months, what killed you?

A. Seizure
B. Auto accident
C. Another stroke
D. Coronary event

44

Atherothrombosis Timeline



Adapted from Stary HC et al. *Circulation*. 1995;92:1355-1374.

46

Polling Question #2

If you've had a stroke, survive, and die > 6 months later, what killed you (in next 5 years)?

A. Seizure
B. Auto accident
C. Another stroke
D. Coronary event

47

Hypertension Guidelines After Stroke

49

Hypertension Guidelines After Stroke

- Neurologically stable patients with cerebrovascular disease a BP goal of <130/80 mm Hg
- BP targets for stroke prevention should be more aligned with targets for prevention of other cardiovascular conditions
- There is insufficient evidence to recommend a lower limit of BP within the normal range for patients with prior stroke (?avoid J-shaped curve)
- Additional research is needed to determine the optimal timing for BP reduction after stroke

Stroke 52:7 AHA/ ASA 2021 Guidelines for Prevention of Stroke

50

Hypertension: How Big is the Problem?

At least 120 million Americans have hypertension

Nearly half of adults in the US have hypertension (systolic > 130 mm Hg or diastolic > 80 mm Hg)

CDC, 2021

51

Populations at Increased Risk for Hypertension

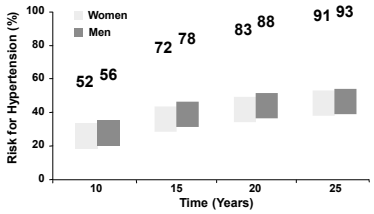
- Elderly[1]
- African Americans[1]
- Mexican Americans[1]
- Patients with type 2 diabetes[1]
- Patients with the metabolic syndrome[1]
- Prehypertensive patients[1]
- Smokers[2]
- Drinkers[3]
- Patients who have abdominal obesity[2] or are overweight or obese[1]
- Patients with elevated hs-CRP levels[2]
- Patients who don't engage in physical activity or who have poor dietary habits[1]

hs-CRP = high-sensitivity C-reactive protein

1. Chobanian AV et al. *Hypertension*. 2003;42:1206-1252.
2. Niskanen L et al. *Hypertension*. 2004;44:859-865.
3. Stranges S et al. *Hypertension*. 2004;44:813-819.

52

Residual Lifetime Risk for Hypertension From Age 55

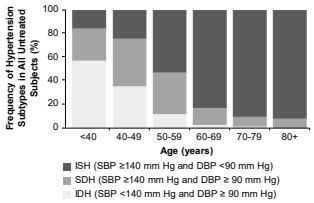


Individuals who are normotensive at age 55 have a 90% lifetime risk of developing hypertension

Vasan RS et al. *JAMA*. 2002;287:1003-1010.

53

Isolated Systolic Hypertension in the Aging U.S. Population

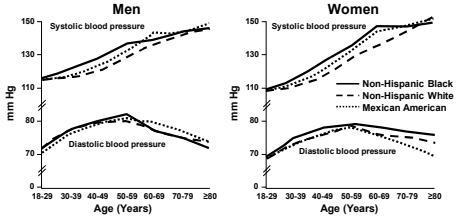


IDH = isolated diastolic hypertension; ISH = isolated systolic hypertension; SDH = combined systolic/diastolic hypertension.

Adapted with permission from Franklin SS et al. *Hypertension*. 2001;37:869-874.

54

JNC 7 Emphasis on SBP: What Prompted the Change?



SBP in the US population increases with advancing age, while DBP tends to plateau after age 60

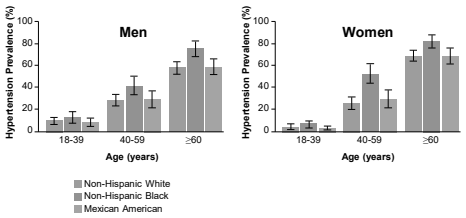
Figure adapted with permission from Burt VL et al. *Hypertension*. 1995;25:305-313.

55

Clinical Features of Hypertension in Various Patient Populations

56

Hypertension Prevalence by Age and Race/Ethnicity in Men and Women



Error bars indicate 95% confidence intervals. Data are weighted to the US population.

Reprinted with permission from Hajjar I, Kotchen TA. *JAMA*. 2003;290:199-206.

57

Clinical Features of Hypertension in the Elderly

- BP is more variable, often due to stiffening of the large arteries and age-related decreases in baroreflex buffering[1]
- Exaggerated BP drops may occur during postural change, after meals, and after exercise[1-3]
- A significant number of elderly persons have widely variable BP with exaggerated high and low extremes[1]
- Systolic BP provides more appropriate classification and risk stratification than diastolic BP[1]

BP = blood pressure

1. Chobanian AV et al. *Hypertension*. 2003;42:1206-1252.
2. Jonsson PV et al. *Arch Intern Med*. 1990;150:1518-1524.
3. Kelley GA, Kelley KS. *Hypertension*. 2000;35:838-843.

58

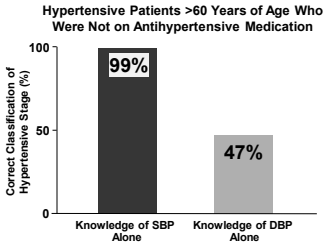
Clinical Features of Hypertension in Minorities

- Hypertension is more prevalent, occurs earlier, and is more severe in African Americans than in whites[1,2]
- Socioeconomic factors and lifestyle may be barriers to blood pressure control[3]
- Salt content of some traditional diets in minorities may be very high[1]

1. Chobanian AV et al. *Hypertension*. 2003;42:1206-1252.
2. Douglas JC et al. *Arch Intern Med*. 2003;163:525-541.
3. Chobanian AV et al. *JAMA*. 2003;289:2560-2572.

59

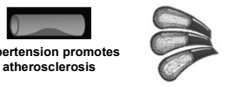
Classification of Hypertension Stage by SBP vs. DBP: Framingham Heart Study



Lloyd-Jones DM et al. *Hypertension*. 1999;34:381-385.

60

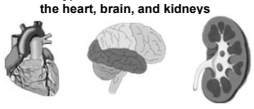
Hypertension is an Independent Risk Factor for CVD, Stroke, and Kidney Disease



Hypertension promotes atherosclerosis

Atherosclerosis involves both coronary and renal arteries

Hypertension can affect the heart, brain, and kidneys



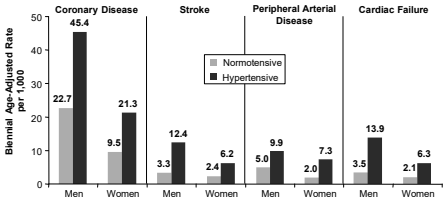
CVD = cardiovascular disease.

Dzau V, Braunwald E. *Am Heart J*. 1991;121(4 pt 1):1244-1263.
Sarnak MJ, Levey AS. *Am J Kidney Dis*. 2000;35(4 suppl 1):S117-S131.
Libby P. *Sci Am*. 2002;286:46-55.
Chobanian AV et al. *Hypertension*. 2003;42:1206-1252.

61

Risk of Cardiovascular Events by Hypertensive Status

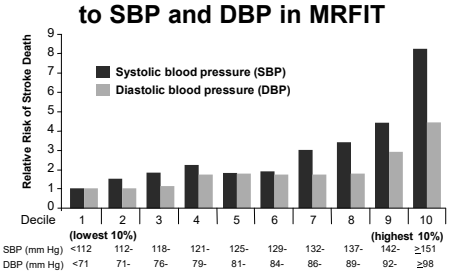
36-Year Follow-up in Patients Aged 35-64 Years



Reprinted with permission from Kannel WB. *JAMA*. 1996;275:1571-1576.

62

Risk of Stroke Death According to SBP and DBP in MRFIT



MRFIT = Multiple Risk Factor Intervention Trial.
Figure adapted with permission from He J, Whelton PK. *Am Heart J.* 1999;138:S211-S219. Copyright 1999, Mosby, Inc. Data from Stamler J et al. *Arch Intern Med.* 1993;153:598-615.

63

Hyvet Trial

- 30% reduction in fatal or nonfatal stroke (95% confidence interval [CI], −1 to 51; P=0.06)
- 39% reduction in the rate of death from stroke (95% CI, 1 to 62; P=0.05)
- 21% reduction in the rate of death from any cause (95% CI, 4 to 35; P=0.02), a 23% reduction in the rate of death from cardiovascular causes (95% CI, −1 to 40; P=0.06

N Engl J Med 2008; 358:1887-1898

64

64

Hyvet Trial

- 3,845 patients from Europe, China, Australasia, Tunisia over age 80 with systolic BP > 160 mm Hg
- Randomized to receive either indapamide (thiazide type diuretic) or placebo
- Median follow-up was 1.8 years

N Engl J Med 2008; 358:1887-1898

65

65

Hyvet Trial

- 64% reduction in the rate of heart failure (95% CI, 42 to 78; P<0.001)

N Engl J Med 2008; 358:1887-1898

66

66

SPARCL Trial

- Median follow-up of 4.9 years
- 265 patients (11.2%) on atorvastatin and 311 patients (13.1%) on placebo had fatal or nonfatal stroke (5-year absolute risk reduction 2.2%)
- Atorvastatin group had 218 ischemic strokes and 55 hemorrhagic strokes, placebo had 274 ischemic and 33 hemorrhagic strokes

N Engl J Med 2006; 355:549-559

67

67

SPARCL Trial

- 4,731 patients with stroke or TIA within 1 to 6 months (no known CAD)
- LDL cholesterol 100 to 190 mg/ dL
- Randomized to 80 mg atorvastatin per day or placebo (double-blinded)

N Engl J Med 2006; 355:549-559

68

68

SPARCL Trial

- Mean LDL cholesterol 73 mg/dL on treatment versus 129 mg/dL on placebo

N Engl J Med 2006; 355:549-559

69

69

Treat Stroke to Target

- Ischemic stroke in previous 3 months or TIA in last 15 days (France and Korea)
- 2,860 patients, 1,430 assigned to each target group
- Mean baseline LDL was 135 mg/dL
- Mean achieved LDL was 65 mg/dL (lower target group) and 96 mg/dL (higher target group)

N Engl J Med 2020; 382:9-19

70

70

Treat Stroke to Target

- Treatment was statin and/ or ezetimibe if not reaching target
- Median follow-up of 3.5 years
- Primary end point: ischemic stroke, MI, new symptoms leading to urgent coronary or carotid revascularization, or death from CV cause

N Engl J Med 2020; 382:9-19

71

71

Treat Stroke to Target

- 121 (8.5%) patients had events in the lower target group and 156 (10.9%) in the higher target group
- Median follow-up of 3.5 years

N Engl J Med 2020; 382:9-19

72

72

Lifestyle Changes

- Tobacco cessation (and probably cannabis cessation) important
- Prediabetes is present in ≈30% of patients with acute ischemic stroke and is associated with increased risk for recurrence
- Mediterranean or DASH diet

Stroke 52:7 AHA/ ASA 2021 Guidelines for Prevention of Stroke

73

73

Lifestyle Changes

- Exercise!

Stroke 52:7 AHA/ ASA 2021 Guidelines for Prevention of Stroke

74

74

Lifestyle Changes

- Stroke risk is associated with heavy alcohol consumption (>4 drinks in a day or >14 drinks a week in men; >3 drinks a day or >7 drinks a week in women)
- High alcohol use (>4 drinks a day) is independent risk factor for stroke recurrence at 90 days

Stroke 52:7 AHA/ ASA 2021 Guidelines for Prevention of Stroke

75

75

Polling Question #3

What is the lifestyle change most effective for lowering blood pressure?

A. Low salt diet
B. DASH diet
C. Weight loss
D. Exercise

76

What is the updated lifestyle change most effective for lowering blood pressure?

	Systolic decrease	Diastolic decrease
DASH diet plus low salt diet	11.5	5.8
DASH diet	5.9	2.9
Low salt (< 1200 mg/d)	6.7	3.5
Potassium salt substitute	4.8	2.4
Aerobics	4.1 to 5.6	1.8 to 5.2
Weight Loss	4.5	3.2
Mod Alcohol	5.5	4.0

79

Notes

Ethics: Racial Disparities in Cancer Screening

Trisha L. Amboree, PhD, MPH

Postdoctoral Fellow, Department of Behavioral Sciences
UT MD Anderson Cancer Center
Houston, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Recognize and address unconscious bias in patient care to provide treatment more equitably to minority and underserved patients.
2. Incorporate into clinical practice appropriate strategies to address disparities to improve access care for patients with cancer.
3. Recommend more effective therapies to patients from underserved communities.
4. Describe ways to implement change to improve care for minority and underserved patients.

Speaker Disclosure

Dr. Amboree disclosed she has no financial relationships with any ineligible organizations or commercial interests.

Racial Disparities in Cancer Screening

Trisha L. Amboree, PhD MPH
Postdoctoral Fellow, Department of Behavioral Science
The University of Texas MD Anderson Cancer Center

2024 C. Frank Webber Lectureship and Interim Session
Texas Academy of Family Physicians
April 13, 2024

1

1

Disclosures

- Honorarium for this talk
- No other financial relationships or conflicts of interest to disclose

2

2

Learning Objectives

1. Recognize and address unconscious bias in patient care to provide treatment more equitably to minority and underserved patients.
2. Incorporate into clinical practice appropriate strategies to address disparities to improve access to care for patients with cancer.
3. Recommend more effective therapies to patients from underserved communities.
4. Describe ways to implement change to improve care for minority and underserved patients.

6

6

What do we mean by racial disparities?

Let's define a few key terms…

7

7

KNOWLEDGE CHECK – 1:

Social construction and categorization of people based on perceived shared physical traits.

A. RACE
B. ETHNICITY

8

8

What do we mean by racial disparities?

RACE ➡ *"social construction and categorization of people based on perceived shared physical traits that result in the maintenance of a sociopolitical hierarchy."*

American Psychological Association, 2024.

10

10

What do we mean by racial disparities?

RACE ⇨ *"social construction and categorization of people based on perceived shared physical traits that result in the maintenance of a sociopolitical hierarchy."*

ETHNICITY ⇨ *"a characterization of people based on having a shared culture (e.g., language, food, music, dress, values, and beliefs) related to common ancestry and shared history."*

American Psychological Association, 2024.

11

11

What do we mean by racial disparities?

RACE ⇨ *"social construction and categorization of people based on perceived shared physical traits that result in the maintenance of a sociopolitical hierarchy."*

ETHNICITY ⇨ *"a characterization of people based on having a shared culture (e.g., language, food, music, dress, values, and beliefs) related to common ancestry and shared history."*

DISPARITY ⇨ *"lack of equality or similarity, especially in a way that is not fair."*

American Psychological Association, 2024.
Cambridge Advanced Learner's Dictionary & Thesaurus

12

12

What do we mean by racial disparities?

RACE ⇨ *"social construction and categorization of people based on perceived shared physical traits that result in the maintenance of a sociopolitical hierarchy."*

ETHNICITY ⇨ *"a characterization of people based on having a shared culture (e.g., language, food, music, dress, values, and beliefs) related to common ancestry and shared history."*

DISPARITY ⇨ *"lack of equality or similarity, especially in a way that is not fair."*

"Imbalance and incongruity between the treatment of racial groups"

American Psychological Association, 2024.
Cambridge Advanced Learner's Dictionary & Thesaurus
Howard University School of Law, 2023

13

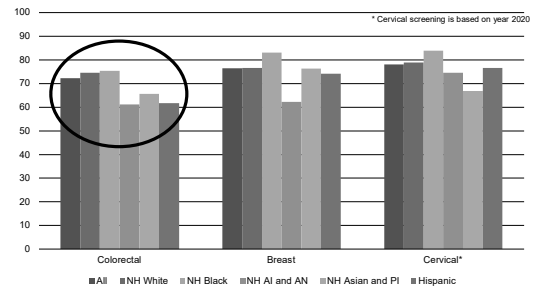
13

But are these disparities currently present in cancer screening and care?

14

14

Racial Disparities in Cancer Screening

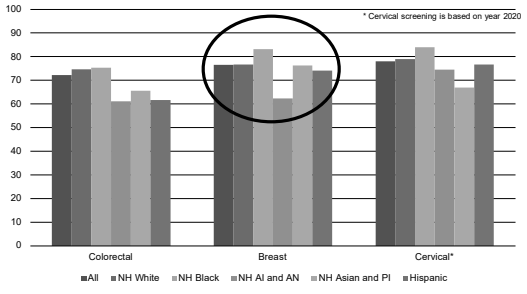


U.S. Cancer Statistics Working Group, 2023.

15

15

Racial Disparities in Cancer Screening

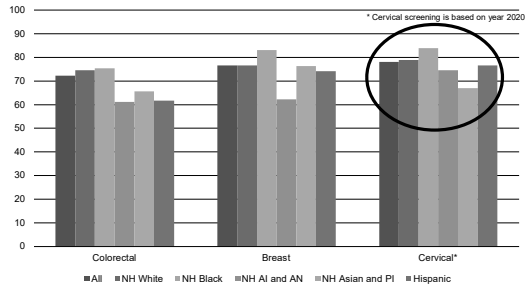


U.S. Cancer Statistics Working Group, 2023.

16

16

Racial Disparities in Cancer Screening



U.S. Cancer Statistics Working Group, 2023.

17

17

Racial Disparities in Cancer Screening

Percentage of women overdue for cervical cancer screenings	
2005	2019
14%	23%

Predicted Probability of Overdue Cervical Screening

	Age 21-29y	Age 30-65y
Asian	36%	36%
Hispanic	31%	30%
NH Black	23%	21%
NH White	22%	21%
Other	28%	29%

	Age 21-29y	Age 30-65y
Private	20%	20%
Public	28%	28%
Other	24%	23%
None	41%	41%

Suk et al., *JAMA Netw Open*, 2022.

18

18

Racial Disparities in Cancer Screening

Percentage of women overdue for cervical cancer screenings	
2005	2019
14%	23%

Predicted Probability of Overdue Cervical Screening

	Age 21-29y	Age 30-65y
Asian	36%	36%
Hispanic	31%	30%
NH Black	23%	21%
NH White	22%	21%
Other	28%	29%

	Age 21-29y	Age 30-65y
Private	20%	20%
Public	28%	28%
Other	24%	23%
None	41%	41%

Suk et al., *JAMA Netw Open*, 2022.

19

19

Racial Disparities in Cancer Screening

Percentage of women overdue for cervical cancer screenings	
2005	2019
14%	23%

Predicted Probability of Overdue Cervical Screening

	Age 21-29y	Age 30-65y
Asian	36%	36%
Hispanic	31%	30%
NH Black	23%	21%
NH White	22%	21%
Other	28%	29%

	Age 21-29y	Age 30-65y
Private	20%	20%
Public	28%	28%
Other	24%	23%
None	41%	41%

Suk et al., *JAMA Netw Open*, 2022.

20

20

Racial Disparities in Cancer Screening

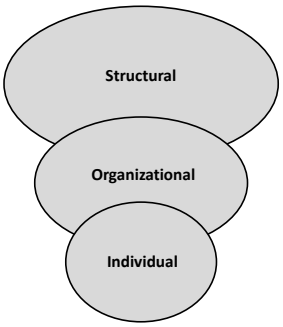
- US counties with higher social vulnerability had lower rates of USPSTF-recommended cancer screenings
- Social vulnerability included SES, housing, racial and ethnic minority groups, language barriers, and more

Bauer et al., *JAMA Netw Open*, 2022.

21

21

- National health policies
- State health policies
- Local community environment
- Healthcare settings
- Provider and team
- Family and social support

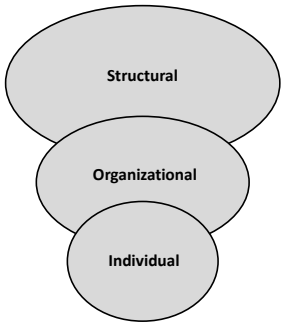


Gorin SS et al., *J Natl Cancer Inst Monogr.*, 2012

29

29

- National health policies
- State health policies
- Local community environment
- Healthcare settings
- Provider and team
- Family and social support



Gorin SS et al., *J Natl Cancer Inst Monogr.*, 2012

30

30

Learning Objectives

1. Recognize and address unconscious bias in patient care to provide treatment more equitably to minority and underserved patients.
2. Incorporate into clinical practice appropriate strategies to address disparities to improve access to care for patients with cancer.
3. Recommend more effective therapies to patients from underserved communities.
4. Describe ways to implement change to improve care for minority and underserved patients.

31

31

What do we mean by unconscious bias?

BIAS ⇨ *"a prejudice in favor of or against one thing, person, or group compared with another usually in a way that's considered to be unfair."*

UCSF: Office of Diversity and Outreach, 2024

32

32

What do we mean by unconscious bias?

BIAS ⇨ *"a prejudice in favor of or against one thing, person, or group compared with another usually in a way that's considered to be unfair."*

UNCONSCIOUS BIAS ⇨ *"are social stereotypes about certain groups of people that individuals form outside their own conscious awareness."*

UCSF: Office of Diversity and Outreach, 2024

33

33

KNOWLEDGE CHECK – 2:

Almost everyone holds some level of unconscious bias.

A. TRUE
B. FALSE

34

34

What do we mean by unconscious bias?

BIAS ⇨ *"a prejudice in favor of or against one thing, person, or group compared with another usually in a way that's considered to be unfair."*

UNCONSCIOUS BIAS ⇨ *"are social stereotypes about certain groups of people that individuals form outside their own conscious awareness."*

EVERYONE holds some level of unconscious bias.

UCSF: Office of Diversity and Outreach, 2024

36

36

KNOWLEDGE CHECK – 3:

Having unconscious bias means that you are racist.

A. TRUE
B. FALSE

37

37

Unconscious Bias if Left Unaddressed…

Can lead to differential treatment of patients
- Deeply impact patient safety
- Lack of patient-centered care
- Lower interpersonal treatment
- Lower patient trust
- Poor communication

39

39

How can we **recognize** our unconscious bias?

Standardized tests to measure implicit bias - The Implicit Association Test (IAT)
- Race IAT: 75% test takers demonstrated automatic white preference
- Prediction of bias but translation to behavior is unclear

Marcelin et al., *J Infect Dis.*, 2019
Greenwald et al., *J Pers Soc Psychol.*, 1998
Banaji et al. *USA: Delacorte Press,* 2013

40

40

How can we **recognize** our unconscious bias?

Standardized tests to measure implicit bias - The Implicit Association Test (IAT)
- Race IAT: 75% test takers demonstrated automatic white preference
- Prediction of bias but translation to behavior is unclear

Deliberative self-reflection

Marcelin et al., *J Infect Dis.*, 2019
Greenwald et al., *J Pers Soc Psychol.*, 1998
Banaji et al. *USA: Delacorte Press,* 2013
Phillips et al., *Plast Reconstr Surg,* 2016

41

41

How can we **address** our unconscious bias?

Multifactorial approaches
- Be Aware
- Be Systematic
- Be Open

Marcelin et al., *J Infect Dis.*, 2019

42

42

How can we **address** our unconscious bias?

Multifactorial approaches
- Be Aware
- Be Systematic
- Be Open

- Cultural Competency and Humility
- Counter-stereotypical encounters
- Diversification of group

Marcelin et al., *J Infect Dis.*, 2019

43

43

Learning Objectives

1. Recognize and address unconscious bias in patient care to provide treatment more equitably to minority and underserved patients.
2. Incorporate into clinical practice appropriate strategies to address disparities to improve access to care for patients with cancer.
3. Recommend more effective therapies to patients from underserved communities.
4. Describe ways to implement change to improve care for minority and underserved patients.

44

44

Strategies to Address Disparities

- Understand the factors contributing to disparities
- Transdisciplinary targeted interventions
- Community engagement

Kale et al., *Cureus.*, 2023

45

45

Strategies to Address Disparities

- Understand the factors contributing to disparities
- Transdisciplinary targeted interventions
- Community engagement

"Community engagement is a key strategy for reducing health inequities, including cancer disparities. By actively involving affected communities, community engagement helps to address the underlying social determinants of health, such as poverty, limited education, discrimination, and a lack of access to resources. It promotes equity by ensuring interventions are tailored to diverse populations' needs and contexts."

Kale et al., *Cureus.*, 2023

46

46

Strategies to Address Disparities

Case study: Community Health Workers (CHWs) in Breast Cancer Prevention

- Engaged in education related to breast cancer screening
- Provided direct assistance in breast cancer screening
- Performed patient navigational services

Kale et al., *Cureus.*, 2023
Hand et al., *Glob Health Action.*, 2021

50

50

KNOWLEDGE CHECK – 4:

Community health workers and patient navigators are the same thing.

