



## FRIDAY SESSIONS

**"How Did We Get into this Fix, and How Do We Get Out?"**

**Knowledge Self-Assessment Study Group - Congestive Heart Failure**

**Overcoming Barriers to Individualized Management of Overactive Bladder in the Primary Care Setting**

**Testosterone Deficiency and Management...Who, What, and How**

**Managing Chronic Hepatitis C in the Primary Care Setting: Best Practices From Screening to Treatment**

**Neurobiology of Addiction**

**A Master Class in Understanding and Applying New Strategies to Improve Early Recognition and Treatment of Heart Failure in Family Practice**

**An Osteopathic Approach to Low Back Pain**

**Breast Cancer Update Prevention and Screening**

**Treatment Alternatives for Substance Abuse**

**Screening, Brief Intervention and Referral to Treatment (SBIRT)**

**Diagnosing and Managing CDK to Avoid Complications and Dialysis**

**Intro to the Top 10 Easy to Use Wellness Apps for Your Patients**

## **SATURDAY SESSIONS**

**ABFM's Family Medicine Certification (FMC)...Recent Enhancements Which Favorably Impact You Now**

**Evaluation and Differential Diagnosis of Syncope**

**Managing Meds During a Problem Pregnancy**

**Is Heart Disease Different in Women?**

**Update in Obstetrics for Primary Care...from A to Zika...What Every FP Who Doesn't Do OB Needs to Know**

**When Does an Ill Child Become An Emergency?**

**AAFP Highlight on Vaccinations 4 Teens**

**KEYNOTE - "The Three P's: Pride, Passion, and Purpose"**

**Panel on Burnout and Discussion Groups**

**Marijuana for Medical Use – Just the Facts M'aam**

**Quick Hits Panel – Q & A – Obstetrics for Board Review**

## **SUNDAY SESSIONS**

**An Overview of Lymphomas**

**Fever and Rash**

**Intimate Partner Violence (IPV)...Screening as a Step to Healing**

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**"How Did We Get into this Fix, and  
How Do We Get Out?"**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***“How Did We Get into this Fix, and How Do We Get Out?”***  
Joseph Garbely, DO

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.



**“The Substance Abuse Epidemic  
and the Essential Role for the  
Family Physician”**

**Joseph Garbely, D.O., FASAM**  
Medical Director  
VP of Medical Services

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**ASAM Disclosure of  
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**No Relevant Financial  
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**How did we get here?**

Good intentions leading to  
unintended consequences

**Confluence of factors, beginning in the 1990's**

- JCAHO standard for pain assessment (2001) and other organizations' (VA) categorization of pain as the 5<sup>th</sup> vital sign (1990's)
- Launch of Oxycontin in 1996, becoming the #1 selling narcotic pain reliever in 2001
- Hospital Consumer Survey of Health Care Providers and Systems (HCAHPS) in 2006 had 3 pain questions
- HCAHPS Optional in 2006....Mandatory in 2010 (ACA)
- CMS tied responses to reimbursement

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## Opioid Use Disorder Epidemic NESARC III

- NIAAA (NIH)
- 2002-2013
- Opioid use: 1.8% (2002) vs 4.1% (2013)
- Opioid use: 10,000,000 adults (4.1%) of US population
- NMU of Rx Opioids more than doubled among US adults
- NMU (lifetime): 4.7% (2002) vs 11% (2013)
- Adults w/ NMP Opioid Use D/O: 2.1 million (0.9%)



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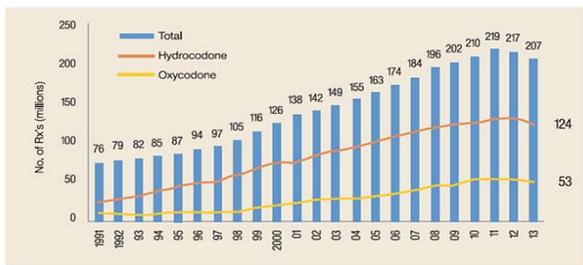
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## Oxycodone and Hydrocodone Prescriptions (1991-2013)



Opioid Prescriptions Dispensed by US Retail Pharmacies IMS Health, Vector One: National, years 1991-1996, Data Extracted 2011. IMS Health, National Prescription Audit, years 1997-2013, Data Extracted 2014.

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## Who's Writing these Prescriptions?



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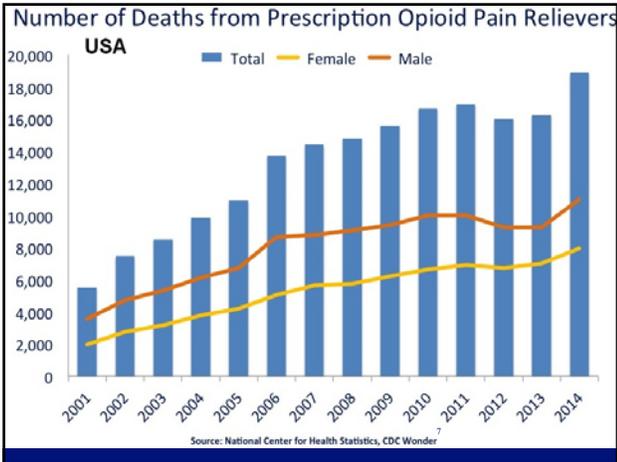
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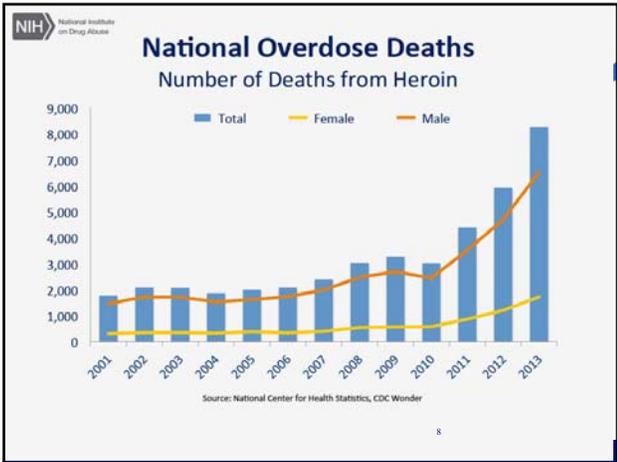
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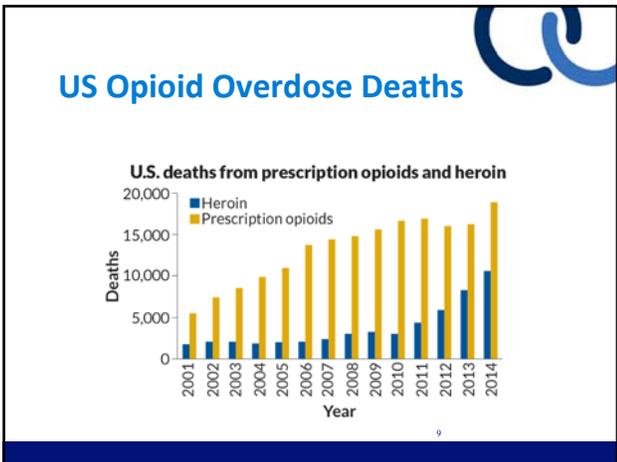
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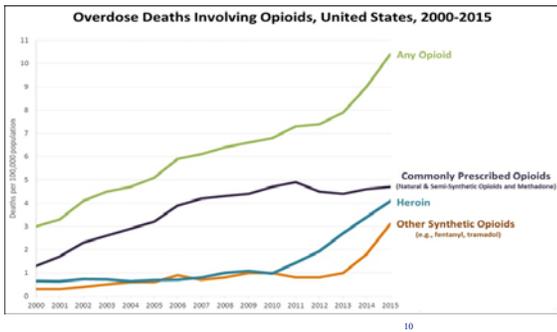
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## The rise of Synthetic opioids



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## Opioid Use Disorder Epidemic

One person dies every **19 MINUTES** from drug overdose in the United States and this increasing trend is driven by Rx painkillers.



Opioid pain relievers are responsible for more overdose deaths than cocaine and heroin combined.



Share this to help #EndMedicineAbuse.

Published by The Partnership at Drugfree.org. Visit [MedicineAbuseProject.org](http://MedicineAbuseProject.org) for more details.

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The percentage of heroin users with opioid pain reliever abuse or dependence more than doubled, from **20.7%** in 2002-2004 to **45.2%** in 2011-2013.



Annual average percentage of past-year heroin users\* with past-year opioid pain reliever abuse or dependence, by time interval - U.S., 2002-2013.

\*Past-year heroin use defined as any use of heroin in the 12 months preceding the National Survey on Drug Use and Health survey interview. Source: CDC Vital Signs release, July 16, 2015

## Opioid Poisoning Deaths (1999-2014) Quadrupled

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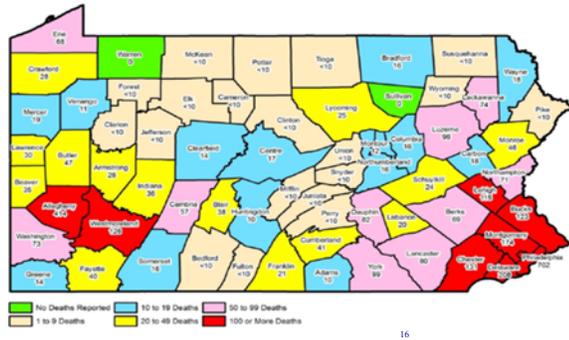
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## 2015 PA OD Deaths by County



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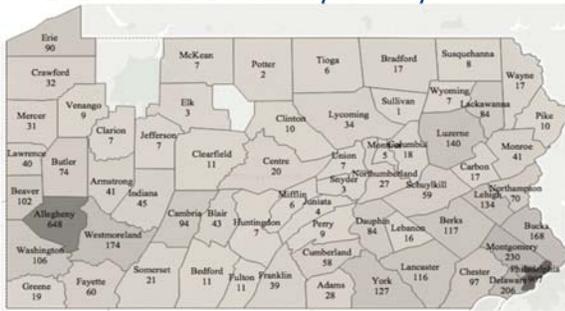
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## 4,652 PA OD Deaths in 2016 2016 PA OD Deaths by County



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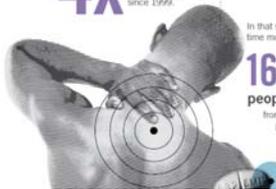
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## Opioid Use Disorder Epidemic

**REDUCE OVERDOSE.  
PRESCRIBE RESPONSIBLY.**  
OVERPRESCRIBING LEADS TO MORE ABUSE AND MORE OVERDOSE DEATHS.

**4x**

increase in sales of  
prescription opioids  
since 1999



In that same  
time more than

**165,000**  
people have died  
from overdose related to  
prescription opioids.

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## Chronic Pain is Overmedicated

- 259,000,000 opioid prescriptions were written in 2012.
- U.S. = 4.6 percent of the world's population
  - consumes 80% of its opioids
  - and 99% of its hydrocodone.



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## Opioid Use Disorder Epidemic

March 15, 2016

What now?



Surgeon General on nation's opioid epidemic | MSNBC

U.S. Surgeon General Dr. Vivek Murthy discusses America's opioid epidemic, saying doctors must be aware that such medications are addictive and not a good solution for chronic pain.

[Read more...](#)

GUIDELINE FOR  
PRESCRIBING  
OPIOIDS FOR  
CHRONIC PAIN

[www.cdc.gov](http://www.cdc.gov)



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## CDC Guideline

- **MMWR**
  - CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016
  - *Recommendations and Reports / March 18, 2016 / 65(1);1–49*



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### Summary of evidence used in determining the recent CDC Opioid prescribing guidelines

- No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤6 weeks in duration).
- Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury).
- Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm

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### As pain becomes chronic, it is represented in different regions of the brain

Subacute Back Pain [~2 mos.]

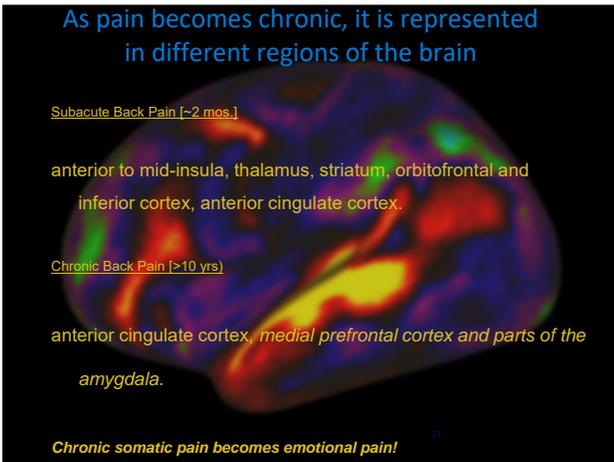
anterior to mid-insula, thalamus, striatum, orbitofrontal and inferior cortex, anterior cingulate cortex.

Chronic Back Pain (>10 yrs)

anterior cingulate cortex, medial prefrontal cortex and parts of the amygdala.

Chronic somatic pain becomes emotional pain!

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### A: Address the unpleasant experience.

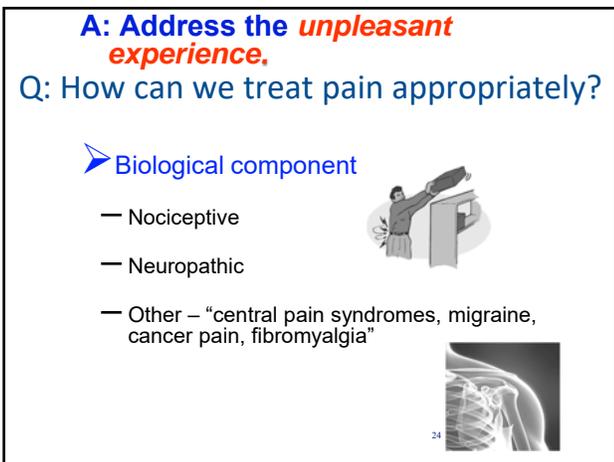
Q: How can we treat pain appropriately?