A. TRUE
B. FALSE

51

51

KNOWLEDGE CHECK:

Community health workers or outreach workers tend to work in a community setting linking patients to primary care providers, health information, health screening, financial assistance or transportation.

PNCT, 2024

53

53

KNOWLEDGE CHECK:

Community health workers or outreach workers tend to work in a community setting linking patients to primary care providers, health information, health screening, financial assistance or transportation.

Patient navigators usually work in a clinic or hospital working closely with patients to reduce the barriers that keep them from getting healthcare. Barriers may be related to low income, transportation, childcare, language or ability to read forms and understand the healthcare system.

54

Example of Patient Navigation:

1. When there is a cultural, language or other issue that the doctor should know about, the patient navigator can explain the situation to the doctor. They also translate for doctors and patients during medical appointments.

2. The patient navigator meets regularly with oncology care team to discuss specific patients. The care team lets the navigator know when test results come back so they can make a follow-up visit with the patient.

3. The navigator works with administrators to coordinate patient appointments and make sure medical records are available. This helps patients go through the process of diagnosis and treatment as quickly as possible.

55

Learning Objectives

1. Recognize and address unconscious bias in patient care to provide treatment more equitably to minority and underserved patients.
2. Incorporate into clinical practice appropriate strategies to address disparities to improve access to care for patients with cancer.
3. Recommend more effective therapies to patients from underserved communities.
4. Describe ways to implement change to improve care for minority and underserved patients.

56

Recommending Effective Therapies

- The issue with the effectiveness of care is often not the care itself, but actually being able to get populations who need care into care
  - Limited access to care
  - Delays in treatment

57

Recommending Effective Therapies

- The issue with the effectiveness of care is often not the care itself, but actually being able to get populations who need care into care
  - Limited access to care
  - Delays in treatment
- Assess the communities you serve to see where gaps in appropriate care are

"A robust culture of equity depends on staff and providers recognizing that disparities may exist within a patient population and taking responsibility for reducing them."

58

Recommending Effective Therapies

The Joint Commission specifically recommends to:

1. Collect and stratify data specific to the communities you serve
2. Analyze data and community feedback to identify opportunities for improvement
3. Commit to achieving diversity and inclusion to address care disparities
4. Undertake initiatives to rectify care disparities

62

Recommending Effective Therapies

The Joint Commission specifically recommends to:

1. Collect and stratify data specific to the communities you serve
2. Analyze data and community feedback to identify opportunities for improvement
3. Commit to achieving diversity and inclusion to address care disparities
4. Undertake initiatives to rectify care disparities

Year	Economic Burden
2020	$126 billion
2050	$353 billion

The Joint Commission., *Sentinel Event Alert*, 2021

Wyatt et al., *IHI White Paper*, 2016

63

63

Learning Objectives

1. Recognize and address unconscious bias in patient care to provide treatment more equitably to minority and underserved patients.
2. Incorporate into clinical practice appropriate strategies to address disparities to improve access to care for patients with cancer.
3. Recommend more effective therapies to patients from underserved communities.
4. Describe ways to implement change to improve care for minority and underserved patients.

64

64

KNOWLEDGE CHECK – 5:

Definition: A growing research field that seeks to improve how evidence-based interventions are successfully adopted, implemented, and maintained in health care delivery and community settings.

A. Intervention mapping
B. Implementation science

65

65

Implementing Change

"The gap between what is known to optimize healthcare delivery and what is actually implemented in everyday practice remains one of the most important issues hindering the healthcare systems and public health around the world. Finding ways to enhance access and awareness of patients, providers and healthcare organizations (dissemination) and to facilitate adoption and integration of best evidence into practice (implementation) are essential to improving health care and health outcomes in underserved communities."

Nooraie & Noyes., *Front Health Serv*, 2023

67

67

Implementing Change

- Supportive infrastructures and coordination among various levels of healthcare system

Nooraie & Noyes., *Front Health Serv*, 2023

68

68

Implementing Change

- Supportive infrastructures and coordination among various levels of healthcare system
  - Multidisciplinary cancer care delivery teams
  - Regional cancer care networks
  - Financial navigators and patient navigators

Nooraie & Noyes., *Front Health Serv*, 2023
Crabtree-Ide et al., *Front Health Serv*, 2022

69

69

Implementing Change

- Supportive infrastructures and coordination among various levels of healthcare system
  - Multidisciplinary cancer care delivery teams
  - Regional cancer care networks
  - Financial navigators and patient navigators

Nooraie & Noyes., *Front Health Serv*, 2023
Crabtree-Ide et al., *Front Health Serv*, 2022
Wheeler et al., *Front Health Serv*, 2022

70

70

In Summary…

- Commitment to growing, learning, reflection, and honesty
- Transdisciplinary collaboration
- Use of patient navigators
- Community engagement

71

71

Some Further Reading…

- Kale S, Hirani S, Vardhan S, et al. Addressing Cancer Disparities Through Community Engagement: Lessons and Best Practices. *Cureus*. 2023;15(8):e43445. Published 2023 Aug 14. doi:10.7759/cureus.43445
- The Joint Commission. Addressing health care disparities by improving quality and safety. *Sentinel Event Alert*, Issue 64, 2021 Nov 10. jointcommission.org.
- UCSF: Office of Diversity and Outreach. Unconscious Bias Training. 2024. Available at: https://diversity.ucsf.edu/programs-resources/training/unconscious-bias-training#item-92.

72

72

References

1. Psychology topics: Race and Ethnicity. *American Psychological Association*. Updated 2024. Accessed March 10, 2024. https://www.apa.org/topics/race-ethnicity
2. Disparity. Cambridge Dictionary, Cambridge University Press and Assessment. Updated 2024. Access March 10, 2024. https://dictionary.cambridge.org/us/dictionary/english/disparity
3. Social Justice: Racial Disparity. Vernon E. Jordan Law Library, Howard University School of Law. Updated October 19, 2023. https://library.law.howard.edu/socialjustice/disparity#:~:text=Racial%20disparity%20refers%20to%20the,aspects%20of%20life%20and%20society
4. U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2022 submission data (1999-2020): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; https://www.cdc.gov/cancer/dataviz, released in November 2023.
5. Suk R, Hong YR, Rajan SS, Xie Z, Zhu Y, Spencer JC. Assessment of US Preventive Services Task Force Guideline-Concordant Cervical Cancer Screening Rates and Reasons for Underscreening by Age, Race and Ethnicity, Sexual Orientation, Rurality, and Insurance, 2005 to 2019. *JAMA Netw Open*. 2022;5(1):e2143582. Published 2022 Jan 4. doi:10.1001/jamanetworkopen.2021.43582
6. Bauer C, Zhang K, Xiao Q, Lu J, Hong YR, Suk R. County-Level Social Vulnerability and Breast, Cervical, and Colorectal Cancer Screening Rates in the US, 2018. *JAMA Netw Open*. 2022;5(9):e2233429. Published 2022 Sep 1. doi:10.1001/jamanetworkopen.2022.33429
7. Gorin SS, Badr H, Krebs P, Prabhu Das I. Multilevel interventions and racial/ethnic health disparities. *J Natl Cancer Inst Monogr*. 2012;2012(44):100-111. doi:10.1093/jncimonographs/lgs015
8. Unconscious Bias Training. UCSF Office of Diversity and Outreach. Updated 2024. https://diversity.ucsf.edu/programs-resources/training/unconscious-bias-training#item-92
9. Marcelin JR, Siraj DS, Victor R, Kotadia S, Maldonado YA. The Impact of Unconscious Bias in Healthcare: How to Recognize and Mitigate It. *J Infect Dis*. 2019;220(220 Suppl 2):S62-S73. doi:10.1093/infdis/jiz214
10. Greenwald AG, McGhee DE, Schwartz JL. Measuring individual differences in implicit cognition: the implicit association test. *J Pers Soc Psychol* 1998; 74:1464–80.
11. Banaji MR, Greenwald AG. Blindspot: hidden biases of good people. 1st ed. USA: Delacorte Press, 2013.
12. Phillips NA, Tannan SC, Kallainen LK. Understanding and overcoming implicit gender bias in plastic surgery. *Plast Reconstr Surg* 2016; 138:1111–6.
13. Kale S, Hirani S, Vardhan S, et al. Addressing Cancer Disparities Through Community Engagement: Lessons and Best Practices. *Cureus*. 2023;15(8):e43445. Published 2023 Aug 14. doi:10.7759/cureus.43445
14. Hand T, Rosseau NA, Stiles CE, et al. The global role, impact, and limitations of Community Health Workers (CHWs) in breast cancer screening: a scoping review and recommendations to promote health equity for all. *Glob Health Action*. 2021;14(1):1883336. doi:10.1080/16549716.2021.1883336
15. Community Health Workers and Patient Navigators. The Patient Navigation & Community Health Worker Training. https://patientnavigatortraining.org/community-health-workers-and-patient-navigators/#:~:text=Community%20Health%20workers%2C%20or%20outreach,a%20clinic%20or%20a%20hospital
16. The Joint Commission. Addressing health care disparities by improving quality and safety. *Sentinel Event Alert*, Issue 64, 10 November 2021. https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-64-addressing-hc-disparities-final.pdf
17. Wyatt R, et al. Achieving Health Equity: A Guide for Health Care Organizations. IHI White Paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2016.
18. Yousefi Nooraie R, Noyes K. Editorial: Challenges for the provision of guideline-recommended cancer care to rural and medically underserved communities. *Front Health Serv*. 2023;2:1113916. Published 2023 Jan 10. doi:10.3389/frhs.2022.1113916
19. Crabtree-Ide C, Sevdalis N, Bellchusen P, et al. Strategies for Improving Access to Cancer Services in Rural Communities: A Pre-implementation Study. *Front Health Serv*. 2022;2:818519. Published 2022 Mar 14. doi:10.3389/frhs.2022.818519
20. Wheeler SB, Birken SA, Wagi CR, et al. Core functions of a financial navigation intervention: An in-depth assessment of the Lessening the Impact of Financial Toxicity (LIFT) intervention to inform adaptation and scale-up in diverse oncology care settings. *Front Health Serv*. 2022;2:958831. Published 2022 Nov 9. doi:10.3389/frhs.2022.958831

73

73

THANK YOU!

Trisha L. Amboree, PhD, MPH
TLAmboree@mdanderson.org

74

74

Notes

Why Family Physicians are Ideally Suited to Reduce Maternal Mortality

Eugene Toy, MD

Professor, Department of OB/GYN and Reproductive Sciences
Assistant Dean for Educational Programs
McGovern Medical School, UT Health Houston
Houston, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Describe the increased maternal mortality rate in the United States and Texas and its comparative rate with other developed countries.
2. List the most common causes of maternal mortality in Texas.
3. Describe the recommended maternal morbidity conditions from the Centers for Disease Control and Prevention.
4. Verbalize some interventions that have impacted maternal morbidity and mortality.
5. Apply key principles of Quality Assurance/Performance Improvement to reduce maternal morbidity and mortality to their healthcare setting.
6. Describe the unique perspective and role of family physicians in impacting maternal morbidity and mortality.

Speaker Disclosures

Dr. Toy disclosed he has no financial relationships with any ineligible organizations or commercial interests.

Why Family Physicians are Ideally Suited to Reduce Maternal Mortality

Eugene C. Toy, MD, FACOG
Diplomate, American Board of Family Medicine
Medical Director, Texas ACOG LoMC Verification Program
Past Chair, HHSC Perinatal Advisory Council
Professor in Obstetrics and Gynecology

April 2024

1

1

Disclosures

- **Dr. Toy is Medical Director for the ACOG Levels of Care Designation Program in Texas. He does not receive any financial renumeration from the designation program.**

2

2

Objectives

1. **Discuss U.S. & TX Maternal mortality rate vs. other developed countries.**
2. **List most common causes of maternal mortality in Texas.**
3. **Review recommended CDC maternal morbidity conditions.**
4. **Interventions impacting maternal M&M.**
5. **QAPI to reduce maternal M&M to their healthcare setting.**
6. **Family physicians' unique role in reducing maternal M&M.**

3

3

It's more than numbers… it's about lives

4

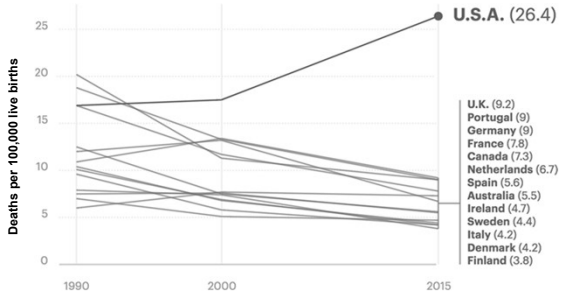
4

Part 1: US & TX Mat Mortality Rates

5

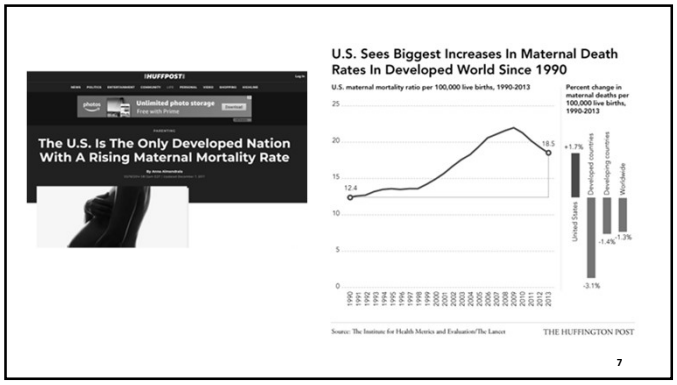
5

U.S .Maternal Mortality Rate

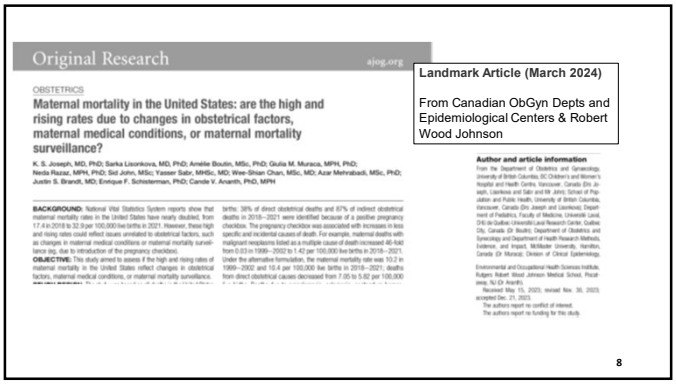


6

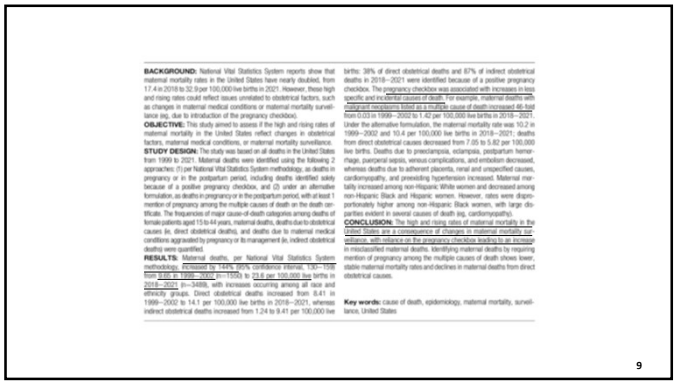
6


HUFFPOST
The U.S. Is The Only Developed Nation With A Rising Maternal Mortality Rate
U.S. Sees Biggest Increases In Maternal Death Rates In Developed World Since 1990
U.S. maternal mortality ratio per 100,000 live births, 1990-2013
Percent change in maternal deaths per 100,000 live births, 1990-2013
12.4
18.5
+1.7%
-1.4%
-3.1%
-1.3%
United States
Developed countries
Developing countries
Worldwide
Source: The Institute for Health Metrics and Evaluation/The Lancet
THE HUFFINGTON POST
7

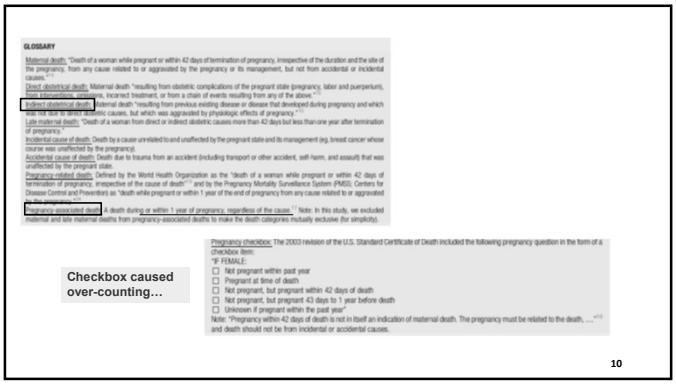
7


Original Research
ajog.org
OBSTETRICS
Maternal mortality in the United States: are the high and rising rates due to changes in obstetrical factors, maternal medical conditions, or maternal mortality surveillance?
Landmark Article (March 2024)
From Canadian ObGyn Depts and Epidemiological Centers & Robert Wood Johnson
Author and article information
8

8


BACKGROUND: National Vital Statistics System reports show that maternal mortality rates in the United States have nearly doubled, from 17.4 in 2018 to 32.9 per 100,000 live births in 2021. However, these high and rising rates could reflect issues unrelated to obstetrical factors, such as changes in maternal medical conditions or maternal mortality surveillance (eg, due to introduction of the pregnancy checkbox).
OBJECTIVE: This study aimed to assess if the high and rising rates of maternal mortality in the United States reflect changes in obstetrical factors, maternal medical conditions, or maternal mortality surveillance.
STUDY DESIGN: The study was based on all deaths in the United States from 1999 to 2021. Maternal deaths were identified using the following 2 approaches: (1) per National Vital Statistics System methodology, as deaths in pregnancy or in the postpartum period, including deaths identified solely because of a positive pregnancy checkbox, and (2) under an alternative formulation, as deaths in pregnancy or in the postpartum period, with at least 1 mention of pregnancy among the multiple causes of death on the death certificate. The frequencies of major cause-of-death categories among deaths of female patients aged 15 to 44 years, maternal deaths, deaths due to obstetrical causes (ie, direct obstetrical deaths), and deaths due to maternal medical conditions aggravated by pregnancy or its management (ie, indirect obstetrical deaths) were quantified.
RESULTS: Maternal deaths, per National Vital Statistics System methodology, increased by 144% (95% confidence interval, 130–159) from 9.85 in 1999–2002 (n=1,093) to 23.6 per 100,000 live births in 2018–2021 (n=3,489), with increases occurring among all race and ethnicity groups. Direct obstetrical deaths increased from 8.41 in 1999–2002 to 14.1 per 100,000 live births in 2018–2021, whereas indirect obstetrical deaths increased from 1.24 to 9.41 per 100,000 live births; 38% of direct obstetrical deaths and 67% of indirect obstetrical deaths in 2018–2021 were identified because of a positive pregnancy checkbox. The pregnancy checkbox was associated with increases in less specific and incidental causes of death. For example, maternal deaths with malignant neoplasms listed as a multiple cause of death increased 46-fold from 0.03 in 1999–2002 to 1.42 per 100,000 live births in 2018–2021.
CONCLUSION: The high and rising rates of maternal mortality in the United States are a consequence of changes in maternal mortality surveillance, with reliance on the pregnancy checkbox leading to an increase in misclassified maternal deaths. Identifying maternal deaths by requiring mention of pregnancy among the multiple causes of death shows lower, stable maternal mortality rates and declines in maternal deaths from direct obstetrical causes.
Key words: cause of death, epidemiology, maternal mortality, surveillance, United States
9

9


GLOSSARY
Maternal death: "Death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes."
Direct obstetrical death: Maternal death "resulting from obstetric complications of the pregnant state (pregnancy, labor and puerperium), from interventions, omissions, incorrect treatment, or from a chain of events resulting from any of the above."
Indirect obstetrical death: Maternal death "resulting from previous existing disease or disease that developed during pregnancy and which was not due to direct obstetric causes, but which was aggravated by physiologic effects of pregnancy."
Late maternal death: "Death of a woman from direct or indirect obstetric causes more than 42 days but less than one year after termination of pregnancy."
Incidental cause of death: Death by a cause unrelated to and unaffected by the pregnant state and its management (eg, breast cancer whose course was unaffected by the pregnancy).
Accidental cause of death: Death due to trauma from an accident (including transport or other accident, self-harm, and assault) that was unaffected by the pregnant state.
Pregnancy-related death: Defined by the World Health Organization as the "death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the cause of death" and by the Pregnancy Mortality Surveillance System (PMSS; Centers for Disease Control and Prevention) as "death while pregnant or within 1 year of the end of pregnancy from any cause related to or aggravated by the pregnancy."
Pregnancy-associated death: A death during or within 1 year of pregnancy, regardless of the cause.
Note: In this study, we excluded maternal and late maternal deaths from pregnancy-associated deaths to make the death categories mutually exclusive (for simplicity).
Pregnancy checkbox: The 2003 revision of the U.S. Standard Certificate of Death included the following pregnancy question in the form of a checkbox item:
"If FEMALE:
Not pregnant within past year
Pregnant at time of death
Not pregnant, but pregnant within 42 days of death
Not pregnant, but pregnant 43 days to 1 year before death
Unknown if pregnant within the past year"
Note: "Pregnancy within 42 days of death is not in itself an indication of maternal death. The pregnancy must be related to the death, ..."
and death should not be from incidental or accidental causes.
Checkbox caused over-counting...
10

10

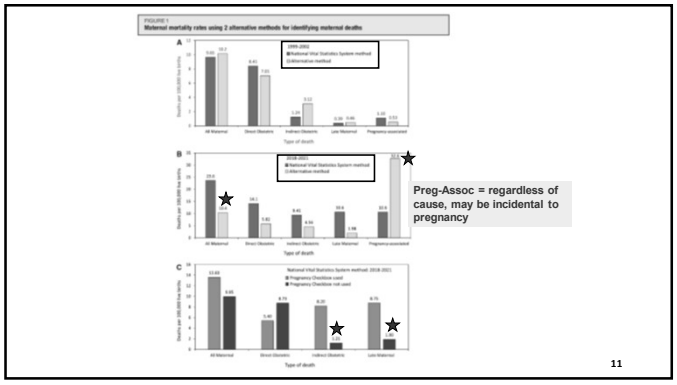


FIGURE 1
Maternal mortality rates using 2 alternative methods for identifying maternal deaths
Preg-Assoc = regardless of cause, may be incidental to pregnancy
11

11

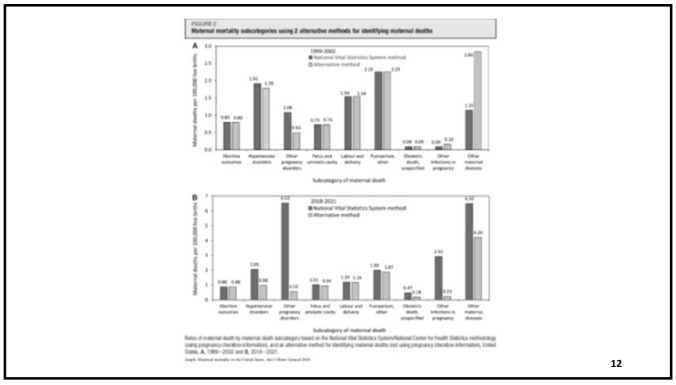
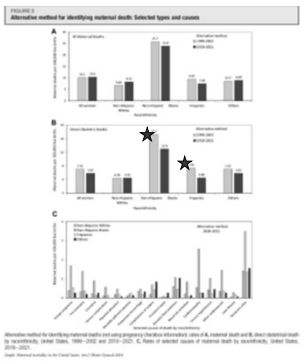


FIGURE 2
Maternal mortality subcategories using 2 alternative methods for identifying maternal deaths
12

12



13

13

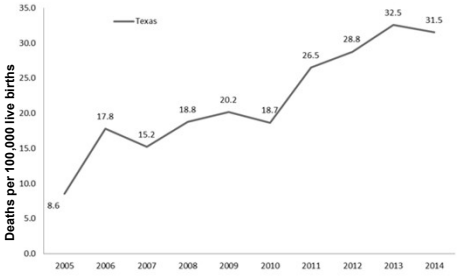
Bottom Line

- All other developed countries have seen a DECREASED Maternal Mortality RATE
- BUT US is seeing an INCREASE (double in last 15 years)!
- We should aim for < 9 deaths/ 100,000 live births
- Instead, US is estimated <u>15-30 per 100,000 live births</u>
  - Need better standardized & constant data
  - Need to remove checkbox

14

14

Texas

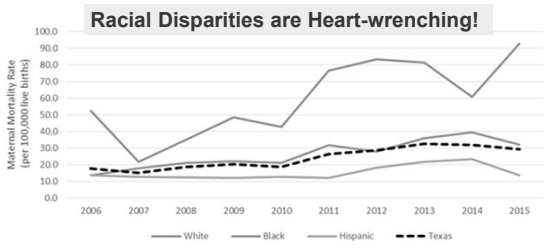


Data sources:
Texas Department of State Health Services, Center for Health Statistics, Death Files, 2005-2014.
State of California, Department of Public Health, California Birth and Death Statistical Master Files, 1999-2013.

15

15

Racial Disparities are Heart-wrenching!



Prepared by: Office of Program Decision Support, Division for Family and Community Health Services, Texas Department of State Health Services, 07/21/2017.
Data Source: Death and Birth Files, Center for Health Statistics, Texas Department of State Health Services.
MMR - computed within 42 days following the end of pregnancy, using ICD-10 codes A34, 000-095, 098-099.

16

16

Original Research

Identifying Maternal Deaths in Texas Using an Enhanced Method, 2012

Half of OB coded deaths were not pregnant !

Sonia Bastu, MA, Debra L. Saxton, MS, Karen Ruggiero, PhD, Michelle L. Kormondy, BS, Lisa M. Hollier, MD, MPH, John Hellerstedt, MD, Manda Hall, MD, and Natalie P. Archer, PhD

OBJECTIVE: To more accurately estimate the 2012 maternal mortality ratio for Texas using an enhanced method for identifying maternal deaths.

METHODS: This population-based descriptive study used both data matching and record review to verify pregnancy or delivery within 42 days for 147 deaths with obstetric cause-of-death codes, and used data matching alone to identify additional maternal deaths within the same time-frame. Crude maternal mortality ratios were calculated for confirmed maternal deaths overall, by race and ethnicity, and by age. These maternal mortality ratios were compared with maternal mortality ratios computed using obstetric cause-of-death codes alone (standard method).

RESULTS: Fifty-six maternal deaths were confirmed to have occurred during pregnancy or within 42 days postpartum. Using our enhanced method, the 2012 maternal mortality ratio for Texas was 14.6 maternal deaths per 100,000 live births, less than half that obtained using the standard method (n=147). Approximately half (50.3%) of obstetric-coded deaths showed no evidence of pregnancy within 42 days, and a large majority of these incorrectly indicated pregnancy at the time of death. Insufficient information was available to determine pregnancy for 15 obstetric-coded deaths, which were excluded from the 2012 maternal mortality ratio estimate; however, had these deaths been included, the resulting maternal mortality ratio would still be significantly lower than that reported using the standard method.

CONCLUSION: Relying solely on obstetric codes for identifying maternal deaths appears to be insufficient and can lead to inaccurate maternal mortality ratios. A method enhanced with data matching and record review yields more accurate ratios. Results likely have national implications, because miscoding of obstetric deaths with the standard method may affect the accuracy of other states' maternal mortality ratios.

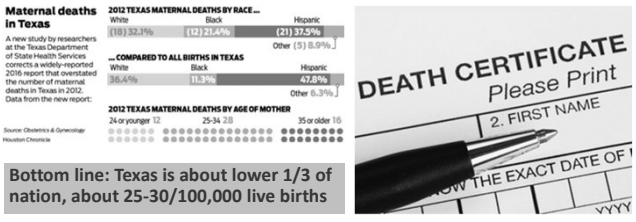
See related editorial on page 739.

(Obstet Gynecol 2018;131:762–9)
DOI: 10.1097/AOG.0000000000002565

17

17

Death Certificate Data Unreliable: Improved



Bottom line: Texas is about lower 1/3 of nation, about 25-30/100,000 live births

18

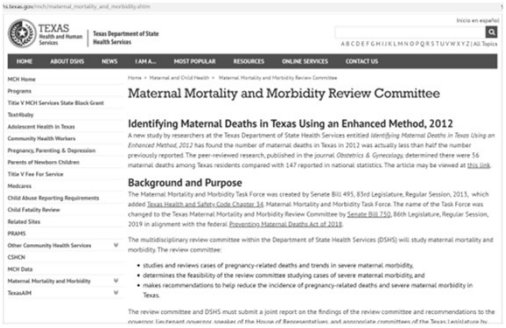
18

Part 2: Causes of Maternal Death in Texas

Image from FeedInspiration.com

19

19



https://www.dshs.texas.gov/mch/maternal_mortality_and_morbidity.shtm

20

20

Task Force Report 2022

21

21

Summary of MMMRC Recommendations

1. Increase access to comprehensive health services during pregnancy, the year after pregnancy, and throughout the preconception and interpregnancy periods to facilitate continuity of care, implement effective care transitions, promote safe birth spacing, and improve lifelong health of women.
2. Engage Black communities and those that support them in the development of maternal and women's health programs.
3. Implement statewide maternal health and safety initiatives and incorporate health equity principles to reduce maternal mortality, morbidity, and health disparities.
4. Increase public awareness and community engagement to foster a culture of maternal health, safety, and disease prevention.
5. Improve integrated behavioral health care access from preconception throughout postpartum for women with mental health and substance use disorders.
6. Improve statewide infrastructure and programs to address violence and intimate partner violence at state and community levels.
7. Foster safe and supportive community environments to help women achieve their full health potential.
8. Support emergency and maternal health service coordination and implement evidence-based, standardized protocols to prevent, identify, and manage obstetric and postpartum emergencies.
9. Improve postpartum care management including education and health care coordination for those with mental health and/or high-risk medical conditions.
10. Prioritize continuing education, diversification, and increasing capacity of the maternal health workforce.
11. Apply continuous process improvement strategies for maternal mortality review protocols to support and increase case review capacity, quality, and recommendation development.

22

22

Finding #2 – Most pregnancy-related deaths were preventable.

The MMMRC determines a pregnancy-related death was preventable if they find there was at least some chance of averting the death by one or more feasible changes to the circumstances of the patient, provider, facility, systems, or community factors contributing to the death. The MMMRC determined there was at least some chance for preventability in 90 percent (n=47) of reviewed 2019 case cohort pregnancy-related deaths (N=52).

90% preventable!!

23

23

Finding #3 –Six underlying causes of death accounted for 79 percent of all reviewed 2019 case cohort pregnancy-related deaths.

Obstetric hemorrhage was the most frequently observed leading cause of pregnancy-related death (25 percent; n=13; N=52), followed by mental health conditions (17 percent; n=9), non-cerebral thrombotic embolism (12 percent; n=6), and injury (10 percent; n=5). Cardiovascular conditions and infection tied for the fifth most frequent underlying causes of death at eight percent each (n=4 each).[6]

Finding #4 – Multiple underlying causes contributed to reviewed pregnancy-related deaths caused by obstetric hemorrhage.

Among the reviewed 2019 case cohort pregnancy-related deaths (n=52), obstetric hemorrhage was the leading cause of death accounting for 25 percent (n=13). Ruptured ectopic pregnancy was the top underlying hemorrhage cause (N=13), accounting for 23 percent of pregnancy-related hemorrhage deaths (n=3). Uterine rupture, placental abruption, and placenta accreta spectrum (n=2 each) were tied as the second leading underlying hemorrhage causes.

24

24

Finding #5 – Obesity, mental disorders, discrimination, and substance use disorder each contributed to pregnancy-related death.

Through case review, the MMMRC identified the following circumstances surrounding death which contributed to many pregnancy-related deaths (N=52).

- Obesity contributed to 21 percent of pregnancy-related deaths (n=11);
- Mental disorders, other than substance use disorder (SUD), contributed to 21 percent of pregnancy-related deaths (n=11);
- Discrimination contributed to 12 percent of pregnancy-related deaths (n=6); [78] and

  SUD, including SUD-associated with mental disorders, contributed to eight 8 percent of pregnancy-related deaths (n=4).

25

25

Finding #6 – Violence contributed to pregnancy-related death.

Violent pregnancy-related deaths with a manner of death of suicide or homicide represented 27 percent of pregnancy-related death (n=14; N=52).[9] The MMMRC found violence, including intimate partner violence, contributed to death. The most frequent means of fatal injury resulting in pregnancy-related death were firearms and airway restriction such as hanging, strangulation, and suffocation. Partners were most likely to be perpetrators of homicide among reviewed homicide cases.

Finding #7 – A complex interaction of factors and characteristics contribute to preventable death.

26

26

Finding #8 – Disparities persist in maternal mortality with Non-Hispanic Black women being most disproportionately impacted.

The final pregnancy-related mortality ratio in 2013 for Non-Hispanic Black women was over twice that for Non-Hispanic White women and over four times higher than Hispanic women (Appendix E). Preliminary assessment of the 2019 case cohort reviewed to date suggests persistence of this trend. DSHS will determine the final 2019 pregnancy-related mortality ratios by race and ethnicity upon MMMRC completion of full review of the 2019 case cohort.

27

27

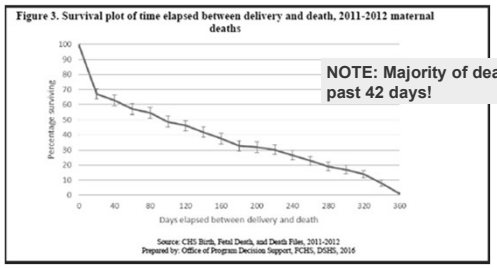
Finding #11 – Overall severe maternal morbidity rates show improvement in obstetric hemorrhage delivery hospitalizations while sepsis and preeclampsia rates increased. Disparities in severe maternal morbidity still persist for Non-Hispanic Black women.

Finding #12 – Beginning in April 2020, severe maternal morbidity associated with COVID-19 appeared to show disproportionate impacts to Hispanic women .[14]

28

28

Women's Health in Texas



NOTE: Majority of deaths past 42 days!

29

29

Bottom Line: Texas' Mat Mortality Rate High (but not as high as previously thought)

- **#1 Cause within 7 days = Hemorrhage**
- **Other big causes: Mental Health, Thromboembolism**
- **Others: Injuries, Cardiovascular, Infection**

30

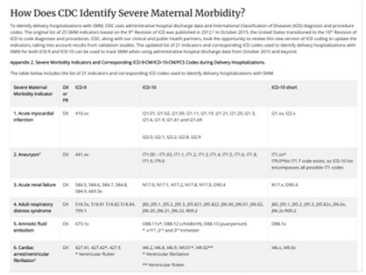
30

Part 3: CDC Severe Maternal Morbidity Conditions

31

31

100-150 Severe Morbidity Cases per 1 Death!


How Does CDC Identify Severe Maternal Morbidity?

CDC Criteria for SMM

https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html

32

32

Examples of Severe Mat Morbidity

- Acute MI
- Aneurysm
- Acute renal failure
- Acute Respiratory Distress Syndrome (ARDS)
- Amniotic fluid embolism
- Cardiac arrest/V fib
- Disseminated intravascular coagulopathy (DIC)
- Eclampsia
- Heart Failure

33

33

Examples of Severe Mat Morbidity (cont)

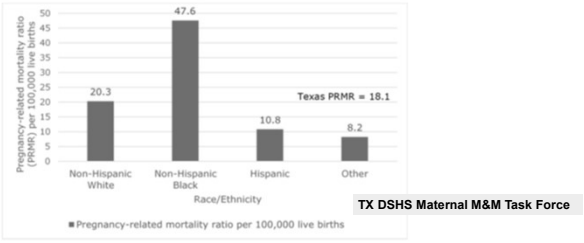
- Ventilation
- Hysterectomy
- Transfusion > = 4 units
- Air and thrombotic embolism
- Sickle cell crisis
- Shock
- Sepsis
- Severe anesthetic complications

34

34

Appendix E. Texas 2013 Pregnancy Mortality Ratio (PRMR) by Race and Ethnicity

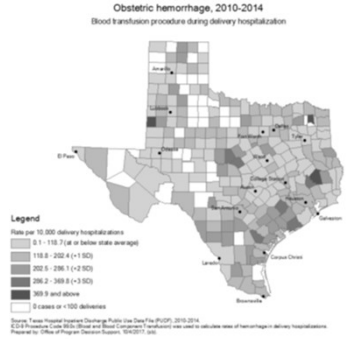
Figure E-1. PRMR by Race and Ethnicity, Texas, 2013



TX DSHS Maternal M&M Task Force

35

35



36

36

Part 4: Evidence based Interventions to Improve Mat M&M (look to Calif)

CMQCC
CALIFORNIA MATERNAL QUALITY CARE COLLABORATIVE

37

37

Creating Change at Scale

Quality Improvement Strategies used by the California Maternal Quality Care Collaborative

Cathie Markow, RN, MBA[a,b], Elliott K. Main, MD[a,c,*]

KEY POINTS

- Engagement of as many partners as possible in a quality improvement project leads to collective impact.
- Availability of a rapid-cycle low-burden data center is an important support for quality improvement activities.
- National safety bundles and tool kits provide guidance but need to be individualized to meet local resources.
- Working with other hospitals in a formal quality collaborative is an effective way to rapidly improve care.

38

38

Four Keys to Change

TOOL KITS
Evidence-based tool kits on leading causes of preventable maternal morbidity and mortality

MATERNAL DATA CENTER
Near real-time benchmarking data to support hospitals' quality improvement

IMPLEMENTATION
Coaching on how to implement best practices and sharing among member hospitals

ENGAGEMENT
Engaging partners around aligned goals and promoting patient awareness

Fig. 1. The CMQCC 4 key principles for driving change.

California Maternal Quality Care Collaborative, 2018

39

39

Principle #1: Engage as Many Partners as Possible: Collective Impact is Powerful

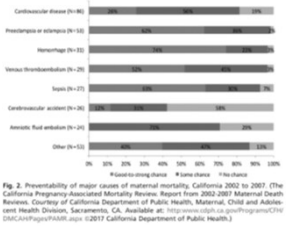


Fig. 2. Preventability of major causes of maternal mortality, California 2002 to 2007. (The California Pregnancy-Associated Mortality Review. Report from 2002-2007 Maternal Death Reviews. Courtesy of California Department of Public Health, Maternal, Child and Adolescent Health Division, Sacramento, CA. Available at: http://www.cdph.ca.gov/Programs/CFH/DMCAH/Pages/PAMR.aspx ©2017 California Department of Public Health.)

California Maternal Quality Care Collaborative, 2018

40

40

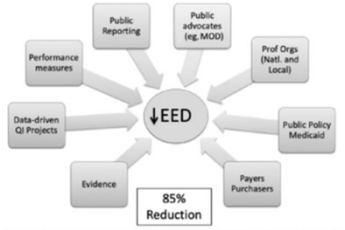


Fig. 3. Power of collaborative action leading to collective impact. This has been a key ingredient for the success of all of the CMQCC quality collaboratives. MOD, march of dimes; Prof Orgs (natal and Local), professional organizations (national and Local); EED, early elective delivery.

California Maternal Quality Care Collaborative, 2018

41

41

Principle #2: Maternal Data Center to Inform and Manage Quality Improvement

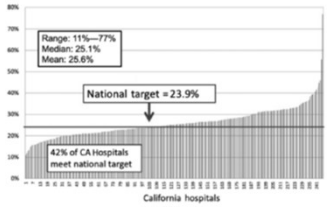


Fig. 5. Hospital variation of NTSV cesarean rates. All 248 California (CA) hospitals, 2015.

California Maternal Quality Care Collaborative, 2018

42

42

Principle #3: Tool Kits: Guidance on Best Practices

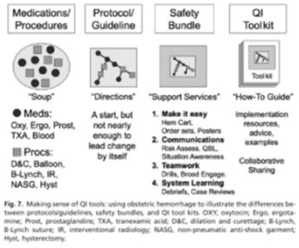


Fig. 7. Making sense of QI tools: using obstetric hemorrhage to illustrate the differences between protocols/guidelines, safety bundles, and QI tool kits. OXY, oxytocin; Ergo, ergotamine; Prost, prostaglandins; TXA, tranexamic acid; D&C, dilation and curettage; B-Lynch, B-Lynch suture; IR, interventional radiology; NASG, non-pneumatic anti-shock garment; Hyst, hysterectomy.

43

Principle #4: Implementation Guidance for Successful Engagement and Improvement

- Engagement by medical staff and nursing staff (clinical)
- QI experience and leadership
- Webinars, mentorship, collaboration, partnerships

44

Part 5: QAPI IS THE KEY

From www.CMS.gov

45

EMS/Trauma Systems Website

46

Maternal Designation Website

47

Maternal Rule

Texas Administrative Code

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 133 HOSPITAL LICENSING
SUBCHAPTER K HOSPITAL LEVEL OF CARE DESIGNATIONS FOR MATERNAL CARE

Rules

§133.201 Purpose
§133.202 Definitions
§133.203 General Requirements
§133.204 Designation Process
§133.205 Program Requirements
§133.206 Maternal Designation Level I
§133.207 Maternal Designation Level II
§133.208 Maternal Designation Level III
§133.209 Maternal Designation Level IV
§133.210 Survey Team

48

Important Points

- Designation is a formal recognition for a hospital's maternal care capabilities and commitment to excellence that exceed minimum hospital licensure requirements.
- The hospital's commitment is evaluated through compliance with the Texas Administrative Code (TAC) requirements.
- The Quality Assurance and Performance Improvement process is essential in the designation program to ensure patients receive appropriate and quality care during their stay in the hospital.
- Peer Review process utilized to evaluate appropriate care and patient outcomes.

49

49

The Perinatal Advisory Council (PAC)

- Established in 2013 by HB 15 of the 83rd Texas Legislature
- Charged with providing clinical recommendations to DSHS → fold them into required rules template
  - Detailed for both Neonatal levels of care and for Maternal levels of care
  - Both rules have been adopted now and the PAC (Sunset 2025) will focus on
    - Best practices
    - Trends in neonatal and maternal results post implementation of the new hospital designation programs.
- Maternal levels of care designation rule effective March 1, 2018; designation for maternal level of care is an eligibility requirement for Medicaid reimbursement beginning September 1, 2020

50

50

PAC – Role of the Family Physician

- Wide knowledge base allows for comprehensive care with low and moderate risk patients
- May serve as the Maternal Medical Director for Level I or Level II facilities
- May serve as the Primary Provider caring for the obstetric patient
- Must be available to attend all deliveries or other obstetrical emergencies at Level I or Level II facilities

51

51

Neonatal and Maternity Designations

Legislation signed into law in 2013 and 2015 and 2019:

Each hospital that provides neonatal and/or maternity care will need to undergo state designation process to receive Medicaid funds

- **Neonatal designation: by September 1, 2018**
- **Maternal designation: by September 1, 2021**

More Information on the Texas state website:

https://www.dshs.texas.gov/emstraumasystems/maternal.aspx

52

52

AIM Bundles

53

53

Edinburgh Postnatal Depression Scale

- Validated for pregnancy, postpartum
- 60+ languages
- Score of 10 or higher = Positive

54

54

DAST (Drug Abuse Screening Test) QUESTIONNAIRE

Each item is given 1 point and interpreted as follows:

- **Score 0: No problems reported**
- **Score 1-2: Low level – reassess at another date**
- **Score 3-5: Moderate level – further investigation**
- **Score 6-8: Substantial level – intensive assessment**
- **Score 9-10: Severe level – intensive assessment**

DAST-10 Questionnaire

I'm going to read you a list of questions concerning information about your potential involvement with drugs, excluding alcohol and tobacco, during the past 12 months.

When the words "drug abuse" are used, they mean the use of prescribed or over-the-counter medications/drugs in excess of the directions and any non-medical use of drugs. The various classes of drugs may include: cannabis (e.g., marijuana, hash), solvents, tranquilizers (e.g., Valium), barbiturates, cocaine, stimulants (e.g., speed), hallucinogens (e.g., LSD) or narcotics (e.g., heroin). Remember that the questions do not include alcohol or tobacco.

If you have difficulty with a statement, then choose the response that is mostly right.
You may choose to answer or not answer any of the questions in this section.

These questions refer to the past 12 months.	No	Yes
1. Have you used drugs other than those required for medical reasons?	0	1
2. Do you abuse more than one drug at a time?	0	1
3. Are you always able to stop using drugs when you want to? (If never use drugs, answer "Yes.")	1	0
4. Have you had "blackouts" or "flashbacks" as a result of drug use?	0	1
5. Do you ever feel bad or guilty about your drug use? If never use drugs, choose "No."	0	1
6. Does your spouse (or parents) ever complain about your involvement with drugs?	0	1
7. Have you neglected your family because of your use of drugs?	0	1
8. Have you engaged in illegal activities in order to obtain drugs?	0	1
9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	0	1
10. Have you had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding, etc.)?	0	1

55

55

Part 6: The Family Physician

TEXAS ACADEMY OF FAMILY PHYSICIANS

56

56

Family Physicians

- **Patient centered**
- **Work well in teams**
- **Flexible based on conditions**
  - **Well versed on cardiovascular disease**
  - **Well versed on substance use disorder**
  - **Well versed on mood disorders**
  - **Well versed coordinating consultants**

57

57

Because Most Maternal Deaths Occur after 60 days…

- **Community approach is best!**

58

58

Family Physicians…

59

59

Family Physicians… Are perfectly Positioned to Reduce Maternal Mortality

60

60

Family Physicians… Perfectly Positioned to Reduce Maternal Mortality

61

61

Conclusions

- 1. US & TX Maternal mortality rate RISING vs. other developed countries (FALLING) – aim for < 9/100,000 live births
  - Death certificate data not reliable (but clearly our MM is too high!)
- 2. List most common causes of maternal mortality in Texas.
  - < 7 days = hemorrhage
  - Mental health, VTE
  - Injury, CV, Sepsis
- 3. Recommended CDC maternal morbidity conditions
  - 100-150 severe morbidity for every mortality

62

62

Conclusions (cont)

- 4. Interventions impacting maternal M&M (CA Collaborative)
  - Evidence and Toolkits
  - Quality & Data
  - Stakeholders
- 5. QAPI to reduce maternal M&M to their healthcare setting.
  - AIM Bundle for PPH
  - Apply Edinburgh Dep Scale
  - DAST score
- 6. Unique role of family physicians in maternal M&M
  - Primary Care
  - See children
  - Great communicators

63

63

Questions?

64

64

Notes

Ethics: Why Improving Access to Mental Health is an Ethical Imperative?

Laurel L. Williams, DO
Medical Director, Centralized Operation Support Hub
Texas Child Mental Health Care Consortium
Program Chair of Child Psychiatry
Baylor College of Medicine
Houston, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Recall the rates of occurrence for common mental health disorders in youth.
2. Recall the rates for common mental health disorders in women pre- and post-partum.
3. Summarize the negative outcomes that may result when youth and women pre- and post-partum are unable to access mental health care.
4. Summarize the favorable outcomes that may result for youth and women pre- and post-partum when their primary care physicians engage in collaborative care models with mental health experts.

Speaker Disclosure

Dr. Williams disclosed she has no financial relationships with any ineligible organizations or commercial interests.

Why Improving Access to Mental Health Care is an Ethical Imperative

Laurel L. Williams, DO
Professor Child and Adolescent Psychiatry
Menninger Department of Psychiatry and Behavioral Sciences
Baylor College of Medicine

1

This program is provided through the Texas Child Mental Health Care Consortium

https://tcmhcc.utsystem.edu

The presenter has no disclosures.

2

2

Presentation Goals

1. Review incidence of mental health disorders in youth and peripartum women.
2. Summarize outcomes for untreated mental health disorders.
3. Describe Access Programs within the Ethical Construct of Beneficence, Nonmaleficence, Justice.
4. Describe Texas' CPAN and PeriPAN Access Projects.
5. Identify barriers to mental health assessment and treatment in your clinical setting.
6. Develop plans for CPAN and PeriPAN utilization to improve patient care within your practice.

3

Goal 1: Review Incidence of Mental Health Disorders in Youth and Peripartum Women

4

Rates of Common Mental Health Disorders

Youth

- 1 in 3 teens ages 13-18 has an anxiety disorder, this is closer to 40% for teenage girls
- Less than 50% of young people reporting depressive symptoms receive treatment
- The isolation caused by the COVID-19 Pandemic worsened mental health distress for youth & parents
- Suicide is the 2nd leading cause of death for youth starting at 10 years of age

Peripartum Women

- 1 in 5 peripartum women suffer with a Maternal Mental Health Condition (MMHC)
- Less than 15% receive professional help
- Women in marginalized communities have even higher rates of peripartum MMHCs and less access to care
- Overdose & suicide combined are the leading causes of death for women in the 1st year postpartum

5

- Primary care clinicians and obstetric clinicians can expect that a significant number of their patients have or have experienced mental health distress.
- Referring out this number of patients means they are often sitting on a wait list getting no care at all.
- Even if there is no wait list, a significant number of patients do not attend mental health appointments due to time commitment and stigma.