#### ➤ Biological component

- Nociceptive
- Neuropathic
- Other – “central pain syndromes, migraine, cancer pain, fibromyalgia”



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- The Psychological Component

Pain – the *unpleasant experience*

- Distraction
- Focused attention
- Inability to concentrate
- Sleep disturbance



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- The Sociologic Component

Pain – the *unpleasant experience*

- Homebound
- Loneliness
- Diminished sense of usefulness
- Dependence on others



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- The Spiritual Component

- *SUFFERING*

Pain – the *unpleasant experience*

- Isolation
- Resistance
- Feeling threatened
- Giving up



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### CDC guideline excerpts

- Because pain management in patients with substance use disorder can be complex, *clinicians should consider consulting substance use disorder specialists and pain specialists* regarding pain management for persons with active or recent past history of substance abuse.

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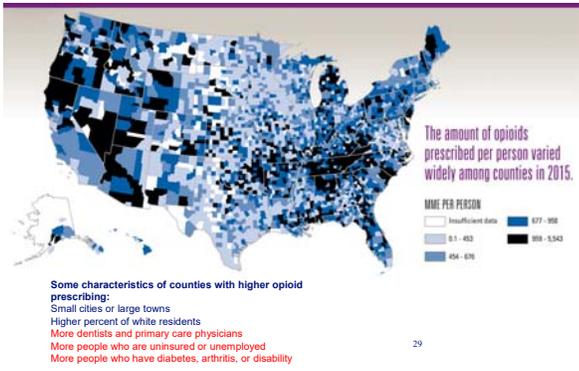
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### Opioid prescribing decreased between 2010 and 2015



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### Medication Assisted Treatment (MAT)

- Evidence based approach to treating opioid use disorders
- Decrease craving
- Reduce risk of relapse/OD
- Harm reduction (decreased criminal behavior and decreased communicable diseases)



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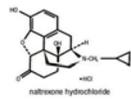
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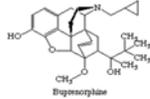
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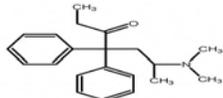
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**MAT**

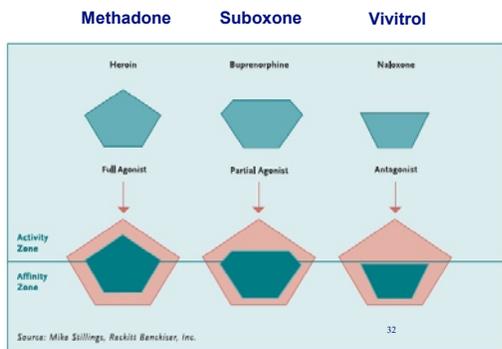


- Methadone Maintenance (Agonist)
- Buprenorphine Maintenance (Partial Agonist)
- Depot Naltrexone (Vivitrol) (Antagonist)



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### MAT action on mu-opioid receptors



### Co-prescribing with Naloxone Naloxone auto-injection for suspected opioid overdose



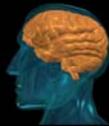
## Co-prescribing with Naloxone Intranasal Naloxone



## Naloxone Intranasal



## Addiction



Addiction is a primary, **chronic disease** of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

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## Summary

- Addiction is a **chronic brain disease** – it is not a lack of willpower or moral failing
- We need to treat addiction as a chronic disease
- Addiction affects all areas of a person's life
- Addiction is a family disease
- Addiction requires a comprehensive solution
  - Body (MAT), mind, spirit
- Treatment works and the brain heals
- Recovery is a lifelong process



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**Knowledge Self-Assessment Study  
Group - Congestive Heart Failure**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Knowledge Self-Assessment Study Group - Congestive Heart  
Failure***

Lou Mancano, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

**\*\*SESSION HANDOUTS ARE NOT AVAILABLE  
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**Overcoming Barriers to Individualized  
Management of Overactive Bladder in  
the Primary Care Setting**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Overcoming Barriers to Individualized Management of  
Overactive Bladder in the Primary Care Setting***

Scott MacDiarmid, MD

**Disclosures:**

Scott A. MacDiarmid, MD, has a financial interest/relationship or affiliation in the form of:

Consultant for: Allergan; Astellas Pharma US, Inc.; and Cogentix Medical.  
Advisory Board for: Allergan; Astellas Pharma US, Inc.; and Cogentix Medical.

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The speaker indicated that the content of the presentation **WILL** include discussion of unapproved or investigational uses of products or devices.

***This activity is supported by an educational grant from Astellas.***

## Overcoming the Barriers to Individualized Management of Overactive Bladder in the Primary Care Settings

**Scott A. MacDiarmid, MD**

Director, Alliance Urology Specialists Bladder Control and Pelvic Pain Center  
Clinical Professor  
Department of Urology  
University of North Carolina  
Chapel Hill, North Carolina

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## Overcoming the Barriers to Individualized Management of Overactive Bladder in the Primary Care Settings

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**Scott A. MacDiarmid, MD**, does intend to discuss either non-FDA-approved or investigational use for the following products/devices:  
Combination therapy with solifenacin and mirabegron.

*This activity is supported by an educational grant from Astellas.*<sub>2</sub>

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### Role of the Primary Care Practitioner

Proactive screening and age-appropriate assessment

Patient discussion on treatment goals, preferences

Consideration of nonpharmacologic and pharmacologic interventions

Monitoring for response, adjustment of therapy to meet treatment goals

Counseling to enhance adherence to therapy

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## Overactive Bladder Definitions From the ICS (2002)<sup>1,2</sup>

### Must be present

<b>Urgency</b>	Complaint of a sudden compelling desire to pass urine which is difficult to defer	<b>Nocturia</b>	Complaint that the individual has to wake one or more times at night to void
<b>Increased daytime frequency</b>	Complaint by the patient who considers that he/she voids too often by day	<b>Urgency UI</b>	Complaint of involuntary leakage accompanied by or immediately preceded by urgency

ICS: International Continence Society; UI: urinary incontinence.  
 1. van Kerrebroeck P et al. *NeuroUrol Urodyn*. 2002;21:179-183.  
 2. Abrams P et al. *NeuroUrol Urodyn*. 2002;21:167-175.

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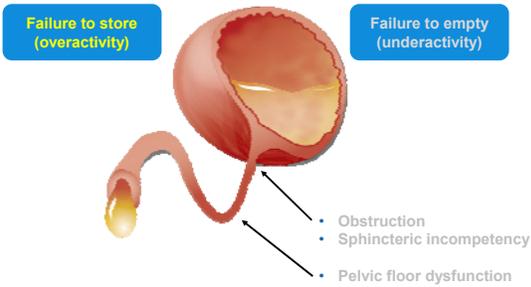
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## Disorders of the Bladder: Relation to OAB



OAB: overactive bladder.

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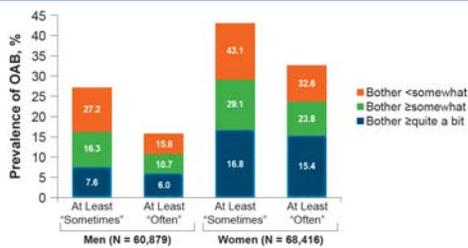
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## Estimated Prevalence of OAB Symptoms in the United States<sup>1</sup>



- Community-dwelling older adults (≥70 years of age): 20%-40%<sup>2,3</sup>
- NHANES
  - Non-institutionalized (>65 years of age): 43.8% reported urinary leakage<sup>4</sup>
  - 72%-75% nursing home residents have UI<sup>5</sup>

NHANES: National Health and Nutrition Examination Survey.  
 1. Coyne KS et al. *Urology*. 2011;77:1081-1087. 2. Aguilar-Navarro S et al. *J Gerontol A Biol Sci Med Sci*. 2012;67:1266-1271.  
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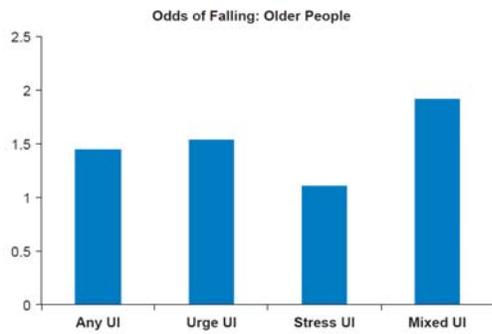
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## Risks Associated With Urge UI and OAB<sup>1</sup>



1. Chiarelli PE et al. *Aust J Physiother.* 2009;55:89-95.

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## OAB: Primary Care Misconceptions and Realities of Management<sup>1</sup>

### Misconceptions

- OAB is a natural, expected part of aging
- Diagnosis and treatment is outside the realm of the primary care setting; to be determined by a specialist

### Realities of OAB management

- The PCP is the initial contact
- Diagnosis and treatment is within the realm of the PCP setting
- Current treatments offer significant improvement of patient symptoms and patient QOL

GU: genitourinary.

1. MacDiarmid S, Rosenberg M. *Curr Med Res Opin.* 2005;21:1413-1421.

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## Normal Age-Related Changes That Can Contribute to UI and OAB<sup>1</sup>

### Bladder

- Decreased capacity
- Decreased sensation filling
- Increased overactivity
- Decreased contractile function
- Increased PVR

### Urethra

- Decreased closure pressure in women

### Prostate

- BPH

### Decreased estrogen

- Genitourinary syndrome of menopause: urgency, dysuria, recurrent UTI<sup>2</sup>

### Increase in nighttime urine production

- Nocturia

### Altered immune function

- Increased risk for UTI

BPH: benign prostatic hyperplasia; PVR: post-void residual.

1. [http://www.ics.org/Publications/ICI\\_5/INCONTINENCE.pdf](http://www.ics.org/Publications/ICI_5/INCONTINENCE.pdf). Accessed November 1, 2016.

2. Steele NM et al. *Urol Nurs.* 2016;36:59-65, 71.

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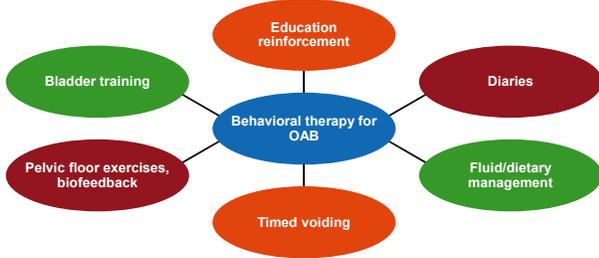
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## First-Line Treatment: Lifestyle Changes and Behavioral Therapy<sup>1-5</sup>

Supported by national and international urology and urogynecology medical societies



No matter what the treatment course, behavioral modification should be offered to every patient

1. <http://www.auanet.org/common/pdf/education/clinical-guidance/Overactive-Bladder.pdf>. Accessed November 1, 2016.  
 2. Qaseem A et al. *Ann Int Med*. 2014;161:429-440. 3. Tse V et al. *BJU Int*. 2016;117:34-47. 4. Moore K et al. *Incontinence: Proceedings From the 5th International Consultation on Incontinence*. Plymouth UK: Health Publications;2013:1101-1228.  
 5. Newman and Burgio. In: *Campbell-Walsh Urology*. 11th ed. 2016;90:1875-1896.

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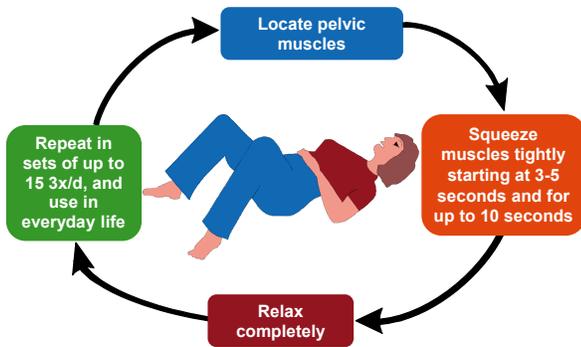
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## Pelvic Muscle Exercises: Expert Instruction<sup>1</sup>



1. Burgio KL et al. *JAMA*. 1998;280:1995-2000.

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## When Behavioral Therapy Is Not Enough...



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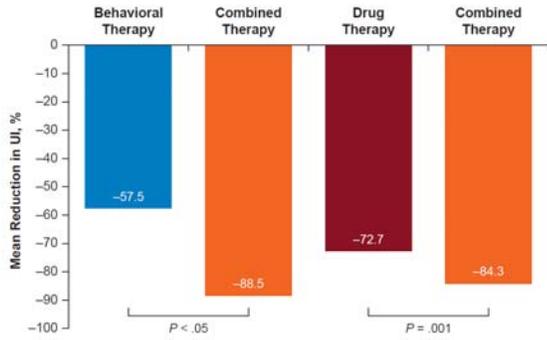
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## Additive Effect of Combining Behavioral and Drug Therapy<sup>1</sup>



1. Burgio KL et al. *J Am Geriatr Soc.* 2000;48:370-374.

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## Second-Line Therapies

- Medication classes for OAB
  - Antimuscarinic agents (anticholinergics)<sup>1</sup>
    - » Function by blocking the  $M_2$  and  $M_3$  receptors in bladder detrusor smooth muscle
  - $\beta_3$ -adrenergic agonists<sup>2</sup>
    - » Function by activating  $\beta_3$  receptors in detrusor thereby enhancing smooth muscle relaxation
- Men with symptoms consistent with BPH:  $\alpha_1$  blockers

BPH: benign prostatic hyperplasia; OAB: overactive bladder.  
 1. Andersson KE. *Eur Urol.* 2011;59:377-386.  
 2. Chapple CR. *Eur Urol.* 2012;62:841-842.

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## Antimuscarinic Agents<sup>1,2</sup>

- General principles
  - Consider route of metabolism
    - » Most include liver metabolism
    - » Transdermal avoids this first-pass effect
  - Some affect cytochrome P450 complex
    - » Darifenacin, fesoterodine, solifenacin, tolterodine
    - » Caution drug-drug interactions
  - Some have risk of QT prolongation ( $\rightarrow$  torsades)
    - » Tolterodine, fesoterodine, solifenacin (case reports)
- Side effects: dry mouth, constipation, confusion, etc.
  - Contraindicated in narrow-angle glaucoma
- Differences exist in the route of administration and dose flexibility
- AUA Guidelines **do not** establish hierarchy
  - May need to try more than one option

AUA: American Urological Association.  
 1. Gormley EA et al. *J Urol.* 2012;188(Suppl 6):2455-2463.  
 2. MacDiarmid SA. *Curr Urol Rep.* 2007;8:364-369.