6

Goal 2: Summarize Outcomes for Untreated Mental Health Disorders

7

Outcomes When Mental Health Disorders are Not Addressed

Youth

- Increase in mental health emergency room visits
- Hospitalizations for children related to mental health increased by 26% between 2009 and 2019
- Increase in substance use
- Increase in school refusal and drop out
- Increase in suicide

Peripartum Women

- Increased smoking and substance use during pregnancy and postpartum
- Preterm delivery, low birth weight, increased NICU admission
- Lactation challenges. bonding issues
- Untreated MMHCs have multigenerational consequences: cognitive delays, motor & growth issues, behavioral problems & mental health distress in offspring
- Untreated MMHCs cost Texas about $2.2B a year when looking at costs associated from conception to 5 years postpartum

8

- The outcomes of untreated mental health distress in peripartum women and youth are devastating.
- This is a public health crisis we must all work together to address.
- It is an ethical imperative that we help identify those who are suffering and provide them care that helps them achieve wellness.

9

Goal 3: Describe Access Programs Within the Ethical Construct of Beneficence, Nonmaleficence, Justice

10

History of Access Projects to Improve Collaborative Care

- Massachusetts Child Psychiatry Access Project (MCPAP) started the very first Access Project in the United States in 2004 to support clinicians caring for youth in MA
- Due to the success of MCPAP, the program was expanded to support clinicians treating pregnant and postpartum women (MCPAP for Moms) in 2012
- Building on the evidence and the experience of MCPAP and MCPAP for Moms Access Projects were launched by states all over the country funded by both state and federal dollars

11

Outcomes When Collaborative Care Access Project Models are Implemented

Youth

- High rates of parent satisfaction with PCPs who utilize the service
- Further strengthened PCP relationship with families
- Enhanced ability to deliver mental health care consistent with family preferences
- PCP applied knowledge gained in previous calls to subsequent patients

Peripartum Women

- Feasible, acceptable, and sustainable approach to increasing access to evidence-based treatments for perinatal mental health and substance use disorders on a population-based level
- Low-cost approach that can help frontline providers effectively identify and manage perinatal depression

12

Beneficence

- Fills gaps and builds capacity to support the mental health of youth and perinatal women
- Improves outcomes
- Reduces stigma

13

Nonmaleficence

- Does not delay care or send patients on a resource bridge to nowhere
- You wouldn't let an asthmatic wheeze for 6 months while waiting on a wait list

14

Justice

- Helps ensure we are providing the right level of care at the right time
- Reduces wait lists so youth and women with more complex diagnoses and symptom sets can get into a higher level of care more quickly

15

Goal 4: Describe Texas' CPAN and PeriPAN Access Projects

16

The State of Texas is clear that we are in a state of urgency around mental health & that this is a population health issue we must work together to address.

2019 The Texas Legislature creates the Texas Child Mental Health Care Consortium to improve support for primary care clinicians through an Access Project.

We called it CPAN!

The Child Psychiatry Access Network

2020 The Texas Maternal Morbidity and Mortality Review Committee recommends to

"improve integrated behavioral health care access from preconception throughout postpartum for women with mental health and substance use disorders."

2021 The Texas Legislature voted to expand CPAN services to serve clinicians seeing pregnant and postpartum women.

We called it PeriPAN!

The Perinatal Psychiatry Access Network

17

CPAN and PeriPAN: Statewide Structure

Health Related Institutions

The 12 state-funded health related institutions of higher education in Texas make up the network for mental health professionals to support providers.

Centralized Operations Support Hub

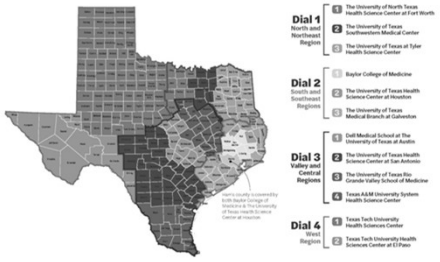
Centralizes communication and data systems to facilitate coordinated care, allowing providers to call one number.

Laurel L. Williams, DO
Sarah Mallard Wakefield, MD

Serve as Medical Directors
CPAN – Dr. Williams
PeriPAN – Dr. Wakefield

18

CPAN and PeriPAN: Statewide Structure



Dial 1 North and Northeast Region
1. The University of North Texas Health Science Center at Fort Worth
2. The University of Texas Southwestern Medical Center
3. The University of Texas at Tyler Health Science Center

Dial 2 South and Southeast Regions
1. Baylor College of Medicine
2. The University of Texas Health Science Center at Houston
3. The University of Texas Medical Branch at Galveston

Dial 3 Valley and Central Regions
1. Dell Medical School at The University of Texas at Austin
2. The University of Texas Health Science Center at San Antonio
3. The University of Texas Rio Grande Valley School of Medicine
4. Texas A&M University System Health Science Center

Dial 4 West Region
1. Texas Tech University Health Sciences Center
2. Texas Tech University Health Sciences Center at El Paso

tcmhcc | CPAN | PeriPAN

19

Goal of our Access Projects: PROVIDE A NETWORK OF SUPPORT FOR YOUTH AND PERINATAL MENTAL HEALTH

- Support providers of youth and maternal health care to identify and manage their patients' mental health
- Expand access to education about youth and maternal mental health disease burden and effective treatments
- Improve the mental health care and systems of care for youth and women who are pregnant, post-partum, suffering perinatal loss or planning pregnancy
- **Improve the mental health care and systems of care for Texas children and adolescents, and the women who care for them, by engaging in collaborative care models that improved equity and access to care**

20

20

Core Components of Our Access Projects

- Prompt, phone-based consultation
- Receive clinical guidance in assessment and treatment for presenting mental health symptoms
- Resource navigation and vetted referral services for your patients with complex needs or substance use issues
- Training and education on mental health care for youth and the women who care for them
- Services are state-funded and free to use; clinician's time to initiate consultation is billable for reimbursement

21

21

Training and Education on Mental Healthcare for Youth and the Women Who Care for Them

WEEK OF	SESSION TITLE
3/4/2024	Intro into ECHO and Behavorial Health
3/18/2024	Assessment of Aggression and Anger
4/1/2024	Out of Control Kids- How to advise parents
4/15/2024	Suicide Assessment/ Safety Planning
4/29/2024	Psychological vs. Neuropsychological Assessment- When and What to Ask For
5/13/2024	Eating Disorders

DATES	SESSION TITLE	PRESENTER
3/12/2024	Introduction to ECHO	Jeff Carr, PhD - Texas Tech University Health Sciences Center
3/26/2024	Intrusive Thoughts vs. Psychosis in the Perinatal/Postpartum Period	Diana Robinson, MD - The University of Texas Southwestern Medical Center
4/9/2024	Cultural Considerations in Perinatal Mental Health	Jasmine Stephens, MD - The University of Texas Southwestern Medical Center
4/23/2024	Mental Health and Infertility Challenges	Kimberly Samuels, PhD - Baylor College of Medicine
5/7/2024	Perinatal Loss	Clarinet Gonzalez - Viera, MD - Baylor College of Medicine
5/28/2024	Hyperemesis Gravidarum	Karan Horst, MD - Baylor College of Medicine

Date & Time	Topic
1/16/2024	Introduction to Perinatal Mood and Anxiety Disorders
2/20/2024	Screening and Diagnosis of Bipolar and Schizophrenia Spectrum in the Pregnancy and Postpartum Period
3/19/2024	Screening and Diagnosis of Anxiety and Depression in Pregnancy and the Postpartum Period
4/16/2024	Suicide Risk and Safety Assessment in Perinatal Mental Health
5/21/2024	Psychotropic Medication in Breastfeeding and Pregnancy
6/18/2024	Psychopharmacology and Perinatal Mood and Anxiety Disorders
7/16/2024	Substance Use in the Perinatal and Postpartum Periods
8/20/2024	Eating Disorders and Perinatal Mental Health
9/17/2024	Perinatal and Postpartum Psychosis
10/15/2024	NICU Parent Supports and Considerations
11/19/2024	Paternal Mental Health and the Perinatal-Postpartum Periods

PeriPAN Webinar Series:
https://tthsclubbock.co1.qualtrics.com/jfe/form/SV_72v80gRmOY33KXY
ECHO PeriPAN:
https://tthsclubbock.co1.qualtrics.com/jfe/form/SV_b8dVJnSGOW1Q6Ls
CPAN ECHO:
CPAN Project ECHO Spring 2024 (office.com)

tcmhcc | CPAN | PeriPAN

22

22

Prompt, Phone-Based Consultation

- Receive clinical guidance in assessment and treatment for presenting mental health symptoms
- Resource navigation and vetted referral services for your patients with complex needs or substance use issues

tcmhcc | CPAN | PeriPAN

- One call to obtain a Clinician-to-Clinician (Curbside) Consultation
  - Pediatricians & Pediatric Nurse Practitioners
  - Family Practice Clinicians (Physician, FNP, PA)
  - OB/GYNs
  - Psychiatrists /Psychiatric Mental Health Nurse Practitioners Psychologists
  - Nurse Midwives
- Speak immediately to a clinician who can assist with resources and referrals
- Schedule a return call to speak with a psychiatry specialist that is convenient for you during business hours or ASAP (<30 minutes)
  - Average time is less than 10 mins

No limit on number of calls

No Call is Too Small!

23

23

tcmhcc | CPAN
Texas Child Mental Health Care Consortium | Child Psychiatry Access Network

Texas now has Access Projects to fill gaps, build capacity, improve outcomes, and reduce stigma to support the mental health of our youth and perinatal women

24

Goal 5: Identify Barriers to Mental Health Assessment and Treatment in Your Clinical Setting

25

Potential Barriers to Improving Mental Health Outcomes

26

There are many barriers. CPAN and PeriPAN teams want to help!

27

Goal 6: Develop Plans for CPAN and PeriPAN Utilization to Improve Patient Care Within Your Practice

28

Develop a Plan for CPAN/PeriPAN Utilization

1. Enroll in CPAN or PeriPAN – right now
2. Enter the Phone and Text Line into your cell phone right now
   - Phone: (888) 901-2726
   - Text: _____
3. Discuss a current case where mental health was a concern – right now (practice calling or texting)
4. Develop screening protocols in your clinic – WHEN TO CALL FOR HELP?
5. Develop workflow that includes contacting CPAN/PeriPAN when a patient:
   - Has a chief complaint of behavioral/mental/substance use concern
   - Screens positive on above screening protocol
   - You have started treatment, and the patient is not improving
   - Patient is in treatment with other mental health providers and you, or the patient/family is concerned that there is not significant improvement

29

Our children deserve it.
Our moms deserve it.
You deserve it.
Together we can do this!

30

"CPAN is a great asset to me. The intake coordinators are extremely knowledgeable and help me in providing the best care for my patients. The child and adolescent psychiatrists are helpful in advising medication therapy and other treatment modalities or evaluations needed. Having limited resources here in East Texas makes CPAN a necessary part of my treatment strategy for kids."

31

"Mental health services are in desperate need. The PeriPAN program allows me to take excellent care of my pregnant and recently delivered patients. I know I will get good advice with a fast phone call. And I don't have to wait and hope a patient calls their insurance and finds a provider that is accepting new patients in a timely manner."

32

32

References

- **NICHM Foundation** *Youth Mental Health*: Trends and Outlook at https://nihcm.org/publications/youth-mental-health-trendsand-outlook, published on: January 28, 2020. Updated on: February 22, 2021. See https://nihcm.org/data-visualization for additional infographics.
- https://www.cdc.gov/prams/prams-data/mch-indicators/states/pdf/2020/Texas-PRAMS-MCH-Indicators-508.pdf
- https://www.nimh.nih.gov/health/statistics/major-depression
- Wisner et al. *JAMA Psychiatry*. 2013;70(5):490.
- CDC National Syndromic Surveillance Program
- Leeb RT, Bitsko RHM Radhakirshnan K, *et al*. Mental-health related emergency department visits among children aged < 18 years during the COVID-19 pandemic – United States, January 1-October 17.2020. *MMWR Morb Mortal Wkly* Rep 2020;069:1675-1680. https://www.cdc.gov/mmwr/volumes/69/wr/mm6945a3.htm
- COVID Adolescent Behaviors & Experiences Survey (ABES) – Adolescent Behaviors and Experiences Survey – United States, January-June 2021, *MMWR Morb Mortal Wkly* Rep 2021; 71 (Suppl).
- https://www.cdc.gov/healthyyouth/data/abes/reports.htm
- Youth Risk Behavior Surveillance System (YRBSS)
- From https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/dash-mental-health.pdf
- Margiotta, Gao, J., Vohra, D., O'Neil, S., & Zivin, K. (2021). Untreated maternal mental health conditions in Texas: costs to society and to Medicaid. Mathematica Progress Together. Mathematica.org. (March 23, 2021).

33

33

References

- Bussieres E, Malboeuf-Hurtubiese C., Meilleur A, *et al*. Consequences of the COVID-19 Pandemic on Children's Mental Health: A Meta-Analysis. *Front Psychiatry* 2021;12: 691659
- Cost KT, Crosbie J, Anagnostou E, *et* al. Mostly worse, occasionally better: impact of COVID-19 pandemic on mental health of Canadian children and adolescents. *E Child Adol Psychiatry* 2002; 31: 671.
- Gloster AT, Lamnisos D, Lubenko J, *et al*. Impact of COVID-19 pandemic on mental health: an international study. *PLoS ONE* 2020; 15(12): e0244809.
- Meherali S, Punjani N, Louie-Poon S, *et al*. Mental health of children and adolescents amidst COVID-19 and past pandemics: a rapid systematic review. *Int J Environ Res Public Health* 2021; 18: 3432
- Nearchou F, Flinn C, Niland R, *et al*. Exploring the impact of COVID-19 on mental health outcomes in children and adolescents: A systematic review. *Int J Environ Res Public Health* 2020; 17: 8479.
- World Health Organization. *Mental health and COVID-19: Early evidence of the pandemic's impact*. 2022. Accessed at https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Mental_health-2022.1
- Adams EL, Smith D, Caccavale LJ, Bean MK. Parents are stressed! Patterns of parent stress across COVID-19. *Front Psychiatry 2021; 12: 626456*.
- Alonzi S, Park J, Pagan A, *et* al. An examination of COVID-19-related stressors among parents. *Eur J Investig Health Psychol Educ* 202; 11: 838.
- Brown SM, Doom JR, Lechuga-Penda S, *et al*. Stress and parenting during the global COLVID-19 pandemic. *Child Abuse & Neglect* 2020; 110: 104699.
- Freisthler, B., Price Wolf, J., Chadwick, C. *et al*. Daily Stress and Use of Aggressive Discipline by Parents during the COVID-19 Pandemic. *J Fam Viol* 2021. https://doi.org/10.1007/s10896-021-00340-y
- Lawson M, Piel M, Simon M. Child maltreatment during the COVID-19 pandemic: consequences of parental job loss on psychological and physical abuse towards children. *Child Abuse & Neglect* 2020; 110(2):104709.
- Spinelli M, Lionetti F, Setti A, Fasolo M. Parenting stress during the COVID-19 outbreak: socioeconomic and environmental risk factors and implications for children emotion regulation. *Fam Process* . 2021;60(2): 639.
- Taubman Ben-Ari O, Ben-Yaakov O, Chasson M. Parenting stress among new parents before and during the COVID-19 pandemic. *Child Abuse & Neglect* 2021; 117: 105080.

34

34

Notes

HIV Prevention with PrEP in Family Medicine

Emily Levy Kamugisha, MD

Associate Program Director and Assistant Professor
Director of HIV Residency Education
Department of Family and Community Medicine
UT Southwestern Medical Center
Dallas, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Discuss the indications and contraindications for use of Pre-Exposure Prophylaxis (PrEP) for HIV.
2. Discuss drugs available for prophylaxis and describe proper dose, timing, and monitoring.
3. Explain potential adverse effects and drug interactions.
4. Discuss and identify issues such as red flags, missing diagnosis or differentials and useful clinical pearls.

Speaker Disclosure

Dr. Levy Kamugisha disclosed she has no financial relationships with any ineligible organizations or commercial interests.

HIV PREVENTION WITH PrEP IN FAMILY MEDICINE

EMILY LEVY KAMUGISHA, M.D., AAHIVS

1

DISCLOSURES

- No financial disclosures
- Site-PI for a HRSA grant working to expand HIV primary care education in Family Medicine Residency

2

LEARNING OBJECTIVES

- Discuss the indications and contraindications for use of Pre-Exposure Prophylaxis (PrEP) for HIV.
- Discuss drugs available for prophylaxis and describe the proper dose, timing, and monitoring.
- Explain the potential adverse effects and drug interactions.
- Discuss and identify issues such as red flags, missing diagnosis or differentials and useful clinical pearls.

3

POLLING QUESTION #1

Have you ever prescribed PrEP for HIV prevention?

A. Yes
B. No
C. I don't know/prefer not to answer

4

POLLING QUESTION #2

On a scale of 0-10, where 0 is "*not at all comfortable*" and 10 is "*very comfortable,*" how comfortable are you with prescribing *PrEP* for HIV prevention?

0 = not at all comfortable
1
2
3
4
5
6
7
8
9
10 = very comfortable

5

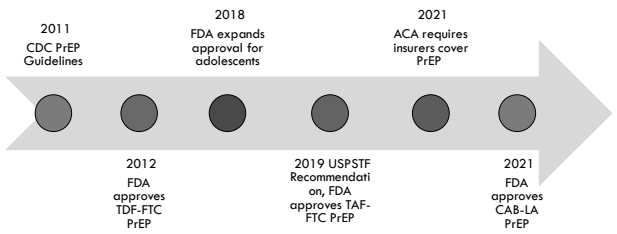
WHAT IS PrEP?

PrEP = **Pre**-**E**xposure **P**rophylaxis

Use of antiretroviral medication to prevent acquisition of HIV infection

6

PrEP IS THE STANDARD OF CARE



7

PrEP IS THE STANDARD OF CARE!

U.S. Preventive Services Task Force (updated August 22, 2023)

Population	Recommendation	Grade
Adolescents and adults at increased risk of HIV	The USPSTF recommends that clinicians prescribe preexpo… fective antiretroviral therapy to persons who are at increased ris… risk of acquiring HIV. See the Practice Considerations section for more info… at increased risk and about effective antiretroviral the…	A

High certainty that the net benefit is substantial

CDC New Graded Recommendations (2021)[2]:

Grade IIIB

Providers should inform all sexually active… adolescents that PrEP can protect them from…
Providers should offer PrEP to anyone that asks for it, incl… active adults who do not report behaviors that put them at risk… HIV. Talking about PrEP may help patients overcome embarrassment or… stigma that may prevent them from telling their healthcare provider about behaviors that put them at risk for getting HIV

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis

8

POLLING QUESTION #3

PrEP is the standard of care. Despite this, many people who would benefit from PrEP are not being prescribed PrEP. The PrEP-to-Need Ratio (PnR) is a measure for whether PrEP use appropriately reflects the need for HIV prevention in a population. A lower PnR indicates **more *unmet* need**. Which region of the United States of America has **the lowest PnR**?

A. Midwest
B. Northeast
C. South
D. West

9

PrEP INEQUITY: GENDER AND RACE

Gender most utilizing PrEP → Male

Race most utilizing PrEP → White

Huang YA, Zhu W, Smith DK, Harris N, Hoover KW. HIV Preexposure Prophylaxis, by Race and Ethnicity — United States, 2014–2016. MMWR Morb Mortal Wkly Rep 2018;67:1147–1150.
DOI: http://dx.doi.org/10.15585/mmwr.mm6741a3external icon

11

HIV Among Women and Girls

18% of new HIV diagnoses in 2021 were among women.

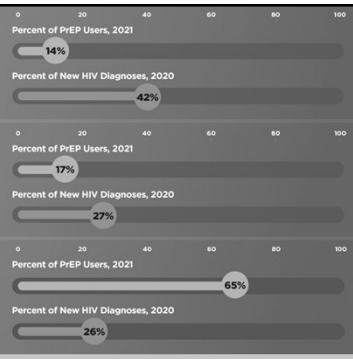
There were **11 male PrEP users** for every new HIV diagnosis among men.

There were **4 female PrEP users** for every new HIV diagnosis among women.

AIDSVu.ORG SOURCE: AIDSVu AIDSVu

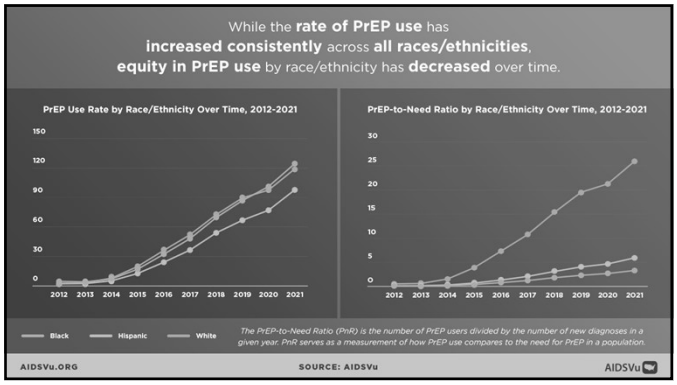
12

Black people represented only **14% of PrEP users (2021) but accounted for 42% of new HIV diagnoses (2020),** indicating a **significant unmet need for PrEP.**

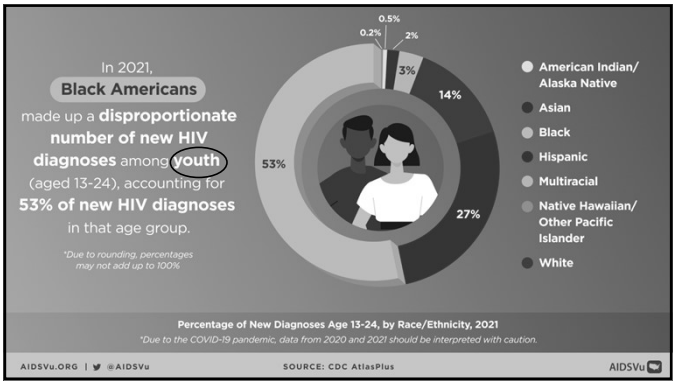


AIDSVu.ORG SOURCE: AIDSVu AIDSVu

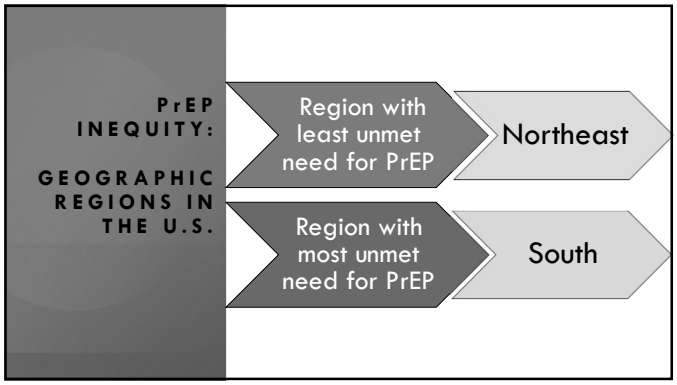
13



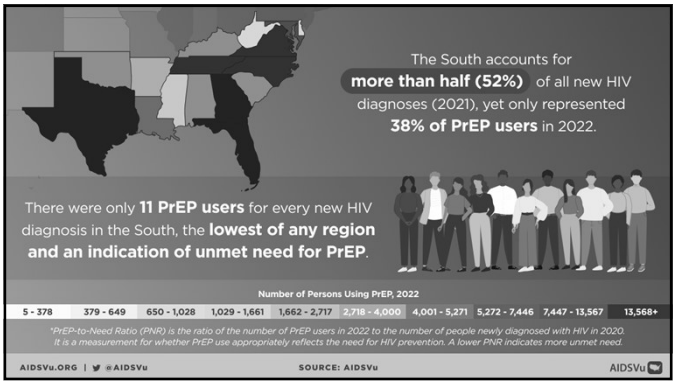
14



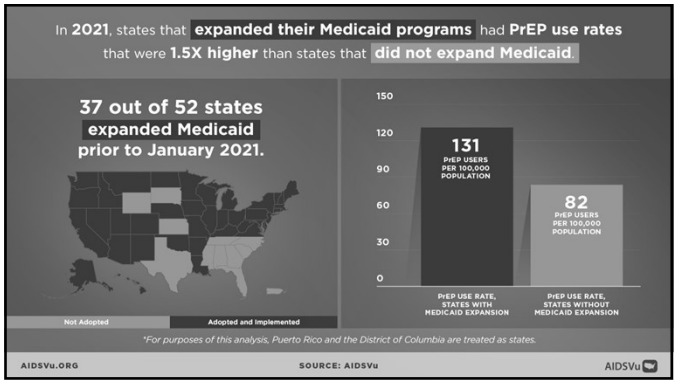
15



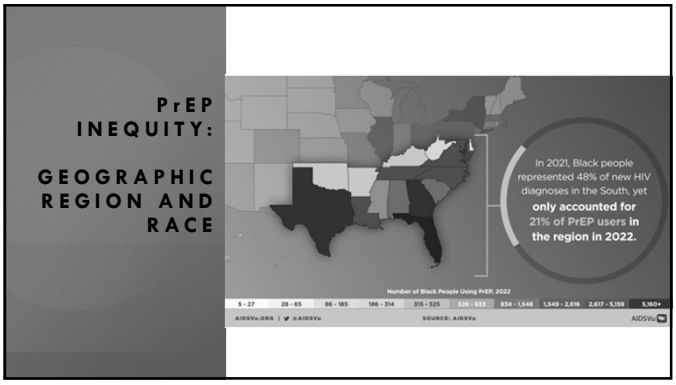
16



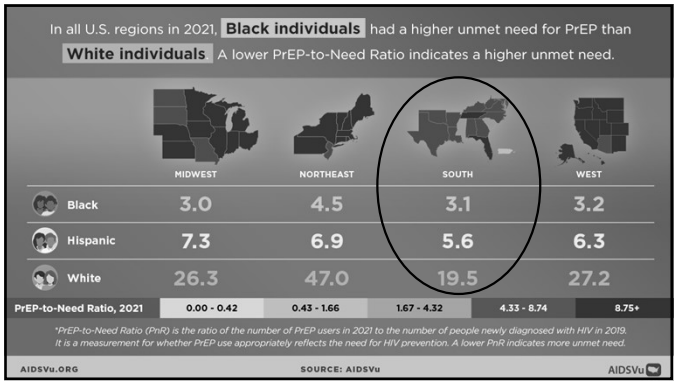
17



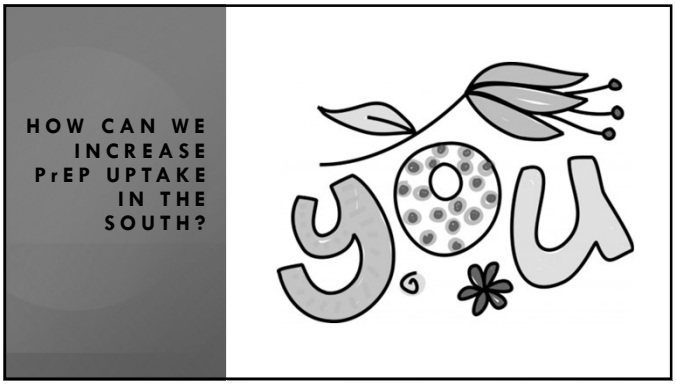
18



19



20



21

INDICATIONS FOR PrEP

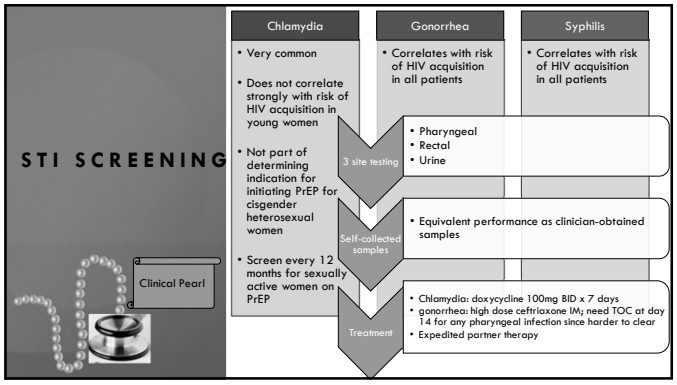
- Adult or adolescent
- Weight ≥ 35kg (77 lbs.)
- At increased risk for HIV acquisition

22

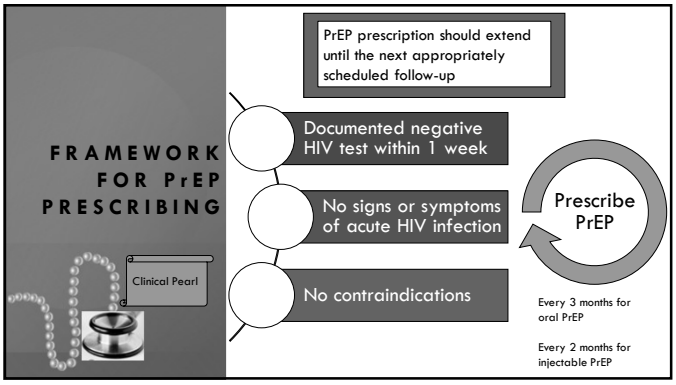
WHO IS AT RISK?

Sexually active adults & adolescents	• Anal or vaginal sex in the past 6 months and any of the following: • HIV+ sexual partner (especially if partner has unknown or detectable viral load) • Bacterial STI in past 6 months • History of inconsistent or no condom use
Persons who inject drugs	• HIV-positive injection partner • Sharing injection equipment
Requesting PrEP	• Anyone who is requesting PrEP may be offered PrEP, even if risk factors are not disclosed

23



24



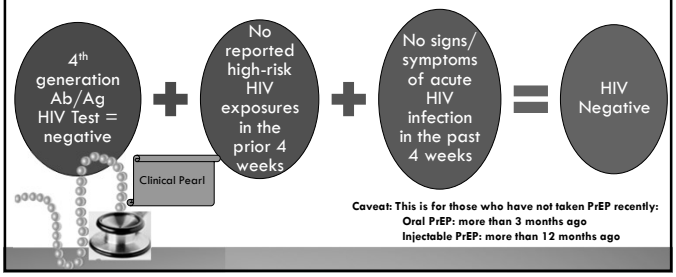
25

ABSOLUTE CONTRAINDICATIONS

- Unknown or positive HIV-1 status
- Weight < 35kg (77 lbs.)
- Prior hypersensitivity reaction to the medication

26

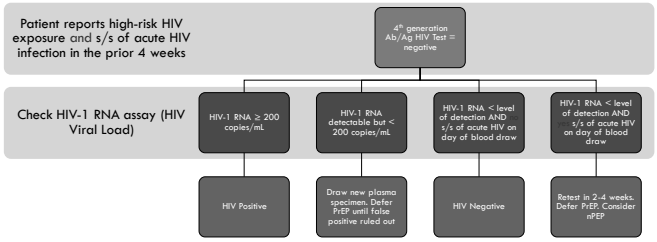
Can also do RAPID blood HIV testing. Rapid oral HIV testing not recommended due to decreased sensitivity to pick-up acute infection



Caveat: This is for those who have not taken PrEP recently:
Oral PrEP: more than 3 months ago
Injectable PrEP: more than 12 months ago

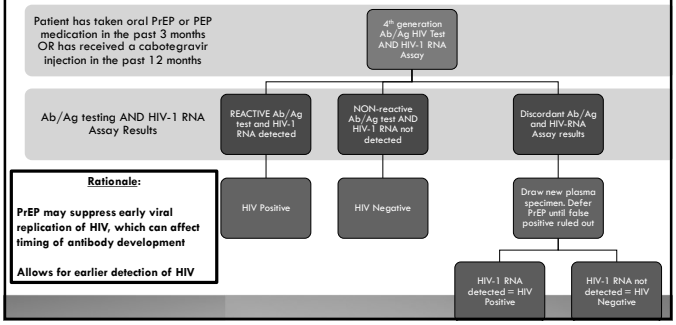
27

HOW DO YOU KNOW IF SOMEONE IS HIV NEGATIVE?



28

HOW DO YOU KNOW IF SOMEONE IS HIV NEGATIVE AND WAS RECENTLY ON PrEP?



29

POLLING QUESTION #4

Clinical scenario: A 55-year-old cisgender male presents for routine primary care follow-up. He has no complaints today.

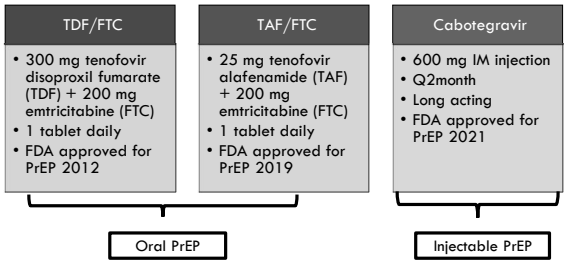
- PMH: Hypertension, prediabetes, chronic kidney disease, stage 3 (eCrCl 45-50)
- SH: Reports having sex with men and women. Inconsistent condom use. History of syphilis and chlamydia in the past 1 year. Denies injection drug use.
- Medications: Lisinopril

Which PrEP agents are options for this patient?

A. Tenofovir disoproxil fumarate and emtricitabine
B. Tenofovir alafenamide and emtricitabine
C. Cabotegravir
D. A and B
E. B and C
F. None of the above

30

THREE FDA APPROVED PrEP OPTIONS



32

CHOOSING A PrEP AGENT

PrEP Drug	Dosing	Population	Estimated CrCl	Hepatitis B
TDF/FTC	• 1 tablet daily	• MSW, WSM • PWID • MSM • Transgender women	≥ 60 mL/min	Treats HBV
TAF/FTC	• 1 tablet daily	• MSM • Transgender women who have receptive anal sex	≥ 30 mL/min	Treats HBV
Cabotegravir IM	• Q2month intramuscular injection (in clinic)	• MSW, WSM • MSM • Transgender women	Not needed*	Does NOT treat HBV

*high protein binding – not expected to dialyze for those patients on dialysis.

33

CHOOSING A PrEP AGENT

PrEP Drug	Dosing	Population	Estimated CrCl	Hepatitis B
TDF/FTC	• 1 tablet daily	• MSW, WSM • PWID • MSM • Transgender women	≥ 60 mL/min	Treats HBV
TAF/FTC	• 1 tablet daily	• MSM • Transgender women who have receptive anal sex	≥ 30 mL/min	Treats HBV
Cabotegravir IM	• Q2month intramuscular injection (in clinic)	• MSW, WSM • MSM • Transgender women	Not needed*	Does NOT treat HBV

*high protein binding – not expected to dialyze for those patients on dialysis.

34

PrEP SAFETY

All FDA approved options are safe!

TDF/FTC	TAF/FTC	CAB-LA
• Rare renal toxicity • Decreases BMD • Lipid lowering	• Weight gain • Even rarer renal toxicity • Increased triglycerides	• Injection site reactions

35

ORAL PrEP OPTIONS

TDF/FTC	TAF/FTC
• 300 mg tenofovir disoproxil fumarate (TDF) + 200 mg emtricitabine (FTC) • FDA approved for PrEP 2012	• 25 mg tenofovir alafenamide (TAF) + 200 mg emtricitabine (FTC) • FDA approved for PrEP 2019

Oral PrEP

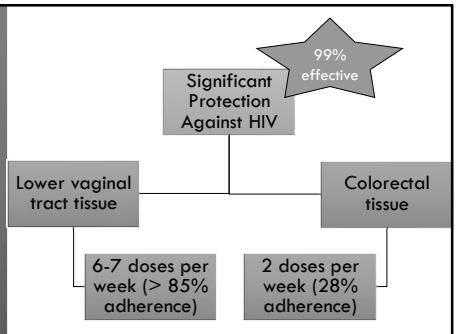
36

EFFICACY + ADHERENCE: ORAL PrEP IN MSM

99% Effective	7 doses per week (taken daily as prescribed)
96% Effective	4 doses per week
76% Effective	2 doses per week

37

EFFICACY + ADHERENCE: VAGINAL AND COLORECTAL TISSUE



High levels of adherence maximizes PrEP effectiveness.

38

EFFICACY + ADHERENCE: PWID

74%-84% Effective

Based on tenofovir alone and not necessarily when taken daily

Likely higher levels of effectiveness when taking TDF/FTC together AND when taking it daily

https://www.cdc.gov/hiv/clinicians/prevention/prep.html

39

HOW LONG DO YOU NEED TO TAKE DAILY ORAL PrEP TO BE PROTECTED?

Cervicovaginal Tissue — 20 days

Rectal Tissue — 7 days

UNKNOWN

40

ORAL PrEP PATIENT COUNSELING

- It takes up to 3 weeks for PrEP to be effective.
  - Condoms are important during that time!
- PrEP only works if you take it!
- Side effects can include GI symptoms, headache
  - Most resolve after 3-4 weeks.
- PrEP does not prevent other STIs; condom use
- Alert your healthcare provider if you develop signs or symptoms of acute HIV (fever, malaise, rash, enlarge lymph nodes)
- Alert your healthcare provider if you intend to stop PrEP.

41

ORAL PrEP OPTIONS

TDF/FTC	TAF/FTC

Combination tablets with two NRTIs

Dosing: 1 tablet daily, without regard to food

Can be used to treat hepatitis B

Approved for MSM & Trans Women who have receptive anal sex.

Oral PrEP

42

CHRONIC HEP B AND ORAL PrEP

- Oral PrEP (TAF/FTC and TDF/FTC) treat Hepatitis B.
- If patient with active Hep B goes on PrEP and then stops, they can have acute Hep B flare. Counsel those patients!
- If a patient with chronic Hep B decides to discontinue PrEP
  - Regular monitoring LFTs and HBsAg and viral load.

43

ORAL PrEP OPTIONS

TDF/FTC	TAF/FTC
• 300 mg tenofovir disoproxil fumarate (TDF) + 200 mg emtricitabine (FTC)	• 25 mg tenofovir alafenamide (TAF) + 200 mg emtricitabine (FTC)
• FDA approved for PrEP 2012	• FDA approved for PrEP 2019

Oral PrEP

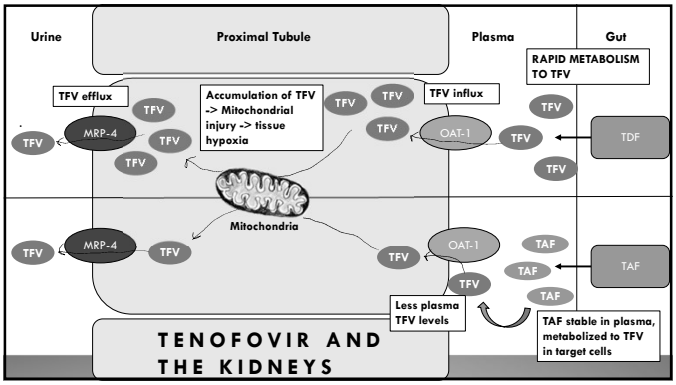
44

ORAL PrEP OPTIONS

TDF/FTC	TAF/FTC
• eCrCl ≥ 60 • MSW, WSM • PWID • MSM • Transgender Women	• eCrCl ≥ 30 • MSM • Transgender Women who have anal receptive sex

Oral PrEP

45



46

ADDITIONAL CONSIDERATIONS FOR ORAL PrEP

TDF/FTC	Lowers lipids	Small risk of renal toxicity	BMD ~1% decrease	Side effects: Headache, GI
TAF/FTC	Increased triglycerides	Lower risk of renal toxicity	Weight gain	Side effects: Headache, GI

47

Avoid use if eGFR<60 mL/min

Proximal Tubular Injury
Fanconi Syndrome
Progression of CKD

TDF/FTC	Lowers lipids	Small risk of renal toxicity	BMD ~1% decrease	Side effects: Headache, GI
TAF/FTC	Increased triglycerides	Lower risk of renal toxicity	Weight gain	Side effects: Headache, GI

48

Clinical Pearl

Occurs during first few months of PrEP and then stabilizes or returns to normal (iPrEx trial).
Routine DEXA scan not indicated*

TDF/FTC	Lowers lipids	Small risk of renal toxicity	BMD ~1% decrease	Side effects: Headache, GI
TAF/FTC	Increased triglycerides	Lower risk of renal toxicity	Weight gain	Side effects: Headache, GI

*may consider further evaluation for those with a history of pathologic or fragility bone fracture or those with significant risk factors for osteoporosis.

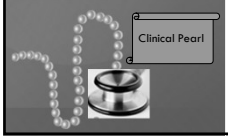
49

TDF/FTC	Lowers lipids	Small risk of renal toxicity	BMD ~1% decrease	Side effects: Headache, GI
TAF/FTC	Increased triglycerides	Lower risk of renal toxicity	Weight gain	Side effects: Headache, GI

Caution in those with elevated cardiovascular risk

50

WHAT IF MY PATIENT'S SERUM CREATININE INCREASES ON ORAL PrEP?



- PrEP does not need to be stopped for a rise in creatinine IF eCrCl remains ≥60 ml/min for TDF/FTC or ≥30 for TAF/FDC.
- If eCrCl is steadily declining, assess for other factors, e.g. NSAID usage, HTN, DM2 prior to stopping PrEP.

51

RELATIVE CONTRAINDICATIONS

TDF/FTC

- eCrCl < 60 mL/min

Caution with concomitant treatment with medications that reduce renal function or compete for active renal tubular secretion

Acyclovir, Valacyclovir
Aminoglycosides
High-dose or multiple NSAIDs

52

RELATIVE CONTRAINDICATIONS

TDF/FTC

- eCrCl < 60 mL/min

Concomitant treatment with medications that treat hepatitis; Serum concentration of TDF may increase -> more toxicity

Avoid Adefovir
Caution with Ledipsavir, sofosbuvir, velpatasvir, voxilaprevir

53

RELATIVE CONTRAINDICATIONS

Caution with concomitant treatment

TAF/FTC

- eCrCl < 30 mL/min

St. John's Wort
Rifampin
Rifabutin
Rifapentine

54

ORAL PrEP BASELINE LABS

Required labs prior to PrEP start

- HIV Antigen/Antibody (negative)
- Estimated Creatinine Clearance (eCrCl)

Other Testing (results not required to start PrEP)

- Hepatitis B surface Ab
- Hepatitis B surface Ag
- STI screening:
  - Gonorrhea/Chlamydia (site-specific "3-site" testing)
  - Syphilis
- Hepatitis C Ab
- Lipid panel (TAF/FTC)

55

MONITORING ON ORAL PrEP

TEST	Baseline Visit	Every 3 Months	Every 6 months	Every 12 months	When Stopping PrEP
HIV	X*	X			X*
eCrCl	X		If age ≥ 50 or eCrCl <90 mL/min at PrEP initiation	If age < 50 and eCrCl≥90 mL/min at PrEP initiation	X
Syphilis	X	MSM/TGW	X		MSM/TGW
Gonorrhea	X	MSM/TGW	X		MSM/TGW
Chlamydia	X	MSM/TGW	X		MSM/TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, PWID only			MSM, TGW, PWID only	

*assess for acute HIV infection

Guideline Update:
HIV Viral Load (NAAT) + HIV Ag/Ab q3 months on PrEP

Guideline Update:
Decreased frequency of eCrCl monitoring.

Guideline Update:
Lipid panel monitoring yearly on TAF/FTC

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

56

MITIGATING SIDE EFFECTS

TDF/FTC	TAF/FTC

"Start-Up Syndrome" (<10%)

HA, nausea, abdominal discomfort

Resolves within 1 month

Treatment: OTC medications

Preempt adverse reaction with a prescription for an antiemetic and recommendations for an anti-diarrheal with the first PrEP prescription

Clinical Pearl

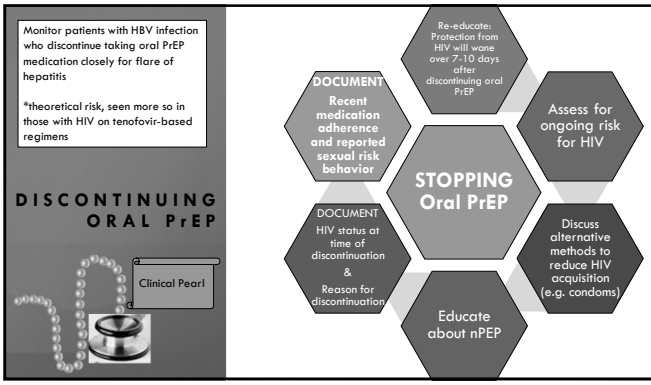
57

DISCONTINUING ORAL PrEP

Monitor patients with HBV infection who discontinue taking oral PrEP medication closely for flare of hepatitis

*theoretical risk, seen more so in those with HIV on tenofovir-based regimens

Clinical Pearl



58

INJECTABLE PrEP OPTION

TDF/FTC	TAF/FTC	Cabotegravir
• 300 mg tenofovir disoproxil fumarate (TDF) + 200 mg emtricitabine (FTC) • 1 tablet daily • FDA approved for PrEP 2012	• 25 mg tenofovir alafenamide (TAF) + 200 mg emtricitabine (FTC) • 1 tablet daily • FDA approved for PrEP 2019	• 600 mg IM injection • Q2month • Long acting • FDA approved for PrEP 2021
Oral PrEP		Injectable PrEP

59

INJECTABLE PrEP OPTION

Cabotegravir

- 600 mg IM injection
  - Baseline, 1 month, Q2 months thereafter
- MSW, WSM
- MSM
- Transgender Women

Injectable PrEP

60

ADMINISTERING CAB-LA PrEP

Optional: Oral lead-in
- Cabotegravir 30 mg PO daily x 4 weeks
- Not required since the trials showed no major safety concerns

Initial Dose:
- Cabotegravir 600 mg (3 ml) IM injection in the gluteal muscle (in clinic)

Second dose:
- 4 weeks after first dose

Maintenance:
- Every 8 weeks thereafter

Oral Lead-in: May be good for patients with anxiety about side effects

Can confirm they tolerate the oral medication prior to starting the long-acting injectable form

Clinical Pearl

61

EFFICACY: INJECTABLE PrEP

66% reduction in risk of HIV compared to TDF/FTC in MSM and TGW — HPTN 083 Trial

Landovitz et al. HPTN083, NEJM August 2021

88% reduction in risk of HIV compared to TDF/FTC in cisgender women — HPTN 084 trial

Delaney-Moretlwe S, et al., Lancet 2022; 399: 1779–89

CAB-LA is SUPERIOR to TDF/FTC in MSM, TGW, and cisgender women

62

HOW LONG AFTER THE FIRST INJECTION TO BE PROTECTED?

Unknown

(probably days-weeks)

63

RELATIVE CONTRAINDICATIONS

UGT1A1 inducers may reduce plasma concentration of cabotegravir

Carbamazepine
Oxcarbazepine
Phenobarbital
Phenytoin
Rifampin
Rifapentine
Rifabutin

Cabotegravir

- Concomitant treatment with UGT1A1 inducers

Injectable PrEP

64

INJECTABLE PrEP(CAB-LA): BASELINE LABS

Required labs prior to PrEP start

- HIV Antigen/Antibody (negative)
- **HIV viral load (NAAT)**

Other Testing (results not required to start PrEP)

- STI screening:
  - Gonorrhea/Chlamydia (site-specific "3-site" testing)
  - Syphilis

65

INJECTABLE PrEP(CAB-LA): BASELINE LABS

Notice: No need to check baseline renal function

Consider CAB-LA for the following patients:

Those with significant renal disease

Those with difficulty adhering to a daily medication

Those who prefer q2mo injection over a daily medication

66

MONITORING ON ORAL PrEP: REMINDER

TEST	Baseline Visit	Every 3 Months	Every 6 months	Every 12 months	When Stopping PrEP
HIV	X*	X			X*
eCrCl	X		If age ≥ 50 or eCrCl <90 mL/min at PrEP initiation	If age < 50 and eCrCl≥90 mL/min at PrEP initiation	X
Syphilis	X	MSM/TGW	X		MSM/TGW
Gonorrhea	X	MSM/TGW	X		MSM/TGW
Chlamydia	X	MSM/TGW	X		MSM/TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, PWID only			MSM, TGW, PWID only	

*assess for acute HIV infection

Guideline Update:
HIV Viral Load (NAAT) + HIV Ag/Ab
q3 months on PrEP

Guideline Update:
Decreased frequency of eCrCl monitoring.