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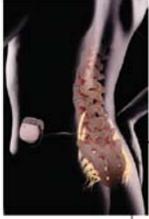




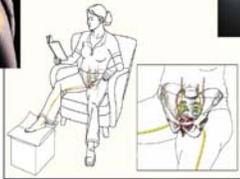


## Treatment Options for Refractory OAB

### Sacral Nerve Stimulation (SNS)



### Percutaneous Tibial Nerve Stimulation (PTNS)



### OnabotulinumtoxinA



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## Third-Line Therapy<sup>1</sup>

	PTNS	SNS	OnabotulinumtoxinA
Primary location of service	Clinic	OR/ASC	Clinic/OR/ASC
AUA/SUFU guideline (recommendation or standard)	✓	✓	✓
Adverse events	<p><b>Reported AEs are minor</b></p> <ul style="list-style-type: none"> <li>Painful sensation during stimulation that did not interfere with treatment</li> <li>Minor bleeding at insertion site</li> </ul>	<ul style="list-style-type: none"> <li>Pain at stimulator site</li> <li>Pain at lead site</li> <li>Lead migration</li> <li>Infection/irritation</li> <li>Electric shock</li> <li>Need for revision</li> </ul>	<ul style="list-style-type: none"> <li>UTI</li> <li>Urinary retention</li> <li>Elevated post-void residual</li> <li>Need for self-catheterization</li> <li>Gross hematuria</li> </ul>
Provider driven	Physician or nurse	Physician	Physician
Provider performed	Nurse	Physician	Physician

ASC: ambulatory surgery center; OR: operating room; SUFU: Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction.

1. Gormley EA et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline. [www.auanet.org/content/media/OAB\\_guideline.pdf](http://www.auanet.org/content/media/OAB_guideline.pdf). Accessed November 1, 2016.

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## Considerations for Therapy Selection in the Individual Patient

- Baseline factors (such as polypharmacy)
- Disease characteristics
- Patient comorbidities (such as uncontrolled hypertension, constipation, cognitive dysfunction)
- Balancing efficacy versus tolerability
- Consider overall anticholinergic burden
- Consider the goals of individual patients
- Cost of therapy to the patient

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## Medication Use in Older Adults<sup>1</sup>

- Titrate dosing to therapeutic effect
- Monitor for adverse events
- Adverse drug events in geriatrics are common, costly, and often preventable (27%-42% of cases)
- Negative outcomes
  - Delirium, dry mouth, constipation, falls, fractures
  - Depression and sensory changes
  - Worsened caregiver burden
  - Increased emergency room use and hospitalization (>99,000 hospitalizations between 2007-2009)

1. Budnitz DS et al. *N Engl J Med*. 2011;365:2002-2012.

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## Drugs With Strong Anticholinergic Properties<sup>1</sup>

- Antihistamines
- Antiparkinson agents
- Skeletal muscle relaxants
- Tricyclic antidepressants
- Antipsychotics
- Antimuscarinics (urinary incontinence)
- Antispasmodics

1. American Urological Association Education and Research, Inc. *AUA White Paper on the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*. 2015.

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## Concerns Regarding Anticholinergic Use in the Elderly<sup>1-3</sup>

- FDA issued warning on oxybutynin in 2008
  - Oxybutynin is associated with the risk of aggravating confusion in patients with dementia, who are receiving ChEIs<sup>1</sup>
- Faster functional decline in LTC for those with dementia treated with bladder antimuscarinics and ChEIs concurrently<sup>2</sup>
- Cumulative anticholinergic medication use associated with long-term, permanent cognitive deterioration<sup>3</sup>
- Clinical manifestations of anticholinergic toxicity are likely to be nonspecific (eg, cognitive impairment, sleep disturbance)
  - No clinically available laboratory test to assess anticholinergic levels

ChEI: cholinesterase inhibitor; LTC: long-term care.  
1. Carnahan RM et al. *J Am Geriatr Soc*. 2004;52:2082-2087.  
2. Sink KM et al. *J Am Geriatr Soc*. 2008;56:847-853.  
3. Gray SL et al. *JAMA Intern Med*. 2015;175:401-407.

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### Beers Criteria for Potentially Inappropriate Medication Use in Older Adults: Implications for Urologic Care<sup>1</sup>

Disease/Syndrome	Drug	Recommendation	Rationale
Delirium	<ul style="list-style-type: none"> <li>All TCAs</li> <li>Anticholinergics</li> <li>Benzodiazepines</li> <li>Chlorpromazine</li> <li>Corticosteroids</li> <li>H<sub>2</sub>-receptor antagonists</li> <li>Meperidine</li> <li>Sedative hypnotics</li> <li>Thioridazine</li> </ul>	Avoid	Avoid in older adults with or at high risk of delirium to prevent inducing or worsening delirium; if discontinuing drugs used chronically, taper to avoid withdrawal symptoms
Dementia and cognitive impairment	<ul style="list-style-type: none"> <li>Anticholinergics</li> <li>Benzodiazepines</li> <li>H<sub>2</sub>-receptor antagonists</li> <li>Zolpidem</li> <li>Antipsychotics, chronic and as-needed use</li> </ul>	Avoid	Avoid because of adverse CNS effects; avoid antipsychotics for behavioral problems of dementia unless nonpharmacological options have failed and patient is a threat to themselves or others; antipsychotics are associated with increased risk of stroke and mortality in patients with dementia

TCA: tricyclic antidepressant.  
 1. American Urological Association Education and Research, Inc. *AUA White Paper on the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*. 2015. **37**

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### Beers Criteria for Potentially Inappropriate Medication Use in Older Adults: Implications for Urologic Care (Cont'd)<sup>1</sup>

Disease/Syndrome	Drugs	Recommendation	Rationale
Chronic constipation	Oral antimuscarinics for UI <sup>a</sup> <ul style="list-style-type: none"> <li>Darifenacin</li> <li>Fesoterodine</li> <li>Oxybutynin (oral)</li> <li>Solifenacin</li> <li>Tolterodine</li> <li>Trospium</li> </ul>	Avoid unless no other alternatives	Can worsen constipation; antimuscarinics differ in incidence of constipation; response variable; consider alternative agent if constipation develops
UI (all types in women)	Estrogen oral and TD (excludes intravaginal estrogen)	Avoid in women	Aggravation of incontinence
LUTS benign prostatic hyperplasia	Inhaled anticholinergic agents; strongly anticholinergic drugs, except antimuscarinics for UI	Avoid in men	May decrease urinary flow and cause urinary retention
Stress or mixed UI	Alpha blockers <ul style="list-style-type: none"> <li>Doxazosin</li> <li>Prazosin</li> <li>Terazosin</li> </ul>	Avoid in women	Aggravation of incontinence

<sup>a</sup> Only medications prescribed by urologists are listed as examples.  
 LUTS: lower urinary tract symptom; TD: transdermal; UI: urinary incontinence.  
 1. American Urological Association Education and Research, Inc. *AUA White Paper on the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults*. 2015. **38**

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### Conclusions

- OAB can and should be managed within the primary care setting
- Providers should proactively engage in OAB case finding
- OAB is more common with aging
- First-line OAB treatment is behavioral and lifestyle changes
- Many patients may benefit from pharmacologic treatment

OAB: overactive bladder. **39**

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## Case Discussions and Q&A

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### Case 1: Jane, a 68-Year-Old Living Independently

#### Presentation

- Has had difficulty holding urine (urgency) for years; has experienced three episodes of urinary accidents over the last 3 months
- Cannot sit through a 2-hour movie
- She drinks 2 to 3 glasses of wine or cocktail every day

#### History

- Hypertension
- Hyperlipidemia
- Family history of late-onset dementia

#### Any Current Therapy

- Lisinopril 10 mg
- Simvastatin 20 mg

#### Examination Notes

- Obesity (BMI is 32.4)
- Neuro: normal
- Cardiac: normal
- Pulm: normal
- Abdomen: protuberant, nontender, no masses
- GU: good vaginal integrity, no cystocele or rectocele
- Rectal: normal
- Ext: normal, without edema

GU: genitourinary.

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### What Is the Best Recommendation for Jane?

Jane was initiated on behavioral therapy, lifestyle modifications, and urge suppression strategies.

At 3 months, she reported improvement in controlling her urinary urgency, but she still continues to have wetting episodes.

In addition to behavioral therapy, the best recommendation would be...

- An antimuscarinic agent
- $\beta_3$ -agonist
- Combination of antimuscarinic and  $\beta_3$ -agonist
- OnabotulinumtoxinA
- Referral to a specialist to consider neuromodulation

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**Case 1: Jane, Failing Therapy With 2 Antimuscarinic Agents**

Jane was started on tolterodine 4 mg for 4 weeks; however, she had no improvement in her condition. Then, she was prescribed darifenacin 7.5 mg but she experienced significant constipation and was unable to tolerate the dry mouth.

The best recommendation for Jane at this stage would be...

- A third antimuscarinic agent
- $\beta_3$ -agonist (mirabegron)
- Combination of antimuscarinic and  $\beta_3$ -agonist
- OnabotulinumtoxinA
- Referral to a specialist to consider neuromodulation

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**Case 2: Joyce, an 87-Year-Old Resident of a Nursing Home**

**Presentation**

- Presents with urinary urgency, UUI; caregivers report that she is "always" asking to go to the toilet; 2-3 wet episodes at night per week
- Problem has worsened over the past 6 months
  - She wears 4-6 pull-ups a day and does not want to wear diaper at night
  - Now taking an over-the-counter pill to help her sleep better
- Uses walker, can walk short distances but is now primarily in wheelchair

**History**

- Hypertension
- GERD
- Arthritis
- Depression
- Mild Alzheimer's; short-term memory impairment

**Current Therapy**

- Metoprolol 25 mg PO QD
- Amlodipine 2.5 mg PO QD
- Furosemide 20 mg QD
- Trazodone 50 mg PO HS
- ASA 81 mg
- Fentanyl transdermal patch 72 h 25 mcg/h
- Pantoprazole 40 mg PO QD
- Milk of Magnesia PRN

ASA: acetylsalicylic acid; HS: half strength; QD: once daily; UUI: urge urinary incontinence.

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**What is the best recommendation for Joyce?**

- Start an antimuscarinic medication at the lowest dose
- Begin a program of timed voiding and mirabegron 25 mg daily
- Combination of solifenacin and mirabegron
- Bedside commode
- OnabotulinumtoxinA
- Referral to a specialist to consider neuromodulation

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**[Return to Top](#)**

# **Testosterone Deficiency and Management...Who, What, and How**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Testosterone Deficiency and Management...Who, What, and  
How***

Michael Baxter, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

## Testosterone Deficiency and Management : Who, What and How

D. Michael Baxter, MD  
Chair, Department of Family and Community Medicine  
Reading Hospital



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### Disclosure

- The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.



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### Goals and Objectives

- \* Summarize the evaluation and management of suspected testosterone deficiency
- \* Compare the different testosterone replacement therapies
- \* Describe the potential adverse effects and monitoring recommendations for testosterone replacement therapy
- \* Discuss evidence based guidelines with patients that ensure therapy only for the appropriate indications



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## Case Considerations

Case 1: 67 y/o male with hx of esophageal and pancreatic cancers who is now 5 years in remission following surgery, chemo and XRT. He is very thankful for his health, has a supportive family and runs his own business. He describes onset of sx of erectile dysfunction, fatigue and loss of hair.

Case 2: 59 y/o male who is obese (BMI= 45) with poorly controlled Type 2 Diabetes Mellitus. He feels that he is easily fatigued, lacks energy and does not have the "sexual stamina" that he formerly had. He retired early in the past year and just doesn't feel "as vital" as he used to. He wonders if his testosterone is low.



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## Questions for Discussion

All men over 60 should be screened for testosterone deficiency?

Testosterone deficiency is defined by low total, free testosterone or both?

All men with low testosterone levels should be treated with replacement therapy?

Even men with normal testosterone levels can benefit from replacement therapy?



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## Is it "Low T" ?

Unwanted Body Changes? >

Mood Changes? >

Sexual Dysfunction? >

Stop living in the shadows.



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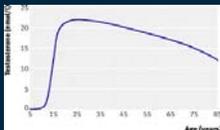
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## Testosterone changes with age: A gradual decline



Unlike estrogen levels in menopause, testosterone levels in men fall by only 1-2 %/year after age 40 and that can be variable.



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## Low T: The next new “social disease”

“ A proportion of older men will predictably have testosterone concentrations below the normal range of healthy young men. It seems a bit harsh to turn an age-related phenomenon into a disease, but that’s what has happened” .