Guideline Update:
Lipid panel monitoring yearly on TAF/FTC

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

67

MONITORING ON CAB-LA PrEP

TEST	Baseline Visit	1 month visit	Every 2 months	Every 4 months	Every 6 months	Every 12 months	When Stopping CAB-LA
HIV	X	X	X	X	X	X	X
Syphilis	X			MSM/TGW	heterosexually active women and men only	X	MSM/TGW
Gonorrhea	X			MSM/TGW		X	MSM/TGW
Chlamydia	X			MSM/TGW		heterosexually active women and men only	MSM/TGW

Guideline Update:
HIV Viral Load (NAAT)
Baseline, 1 mo F/U, q2 months onwards

Guideline Update:
No eCrCl monitoring.
No hepatitis serology monitoring
No Lipid monitoring

Guideline Update:
STI testing q4mo for MSM/TGW
STI testing q6mo for MSW/WSM

Exception:
Chlamydia testing q12 mo for MSW, WSM

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

68

MITIGATING SIDE EFFECTS

Cabotegravir

Injection Site Reaction

Mild to moderate pain, tenderness, induration

Resolves within a few days; AND after first 2-3 doses

Treatment: OTC analgesics 2-hours prior to injection; warm compress/heating pad following injection

Injectable PrEP

69

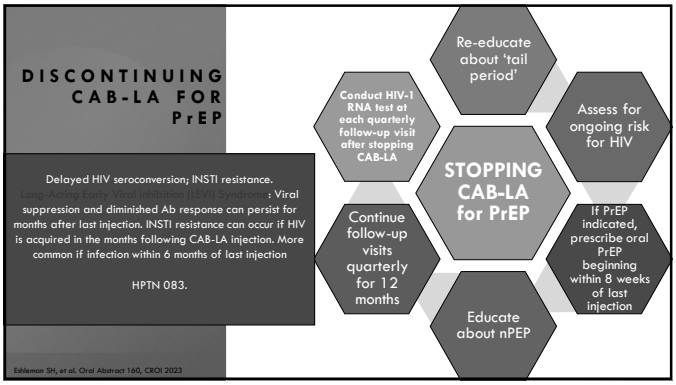
DISCONTINUING CAB-LA FOR PrEP

Delayed HIV seroconversion; INSTI resistance.

Long-Acting Early Viral Inhibition (LEVI) Syndrome: Viral suppression and diminished Ab response can persist for months after last injection. INSTI resistance can occur if HIV is acquired in the months following CAB-LA injection. More common if infection within 6 months of last injection

HPTN 083.

Eshleman SH, et al. Oral Abstract 160, CROI 2023



70

SPECIAL CONSIDERATIONS: PREGNANCY/LACTATION

(BASED ON DATA FROM CISGENDER WOMEN)

Pregnancy

- TDF/FTC: safe, preferred
- TAF/FTC: N/A
- CAB-LA: shared decision making; data insufficient

Lactation

- TDF/FTC: safe, preferred
- TAF/FTC: N/A
- CAB-LA: unknown if cabotegravir is present in breast milk

71

PrEP IS ONLY ONE PART OF HIV RISK REDUCTION STRATEGIES

Risk reduction counseling should be performed at every PrEP visit

72

POLLING QUESTION #5

Clinical scenario: A 21-year-old cisgender, AA female presents for routine primary care follow-up.

- **PMH:** seasonal allergies, mild-intermittent asthma, eczema
- **SH:** She is currently studying early-childhood education in college and works as a teaching assistant at a daycare. She has had 1 male sex partner in the past 6 months and does not consistently use condoms. She has no history of a STI. She denies injection drug use.
- **Medications:** albuterol PRN and daily oral antihistamine.
- **ROS:** subjective fever, sore throat, and fatigue. ("lots of kids at the daycare have been sick")
- **PE:**

VS: T 97.8 F, wt. 145 lbs., RR 18, HR 68, BP 114/62
HEENT: mildly erythematous OP, cervical LAD
Pulm: Normal respiratory effort, lungs CTAB
CV: RRR, no m/r/g

- **LABS:**

Rapid strep test: negative
eCrCL: 70 mL/min

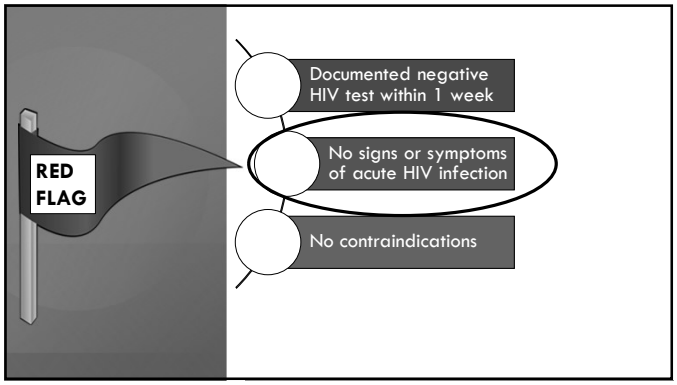
73

POLLING QUESTION #5

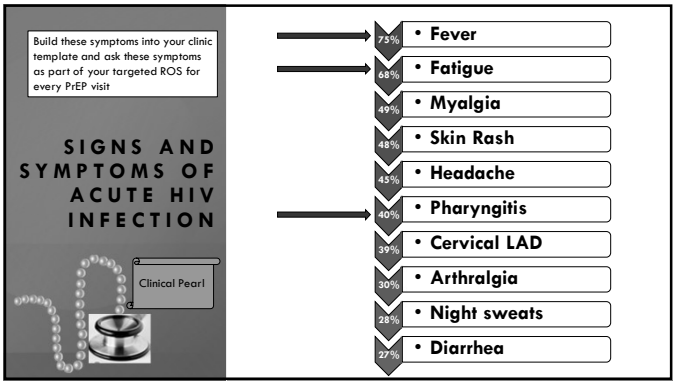
In managing her risk for HIV acquisition, which of the following would you recommend next?

A. Check a 4th generation Ab/Ag HIV screening test and if negative, prescribe PrEP with TDF/FTC if she is interested in PrEP
B. Check a 4th generation Ab/Ag HIV screening test and if negative, prescribe PrEP with TAF/FTC if she is interested in PrEP
C. Do not prescribe PrEP because she is not at risk for HIV acquisition
D. None of the above

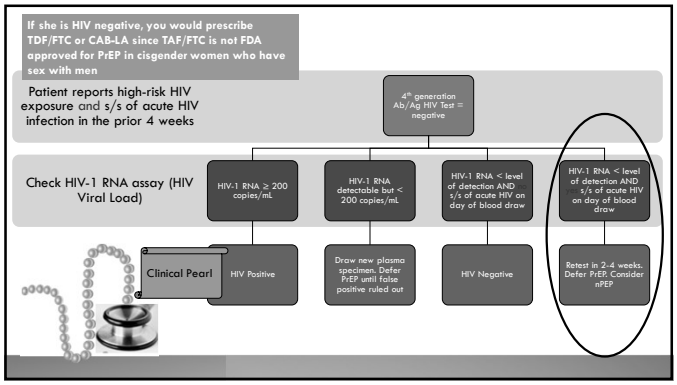
74



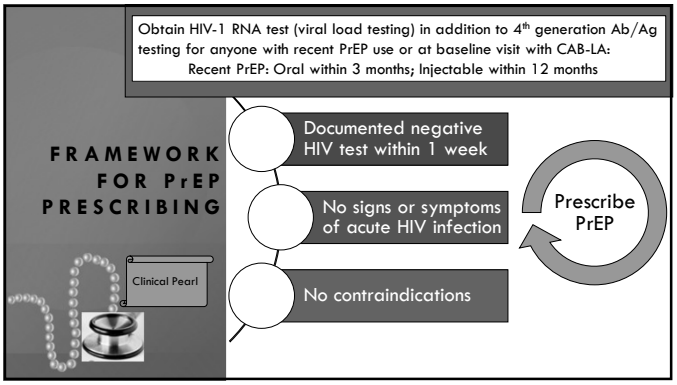
76



77



78



79

WHAT IF MY PATIENT DEVELOPS ACUTE HIV WHILE ON PrEP?

- Confirmation of HIV diagnosis
- Counseling and quick referral to HIV care
- CDC recommendation: convert from PrEP regimen to an HIV treatment regimen without waiting for additional laboratory test results (e.g. TAF/FTC + dolutegravir or bictegravir if on oral PrEP or TAF/FTC + darunavir/cobicistat if on CAB-LA)
- Call CDC PrEP line: **1-855-448-7737 (1-855 HIV-PREP)**

80

PrEP ACCESSIBILITY

- ACA requires insurers to cover PrEP
- TDF/FTC is generic
- Insurers *may* require prior auth for TAF/FTC
- Insurers may NOT cover CAB-LA
- If unfunded, there are options:
  - Patient assistance program (income-based)
  - Ready, Set, PrEP https://readysetprep.hiv.gov/
  - If funded but high copays, can apply for copay assistance

81

CONCLUSIONS

- PrEP is highly effective at preventing HIV
- PrEP is safe
- PrEP is underutilized
- PrEP has an increasing number of options including injectable!
- PrEP is standard of care for prevention of HIV (thank you USPSTF!)
- **PrEP is not being used in populations who would benefit the most**

82

POLLING QUESTION #6

On a scale of 0-10, where 0 is "*not at all comfortable*" and 10 is "*very comfortable,*" how comfortable are you with prescribing *PrEP* for HIV prevention?

0 = not at all comfortable
1
2
3
4
5
6
7
8
9
10 = very comfortable

83

SELECTED REFERENCES

- Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published XXX 2021
- Huang YA, Zhu W, Smith DK, Harris N, Hoover KW. HIV Preexposure Prophylaxis, by Race and Ethnicity — United States, 2014–2016. *MMWR Morb Mortal Wkly Rep* 2018;67:1147–1150. DOI: http://dx.doi.org/10.15585/mmwr.mm6741a3external icon
- Sullivan PS, Woodyatt C, Koski C, Pembleton E, McGuinness P, Taussig J, Ricca A, Luisi N, Mokotoff E, Benbow N, Castel AD. A data visualization and dissemination resource to support HIV prevention and care at the local level: analysis and uses of the AIDSVu Public Data Resource. *Journal of medical Internet research*. 2020;22(10):e23173.
- https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis
- Jotwani, Vasantha*,†; Atta, Mohamed G.‡; Estrella, Michelle M.*,†. Kidney Disease in HIV: Moving beyond HIV-Associated Nephropathy. *Journal of the American Society of Nephrology* 28(11):p 3142-3154, November 2017. | DOI: 10.1681/ASN.2017040468

84

THANK YOU!

85

Notes

TAFP Update

Terrance Hines, MD

President, Texas Academy of Family Physicians
Executive Director & Chief Medical Officer
University Health Services, The University of Texas at Austin
Austin, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Discuss the Texas Academy of Family Physicians' position on top state health policy issues for the patients of Texas.
2. Discuss involvement of family physicians individually and collectively through the Academy's efforts and the vital importance of practice and patients.

Speaker Disclosure

Dr. Hines disclosed he has no financial relationships with any ineligible organizations or commercial interests.

TAFP Update April 2024

YOUR ACADEMY IN ACTION

1

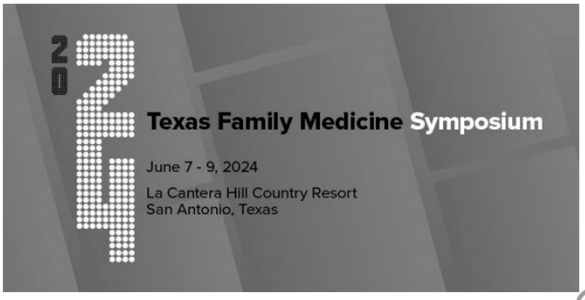
Social Media — Follow TAFP

2

New TAFP Membership App

Scan to download app

3



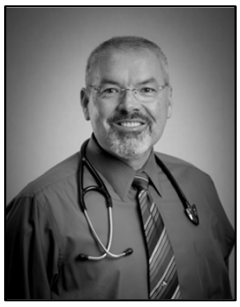
4

5

Will You Be at TexMed?

TAFP Reception
Friday, May 3, at 1:30 p.m.

Rodney Young, MD
for At-Large Trustee



6

TMA Elections

Linda Siy, MD
for Alternate Delegate to the AMA

Samuel Mathis, MD
for Alternate Delegate to the AMA

7

TAFP Awards – Nominate a Colleague

- Texas Family Physician of the Year
- Physician Emeritus
- Physician Executive Award
- Public Health Award
- Exemplary Teaching Award
- Humanitarian Award
- Diversity and Health Equity Leadership Award
- Rising Star Award

Deadline for nominations is May 31.
Go to www.tafp.org/academy/awards.

8

TAFP STUDENT & RESIDENT SUMMIT

August 24, 2024
Grapevine, Texas

9

TEXAS FAMILY MEDICINE PRECEPTORSHIP PROGRAM
TAFP.ORG/PRECEPTORSHIP

10

Representing Texas Family Physicians

11

Thank you!

12

12

Notes

U.S. Preventive Services Task Force Update

Rebecca Hart, MD
Family Physician, Private Practice
Fredericksburg, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Consider the relevance of the strength of evidence in the guideline grading system.
2. Be well versed in the most recent updates in USPSTF guidelines in the past 2 years.
3. Decide when to apply USPSTF guidelines versus other national guidelines.
4. Start to use the USPSTF app for point of care decision making.

Speaker Disclosure

Dr. Hart has disclosed she is a stockholder of BioTE.

1

US Preventive Services Task Force Update:

January 2022-March 2024

Rebecca Hart, MD, FAAFP
2024 C. Frank Webber Lectureship
Renaissance Austin Hotel
Austin, Texas
Saturday, April 13, 2024

Speaker Disclosure: Stockholder for BioTE

1

Objectives

2

At the end of the presentation, attendees will:

- Discuss the make-up, processes, and history of the USPSTF.
- Consider the relevance of the strength of evidence in the USPSTF guideline grading system.
- Review the most recent updates in USPSTF guidelines 2022-present.
- Decide when to use USPSTF guidelines versus other national guidelines.
- Learn how to incorporate USPSTF guidelines into their practices using the USPSTF app.

2

16 TASK FORCE MEMBERS

3

- First Established in 1984
- 16 Nationally recognized experts in prevention, evidence-based medicine, and primary care
- Their fields of practice and expertise include behavioral health, family medicine, geriatrics, internal medicine, pediatrics, obstetrics and gynecology, and nursing.
- 4-year terms

3

How are members selected?

4

- Each member is a volunteer for a 4-year term.
- Each year, the Secretary of HHS selects new members to replace those members who are completing their appointments.
- Nominations can be from anyone, Use website to nominate
- Members must have demonstrated knowledge, expertise, and national leadership in the following areas:
  1. The critical evaluation of research published in peer-reviewed literature and in the methods of evidence review.
  2. Clinical prevention, health promotion, and primary health care.
  3. Implementation of evidence-based recommendations in clinical practice, including at the clinician-patient level, practice level, and health system level.
  - OR
  - Have expertise in methodology such as meta-analysis, epidemiology, etc.

4

USPSTF MEMBERS

5

Michael J. Barry, MD – Harvard Medical School, Boston, Massachusetts, Chair

Wanda K. Nicholson, MD, MPH, MBA – Chair, Washington University

Michael Silverstein, MD, MPH – Vice Chair, Brown University School of Public Health

David Chelmow, MD, Ob Gyn – Virginia Commonwealth

Esa M. Davis, MD, MPH – University of Pittsburgh

Tumaini Rucker Coker, MD, MBA – Pediatrics, University of Washington

Sandra Millon Underwood, RN, PhD – University of Wisconsin

Sarah Wiehe, MD, MPH – Pediatrics, University of Indiana School of Medicine

5

Members

6

- Li Li, MD, PhD, MPH – University of Virginia, Charlottesville
- M. (Tonette) Krousel-Wood, MD, MSPH – Tulane
- Sei Lee, MD, MAS – Medicine, Geri – UCSF
- Goutham Rao, MD, FAHA – Case Western Family Medicine
- Michael Silverstein, MD, MPH – Boston University, Boston, Massachusetts
- James Stevermer, MD, MSPH – University of Missouri, Columbia
- Roberto Jaén, MD, PhD, MS, FAAFP – Family Medicine, UT Health San Antonio
- Joel Tsevat, MD, MPH – Internal Medicine, UT Health San Antonio

6

Screening Test Grading Systems

7

- A Recommendation
  - High certainty of substantial benefit
- B Recommendation
  - Moderate certainty of moderate benefit
- C Recommendation
  - Moderate certainty of small net benefit
- D Recommendation
  - No Benefit or Net Harm – the preventive service is not recommended
- I Recommendation
  - Low level or certainty – no recommendation can be made

7

Insufficient Evidence

8

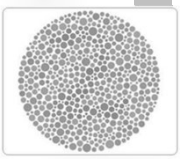
FROM THE USPSTF:

- The USPSTF issues a statement of **insufficient evidence** when the current available evidence is insufficient to assess the balance of benefits and harms of a service.
- Evidence may be insufficient because of the **limited number or size of studies**, important flaws in study design or methods, inconsistency of findings across studies, findings that are not generalizable to routine US primary care practice, or a lack of information on important health outcomes.
- An "I" statement does not mean that the USPSTF recommends against providing a service. Rather, it means that the USPSTF cannot determine whether there is an overall benefit or harm to providing the service, and more information in the future may allow an estimation of effects on health outcomes.
- An "I" statement is also a call for research to close gaps in the evidence.

8

Screening versus Testing

9



- Screening Test
  - Asymptomatic patient
  - Benefits must outweigh risks of test
  - Performed on a population at risk
    - i.e. Adults, children, pregnant women, age group
- Testing
  - Performing a test based on presenting symptoms
  - Not a true screening of a population
  - Patient specific

9

Process

10

- Topics Re-evaluated Every 5 years
- New topics continuously being added
- Task Force methods were first described in a special issue of the ***American Journal of Preventive Medicine, 1989***
- Following this publication, the Task Force began systematically using an analytic frameworks to structure literature reviews and develop recommendations on every topic.

10

Process to Add a New Topic – 5 STEPS

11

1. **Review Topic Nominations**
   1. Anyone can nominate a new topic for review at any time.
   2. USPSTF reviews nominated topics for relevance to and impact on prevention, primary care and public health.
   3. USPSTF selects and prioritizes topics for review.
2. **Develop Draft Research Plan**
   1. Once a topic is prioritized for review, USPSTF and an **Evidence-based Practice Center** (EPC) develop a research plan and seek expert input.
   2. USPSTF posts the draft research plan to website for public comment.
3. **Review Public Comments & Finalize Research Plan**
   1. USPSTF and EPC review all comments carefully and revise the research plan.
   2. USPSTF posts the final research plan to website.

11

Process to Add a New Topic

12

4. **Review Evidence & Develop Draft Recommendation**
   1. EPC analyzes peer-reviewed evidence; develops a draft evidence review.
   2. USPSTF assess EPC-gathered evidence, weighing effectiveness and benefits/harms and develops a draft recommendation statement.
   3. USPSTF posts the draft recommendation statement and EPC evidence review to its website for public comment.
5. **Review Public Comments & Finalize Recommendation**
   1. USPSTF and EPC consider all comments on the draft evidence review, then EPC finalizes.
   2. USPSTF considers all comments on the draft recommendation statement, then finalizes.
   3. USPSTF posts the final recommendation statement and evidence summary to website and publishes in a peer-reviewed journal. (JAMA) (ref 1)

12

USPSTF History and Purpose

13

- Established in 1984 by Congress
- Placed under the Dept. of Health and Human Services
- Initial Congressional mandate **to improve the health of people nationwide by making evidence-based recommendations about clinical preventive services and health promotion.**
- Programmatic support for the Task Force was transferred to AHRQ in 1995.
  - Agency for Health Care Research and Quality is a division of HHS

13

ACA Changes Mandate, Rules

14

- The Affordable Care Act of 2010 reauthorized the USPSTF with a slightly different and expanded mandate.
  - Due to the Nation's greater emphasis on prevention, **insurers are required to cover preventive services that are recommended by the USPSTF with a grade of A or B.**
- The Affordable Care Act requires insurers to cover these services with no deductible and no co-pay.
  - **Sec. 2713** of the ACA requires private insurers to cover preventive services recommended by the USPSTF with a grade of A or B, as well as ACIP, Bright Futures, and HRSA's guidelines for women's health.

14

Recent Court Challenge to USPSTF

Braidwood Management Inc. v. Becerra

15

- ACA requires private insurers to cover preventive services recommended by the USPSTF with a grade of A or B without cost sharing.
- In *Braidwood Management v. Becerra* Christian owned businesses and six individuals in Texas assert that
  - (1) the requirements in the law for specific expert committees and a federal government agency to recommend covered preventive services is unconstitutional

  and
  - (2) that the requirement to cover preexposure prophylaxis (PrEP), medication for HIV prevention, violates their religious rights.

15

Judge's Decision:

16

- Previous Case Law:
- In a recent Supreme Court case, *United States v Arthrex*, the court provided a workaround that permitted administrative patent judges, who—like USPSTF panel members—are not appointed by the president, to conduct the work of "officers of the United States" as long as their decisions are subject to review by their agency's director, in this case the director of the Patent and Trademark Office.
- In *Braidwood*, Judge O'Connor reasoned that **because the USPSTF is an independent panel, there is no agency director to review the panel's decisions about preventive services.**

- Considering that there is no comparable workaround for the USPSTF, the judge ruled that the panel's appointments—effectively as officers of the US—are unconstitutional.
- Members of the USPSTF are appointed by AHRQ, an agency of the Department of HHS, and USPSTF recommendations are not subject to review by AHRQ. There is no AHRQ or HHS oversight or approval of USPSTF committee work.

16

Court Challenge

17

- March 2023: Judge O'Connor (US District Court in the Northern District of Texas), ruled in favor of the plaintiff in *Braidwood Management v. Becerra:*
  - that the preventive service requirement was a violation of the Appointments Clause as USPSTF members were neither confirmed by the Senate nor answerable to the secretary of the U.S. Department of Health and Human Services.
  - And that the requirement to cover pre-exposure prophylaxis (PrEP), a medication used to reduce HIV transmission, violated the employer-plaintiff's rights under the Religious Freedom Restoration Act.
    - (Similar to case law in the Burwell vs. Hobby Lobby case refusing to cover contraception due to religious objections – that a for-profit corporation can have religious freedom and act as persons.)

17

Now: Administrative Stay

18

- The Fed appealed the decision.
- **May 15, 2023: The 5th Circuit Court of Appeals issued an administrative stay of the district court's ruling.**
- **FOR NOW- the federal government can continue enforcing the preventive services requirement** while the 5th Circuit considers the Department of Justice's motion.

Ref 22

Stay tuned… This will likely be appealed to the Supreme Court.

18

19

USPSTF GUIDELINES 2022-Present

32 Guidelines Reviewed

AN UPDATE FOR FAMILY PHYSICIANS AND CLINICIANS IN PRIMARY CARE

19

20

2022-2024 Recommendation Areas

- **Screening**
  - Syphilis
  - Hypertensive Disorders in Pregnancy
  - Anxiety Disorders
  - Depression in Adults
  - Latent TB
  - COPD
  - Genital Herpes
- **Counselling**
  - Diet and Exercise
- **Preventive Medication**
  - Statins
  - Folic Acid
  - Aspirin to lower CVD risk
  - Beta Carotene
  - Estrogen
  - PrEP

20

21

Grade A and B Recommendations 2022-2024

Grade A

- PrEP for Prevention of HIV*
- Folic Acid for Prevention of Neural Tube Defects*
- Screening for Syphilis in Nonpregnant Adolescents and Adults*

*** = No Change from Previous**

No Change

Grade B

- Screening for Hypertensive Disorders in Pregnancy*
- Screening for Anxiety Disorders in Adults
- Screening for Depression in Adults*
- Screening for Depression in Adolescents
- Screening for Latent TB infection in Adults*
- Screening for Anxiety in Children aged 8-18
- Prescribe a statin for the primary prevention of CVD for adults aged 40 to 75*

21

22

Only Three Grade A Recommendations

22

23

PrEP for Prevention of HIV **GRADE A**

- The USPSTF recommends that clinicians prescribe preexposure prophylaxis using effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV.
- All persons being considered for PrEP must have a recently documented negative HIV antigen-antibody test result.

Ref 5

23

24

Who is High Risk?

- The USPSTF recommends that the following persons be considered for PReP:

1. Sexually active adults and adolescents weighing at least 35 kg (77 lb) who have engaged in anal or vaginal sex in the past 6 months and have any of the following:
   1. A sexual partner who has HIV (especially if the partner has an unknown or detectable viral load).
   2. A bacterial sexually transmitted infection (STI) (syphilis, gonorrhea, or chlamydia for men who have sex with men and transgender women; gonorrhea and syphilis for heterosexual women and men) in the past 6 months.
   3. A history of inconsistent or no condom use with sex partner(s) whose HIV status is not known; assessing risk in conversation with the patient and considering factors such as number of partners, the specific sexual activities a person engages in, and whether their sex partner or partners are in a group with a higher prevalence of HIV (i.e. men who have sex with men or with men and women, transgender women, persons who inject drugs, and persons who engage in transactional sex).
2. Persons who inject drugs and share injection equipment or have a drug-injecting partner who has HIV.