Tony Delamothe, deputy editor British Medical Journal 2012



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## Physiology of Testosterone (Causes of Hypogonadism in Males)

Primary -- (v total testosterone, ^ LH and FSH) congenital or acquired (Chemo or XRT, orchitis e.g. mumps)

Secondary -- (v total testosterone, nl or v FSH or LH) congenital or acquired (chronic opioid use, hyperprolactinemia/pituitary tumors, trauma, surgery)

Mixed—(v total testosterone, variable LH and FSH) acquired (Aging, Cancer, CKD, COPD, Diabetes Mellitus, Cirrhosis, Obesity)

\*Petering, Brooks "Testosterone Therapy: Review of Clinical Applications", AFP Oct 1, 2017



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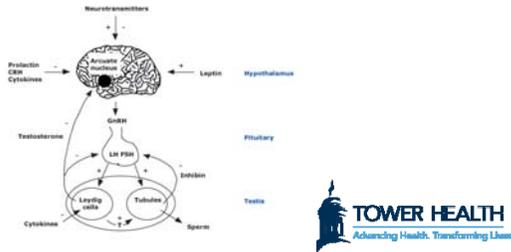
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## The Hypothalamic--Pituitary--Testicular Axis

(Up to Date: "Male Reproductive Physiology", 2017)



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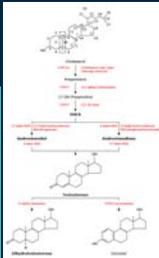
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## Testosterone formation and metabolism



Testosterone is formed in the Leydig cells in the testes from a cholesterol precursor in response to Leutenizing Hormone (LH) which is produced by the pituitary gland. Primary hypogonadism-failure of the testes to produce sufficient testosterone. Secondary hypogonadism – caused by decreased production of LH (FSH and testosterone essential to spermatogenesis)



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## Testosterone Deficiency Diagnostic Challenges

Wide range of normal levels

Total testosterone (300-720)

Free (unbound) testosterone (47-244)

Levels vary by time of day and acute illness

Many chronic illnesses/conditions affect Sex Hormone Binding Globulin

Chronic Diseases -DM, Nephrotic Syndrome,Thyroid Disease, Cirrhosis, HIV

Obesity, Aging

Certain medications - e.g. Glucocorticoids, anticonvulsants



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## Diagnosis of Testosterone Deficiency (Androgen Deficiency)

Consistent signs and symptoms of androgen deficiency (1)

Low morning total testosterone level obtained by a reliable assay (2)

Confirmation by a repeat morning total testosterone level and in some cases measurement of free (bioavailable) testosterone level. (1)

\* Evidence based guidelines: The Endocrine Society



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## Signs and Symptoms of Androgen Deficiency in Men

Incomplete sexual development, aspermia and inability to father children

Reduced sexual desire (libido) and activity

Decreased spontaneous erections

Gynecomastia, breast discomfort

Loss of body hair (axillary and pubic)

Very Small or shrinking testes

Height loss, low bone mineral density

Reduced muscle bulk and strength



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## Other signs and symptoms of Androgen Deficiency in Men

Decreased energy, motivation, initiative, self confidence

Depressed mood, dysthymia

Poor concentration and memory

Sleep disturbance, increased sleepiness

Mild anemia (normochromic, normocytic)

Increased body fat, body mass index

Diminished physical or work performance



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## Potential Benefits of TR RX in Hypogonadal Men

Maintenance of virilization and improved libido and energy

Improvement in muscle strength and fat-free mass (1)

Increase in bone density (2)

Inconsistent data on improved mood (3)

No significant change on improved cognition (4)

1) Bhasin S et al. "Testosterone replacement increases fat-free mass and muscle size in hypogonadal men". J Clin Endocrinol Metab 1997; 82:407

2) Behre HM et al. "Long-term effect of testosterone therapy on bone mineral density in hypogonadal men". J Clin Endocrinol Metab 1997; 82:2386

3) Jockenhovel F et al. "Comparison of long-acting testosterone...on sexual dysfunction and mood in hypogonadal men. Eur J Endocrinology 2009; 160:815

4) Vaughn C et al. "Exogenous testosterone...does not improve cognition in healthy older men..." J Androl 2007; 28:875.



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## Potential Risks and Side Effects of TR RX

Erythrocytosis/Polycythemia (Stimulation of erythropoiesis)

Cardiovascular risk (FDA warning for possibility of ^ risk)

Potential for ^ risk of venous thromboembolism (FDA warning)

Induction or worsening of Obstructive Sleep Apnea (Review symptoms and evaluate further)

Worsening of BPH sx: LUTS –Lower Urinary Tract Symptom assessment e.g. IPSS (International Prostate Sx Score if > 19 demands further work up and treatment)



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## Potential Risks and Side Effects of TR Rx

Potential for increased risk of prostate cancer (Evidence unclear but prudent to evaluate with PSA/DRE prior to initiating and monitor closely)

Gynecomastia (?breast cancer risk)

Male pattern baldness

Increase in acne and oily skin



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## Monitoring Guidelines for TR Rx (Endocrine Society)

Evaluate patient at 3 months and then annually for both signs of improvement and adverse effects

Monitor testosterone levels 2-3 months after initiation of Rx

(Rx should aim to raise testosterone level to mid normal range)

Check hematocrit at baseline, 3 months and annually. If hct > 54% stop until normal and then consider restarting at a lower dose

Measure bone mineral density of L/S spine and femoral neck at 1-2 years of therapy

Perform DRE and check PSA level before initiating at 3 months and then based on standard guidelines per race and age



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## Monitoring Guidelines for TR Rx

Consult Urology for abnormal DRE, <sup>^</sup> in PSA above 4.0 ng/ml or <sup>^</sup> PSA velocity > 0.4 ng/ml or IPSS > 19

Other e.g. skin irritation with transdermal application

Avoid transdermal contact with others especially women and children



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## Who Should Not Receive Testosterone Replacement Therapy?

Do not prescribe testosterone to men with ED who have normal testosterone levels (American Urological Association)

Do not prescribe testosterone therapy unless there is biochemical evidence of testosterone deficiency (Endocr Soc)

Do not prescribe testosterone to men contemplating or initiating pregnancy (American Society for Reproductive Medicine)

\*Petering, Brooks: "Testosterone Therapy: Review of Clinical Applications"; AFP, October 1, 2017



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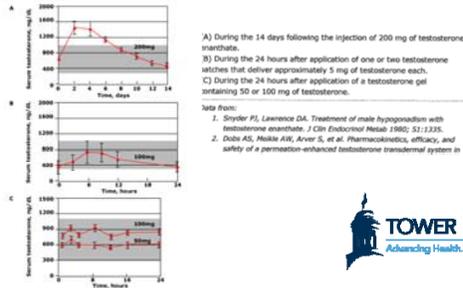
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## Serum Testosterone levels with 3 different testosterone preparations




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## Summary recommendations (The Endocrine Society, et al):

Testosterone deficiency aka androgen deficiency or male hypogonadism is defined as a low total testosterone level drawn in the am on at least two occasions in association with symptoms that are consistent with androgen deficiency. A free (unbound testosterone) level may be useful to confirm.

Testosterone replacement therapy should be offered to the appropriate patient who meet diagnostic criteria and they should be monitored for both beneficial response as well as side effects.

There is no indication for prescribing testosterone replacement therapy to men with normal testosterone levels regardless of symptoms as the benefit does not outweigh the risk.

Testosterone therapy should not be offered to all older men with low testosterone levels, but may be considered on an individualized basis.

There is no indication for screening the general male population for testosterone deficiency.




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## Case Considerations

**Case 1:** 67 y/o male with hx of esophageal and pancreatic cancers who is now 5 years in remission following surgery, chemo and XRT. He is very thankful for his health, has a supportive family and runs his own business. He describes onset of sx of erectile dysfunction, fatigue and loss of hair.

Total testosterone = 54, Free = 12 (Total 300-720, Free 47-244)

**Case 2:** 59 y/o male who is obese (BMI= 45) with poorly controlled Type 2 Diabetes Mellitus. He feels that he is easily fatigued, lacks energy and does not have the "sexual stamina" that he formerly had. He retired early in the past year and just doesn't feel "as vital" as he used to. He wonders if his testosterone is low.

Total testosterone = 375, Free = 52




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## Questions for Discussion

All men over 60 should be screened for testosterone deficiency?

Testosterone deficiency is defined by low total, free testosterone or both?

All men with low testosterone levels should be treated with replacement therapy?

Even men with normal testosterone levels can benefit from replacement therapy?



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## Healthy Lifestyle/ Sexual Health



### Testosterone therapy: Potential benefits and risks as you age

Considering testosterone therapy to help you feel younger and more vigorous as you age? Know the risks before you make your decision.

#### Is testosterone therapy safe?

The promise of testosterone therapy may seem enticing, but there are a lot of misconceptions about what the treatment can and can't do for you. As you get older, testosterone therapy may sound like the ultimate anti-aging formula.

Yet the health benefits of testosterone therapy for age-related decline in testosterone aren't as obvious as they may seem. Find out which issues — and not to worry — about testosterone therapy for normal aging.

#### What is testosterone?

##### Multimedia



#### The influence of testosterone in men

Testosterone is a hormone produced primarily in the testicles. Testosterone helps regulate men's:

- Bone density
- Fat distribution
- Muscle strength and mass
- Facial and body hair
- Red blood cell production
- Sex drive
- Sperm production



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## References:

"Testosterone Therapy in Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline". The Journal of Clinical Endocrinology & Metabolism, Volume 95, Issue 6, 1 June 2010, pp 2536-2559.

"Testosterone Therapy: Review of Clinical Applications", Petering R and Brooks N, American Family Physician 2017 October 1, 96 (7):441-449.

"Treating Aging with Testosterone", Fugh-Berman, A, American Family Physician 2017 October 1, 96(7): 428-430.

Choosing Wisely, American Family Physician 2017, October 1, 96(7) "Male Treatment of Hypogonadism", Snyder, P. Up to Date

"Evidence-based medicine update on testosterone replacement therapy in male hypogonadism: focus on new preparations", Giagulli, VA et al, Current Pharmaceutical Design 201; 17(15):1500-1511

"Testosterone therapy: Potential benefits and risks as you age". Mayo Clinic E-newsletter



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**Managing Chronic Hepatitis C in the  
Primary Care Setting: Best Practices  
From Screening to Treatment**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Managing Chronic Hepatitis C in the Primary Care Setting:  
Best Practices From Screening to Treatment***

Mark Sulkowski, MD

**Disclosures:**

Mark S. Sulkowski, MD, has a financial interest/relationship or affiliation in the form of:

Advisory Board for: AbbVie Inc.; Cocrystal Pharma, Inc.; Gilead; Merck & Co., Inc.; and Trek Therapeutics, PBC.

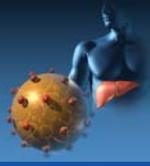
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***This activity is supported by an educational grant from Gilead Sciences, Inc.***

## Managing Chronic Hepatitis C in the Primary Care Setting: Best Practices From Screening to Treatment



**Mark S. Sulkowski, MD**  
Professor of Medicine  
Johns Hopkins University School of Medicine  
Medical Director, Viral Hepatitis Center  
Divisions of Infectious Diseases and  
Gastroenterology/Hepatology  
Johns Hopkins Department of Medicine  
Baltimore, Maryland

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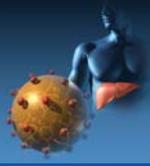
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## Managing Chronic Hepatitis C in the Primary Care Setting: Best Practices From Screening to Treatment



**Mark S. Sulkowski, MD**, has a financial  
interest/relationship or affiliation in the form of:

*Advisory Board for:* AbbVie Inc.; Cocrystal Pharma, Inc.;  
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*Other Financial or Material Support from:* Gilead for the  
Data and Safety Monitoring Board (DSMB).

*This activity is supported by an educational grant  
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***“There is no reason that a primary  
care provider cannot successfully  
treat the uncomplicated patient  
with chronic hepatitis C.  
However, it is important that  
prospective treaters receive proper  
education and training first.”***

- **Raymond Chung, MD**  
Chief of Hepatology  
Massachusetts General Hospital  
Boston, Massachusetts

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## Identifying and Overcoming Barriers to HCV Screening and Diagnosis in Primary Care

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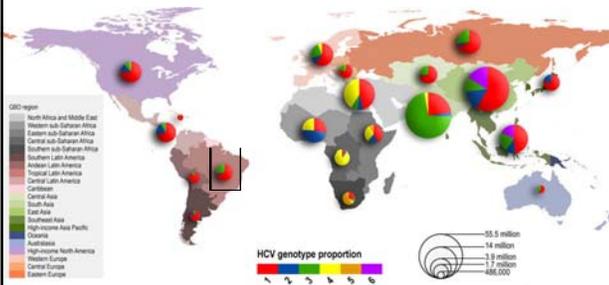
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## Global Burden of HCV Infection: 150-170 Million People Infected and 500,000 Deaths Annually<sup>1</sup>



HCV: hepatitis C virus.  
1. Messina JP et al. *Hepatology*. 2015;61:77-87.

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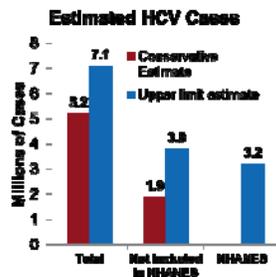
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## Prevalence of HCV Infection in the United States<sup>1-3</sup>

- 2.7 to 5.0 million living with chronic HCV in the United States
- 45%-60% unaware of infection
- Not included or underestimated in NHANES estimate:
  - Homeless (142,761-337,610)
  - Incarcerated (372,754-664,826)
  - Veterans (1,237,461-2,452,006)
  - Active military (6,805)
  - Healthcare workers (64,809-259,234)



NHANES: National Health and Nutrition Examination Survey.  
1. Denniston M et al. *Ann Intern Med*. 2014;160:293-300.  
2. Chak E et al. *Liver Int*. 2011;31:1090-1101.  
3. Zaleski M et al. *PLoS One*. 2013;8:e63959.

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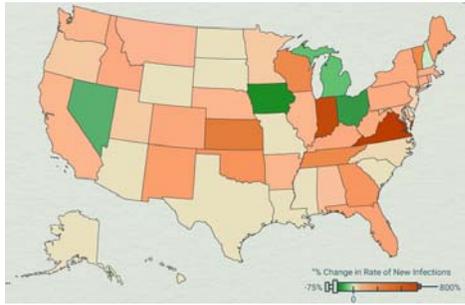
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### Change in Hepatitis C Infection Rate Between 2008 and 2012<sup>1</sup>



1. Adapted from CDC. Surveillance for Viral Hepatitis – United States, 2012. Available at <https://www.cdc.gov/hepatitis/statistics/2012surveillance/index.htm#tabs-501600-1>; accessed June 5, 2017. .

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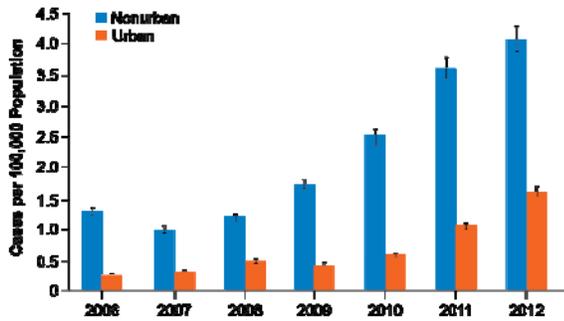
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### Increases in HCV Infection Related to Injection Drug Use Among Persons Aged ≤30 Years<sup>1</sup>



1. Zibbell JE et al. *MMWR Morb Mortal Wkly Rep*. 2015;64:453-458.

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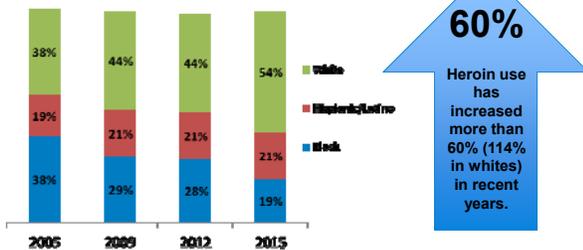
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### Changes in Who is Starting to Inject Drugs<sup>1</sup>

Percent of new PWID by race suggests fewer blacks, and more whites, are starting to inject drugs



1. <https://www.cdc.gov/vitalsigns/hiv-drug-use/infographic.html#graphic>

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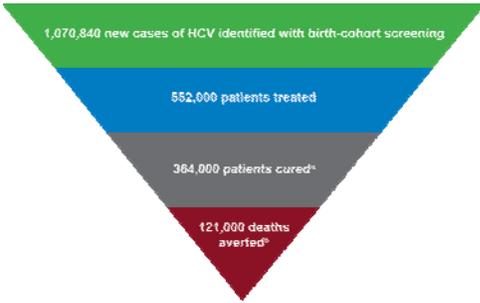
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## Screening of Baby Boomers Could Prevent More Than 120,000 HCV-Related Deaths<sup>1,2</sup>



\* Cured with PEG-IFN and RBV plus direct-acting antiviral treatment.  
<sup>b</sup> Deaths due to decompensated cirrhosis or HCC within the 1945-1965 birth cohort; 470,000 deaths under birth-cohort screening vs 592,000 deaths under risk-based screening.  
 PEG-IFN: pegylated interferon, RBV: ribavirin.  
 1. Rein DB et al. *Ann Intern Med.* 2012;156:263-270.  
 2. McGarry LJ et al. *Hepatology.* 2012;55:1344-1355.




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## Other At-Risk Groups Who Should Be Screened<sup>1,2</sup>

### CDC Recommendations

- Everyone born from 1945 through 1965 (one time)
- Persons who ever injected illegal drugs
- Persons who received clotting factor concentrates produced before 1987
- Recipients of chronic (long-term) hemodialysis
- Persons with persistently abnormal ALT levels
- Recipients of transfusions or organ transplants prior to 1992
- Persons with recognized occupational exposures
- Children born to HCV-positive women
- HIV-positive persons

### USPSTF Grade B Recommendations<sup>a</sup>

- Everyone born from 1945 through 1965 (one time)
- Past or present injection drug use
- Sex with an injection drug user; other high-risk sex
- Blood transfusion prior to 1992
- Persons with hemophilia
- Long-term hemodialysis
- Born to an HCV-infected mother
- Incarceration
- Intranasal drug use
- Receiving an unregulated tattoo
- Occupational percutaneous exposure
- Surgery before implementation of universal precautions

<sup>a</sup> Only pertains to persons with normal liver enzymes; if elevated liver enzymes, need hepatitis B virus and HCV testing.  
 USPSTF: U.S. Preventive Services Task Force.  
 1. Smith BD et al. *Ann Intern Med.* 2012;157:817-822.  
 2. Moyer VA et al. *Ann Intern Med.* 2013;159:349-357.




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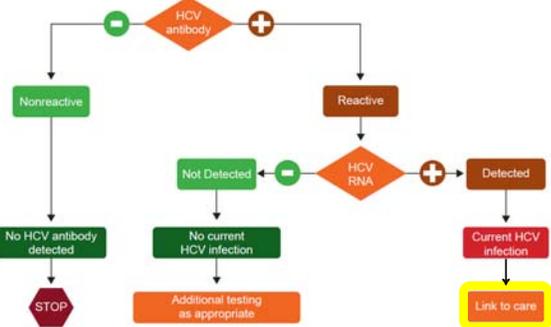
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## Recommended Testing Sequence for Identifying Current HCV Infection<sup>1</sup>



1. [https://www.cdc.gov/hepatitis/HCV/PDFs/hcv\\_flow.pdf](https://www.cdc.gov/hepatitis/HCV/PDFs/hcv_flow.pdf). Accessed October 12, 2017.




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Newly Diagnosed Patients with HCV:  
Next Steps for the Primary Care Clinician

All persons with current active HCV infection should be linked to a practitioner who is prepared to provide comprehensive management.<sup>1</sup>



**CURE IS POSSIBLE!**

1. AASLD/IDSA. HCV Guidelines. www.hcvguidelines.org. Accessed October 12, 2017.



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Newly Diagnosed Patients with HCV:  
Next Steps for the Primary Care Clinician (Cont'd)

- Educate regarding HCV transmission
  - Screen sexual partners, but CDC does not recommend barrier methods for monogamous heterosexual partners
  - Higher risk of sexual transmission among MSM, particularly those with HIV infection
  - Children born to HCV-positive mothers should be screened (<3% risk)
- Screen for immunity to hepatitis A Ab total and hepatitis B (HBsAb) and vaccinate if non-immune

MSM: men who have sex with men.



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Newly Diagnosed Patients with HCV:  
Next Steps for the Primary Care Clinician (Cont'd)

- Assess alcohol use in all patients with HCV (CDC guidelines)
  - There is no “safe” amount of alcohol consumption for patients with HCV
  - Refer patients with risky use for alcohol treatment
    - Men: >2 drinks/day (>14/week) or more than 4 in one day
    - Women: >1 drink/day (>7/week) or more than 3 in one day
- Advise on a liver-healthy diet, which equates to a normal body mass index

HBsAb: hepatitis B surface antibody test.



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## A Closer Look at Current Recommendations and Options for the Treatment of HCV

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## Guidance for the Treatment of HCV Infection

The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America Present

### HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

Last Updated: September 21, 2017  
www.hcvguidelines.org



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## Goal of HCV Therapy<sup>1,a</sup>

The goal of treatment of HCV-infected persons is to **reduce all-cause mortality and liver-related health adverse consequences**, including end-stage liver disease and hepatocellular carcinoma, by the **achievement of virologic cure** as evidenced by a sustained virologic response (SVR).

<sup>a</sup>Rating: Class I, Level A.  
HCV: hepatitis C virus.  
1. AASLD/IDSA. HCV Guidelines. www.hcvguidelines.org. Accessed October 12, 2017.

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## When and in Whom to Initiate HCV Therapy<sup>1,a</sup>

Treatment is recommended for *all patients with chronic HCV infection*, except those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert.

<sup>a</sup>Rating: Class I, Level A.  
HCV: hepatitis C virus.  
1. AASLD/IDSA. HCV Guidelines. www.hcvguidelines.org. Accessed October 12, 2017.



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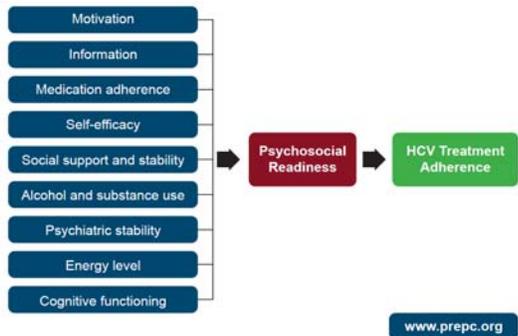
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## Assessing Readiness for HCV Treatment: PREP-C



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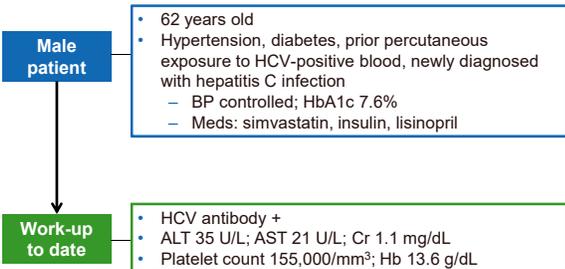
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## Patient Case



Cr: creatinine; HbA1c: hemoglobin A1c.



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## Recommended Assessments Prior to Starting Antiviral Therapy<sup>1,a</sup>

- **Staging of hepatic fibrosis is essential prior to HCV treatment.**
- Assessment of potential drug-drug interactions with concomitant medications is recommended prior to starting antiviral therapy.
  - Patients should also be educated on the proper administration of medications (eg, dose, frequency of medicines, food effect, missed doses, adverse effects, etc), the crucial importance of adherence, and the necessity for close supervision and blood tests during and after treatment.

<sup>a</sup>Rating: Class 1, Level C.

1. AASLD/IDSA. HCV Guidelines. www.hcvguidelines.org. Accessed October 12, 2017.




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## Evaluation and Staging of Liver Fibrosis<sup>1</sup>

Comparative Scoring Systems for Histologic Stage (Fibrosis)			
Score	IASL	Batts-Ludwig	Metavir
0	No Fibrosis	No Fibrosis	No Fibrosis
1	Mild fibrosis	Fibrous portal expansion	Periportal fibrotic expansion
2	Moderate fibrosis	Rare bridges or septae	Periportal septae (> 1 septum)
3	Severe fibrosis	Numerous bridges or septae	Portal-central septae
4	Cirrhosis	Cirrhosis	Cirrhosis

1. <https://www.hepatitisc.uw.edu/go/evaluation-staging-monitoring/evaluation-staging/core-concept/all>




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## Four-Stage Cirrhosis Classification System<sup>1</sup>

Stage	Compensated Cirrhosis		Decompensated Cirrhosis	
	Stage 1	Stage 2	Stage 3	Stage 4
Clinical	No Varices No Ascites	Varices No Ascites	Ascites +/- Varices	Bleeding +/- Ascites
Death (at 1 Year)	1%	3%	20%	57%

1. <https://www.hepatitisc.uw.edu/go/evaluation-staging-monitoring/evaluation-prognosis-cirrhosis/core-concept/all>




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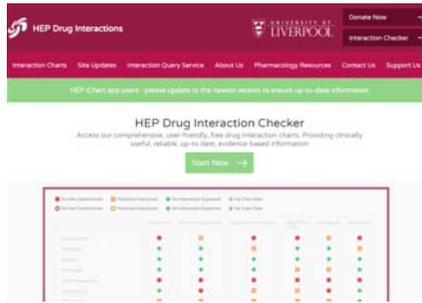
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## Evaluating Potential Drug-Drug Interactions with Selected Antiviral Medications



<http://www.hep-druginteractions.org>




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## Recommended Laboratory Testing<sup>1,a</sup>

### Within 12 weeks prior to starting antiviral therapy

- ✓ CBC
- ✓ INR
- ✓ Hepatic function panel (ie, albumin, total and direct bilirubin, ALT, AST, and alkaline phosphatase levels)
- ✓ Calculated GFR

### At any time prior to starting antiviral therapy

- ✓ HCV genotype and subtype
- ✓ Quantitative HCV RNA (HCV viral load)
- ✓ HIV serology

All patients initiating HCV DAA therapy should be assessed for HBV coinfection with HBsAg testing, and for evidence of prior infection with anti-HBs and anti-HBc testing.<sup>b</sup>

<sup>a</sup>Rating: Class I, Level C. <sup>b</sup>Rating: Class IIa, Level B.  
1. AASLD/IDSA. HCV Guidelines. www.hcvguidelines.org. Accessed October 12, 2017.




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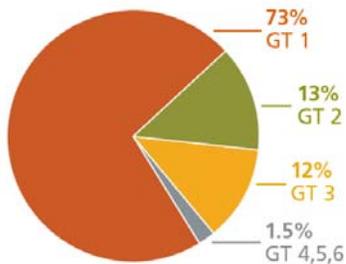
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## Distribution of HCV Genotypes in the United States<sup>1</sup>



HCV genotypes 1, 2, and 3 are the most prevalent genotypes in the US, representing >98% of all infections.

1. Germer JJ et al. J Clin Microbiol. 2011;49:3040-3043.




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### Patient Case: HCV Work-Up

<b>Male patient</b>	<ul style="list-style-type: none"> <li>62 years old</li> <li>Hypertension, diabetes, prior percutaneous exposure to HCV-positive blood, newly diagnosed with hepatitis C infection                             <ul style="list-style-type: none"> <li>- BP controlled; HbA1c 7.6%</li> <li>- Meds: simvastatin, insulin, lisinopril</li> </ul> </li> </ul>
<b>Work-up to date</b>	<ul style="list-style-type: none"> <li>HCV antibody +</li> <li>ALT 35 U/L; AST 21 U/L; Cr 1.1 mg/dL</li> <li>Platelet count 155,000/mm<sup>3</sup>; Hb 13.6 g/dL</li> </ul>
<b>HCV work-up</b>	<ul style="list-style-type: none"> <li>HCV genotype 1a</li> <li>HCV RNA level = 3.4 million U/mL</li> <li>HAV antibody total +</li> <li>HBsAb non-reactive; HBcAb non-reactive; HBsAg non-reactive</li> </ul>

HBcAb: hepatitis B core antibody; HBsAb: hepatitis B surface antibody test; HBsAg: hepatitis B surface antigen.