(Ref. 6,7)

24

PrEP Medications:

25

- FDA approved:
- Oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC)
- Cabotegravir injectable
  - Is FDA approved for use in at-risk adults and adolescents weighing at least 35 kg (77 lb) to reduce the risk of sexually acquired HIV.
  - Note: No PrEP medications have FDA approval to reduce the risk of acquiring HIV from injection drug use.
    - CDC guidelines note that persons who inject drugs *are likely to benefit from PrEP* with any FDA-approved PrEP medication.
  - No trials of PrEP enrolled persons who were pregnant:
    - FDA labeling permits the use of TDF/FTC in pregnant persons
    - It also permits the use of TDF/FTC for breastfeeding
    - The potential benefits should be considered along with any potential adverse effects on the breastfed child.

25

Folic Acid for Prevention of Neural Tube Defects*

26

GRADE A

- The USPSTF recommends that all persons planning to or who could become pregnant take a daily supplement containing 0.4 to 0.8 mg (400 to 800 mcg) of folic acid.
- **Persons who plan to or could become pregnant:** Take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.
- No Change from 2017 statement*

No Change

26

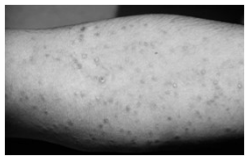
Screening for Syphilis in Nonpregnant Adolescents and Adults

27

GRADE A

- The USPSTF recommends screening for syphilis infection in persons **who are at increased risk for infection.**
- 2016 Reaffirmation with no new evidence.

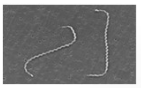
No Change



27

Who is at Increased Risk for Syphilis?

28



<u>Prevalence of syphilis is higher in</u>:

- Men who have sex with men
- Persons with HIV infection
- Young adults
- History of incarceration, sex work, or military service.
- illicit drugs use, particularly methamphetamine.
- Diagnosis of another STI may signal that a person is having condomless sex, which increases their risk of syphilis infection.
- Local prevalence rates may change over time, so clinicians should be aware of the latest data and trends for their specific population and geographic area.

From CDC website – Ref 8

28

29

Seven Grade B Recommendations

MODERATE CERTAINTY OF MODERATE BENEFIT

29

Screening for Hypertensive Disorders in Pregnancy

30

No Change

GRADE B

- The USPSTF recommends screening for hypertensive disorders in pregnant persons with blood pressure measurements throughout pregnancy.
- Screen for hypertensive disorders of pregnancy with blood pressure measurements throughout pregnancy. (each visit)
- New-onset hypertension during pregnancy defn:
  - systolic blood pressure ≥140 mm Hg

  Or
  - diastolic blood pressure ≥90 mm Hg in the absence of chronic hypertension measured twice at least 4 hours apart
- Reaffirmation of 2017 statement.*

30

Screening for Anxiety Disorders in Adults
GRADE B

31

- For adults 64 years and younger
- The USPSTF recommends screening for anxiety disorders in adults, including pregnant and postpartum persons.
- The GAD-2 and GAD-7 demonstrated adequate sensitivity and specificity to detect generalized anxiety disorder
- Conditions reviewed included generalized anxiety disorder, social anxiety disorder, panic disorder, and anxiety not otherwise specified.
- *NOTE: Very Little evidence found for screening in adults aged 65 or older Category I*

This is a new guideline.

31

Screening for Depression in Adults
GRADE B

32

- The USPSTF recommends screening for depression in the adult population, including pregnant and postpartum persons, as well as older adults >=65.
- The USPSTF recommended screening for MDD in in the general adult population, including pregnant and postpartum persons, noting that screening *should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up*.
- This is for asymptomatic adults 19 years or older.
- Does not address screening for other depressive disorders, such as minor depression or dysthymia
- Reaffirmation of 2014 guideline*

No Change

32

Adult MDD Screening Tools Recommended

33

- Patient Health Questionnaire (PHQ) in various forms in adults
  - PHQ 2
  - PHQ 9
- Center for Epidemiologic Studies Depression Scale (CES-D)
- Geriatric Depression Scale (GDS) in older adults
- Edinburgh Postnatal Depression Scale (EPDS) in postpartum and pregnant persons.[1]

33

Screening for Depression in Adolescents aged 12-18
Grade B

No Change

34

- The USPSTF recommends screening for major depressive disorder (MDD) in adolescents aged 12 to 18 years.
- Optimal screening interval is unknown
- Reaffirmation of guideline 2014*
- Screening Tests Recommended:

1. PHQ modified for adolescents (PHQ-A)
2. Center for Epidemiologic Studies Depression Scale

REF 14

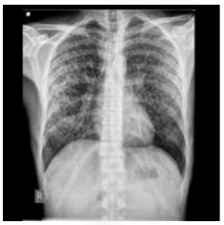
34

Screening for Latent TB infection in Adults
GRADE B

35

- The USPSTF recommends screening for LTBI in populations at **increased risk**. (Next Slide)
- Reaffirmation of 2016 guideline*

No Change



35

Definition of Increased TB Risk Populations:

36

- Persons who were born in, or are former residents of, countries with high tuberculosis prevalence:
  - In 2020, among persons with new tuberculosis living in the US who were born outside the US, the most common countries of birth were
    - Mexico (18.0% of cases)
    - Philippines (12.5%),
    - India (10.4%), Vietnam (8.2%)
    - China (5.1%)
    - Accounts for 54.2% of total cases in US

- Persons who live in, or have lived in, high-risk congregate settings (such as homeless shelters or correctional facilities).
- Most of these cases are believed to be due to progression of latent infection to active tuberculosis disease rather than new transmission within communities.

Ref 4

36

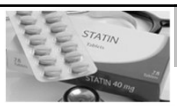
Screening for Anxiety in Children aged 8-18
GRADE B

37

- The USPSTF recommends screening for anxiety in children and adolescents aged 8 to 18 years.
- **Insufficient evidence for age 7 years and under.**
- Optimal screening interval unknown.
- Anxiety screening tools alone are not sufficient to diagnose anxiety. If the screening test is positive for anxiety, a confirmatory diagnostic assessment and follow-up is required.
- Screening instruments designed to assess for a specific anxiety disorder:
  - Social Phobia and Anxiety Inventory for Children, which screens for social phobia and anxiety disorder)
  - Screen for Child Anxiety Related Disorders (SCARED) (global anxiety and any anxiety disorder)
  - Patient Health Questionnaire–Adolescent (GAD and panic disorder).

37

Statins for Prevention of CVD
GRADE B
Preventive Medication



38

- The USPSTF recommends that clinicians **prescribe a statin** for the primary prevention of CVD for adults aged 40 to 75 years who have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) **and** an estimated 10-year **risk of a cardiovascular event of 10% or greater.**
- Consistent with 2016 recommendation.*

Ref 3, 9

No Change

Try using the new **PREVENT ™ Calculator** from AHA

(ref 10)

- 10-year risk for CVD:
  - Low risk (<5%)
  - Borderline risk (5% to 7.4%)
  - Intermediate risk (7.5% to 19.9%)
  - High risk (≥20%)

38

Grade C Recommendations:
Moderate certainty of small net benefit
2022-2024

39

STATINS

- Selectively offer a statin for the primary prevention of CVD **for adults aged 40 to 75 years who have 1 or more CVD risk factors** and an estimated 10-year risk of a cardiovascular event of 7.5% to less than 10%.
- The likelihood of benefit is smaller in this group than in persons with a 10-year risk of 10% or greater.

DIET and PHYSICAL ACTIVITY

- Individualize the decision to offer or refer adults **without cardiovascular disease risk factors** to behavioral counseling interventions to promote a healthy diet and physical activity.

ASPIRIN

- The decision to initiate low-dose aspirin use for the primary prevention of CVD in adults aged **40 to 59 years who have a 10% or greater 10-year CVD risk** should be an individual one.
- Evidence indicates that the net benefit of aspirin use in this group is small.
- Persons who are not at increased risk for bleeding and are willing to take low-dose aspirin daily are more likely to benefit.

39

40

Six Grade D Recommendations

40

Grade D Recommendations
No Benefit or Net Harm – the preventive service is not recommended
2022-2024

41

Screening:

- Genital Herpes
- Chronic obstructive pulmonary disease (COPD)

Preventive Treatment:

- Estrogen for the primary prevention of chronic conditions in postmenopausal persons who have had a hysterectomy.
- Combined estrogen and progestin for the primary prevention of chronic conditions in postmenopausal persons.
- Beta carotene or vitamin E supplements for the prevention of cardiovascular disease or cancer.
- Low-dose aspirin for the primary prevention of CVD for >=60yrs old.

41

Genital Herpes
Grade D

No Change

42

- **Do not screen for Genital Herpes**
- 2016 Reaffirmation
- HARMS:
- **High False positive rate**
- Using the widely available serologic tests for HSV-2, nearly 1 of every 2 diagnoses in the general US primary care population could be **false.**
- A previous USPSTF review estimated that in a population of 10,000 persons with an HSV-2 prevalence of 15%, serologic screening could result in approximately 1,585 true-positive and 1,445 false-positive results.
- Current US estimated prevalence = 12%

42

Estrogen and Progestins for Primary Prevention of Chronic Conditions **Grade D**

43

1. The USPSTF recommends against the use of estrogen alone for the primary prevention of chronic conditions in postmenopausal persons who have had a hysterectomy.
2. The USPSTF recommends against the use of combined estrogen and progestin for the primary prevention of chronic conditions in postmenopausal persons.
3. Data from the WHO study aimed at finding primary prevention strategies **did not find** that these postmenopausal hormones prevented any chronic conditions.
4. 2017 Reaffirmation – No Change

No Change

43

For Menopausal Hormone Therapy

44

USPSTF recommends that more research is needed for the following issues:

- Whether age or the timing of initiation of hormone therapy with respect to menopause affects health outcomes.
- Whether the benefits and harms of menopausal hormone therapy might vary across population groups.
- The comparative benefits and harms of different formulations and treatment durations of menopausal hormone therapy.
- (Ref 16,17)

44

Other Societies:

45

North American Menopause Society (NAMS):

- **Recommends that hormone therapy should not be prescribed for chronic disease prevention.**
- **It also notes that extended duration of hormone therapy use might be appropriate in symptomatic women or for the prevention of osteoporosis, if alternative therapies are not tolerated.**

45

Prevention: Beta Carotene or Vitamin E **Grade D**

46

- The USPSTF recommends against the use of beta carotene or vitamin E supplements for the prevention of cardiovascular disease or cancer.
- Harms:
- Beta carotene was associated with an increased risk of lung cancer and other harmful outcomes in persons at high risk of lung cancer.
- The most serious harm identified was increased cardiovascular disease mortality and **increased risk of lung cancer in persons who smoke or had workplace asbestos exposure, associated with beta carotene supplementation at doses of 30 and 20 mg/d.**
- **Ref 23**

46

COPD Screening **Grade D**

47

- The USPSTF recommends against screening for chronic obstructive pulmonary disease in asymptomatic adults
- The USPSTF found inadequate direct evidence that **screening for COPD in asymptomatic adults** reduces morbidity or mortality or improves health-related quality of life.
- The USPSTF found inadequate evidence that **treatment of asymptomatic COPD** reduces morbidity or mortality or improves health-related quality of life.

- **Risks of Screening Outweigh the Benefits – Grade D.**
- **(Ref 18)**

47

COPD Screening **Grade D**

48

- Harms of Screening and Treatment
  - **New Data FOUND since last recommendation in 2016:**
- The USPSTF examined new data from 6 of the included treatment trials and 2 observational studies (n = 243,517) that reported on pharmacologic or nonpharmacologic treatment harms in adults with mild to moderate COPD.
- ****One study of cardiovascular risk associated with treatment with LABAs or LAMAs found an increased risk of a serious cardiovascular event after the initiation of LABAs or LAMAs
- ****A second study found that ICS may increase the risk of developing diabetes.
- These 2 observational studies represent a subset of a much larger body of evidence on serious harms of bronchodilators and ICS in the treatment of COPD, such as heart failure and pneumonia.
- Ref 18

48

Aspirin for Primary Prevention of CVD **in adults over 60**
Grade D

- The USPSTF recommends against initiating low-dose aspirin use for the primary prevention of CVD in adults 60 years or older.
- **UPDATE FROM PREVIOUS RECOMMENDATION:**
  For the current recommendation, the USPSTF has changed the age ranges and grades of its recommendation on aspirin use.
  - The USPSTF recommends that the decision to initiate low-dose aspirin use for the primary prevention of CVD in adults aged 40 to 59 years who have a 10% or greater 10-year CVD risk should be an individual one
  - Recommends against initiating low-dose aspirin use for the primary prevention of CVD in adults 60 years or older.
    - The evidence is inadequate that low-dose aspirin use reduces CRC incidence or mortality.

49

Aspirin Effect Data Based on Modeling

50

- USPSTF used a microsimulation model to estimate the magnitude of net benefit of low-dose aspirin use:
- Models examined concluded that:
- ***Initiation of aspirin use in persons aged 60 to 69 years results in quality-adjusted life-years gained that range from slightly negative to slightly positive depending on CVD risk level, **and life-years gained are generally negative**.
- In the age range of 70 to 79 years, initiation of aspirin use results in a loss of both quality-adjusted life-years and life-years.
- The USPSTF thus determined that initiation of aspirin use has no net benefit in persons 60 years or older.

50

Grade I

51

Insufficient Evidence
Low level or certainty;
No recommendation can be made

(13 Recommendations)

FOR THESE – OTHER SOCIETIES HAVE MADE CERTAIN RECOMMENDATIONS THAT MAY BE WORTHY OF CONSIDERATION BY PRIMARY CARE CLINICIANS.

51

Insufficient Evidence – 2022-2024
Grade I = Low level of certainty; No recommendation can be made

52

- Screening for Speech and Language Delay in Children
- Oral Health Screening and preventive care interventions in adults and adolescents by primary care clinicians (not dental health clinicians)
- Screening for Lipid Disorders in Adolescents and children under 20 years old
- Screening for Anxiety Disorders in Adults over 65
- Screening for Anxiety Disorders in Children under 7 years old
- Screening for Suicide Risk – all ages

?

52

Insufficient Evidence – 2022-2024

53

Grade I = Low level or certainty;
No recommendation can be made

- Screening for Prediabetes in Children and Adolescents
- Screening for Skin Cancer
- Screening for OSA in adults
- Screening for Primary Open Angle Glaucoma
- Use of MVI and nutrient supplements to Prevent CV disease and Cancer
- Screening for Eating Disorders in Adolescents and Adults
- Screening for Impaired Visual Acuity in Adults

?

53

Screening for Speech and Language Delay in Children

No Change

54

- There is insufficient evidence to recommend for or against screening for speech and language delay and disorders in younger children.
- The USPSTF is calling for **more research** on the benefits and harms of screening for speech and language delays and disorders, especially in populations known to have the highest burden:
  - Black and Hispanic/Latino children and children from households with low incomes
- Use your clinical judgment regarding whether and how to screen for speech and language delay and disorders.
- Be aware of signs and symptoms of speech and language delays and disorders and listen to any caregiver concerns.
- No change from 2015 Recommendation

?

54

Oral Health Screening and Preventive Treatment
Grade I

55

- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of routine screening **performed by primary care clinicians** for oral health conditions, including dental caries or periodontal-related disease, in adults.
- Same applies to preventive treatments by primary care clinicians.
- The evidence review found only studies focused on dental caries interventions performed by dental health professionals in a dental setting.
- Same was found for adolescents and children – hardly any studies done on this.
- **New Topic**

?

55

Screening for Lipid Disorders in Adolescents and Children under 20 years old
Grade I

56

No Change

- Same as 2016 statement***
- Still not enough strong evidence to make a recommendation.
- Familial hypercholesterolemia (FH) and multifactorial dyslipidemia are 2 conditions that cause abnormally high lipid levels in children, which can lead to premature cardiovascular events (eg, myocardial infarction and stroke) and death in adulthood.
- The prevalence of FH in US children and adolescents is low:
  - ranges from 0.2% to 0.4%
- **Multifactorial dyslipidemia is much more common than FH, with prevalence in children and adolescents**
  - ranges from 7.1% to 9.4%.

Ref 11

?

56

Multifactorial Dyslipidemia

57

- Adult Multifactorial dyslipidemia is known as a risk factor for cardiovascular disease
- **Linking elevated lipid levels in children to adult cardiovascular outcomes requires long follow-up**
- Best evidence:
- International Childhood Cardiovascular Cohorts Consortium (2022)
  - elevated lipid levels in childhood (ages 3 to 19 years) associated with fatal cardiovascular events in adulthood with 35 years of follow-up
- The evidence is complicated by childhood risk factors tracking into adulthood and the lack of control for other risk factors.
- Still inadequate

57

Screening for Anxiety in Persons over 65
Grade I

58

- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for anxiety disorders in older adults.
- (This is different than the recommendation for adults, and pregnant and postpartum patients – a B statement.)
- Just not enough studies done on this older population.
- Requires more data

?

58

Screening for Anxiety in Children
Grade I

59

- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for anxiety in children 7 years or younger.
- Not enough studies on screening for anxiety in this particular age group. For those 8-18 – it is a grade B.

- **OTHER SOCIETIES:**
- **The American Academy of Pediatrics** and Bright Futures **recommends annual screening** for behavioral, social, and emotional problems (including anxiety in children and adolescents) in patients from birth to age 21 years.

?

59

Screening for Suicide Risk – Adults
Grade I

60

No Change

- For Adults, Pregnant and Postpartum patients, and older adults:
- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of **screening for suicide risk.**
- No change from 2014*

- **Other guidelines:**
- The only other group that recommends this is The US **Department of Veterans Affairs**
  - recommends universal screening for suicide risk in veterans

Ref 12.

?

60

Screening for Suicide Risk in children and adolescents
Grade I

61

No Change

- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for suicide risk in children and adolescents.
- Update from 2014 – no change

- AAP Recommendations – similar findings
- The American Academy of Pediatrics, the American Foundation for Suicide Prevention, and experts from the National Institute of Mental Health released a "Blueprint for Youth Suicide Prevention" that recommends universal screening for suicide risk in youth 12 years or older; children aged 8 to 11 years should be screened as clinically indicated.

?

61

Screening for Depression in Childhood
Grade I

62

No Change

- The USPSTF concludes that the current **evidence is insufficient** to assess the balance of benefits and harms of screening for MDD in **children 11 years or younger**.
- ***This is the only population that is NOT recommended for Depression screening****
- Unchanged from 2016 – still not enough data to warrant screening

- **Remember – Do screen Children ages 12-18 for MDD.**
  - **It is a GRADE B for age 12-18, adults and older adults.**
  - **DO Screen for Depression in Adults and older adults .**

62

Screening for Prediabetes and Diabetes in Children and Adolescents
Grade I

63

- The USPSTF concludes that the ***current evidence is insufficient*** to assess the balance of benefits and harms of screening for type 2 diabetes in children and adolescents. (Ref 13)
- New Recommendation – insufficient data

- Other Societies:
- **The American Diabetes Association**
  - Use Risk-based screening
  - After onset of puberty or age 10 years
  - In overweight (defined as a BMI ≥85th percentile) or obese (defined as a BMI ≥95th percentile) **and 1 or more additional risk factors for diabetes.**
  - In children who are deemed at high risk, it recommends screening every 3 years if tests are normal or more frequently if BMI increases.

?

63

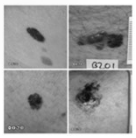
Screening for Skin Cancer
Grade I

64

No Change

- In 2016, the USPSTF found insufficient evidence to assess the balance of benefits and harms of visual skin examination by a clinician to screen for skin cancer in adults (I statement).
- This recommendation concurs with the previous I statement.
- The USPSTF reviewed 6 nonrandomized observational studies (n = 2,947,595) assessing the effectiveness of skin cancer screening on earlier detection (measured by cancer stage or lesion thickness).
- Results were either inconsistent or showed no association between routine clinician skin examination and increased detection of any skin compared with usual care or lesion-directed examination.

Ref 19



?

64

OSA Screening
Grade I

65

No Change

- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for obstructive sleep apnea in the general adult population.
- This recommendation replaces the 2017 USPSTF recommendation on screening for OSA. – Reaffirmation

- Other Societies:
- **The American Academy of Sleep Medicine** has a health advisory recommending **annual OSA screening** for adult patients who belong to certain high-risk groups.
- In 2014, the **American College of Physicians** recommended conducting a sleep study for patients with unexplained daytime sleepiness (weak recommendation, low-quality evidence).

?

65

Glaucoma Screening
Grade I

66

No Change

- Same as 2013 Recommendation: Reaffirmation
- In adults 40 years or older:
- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for primary open-angle glaucoma in adults.
- Based on **inadequate direct evidence** that screening for open-angle glaucoma **in primary care** improves intermediate outcomes (changes in the optic nerve, visual field, or intraocular pressure) or health outcomes such as reduced visual impairment, vision-related function, and quality of life.

- Other organizations:
- **American Academy of Ophthalmology**
  - Examinations every 2 to 4 years for persons aged 40 to 54 years, every 1 to 3 years for persons aged 55 to 64 years, and every 1 to 2 years for persons 65 years or older.

?

66

Use of MVI or Nutrient Supplements to Prevent CV Disease and Cancer – ADULTS

67

Grade I

- TWO STATEMENTS
- 1. The USPSTF concludes that the current evidence ***is insufficient*** to assess the balance of benefits and harms of the use of **multivitamin supplements** for the **prevention of cardiovascular disease or cancer**.

No Change

AND

- 2. The USPSTF concludes that the current evidence *is insufficient* to assess the balance of benefits and harms of the use of single or paired **nutrient supplements** (other than beta carotene and vitamin E) for the **prevention of cardiovascular disease or cancer.**
- Update of 2014 – Reassessed new studies and came to same conclusion.

67

Screening for Eating Disorders in Adolescents and Adults

68

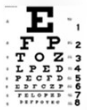
Grade I

- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for eating disorders in adolescents and adults.
- Not enough studies…
- **New Recommendation**

- AAP:
- **The American Academy of Pediatrics** recommends that pediatricians include screening for eating disorders in their annual health supervision or sports examinations through longitudinal weight and height monitoring as well as looking for signs of disordered eating. All preteens and adolescents should be screened about eating patterns and body image issues.

68

Screening for Impaired Visual Acuity in Adults



69

Grade I

No Change

- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for impaired visual acuity in older adults.
- Update from 2016 – No Change
- Visual acuity tests had poor diagnostic accuracy when compared with a complete ophthalmological examination for identifying visual conditions.

- **OTHER SOCIETIES:**
- **The American Academy of Ophthalmology** recommends a comprehensive examination conducted by an ophthalmologist every 1 to 2 years in patients >65 years
- The American Optometric Association recommends an annual comprehensive eye and vision examination for all adults older than 65 years.

69

What's Next? 2024 Topics:

70

- **New research plans:**
- Screening for Unhealthy Alcohol Use in Adolescents and Adults
- Risk Assessment, Genetic Counseling and Testing for BRCA-Related Cancer
- Breast Cancer Medication to Reduce Risk

Finalization Stage

- Breast Cancer Screening
- Interventions to Prevent Falls in Older Adults
- Prevention of Child Maltreatment
- Interventions for High Body Mass in Children and Adolescents

Topics Under Review

- Screening for Autism
- Breastfeeding Interventions
- Screening for Cervical Cancer
- Screening for Chronic Kidney Disease
- Preventive Services for Food Insecurity
- Behavioral Counseling for Healthy Diet, Exercise and Weight Loss in Adults
- HIV Screening
- Intimate Partner Violence Screening
- Iron Deficiency Screening and Supplementation
- Osteoporosis Screening
- Prevention of Perinatal Depression
- Prostate Cancer Screening
- Screening for Syphilis Infection in Pregnancy
- Vitamin D, Calcium for Primary Prevention of Falls in Community Dwelling Adults

70

Summary

71

- The USPSTF
  - Provides us a clearing house for prevention and screening guidelines
  - Continually updates recommendations
  - Uses evidence-based methodology
  - Is easy to use, and easy to search on the USPSTF website and app
- Other valid guidelines exist for many issues
- Clinicians can safely use guidelines from national medical societies (USPSTF, ACOG, AAFP, etc.) in their practices as they all have been vetted by groups of experts.
- Groups of experts may interpret evidence differently.

71

To Learn More:

72

- http://www.uspreventiveservicestaskforce.org
- Electronic Preventive Services Selector
- http://epss.ahrq.gov/PDA/index.jsp
- Ebook: http://www.ahrq/gov/professionals/clinicians-providers/guidelines-recommendations/guide
- https://www.uspreventiveservicestaskforce.org/BrowseRec/Index/browse-recommendations

72

There's an app for that!

73

- USPSTF app available – **FREE**
- **(Ref 2)**
- Last updated 2/05/24
- Asks to enter patient data
- Gives relevant guidelines on the specific patient entered based on:
  - Age
  - Weight
  - Height
  - Sex
  - Pregnancy status
  - Tobacco user
  - Sexually active

73

Post Test Question 1

74

The USPSTF is the only evidence-based guideline I should use in my clinical practice.