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### Patient Case: Critical Data Summary

**62-year-old man**

- HCV genotype/subtype? **1a**
- HCV RNA level? **3.4 million U/mL**
- Liver disease stage? **Cirrhosis**
- Prior treatment experience? **None**
- Concern with ribavirin use (eg, anemia or renal dysfunction)? **No**

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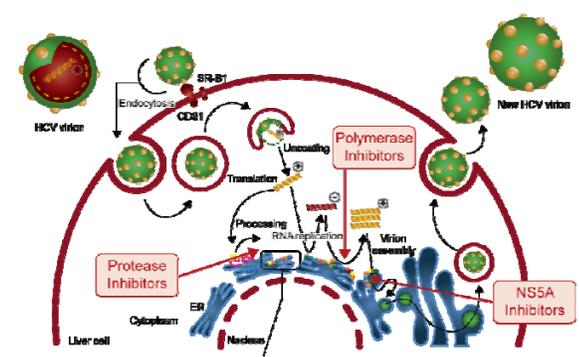
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### HCV Life Cycle Presents Multiple Targets for Direct Acting Antiviral Drugs<sup>1</sup>



NS5A: nonstructural protein 5A. 1. Manns MP et al. Nat Rev Drug Discov. 2007;6:991-1000.

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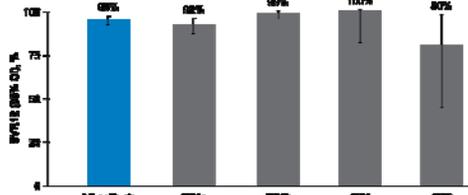
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### Grazoprevir/Elbasvir for 12 Weeks in Persons With HCV Genotype 1 Infection<sup>1</sup>



SVR12 (95% CI), n/N %	All patients	GT1a	GT1b	GT4	GT6
Range	299/316 95% (92%-97%)	144/157 92% (86%-96%)	129/131 99% (95%-100%)	18/18 100% (82%-100%)	8/10 80% (44%-98%)
Lost to follow-up or discontinued early due to reasons other than virologic failure	4	3	1	0	0
Virologic breakthrough	1	1	0	0	0
Virologic relapse	12	9	1	0	2

GT1a: genotype 1a; GT1b: genotype 1b; GT3: genotype 3; GT4: genotype 4; GT6: genotype 6.  
1. Zeuzem S et al. *Ann Intern Med.* 2015;163:1-13.




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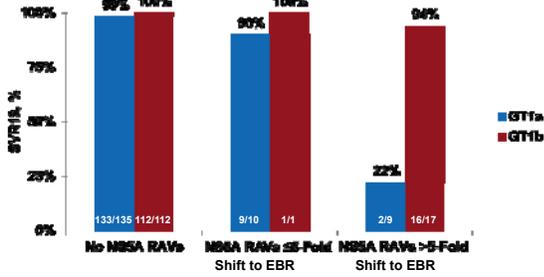
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### Impact of NS5A RAVs on Grazoprevir/Elbasvir Efficacy in Noncirrhotic and Cirrhotic Patients With HCV GT1<sup>1</sup>



RAV: resistance-associated variant.  
1. Zeuzem S et al. *Ann Intern Med.* 2015;163:1-13.




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## Treatment-Naïve Genotype 2




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## Recommended Regimens<sup>1</sup>

### Treatment-Naïve Genotype 2 Patients Without Cirrhosis

RECOMMENDED	DURATION	RATING
Daily fixed-dose combination of glecaprevir (300 mg)/pibrentasvir (120 mg) <sup>a</sup>	8 weeks	I, A
Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg)	12 weeks	I, A

### Treatment-Naïve Genotype 2 Patients With Compensated Cirrhosis<sup>a</sup>

RECOMMENDED	DURATION	RATING
Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg)	12 weeks	I, A
Daily fixed-dose combination of glecaprevir (300 mg)/pibrentasvir (120 mg) <sup>b</sup>	12 weeks	I, B

1. AASLD/IDSA. HCV Guidelines. www.hcvguidelines.org. Accessed October 12, 2017.




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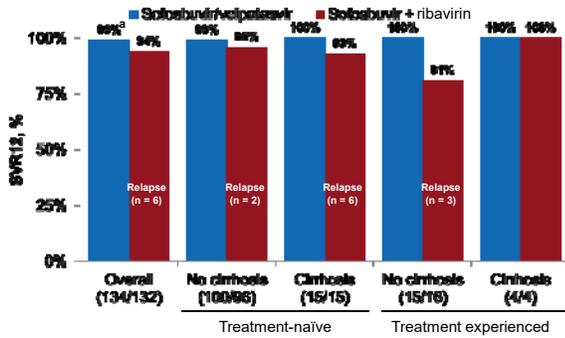
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## Sofosbuvir/Velpatasvir vs Sofosbuvir + Ribavirin for 12 Weeks: ASTRAL-2<sup>1</sup>



<sup>a</sup> Met non-inferiority and superiority criteria.

All patients with baseline NS3 and NS5A RAVs achieved SVR12. No virologic relapse in the sofosbuvir/velpatasvir arm.

1. Foster GR et al. *N Engl J Med*. 2015;373:2608-2617.




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## Treatment-Naïve Genotype 3




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### Summary of Recommended Regimens for Treatment-Naïve Patients Without Cirrhosis<sup>1</sup>

Regimen	Genotype						
	1a	1b	2	3	4	5	6
Elbasvir/grazoprevir	✓	✓			✓		
Ledipasvir/sofosbuvir	✓	✓			✓	✓	✓
Sofosbuvir/velpatasvir	✓	✓	✓	✓	✓	✓	✓
Glecaprevir/pibrentasvir	✓	✓	✓	✓	✓	✓	✓

1. AASLD/IDSA. HCV Guidelines. www.hcvguidelines.org. Accessed October 12, 2017.




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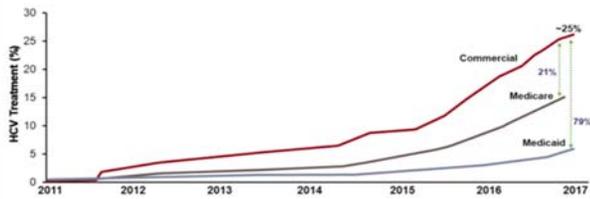
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### HCV Treatment Access Based on Insurance Status (2011 – 2017)

HCV Treatment by Payer



Over 18,000 chronic HCV patients in safety net hospital systems.

1. Wong RJ et al. Hepatology. 2017;66(suppl S1):307A. Abstract 561.




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### Potential Requirements to Acquire HCV Treatment Medications for Patients<sup>1,a</sup>

- Provider experience
  - General medical providers may need documentation of consultation support by experts, such as through the ECHO programs
- Proof of fibrosis staging
- Baseline laboratory studies
  - eg. HCV genotype; HCV RNA; CBC; hepatic function panel
- Clinic note documentation
  - eg. Alcohol sobriety for at least 6 months; CAGE or AUDIT-C alcohol use survey if the patient is not 100% abstinent to alcohol; no injection drug use for at least 6 months; drug or alcohol screening tests; evaluation of psychosocial readiness for treatment; justification of choice of regimen and duration of treatment

<sup>a</sup>Potential requirements vary by insurance and state.

1. <http://www.hepatitisc.uw.edu/browse/all/core-concepts/#process-to-acquire-hcv-treatment-medications>. Accessed October 13, 2017.




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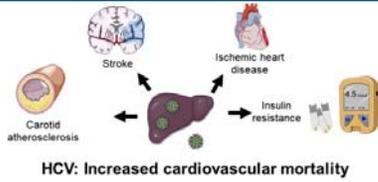
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## Cardiovascular Manifestations of Hepatitis C Virus<sup>1</sup>



1. Goossens N, Negro F. *Clin Liver Dis*. 2017;21:465-473.




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## Special Populations: HCV in Pregnancy<sup>1</sup>

### Recommendations for HCV Testing in Pregnant Women

RECOMMENDED	RATING
There is no recommendation at this time for universal HCV screening in pregnant women, however this is under review.	II, C
Screening with an HCV antibody assay is recommended for pregnant women with known or suspected risk factors for HCV infection. Confirmatory HCV nucleic acid testing is recommended for women with a positive screening test.	I, A

### Recommendation Regarding HCV Treatment and Pregnancy

RECOMMENDED	RATING
For women of reproductive age with known HCV infection, antiviral therapy is recommended <u>before</u> considering pregnancy, whenever practical and feasible, to reduce the risk of HCV transmission to future offspring.	I, B

### Not Recommended Regarding HCV Treatment and Pregnancy

NOT RECOMMENDED	RATING
Treatment during pregnancy is not recommended due to the lack of safety and efficacy data.	IIb, C

1. AASLD/IDSA. HCV Guidelines. [www.hcvguidelines.org](http://www.hcvguidelines.org). Accessed October 13, 2017.




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## Treating Hepatitis C Can Reactivate Hepatitis B

- Previous meta-analysis showed that up to a third of co-infected patients with HCV and inactive or resolved HBV who received interferon-based HCV therapy had reactivation of HBV (HBV-R)<sup>1</sup>
- To examine HBV-R associated with newer DAAs, investigators reviewed post-marketing reports of 29 patients with HCV/HBV co-infection who experienced HBV-R after receiving a second-generation DAA for HCV infection between 11/2013 and 10/2016:<sup>2</sup>
  - mean time to HBV-R after starting DAA therapy was 53 days
  - clinical illness due to HBV-R occurred in 28%
  - more than half of patients received anti-HBV therapy
  - **despite being monitored for liver-related events, patients experienced a significant delay before anti-HBV therapy was initiated**
  - **no relationship found between the specific DAA used and emergence of HBV-R, and no mechanism for this phenomenon is known**

1. Liu JY et al. *Viral J*. 2012;9:186. 2. Bersoff-Matcha SJ et al. *Ann Intern Med*. 2017;166:792-798.




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## HCV Elimination in the US

# NEWS

The National Academies of  
SCIENCES • ENGINEERING • MEDICINE

March 28, 2017

### FOR IMMEDIATE RELEASE

U.S. Could Be Rid of Hepatitis B and C as Public Health Problems, Preventing Nearly 90,000 Deaths by 2030, With Better Attention to Prevention, Screening, Treatment, and Creative Financing for Medicines

WASHINGTON – Hepatitis B and C kill more than 20,000 people every year in the United States. A new report from the National Academies of Sciences, Engineering, and Medicine presents a strategy to eliminate these diseases as serious public health problems and prevent nearly 90,000 deaths by 2030.

"Viral hepatitis is simply not a sufficient priority in the United States," said Brian Strom, chair of the committee that carried out the study and chancellor and university professor, Rutgers Biomedical and Sciences, Rutgers University, Newark, N.J. "Despite being the seventh leading cause of death in the world – and killing more people every year than HIV, road traffic accidents, or diabetes – viral hepatitis accounts for less than 1 percent of the National Institutes of Health research budget."

ELISA: enzyme-linked immunosorbent assay.



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## Considerations for Treating HCV in the Primary Care Setting

- **Decide which patients you are comfortable treating!**
  - Genotypes?
  - Degree of fibrosis?
  - Co-infected?
  - Renal impairment?
- Refer to a specialist for remainder of patients



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**Please remember to complete and submit your Post-Test and Evaluation for CME credit.**

### *Missed anything?*

Visit us at: [www.peerview.com/UYC](http://www.peerview.com/UYC)

- Download slides and Practice Aids
- Watch the online version of this activity
- Join the conversation on Twitter @PeerView
- If you have any additional questions, please contact Patricia Siple at [patricia.siple@peerview.com](mailto:patricia.siple@peerview.com).

*Thank you and have a good day!*



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**[Return to Top](#)**

# **Neurobiology of Addiction**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Neurobiology of Addiction***  
Joseph Garbely, DO

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

# The Neurobiology of Addiction

Dr. Joseph Garbely  
Medical Director  
VP of Medical Services  
Caron Treatment Centers



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ASAM Disclosure of Relevant  
Financial Relationships

**No Relevant Financial  
Relationships with Any  
Commercial Interests**

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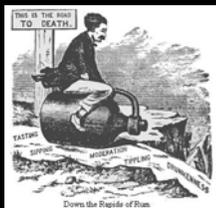
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## What is Addiction?

- *Possession by evil spirits?*
  - Demon rum
- *Lack of moral fiber?*
  - War on drugs
  - "Just say no"
- *Disease?*
  - Alcoholism recognized in 1956 by the AMA
  - Addiction recognized in 1987 by the AMA



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## ASAM definition of addiction



- Addiction is a stress induced, genetically mediated, primary, chronic disease of brain reward, motivation, memory and related circuitry.
- Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations.
- This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors...

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## ASAM definition of addiction



- Addiction is a stress induced, genetically mediated, primary, chronic disease of brain reward, motivation, memory and related circuitry.

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Addiction is *stress induced*



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# Childhood stress

Adverse Childhood Experiences Study (ACES),  
V.J. Felitti, MD and R.F. Anda, MD

## ACEs: The 10 Areas of Trauma

1. Psychological Abuse
2. Physical Abuse
3. Sexual Abuse
4. Emotional Neglect
5. Physical Neglect
6. Loss of a Parent (for any reason)
7. Mother Treated Violently
8. Substance Abuse
9. Mental Illness
10. Criminal Behavior in the Household

The questions are described on the ACE website  
[www.acestudy.com](http://www.acestudy.com)

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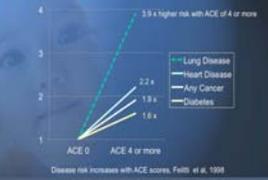
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## Childhood stress (ACEs) predicts development of disease as an adult

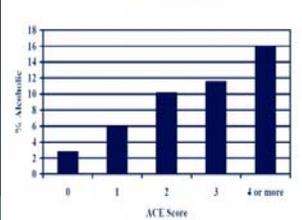
ACEs predict chronic disease in adulthood

4 ACEs are predict a 7x risk of alcoholism

ACE Score & Risk for Chronic Disease



ACE Score vs. Adult Alcoholism




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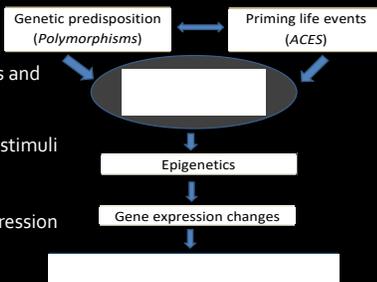
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## Plasticity of the Brain

Brain adapts to experience

- Changes in receptors and neurotransmitters
- Changes in chemical reactions elicited by stimuli
- "Rewiring" of nerve connections
- Changes in gene expression aka *epigenetics*



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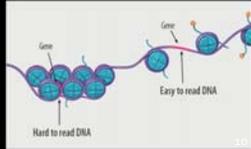
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# Epigenetics

- Modifications of genes that affect gene expression - mask/unmask
- Environment and experience influence gene expression
- Heritable, reversible (?)
- Accounts for characteristics to be inherited without changes to DNA sequence




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# ...genetically mediated...

- Genetic predisposition accounts for about 50% of the likelihood that an individual will develop addiction

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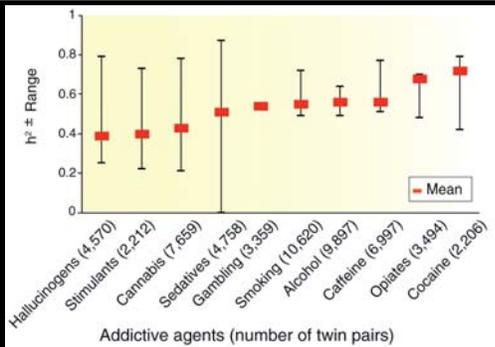
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# Heritability of Addiction



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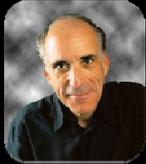
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## Genetic Vulnerability vs. Resistance

- Numerous genetic differences and *endophenotypes*
  - Low vs. high responders to alcohol effects
  - Impulsiveness/behavioral disinhibition
  - Personality styles
  - Opioid receptors
  - Alcohol metabolism



Mark Schuckit, MD, UCSD<sub>3</sub>

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## Numerous genes associated with Addiction

TABLE 98.2. POSSIBLE FAMILIES OF RISK FACTORS

	LR	Disinhibition	Axis II	Opioids	ALDH/ADH
<b>Broad markers</b>					
EEG alpha	X		X		
Voltage	X		X		
HPA	X		X	X	X
5-HT levels		X	X	X	
DA levels		X	X	X	
Neuropsychiatric		X	X		
<b>Genes/proteins</b>					
AC	X		X		
G protein	X		X		
PKC	X			X	
NPY	X		X	X	
5-HT <sub>1A/1B/2C</sub>	?	?	?		
5-HT <sub>2</sub>	X				
5-HTT	X	X	X		
TOH		X	X		
DRD2		X			
D4		X			
DAT		X			
GABA <sub>A</sub>	X	X	X		

AC, adenylyl cyclase; ADH, alcohol dehydrogenase; ALDH, aldehyde dehydrogenase; DA, dopamine; DAT, dopamine transporter; DRD2, dopamine receptor D2; GABA,  $\gamma$ -aminobutyric acid; HPA, hypothalamic-pituitary-adrenal axis; 5-HT, serotonin; LR, level of response; NPY, neuropeptide Y; PKC, protein kinase C.

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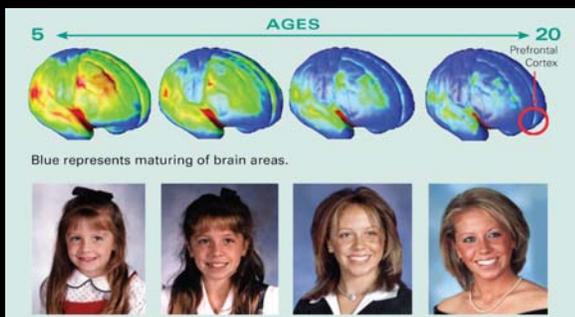
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## Adolescents are highly vulnerable to addiction beyond their genetic predisposition



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...primary, chronic disease of...

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## Disease



■ A "defect in an organ system that produces a consistent pattern of signs and symptoms"



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## An Evil Disease



- Doesn't look like a disease
- Self-deception (denial) is a sign
- Affects genetically susceptible (vulnerable) people
- Has a highly variable prognosis
  - Poor prognosis if untreated
  - Some recover spontaneously
  - Chronic/relapsing
- Culturally & politically divisive: challenges societal values and norms.

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# Chronic Diseases.....

- Treated, not cured
  - characterized by relapse and remission
- Outcomes depend on continuity of care over time
- Genetic plus environmental factors determine.....  
"vulnerability"



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...brain reward, motivation, memory...

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Nora Volkow, MD. Director, National Institute of Drug Abuse, 2003- present

"Thus, those who say 'it was their own choice' after a person dies of an overdose fall to grasp that an addicted person's brain has a disrupted choice mechanism."

"It isn't enough to say that addiction is a chronic brain disease. ...the circuits that enable us to exert free will no longer function as they should."

"...The good news is that behavioral therapies and medications can help addicted individuals repair their damaged self-control capacities, as long as they actively participate in treatment."



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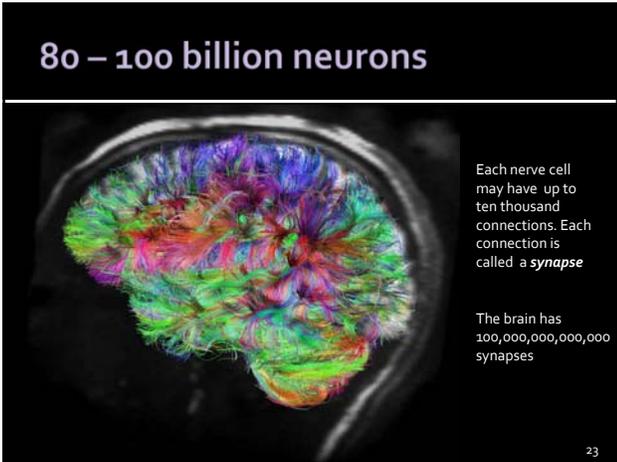
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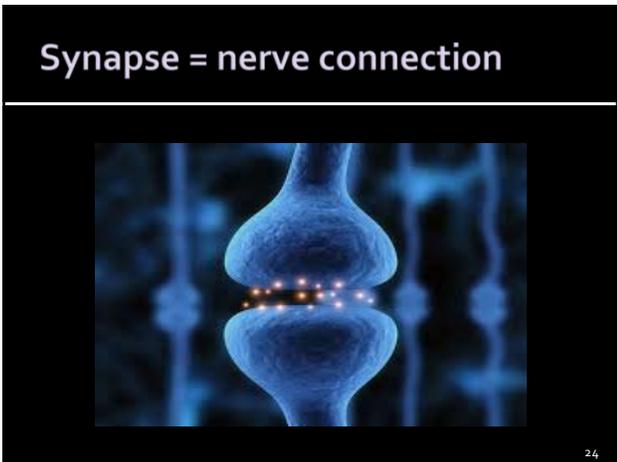
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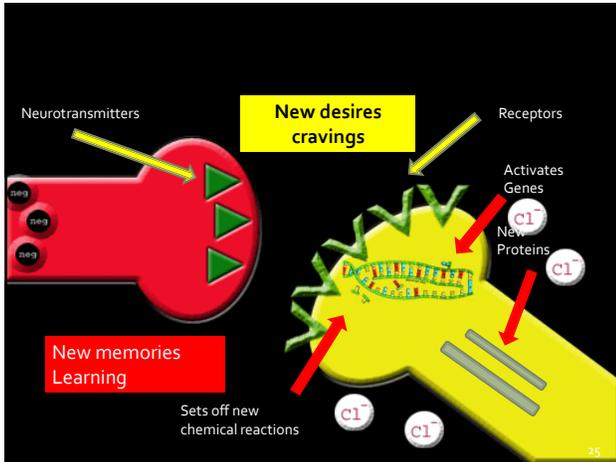
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## Memory

- Simple model of memory:
  - Encoding
  - Storage
  - Retrieval

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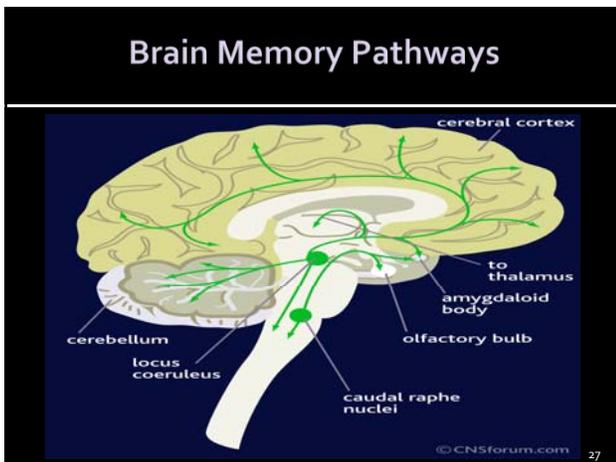
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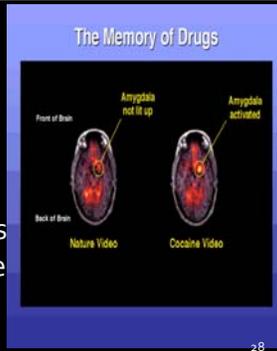
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## Memory for Drugs and Related Cues

- Memory of prior euphoric experiences
- Both drugs *and* associated memories
  - drug cues
- Cues motivate behaviors associated with drug use
  - Craving, drug seeking



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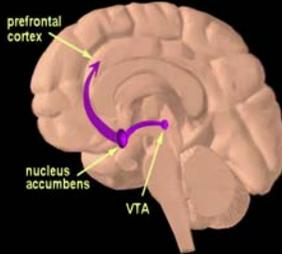
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## "Reward circuit" re-enforces survival behavior

- Midbrain (VTA): Reward driven, impulsive (motivation)
- Nucleus Accumbens: memory and learning associated with reward
- Prefrontal cortex: Executive function
  - Top down decision making
  - Inhibitory control: "Brakes and steering" (choice)



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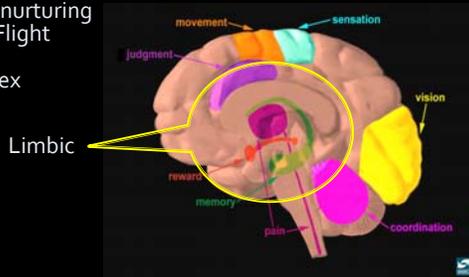
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## Survival Brain (Limbic Area)

Brain connections ensure that we will repeat life-sustaining activities by associating those activities with pleasure.

- Survival behaviors:
- Food/Fluid intake
  - Feelings/nurturing
  - Fight or Flight response
  - Flirting/sex



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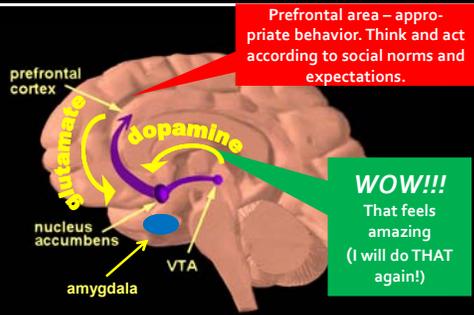
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# Reward system affects thinking



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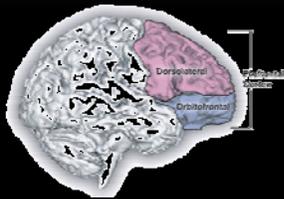
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# THE PREFRONTAL CORTEX (PFC)



PFC is known to mediate:<sup>1</sup>

- Decision Making
- Planning
- Working Memory
- Inhibition
- Attention
- Saliency
- Value
- “Brakes and Steering”

1) Fuster (2008) The Prefrontal Cortex, Academic Press

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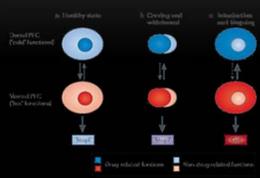
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# THE PREFRONTAL CORTEX IN ADDICTION



Dysregulation of the PFC in addiction leads to compulsive, drug-seeking behavior

1. Impaired inhibition of unhealthy or drug-taking behavior (i.e. drinking)
2. Excessive saliency attributed to alcohol and alcohol-related stimuli

Impaired Response Inhibition and Saliency Attribution (IRISA)  
Goldstein & Volkow 2002, 2011

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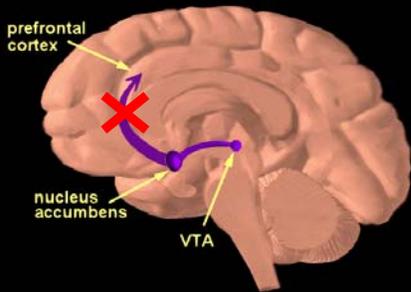
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## The "brakes" have failed



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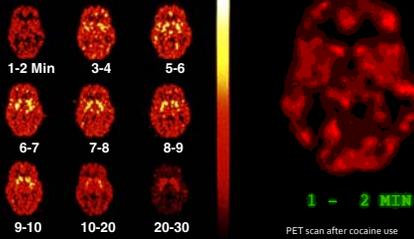
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## Neuroimaging (PET scan)

Shows activation of reward areas of human brain after exposure to cocaine.