A. TRUE
B. FALSE

74

Post Test Question 2

75

The consistent use of national guidelines in my practice, such as the USPSTF, is a risk management technique.

A. TRUE
B. FALSE

75

Post Test Question 3

76

A Guideline given an "I" recommendation: (Insufficient Evidence)

A. Means that evidence may be insufficient because of a limitation in the number or size of studies done to date.
B. Could mean there are important flaws in major study design or methods regarding the subject.
C. May mean there are inconsistencies of findings across studies, findings that are not generalizable to routine US primary care practice.
D. Suggests a lack of information on important health outcomes for the subject
E. Usually means further research should be carried out.
F. All of the above

76

Post Test Question 4

77

According to USPSTF guidelines, clinicians should recommend beta carotene supplements for patients to reduce the risk of cancer.

A. True
B. False

77

Post Test Question 5

78

According to USPSTF guidelines, clinicians should screen children under 11 for major depression.

A. True
B. False

78

Post Test Question 6

79

According to the ACA, Grade C Recommendations are mandated to be covered by insurance.

A. True
B. False

79

AAFP Guideline Endorsement Process

80

- AAFP Commission on Health of the Public and Science
  - Subcommittee on Clinical Practice Guidelines
- Meets to review guidelines from other sources including:
  - Major subspecialty guidelines, USPSTF, AAP, AIM, etc.
- Makes recommendations to endorsing existing guidelines in categories.
- Recommendations are then subject to AAFP Board approval:
- Categories of endorsement:
  - **(1) ENDORSED** - the AAFP fully endorses the guideline;
  - **(2) AFFIRMATION OF VALUE** - the guideline does not meet the requirements for full endorsement, or the AAFP cannot endorse all recommendations, but the guideline provides some benefit for family physicians.
  - **(3) NOT ENDORSED** - the AAFP does not endorse the guideline and the reasons are stated.
- https://www.aafp.org/patient-care/browse/type.tag-clinical-practice-guidelines.html Ref 21

80

References:

81

1. Fontanarosa, P, Golub R, JAMA and the US Preventive Services Task Force", *JAMA*, December 28.2021 Vol 326(24) p 2477.
2. USPSTF app. – available on the app store. Version 4.5.1, US department of Health and Human Services.
3. "Task Force Recommends statins for CVD prevention", News AAFP, March 10, 2022,, https://www.aafp.org/news/health-of-the-public/statins-draft-recommendation.html
4. Reported tuberculosis in the United States, 2020; table 5: tuberculosis cases, percentages, and incidence rates per 100,000 population by origin of birth: United States, 1993–2020. Centers for Disease Control and Prevention. Accessed March 9, 2023. https://www.cdc.gov/tb/statistics/reports/2020/table5.htm
5. US Preventive Services Task Force. Preexposure prophylaxis for the prevention of HIV infection: US Preventive Services Task Force recommendation statement. *JAMA*. 2019;321(22):2203-2213.
6. HIV Infection, Stage 3 (AIDS): 2019. Centers for Disease Control and Prevention. Accessed June 28, 2023. https://www.cdc.gov/hiv/pdf/library/slidesets/cdc-hiv-infection-stage-3-2019.pdf
7. HIV Surveillance Report: diagnoses of HIV infection in the United States and dependent areas; 2020. Centers for Disease Control and Prevention. Published May 2022. Accessed June 28, 2023. https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-33/index.html
8. Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2019*. US Dept of Health and Human Services; 2021.

81

References:

82

9. Goff DC Jr, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014;129(25 Suppl 2):S49-73.
10. PREVENT calculator, https://professional.heart.org/en/guidelines-and-statements/prevent-calculator
11. Guirguis-Blake JM, Evans CV, Coppola EL, Redmond N, Perdue LA. *Screening for Lipid Disorders in Children and Adolescents: An Evidence Update for the U.S. Preventive Services Task Force. Evidence Synthesis No. 229*. Agency for Healthcare Research and Quality; 2023. AHRQ publication 22-05301-EF-1.
12. Department of Veterans Affairs, Department of Defense. *VA/DoD Clinical Practice Guideline: The Management of Major Depressive Disorder*. US Government Printing Office; 2022.
13. American Diabetes Association. Children and adolescents: standards of medical care in diabetes—2020. *Diabetes Care*. 2020;43(suppl 1):S163-S182.
14. Zuckerbrot RA, Cheung A, Jensen PS, Stein REK, Laraque D; GLAD-PC Steering Group. Guidelines for Adolescent Depression in Primary Care (GLAD-PC): part I: practice preparation, identification, assessment, and initial management. *Pediatrics*. 2018;141(3):e20174081.

82

References:

83

15. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. American Psychiatric Association; 2013.
16. Shifren JL, Gass ML; NAMS Recommendations for Clinical Care of Midlife Women Working Group. The North American Menopause Society recommendations for clinical care of midlife women. *Menopause*. 2014;21(10):1038-1062.
17. Manson JE, Chlebowski RT, Stefanick ML, et al. Menopausal hormone therapy and health outcomes during the intervention and extended post stopping phases of the Women's Health Initiative randomized trials. *JAMA*. 2013;310(13):1353-1368.
18. Lin, JS, Webber EM, Thomas RG. *Screening for Chronic Obstructive Pulmonary Disease: A Targeted Evidence Update for the U.S. Preventive Services Task Force*. Evidence Synthesis No. 215. Agency for Healthcare Research and Quality; 2022. AHRQ publication 21-05287-EF-1.

83

References:

84

19. Henrikson NB, Ivlev I, Blasi PR, et al. Skin cancer screening: updated evidence report and systematic review for the US Preventive Services Task Force. *JAMA*. Published April 18, 2023.
20. Costello EJ, Mustillo S, Erkanli A, et al. Prevalence and development of psychiatric disorders in childhood and adolescence. *Arch Gen Psychiatry*. 2003;60(8):837-844.
21. https://www.aafp.org/patient-care/browse/type.tag-clinical-practice-guidelines.html
22. Brief by: Laurie Sobel, Usha Ranji, Kaye Pestaina, Lindsey Dawson, and Juliette Cubanski, Published: May 15, 2023
23. Moyer VA; U.S. Preventive Services Task Force. Vitamin, mineral, and multivitamin supplements for the primary prevention of cardiovascular disease and cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2014;160(8):558-564.

84

85

Thank You!

Please email me with any questions:

Dr. Hart Contact Information

Rebecca Hart, MD, FAAFP

rxhart@icloud.com

rebeccaeileenhart@outlook.com

85

Notes

Substance Use Disorder Screening and Interventions for the Family Physician

Daniel Hochman, MD
Psychiatrist, Private Practice
Founder and Creator of SelfRecovery.com
Austin, Texas

Educational Objectives

By completing this educational activity, the participant should be better able to:

1. Discuss screening instruments for detecting substance abuse and dependence and take a thorough history of substance use.
2. Describe clinical characteristics of substance abuse, dependence, and withdrawal.
3. Learn the latest pharmacological treatment options for the treatment of substance use disorder.
4. Learn the psychiatric and medical co-morbidities associated with substance abuse.

Speaker Disclosure

Dr. Hochman disclosed he has no financial relationships with any ineligible organizations or commercial interests.

Substance Use Disorder: Screening and Interventions for the Family Physician

Texas Academy of Family Physicians
2024 C. Frank Webber Lectureship

Daniel Hochman, MD
Affiliate Faculty, Dell Medical School
Founder, selfrecovery.org

Disclosure – Dr. Hochman disclosed he has no financial relationships with any ineligible organizations or commercial interests.

1

Feel uncomfortable dealing with substance use?

You're not alone! A survey of Primary Care Providers (PCP's) showed:

- Only 2% of PCP's believe substance abuse treatment is very effective (vs 43% for depression)
- 95% of patients lie to their PCP about their addiction due to: Shame > Don't want treatment > Afraid PCP will tell family
- 6% of PCP's identify substance use in a classic case vignette
- 1/4 PCP's were concerned that the discussion would anger their patients

National Center on Addiction and Substance Abuse (CASA) at Columbia University. Missed Opportunity: National Survey of Primary Care Physicians and Patients on Substance Abuse, 2000.

2

What We Will Cover

1. **Define substance use disorder.**
2. **Review screening instruments for detecting substance use disorder.**
3. **Describe clinical comorbidities and characteristics of substance use disorder.**
4. **Review pharmacological treatment options.**
5. **Learn brief motivational interviewing techniques.**
6. **Learn what services exist in the continuum of care.**

3

DEFINE SUBSTANCE USE DISORDER (SUD)

4

Substance Use Disorder (SUD)

- Includes alcohol, illicit drugs, prescription drugs
- Past-year prevalence of SUD: 17% (alcohol>cannabis>nicotine>>pills)
- **Lifetime prevalence of SUD: >40%**

https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFRPDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf

5

11 Criteria for SUD

"In the past year, have you _____ ?"

1. **Amount** – Had times when you ended up using more, or longer, than you intended?
2. **Loss of control** – More than once wanted to cut down or stop, but couldn't?
3. **Time lost** – Spent a lot of time using? Or being sick or getting over other aftereffects?
4. **Cravings** – Wanted a substance so badly you couldn't think of anything else?
5. **Failed responsibilities** – Found that it often interfered with taking care of your home or family? Or caused job troubles? Or school problems?
6. **Relational problems** – Continued to use even though it was causing trouble with your family or friends?
7. **Loss of interests** – Given up or cut back on activities that were important or interesting to you, or gave you pleasure, in order to use?
8. **Physically hazardous** – More than once gotten into situations while or after using that increased your chances of getting hurt (such as driving, swimming, using machinery, walking in a dangerous area, or having unsafe sex)?
9. **Health consequences** – Continued to use even though it was making you feel depressed or anxious or adding to another health problem?
10. **Tolerance** – Had to use much more than you once did to get the effect you want? Or found that your usual amount had much less effect than before?
11. **Withdrawal** – Found that when the effects were wearing off, you had withdrawal symptoms?

6

Definition of Substance Use Disorder

Anyone meeting any 2 of the 11 criteria during the same 12-month period.

Severity sub-classifications:

Mild: 2-3 symptoms

Moderate: 4-5 symptoms

Severe: 6+ symptoms

7

Audience Polling Question #1

A 38 year old male patient reports smoking marijuana most nights. He and his wife get into arguments about it, and he admits he's less productive with it.

Is this Substance Use Disorder?

A. Yes
B. No

8

SCREENING INSTRUMENTS FOR DETECTING SUBSTANCE USE DISORDER

9

Three of the Briefest, Valid Screening Tools:

- Single-Item Alcohol Screener
- Single-Item Drug Use Screener
- TAPS: Tobacco, Alcohol, Prescription medication, and other Substance use Tool

U.S. Preventive Services TASK FORCE

https://nida.nih.gov/taps2/

McNeely J, Cleland CM, Strauss SM, Palamar JJ, Rotrosen J, Saitz R. Validation of self-administered single-item screening questions (SISQs) for unhealthy alcohol and drug use in primary care patients. *J Gen Intern Med*. 2015;30(12):1757–1764.
Reinert DF, Allen JP. The alcohol use disorders identification test: An update of research findings. *Alcohol Clin Exp Res*. 2007;31(2):185–199.

10

Single Item Alcohol Screener

How many times in the past year have you had five (four for women) or more drinks in a day?

If > 0, it is a positive response.

- Sensitivity 82%
- Specificity 79%

Smith P, Schmidt S, Allensworth-Davies D, Saitz R. Primary care validation of a single-question alcohol screening test. *J Gen Intern Med*. 2009;24(7):783–788.

11

Single Item Drug Use Screener

How many times in the past year have you used an illegal drug or used prescription medications for nonmedical reasons?

If > 0, it is a positive response.

- Sensitivity 100%
- Specificity 74%

McNeely J, Cleland CM, Strauss SM, Palamar JJ, Rotrosen J, Saitz R. Validation of self-administered single-item screening questions (SISQs) for unhealthy alcohol and drug use in primary care patients. *J Gen Intern Med*. 2015;30(12):1757–1764.

12

TAAPS Screener

4 questions → more if yes responses to those

Example: "In the past 12 months, how many times have you used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you?"

- Sensitivity 82%
- Specificity 92%

https://pubmed.ncbi.nlm.nih.gov/27595276/
https://nida.nih.gov/taps2/

13

Labs and Drug Testing

- Don't drug test without permission (unless an emergency)
- General drug screening always includes: amphetamine, cocaine, marijuana, opioids
- **Testing has not been shown to be of clinical benefit**
- Only test for a clear indication
  - Avoid phenytoin or beta blocker if positive for cocaine
  - New onset psychosis
  - Forensic cases
- Alcohol → Macrocytic Anemia, HDL >60

Emergency physician practices and requirements regarding the medical screening examination of psychiatric patients. Broderick KB, Lerner EB, McCourt JD, Fraser E, Salerno K. *Acad Emerg Med*. 2002;9(1):88.
Jones A. Evidence-based survey of the elimination rates of ethanol from the blood with applications in forensic casework. *Forensic Sci Int*. 2010;200(1-3):1–20.

14

Audience Polling Question #2

In the Single Item Alcohol Screener, how many drinks does a man need to have in one day for it to be considered a positive result?

A. 3
B. 4
C. 5
D. 6

15

PSYCHOLOGICAL ETIOLOGY OF SUBSTANCE USE DISORDER

16

Addiction is NOT Caused by Genes or Substances

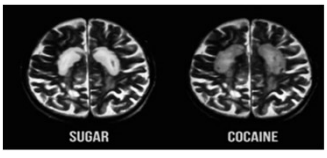
- Genes cause traits, not behavior
- Substances interact with the addiction pathway, but do not cause it.

Felitti, Vincent J. "The origins of addiction: Evidence from the adverse childhood experiences study." *Praxis der Kinderpsychologie and Kinderpsychiatrie* 52.8 (2003): 547-559.
Lewis, Marc. "Brain change in addiction as learning, not disease." *New England Journal of Medicine* 379.16 (2018): 1551-1560.

17

We're All Wired for Addiction

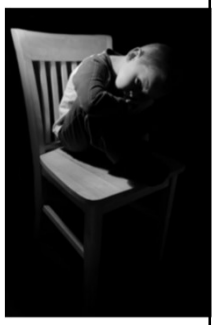
- We actually *need* the addiction pathway:
  - Motivation / Pursuit
  - Impulsivity



18

The 3 Learned Traits in Addiction

1. Lack of belonging
2. Poor impulse control
3. Emotional distress (frustration intolerance)



Shedler, Jonathan, and Jack Block. "Adolescent drug use and psychological health: A longituidinal inquiry." *American psychologist* 45.5 (1990):612.

19

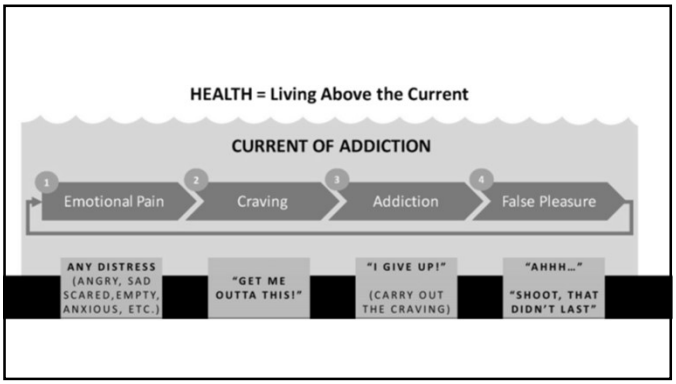
Definitions

National Institute of Drug Abuse:
"A chronic, relapsing brain disease that's characterized by compulsive drug seeking and use, despite harmful consequences."
- Negative implications, sets a critical tone from the outset, limited to chemicals/compounds

Alternative definition:
"Seeking pleasure to escape intolerable emotion."

Courtwright, David T. "The NIDA brain disease program paradigm: History, resistance, and spinoffs." *Expanding addiction: Critical essays.* Routledge, 2014. 62-69.

20



21

Audience Polling Question #3
Which is true?

A. If we teach people the harms of substances, they will just say no to drugs and avoid addiction.
B. Addiction is a pattern of turning to a substance to escape an intolerable emotional state.
C. Genes are the main cause of addiction.
D. Addiction is a moral issue one needs to care enough to control.

22

PHARMACOLOGICAL TREATMENT OPTIONS: GENERAL

23

Naltrexone

- Opioid antagonist. Reduces cravings and prevents relapse for both substances and behaviors (binge eating)
- Recommended dose: 25-50mg
- Long-acting form is 380mg intramuscular (IM) monthly injection
- Common side effects: nausea, headache, dizziness (all transient)
- Avoid in severe liver disease due to rare hepatotoxic potential, or those on opioid therapy as it precipitates withdrawal
- Labs: initial liver function testing with follow-up every 3-6 months
- Continue until recovery is stable

Volpicelli JR, Alterman AI, Hayashida M, O'Brien CP. Naltrexone in the treatment of alcohol dependence. A controlled study. *Arch Gen Psychiatry.* 1992;49(11):881–887.

24

PHARMACOLOGICAL TREATMENT OPTIONS: FOR NICOTINE

25

Bupropion

- Helps to replace "uppers" (cocaine, stimulants, methamphetamine) and nicotine
- Recommended dose: 150-300mg
- Great choice for co-occurring depression or attentional issues
- Side effect: increased seizure risk (especially with eating disorder, alcohol, or sedative use)
- Continue for 3-6 months, or until recovery is stable

26

Varenicline

- Partial nicotinic agonist
- Recommended dose: titrate from 0.5mg to 1mg twice daily
- Side effects: nausea, disturbing dreams, rarely psychosis, or depression
- Continue for 12 weeks, or until recovery is stable

27

Nicotine Replacement

- Over the counter: gum, patch, lozenge
- Prescription: nasal spray, inhaler
- Can be used as ongoing replacement (harm reduction), or help quit
- Can combine with other medications
- Failure if under-replace their usual nicotine amount

28

PHARMACOLOGICAL TREATMENT OPTIONS: FOR ALCOHOL

29

For Anyone with Heavy Alcohol Intake:

- Thiamine (B-1) 100mg daily to prevent Wernicke encephalopathy
- Multivitamin and folic acid (B-9) 1mg for any underlying nutritional deficiencies

30

Acamprosate

- Acts on glutamate and GABA systems
- Shown to reduce drinking and increase rates of abstinence
- Good option if patient needs opioid treatment or has severe liver disease
- Dose: 666mg TID (start and maintenance). Dosing causes adherence issues.
- Common side effects: diarrhea, nausea, dizziness, muscle weakness
- Avoid in patients with reduced creatinine clearance
- Continue until recovery is stable

Donoghue K, Elzerbi C, Saunders R, Whittington C, Pilling S, Drummond C. The efficacy of acamprosate and naltrexone in the treatment of alcohol dependence, Europe versus the rest of the world: A meta-analysis. *Addiction*. 2015;110(6):920–930.

31

Disulfiram

- Alcohol-sensitizing agent. Inhibits aldehyde dehydrogenase (= elevated acetaldehyde if drink)
- Effects if drink: flushing, nausea, vomiting, tachycardia, palpitations, diaphoresis, blurred vision, dizziness, confusion
- Rare severe reaction: cardiovascular collapse and seizure
- Great choice for motivated patients
- Dose: wait at least 12 hours after last drink, 125-500mg daily (average 250mg)
- Side effects: hepatotoxicity, drowsiness, headache, acne
- Avoid in liver disease, severe cardiac disease, psychotic
- Monitor liver function annually
- Educate on common products with alcohol (cologne, mouthwash, lotions, cough medications)

Anton RF, Myrick H, Wright TM, et al. Gabapentin combined with naltrexone for the treatment of alcohol dependence. *Am J Psychiatry*. 2011;168(7):709–717.

32

PHARMACOLOGICAL TREATMENT OPTIONS: FOR OPIOIDS

33

Buprenorphine

- High affinity mu-opioid partial agonist
- Blocks other opioids so protects from other drug use
- Low ceiling effect = overdose is extremely rare = "harm reduction"
- Will precipitate withdrawal if not off of usual opioid
- Great choice for comorbid pain or high risk
- Absorbed sublingually
- Two formulations: with/without naloxone to prevent IV use
- Starting: wait until withdrawing from last use (12-24 hours)
- Dose: 4-24mg daily (usually 8mg)
- Side effects: constipation, nausea, headache, sweating

Kleber HD. Treatment of narcotic addicts. *Psychiatr Med*. 1985;3(4): 389–418.

34

Naloxone

- Opioid antagonist
- For high risk patients: prior overdose, taking >50 morphine mg equivalents, taking benzodiazepines with opioids, psychosocial concerns
- Bystanders are present in ~40% of opioid overdoses. Have patient inform people they have it.
- Fentanyl lacing is increasingly common
- In Texas a prescription is no longer needed
- Nasal spray or IM
- Works in 2 minutes. Lasts 60-90 minutes.
- Safe to use if mistaken

https://www.cdc.gov/stopoverdose/naloxone/index.html

35

Audience Polling Question #4

You discuss options with a patient who drinks heavily, and agree to begin disulfiram. Which of the following is true?

A. You must wait at least 12 hours after their last drink before starting.

B. It should only be prescribed by an addiction medicine physician.

C. If they experience nausea on the first dose, it should be stopped.

D. It cannot be prescribed with hydrocodone.

36

BRIEF MOTIVATIONAL INTERVIEWING TECHNIQUES

37

Motivational Interviewing: Quick & Easy

- Don't carry the responsibility/burden of the patient!
- Ambivalence about change is normal, and can be resolved by working with intrinsic motivations and values
- An empathic, yet direct style is best
- Can be just 2 minutes
- Pick a goal they're interested in

Treatment Improvement Protocols. Enhancing Motivation for change in Substance Abuse Treatment. Chapter 3—Motivational Interviewing as a Counseling Style. SAMHSA. (1999, Rockville, MD)

38

How do you do this?

5 Principles:

Develop discrepancy

Express empathy

Amplify ambivalence

Roll with resistance

Support self-efficacy

Hall, K., Gibbie, T., & Lubman, D.I. (2012). Motivational interviewing techniques: Facilitating behaviour change in the general practice setting. *Australian Family Physician*, Vol. 41(9), Sept., 2012, pp 660-667.

39

Sample Statements:

- On a scale from 1-10 (most interested), how interested are you in a change?.... Why not a lower number?
- "It sounds like on the one hand _____, yet on the other hand _____."
- "This must be terribly hard on you."
- "Perhaps now is not the time for a change."
- "I like your plan."

40

Audience Polling Question #5

Which of the following is part of the motivational interviewing technique?

A. "Your friends are making things worse."
B. "Have you considered changing friend groups?"
C. "You're saying you drink too much with your friends, but you don't want to cut them out of your life."
D. "You really need to think about your priorities."

41

WHAT SERVICES EXIST IN THE CONTINUUM OF CARE

42

- YOU!
  - **Consider medication, brief motivational interviewing, referral**
  - At follow-ups, ask about: substance amount, functional status, adherence to medication / recommendations made, other substance use
- Support Groups
- Counseling
- Psychiatry
- IOP (Intensive Outpatient Program)
  - Almost entirely group therapy
  - ~3 hours, 3 days per week, 10-12 weeks
- PHP (Partial Hospitalization Program):
  - Almost entirely group therapy
  - ~6 hours, 5 days per week, 2-4 weeks
- Rehab
  - May or may not include detoxification
  - ~1-2 nurse practitioner or psychiatrist visits
  - ~1 individual session per week, mostly group therapy
  - 3-5% success rate
  - 30-90+ days

Addiction Center, NCDAS: Substance Abuse and Addiction Statistics, SAMHSA

43

If you're serious about integrating care or learning more

Websites:

- https://www.samhsa.gov/integrated-health-solutions
- https://aspe.hhs.gov/basic-report/evaluation-samhsa-primary-and-behavioral-health-care-integration-pbhci-grant-program-final-report

Course:

- https://www.selfrecovery.org/addiction-toolbox-for-clinicians/

Books:

- Integrating Behavioral Health and Primary Care.: Robert E. Feinstein, Joseph V. Connelly, and Marilyn S. Feinstein (2017) Oxford: Oxford University Press.

44

THANK YOU

QUESTIONS?
CASES?

45

Notes

The Texas Academy of Family Physicians would like to gratefully acknowledge the following companies for their support of the 2024 C. Frank Webber Lectureship:

Babson

California Academy of Family Physicians

Eleos

Opioid Analgesics REMS Program Companies

Texas Family Medicine Preceptorship Program

TMLT

TEXAS ACADEMY OF FAMILY PHYSICIANS