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## Substances and behaviors associated with dopamine release

- Alcohol/Sedative hypnotics
- Opioids
- Cocaine/Amphetamines
- Ecstasy (MDMA)
- Hallucinogens
- Dissociants
- Cannabinoids
- Nicotine
- Anabolic Steroids
- Food/sugar
- Sex/love
- People, "co-dependency"
- Gambling
- Exercise
- Achievement
- Collection/Accumulation
- Rage/Violence
- Media/Entertainment

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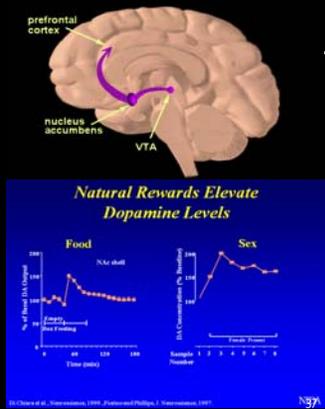
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Magnitude of Dopamine release determines the degree of re-enforcement




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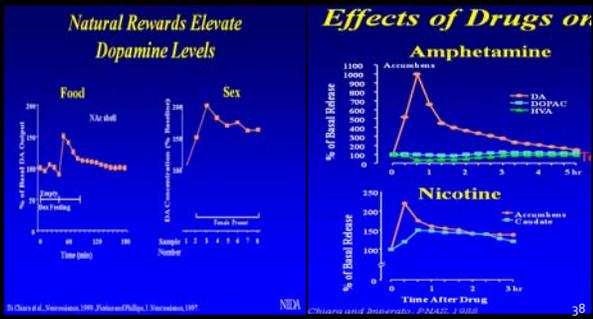
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ALL drugs of abuse cause release of dopamine in the reward pathway that is out of proportion to natural rewards




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Dopamine D2 receptors are reduced in addicted brains

“Anhedonia”

The brain adapts to massive dopamine release by decreasing dopamine receptors



In doing so, the brain becomes numb to natural rewards

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So, why do people use drugs?

BECAUSE THEY LIKE THEM!



Energized

+



WOW!



+

Well-being

= *Euphoria*

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Like Becomes Need

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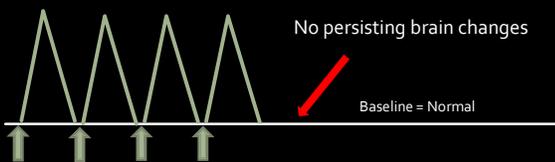
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Non-addict brain response to drug



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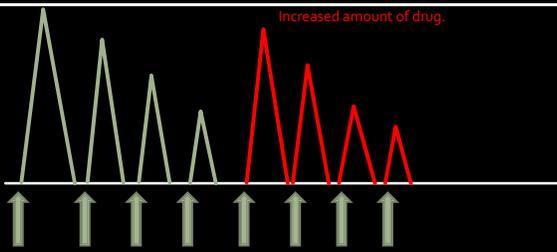
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## Tolerance



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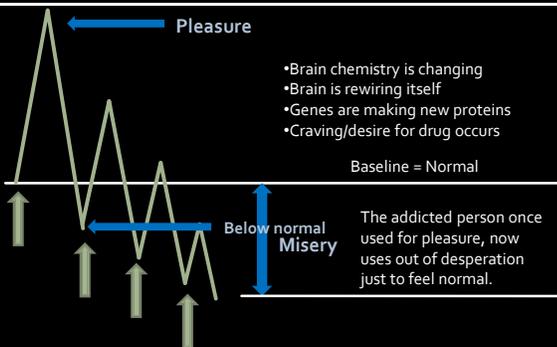
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## Addicted Brain Response



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## ASAM definition of addiction



- Addiction is a stress induced, genetically mediated, primary, chronic disease of brain reward, motivation, memory and related circuitry.
- Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations.
- This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors...

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## Psychosocial manifestations

- Inability to consistently *ABSTAIN*
- Impairment in *BEHAVIORAL CONTROL*
- *CRAVING*
- *DIMINISHED RECOGNITION* of problems with one's behavior and interpersonal relationships
- Dysfunctional *EMOTIONAL RESPONSE*

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## Spiritual manifestations

- Distortion in meaning, purpose and values
- Distortion in connection with self, others and the transcendent
  - God, Higher Power, Absolute, Allah, Buddha, Brahman, Universal Spirit, etc.

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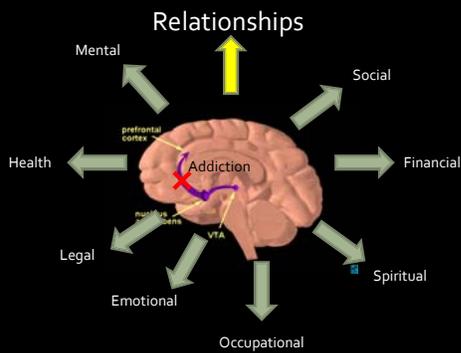
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## All areas of life become unmanageable



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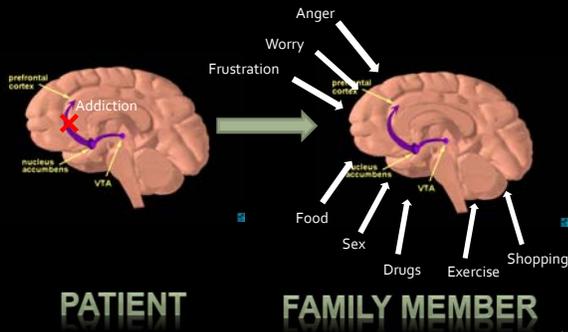
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## Family Disease



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## ASAM definition of addiction



- Addiction is a stress induced, genetically mediated, primary, chronic disease of brain reward, motivation, memory and related circuitry.
- Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations.
- This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors...

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## Substances *and* behaviors associated with dopamine release

- Alcohol/Sedative hypnotics
- Opioids
- Cocaine/Amphetamines
- Ecstasy (MDMA)
- Hallucinogens
- Dissociants
- Cannabinoids
- Nicotine
- Anabolic Steroids
- Food/sugar
- Sex/love
- People, "co-dependency"
- Gambling
- Exercise
- Achievement
- Collection/Accumulation
- Rage/Violence
- Media/Entertainment

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## Use of other drugs of abuse – supplementation or substitution

- Once addiction is established, other substances which stimulates the reward system may satisfy cravings.
- Or stimulate them.



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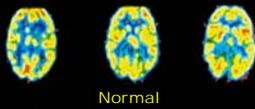
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## Persistent brain changes



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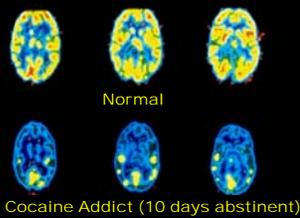
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## Persistent brain changes



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## Persistent brain changes



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Heroin addicts who have been clean and sober may have violent withdrawal symptoms including nausea, vomiting and stomach cramps from watching a video of drug use.



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## Summary

- Addiction is a chronic disease that affects the brain – it is not a lack of willpower or moral failing
- Addiction is a complex disease that requires a comprehensive solution
- Medication alone is insufficient to treat addiction
- Recovery is more than abstinence
- Recovery is a progression toward optimum wellness across biological, psychological, social, and spiritual dimensions.
- Recovery is a lifelong process
- We have much to learn



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**[Return to Top](#)**

**A Master Class in Understanding and  
Applying New Strategies to Improve  
Early Recognition and Treatment of  
Heart Failure in Family Practice**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***A Master Class in Understanding and Applying New Strategies to  
Improve Early Recognition and Treatment of Heart Failure in  
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**Garrick Stewart, MD**

**Disclosures:**

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The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

***This activity is supported by an educational grant from Novartis  
Pharmaceuticals Corporation.***

# A Master Class in Understanding and Applying New Strategies to Improve Early Recognition and Treatment of Heart Failure in Family Practice

**Garrick C. Stewart, MD**  
Associate Physician, Brigham and Women's Hospital  
Instructor, Harvard Medical School  
Boston, Massachusetts

PeerView  
Live

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# A Master Class in Understanding and Applying New Strategies to Improve Early Recognition and Treatment of Heart Failure in Family Practice

**Garrick C. Stewart, MD**, has no financial interests/relationships or affiliations in relation to this activity.

*This activity is supported by an educational grant from Novartis Pharmaceuticals Corporation.*

PeerView  
Live

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## Initial Evaluation and Diagnosis of the Patient With Heart Failure

PeerView  
Live

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## Burden of Heart Failure in the United States



- HF affects **5.7 million** people<sup>1</sup>



- 1-year mortality rate is ~29%<sup>1</sup>
- 5-year mortality rate is ~50%<sup>1</sup>



- HF costs ~\$31 billion<sup>2</sup>
  - Up to 80% of direct costs are due to hospitalization<sup>2</sup> (~50% readmitted within 6 months<sup>3</sup>)

1. Mozzafarian D et al. *Circulation*. 2016;133:e38-e360. 2. Heidenreich PA et al. *Circ Heart Fail*. 2013;6:606-619. 3. Desai AS and Stevenson LW. *Circulation*. 2012;126:501-506.




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## Primary Care Physician Diagnosis

**EARLY diagnosis and treatment of HF is important for better clinical outcomes, including quality and length of life**

- Team approach to care
  - Establish diagnosis whenever possible prior to referring to cardiologist
  - Partner with cardiologist to manage side effects and tolerability to medication
- In-office diagnosis
  - Identification of signs and symptoms of HF




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## Case 1: 67-Year-Old Woman With a History of Hypertension

### Presentation

- Complains of shortness of breath and coughing at night
- Recent swelling of feet and ankles

### Examination Notes

- Euvolemic, BP: 135/80 mmHg, heart rate: 67 bpm

### Laboratory Results

- Cr: 1.6 mL/min
- K: 4.7 mmol/L
- NT-proBNP: 1,100 pg/mL

### Medications

- Lisinopril 10 mg once daily
- Carvedilol 12.5 mg twice daily
- Spironolactone 25 mg once daily

- Would you evaluate this patient for HF?
- Is noninvasive imaging appropriate for initial evaluation of HF?




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## Heart Failure Is a Clinical Diagnosis<sup>1</sup>

### Typical Symptoms and Signs

#### Major Criteria

- Orthopnea/PND
- Venous distension
- Rales
- Cardiomegaly
- Acute pulmonary edema
- JVD >16 cm
- Hepatojugular reflux
- S3

#### Minor Criteria

- Ankle edema
- Night cough
- Exertional dyspnea
- Hepatomegaly
- Pleural effusion
- Tachycardia (>120 bpm)
- Decreased vital capacity
- Weight loss with HF treatment

**HF = 2 major or 1 major + 1 minor**

1. McKee PA et al. *N Engl J Med*. 1971;285:1441-1446.

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## Initial Workup of Newly Diagnosed Heart Failure<sup>1</sup>

### In all cases:

- History, examination, ECG
- Echocardiogram
- Laboratory testing
- Assessment of functional capacity
- Assessment for CAD in patients at risk

### In selected cases:

- Cardiac catheterization
- Cardiac MRI
- Endomyocardial biopsy
- Genetic testing

1. Yancy CW et al. *J Am Coll Cardiol*. 2013;62:e147-e239.

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## Diagnosing Heart Failure: Diagnostic Tests

**Serum BNP in the acute setting can help hone the diagnosis of HF**

**Serum BNP serial testing has not been definitively found to be clinically useful in monitoring the stable patient**

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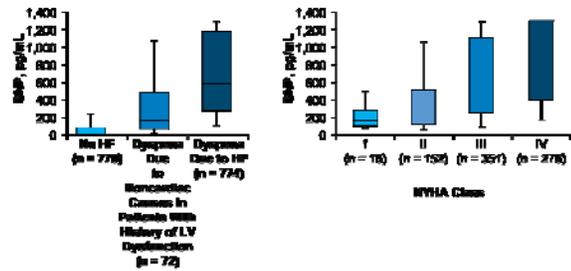
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## BNP for Heart Failure Diagnosis<sup>1</sup>

- Patients presenting to ED with dyspnea



1. Maisel AS et al. *N Engl J Med.* 2002;347:161-167.

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## BNP for Heart Failure Diagnosis (Cont'd)<sup>1,2</sup>

**BNP  $\geq 100$  pg/mL**  
 Positive predictive value: 79%  
 Negative predictive value: 89%

**NT-proBNP  $\geq 900$  pg/mL**  
 Positive predictive value: 77%  
 Negative predictive value: 92%

1. Maisel AS et al. *N Engl J Med.* 2002;347:161-167. 2. Krauser DG et al. *Am Heart J.* 2005;149:744-750.

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## Common ECG Findings<sup>1</sup>

- LV hypertrophy
- Left bundle branch block
- Intraventricular conduction delay
- Nonspecific ST-segment and T-wave changes
- Q waves in contiguous leads strongly implicate a previous MI and CAD as the cause

1. <http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/heart-failure>. Accessed September 19, 2017.

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## Case 2: 73-Year-Old Man With CHF

### Presentation

- NYHA FC III, hospitalized twice for HF in past 6 months, EF 27%

### Examination Notes

- JVP 2 cm above clavicle, BP: 112/65 mmHg, heart rate: 79 bpm

### Laboratory Results

- Cr: 2.0 mL/min
- K: 5.0 mmol/L
- NT-proBNP: 2,700 pg/mL

### Medications

- Valsartan 80 mg twice daily
- Carvedilol 3.125 mg twice daily
- Unable to tolerate MRA because of concerns about hyperkalemia
- Furosemide 80 mg twice daily

- Would you continue with patient's current medications or switch to a different treatment?
- Which methods should we use to encourage self-monitoring and ensure adherence to treatment?

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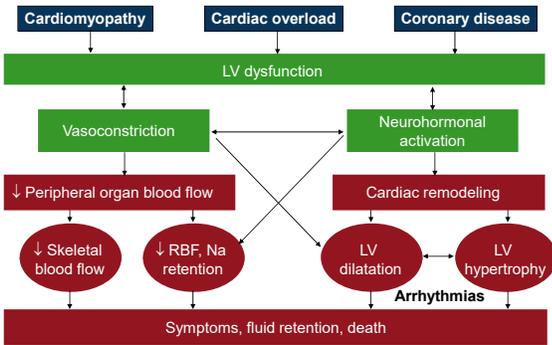
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## Pathophysiology of HFrEF



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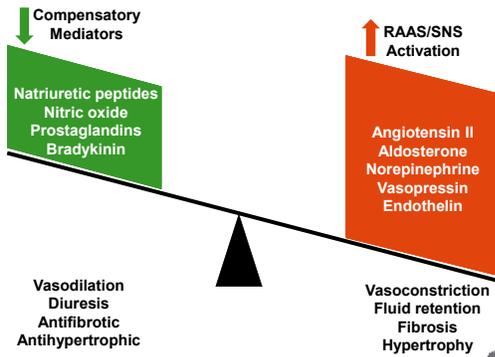
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## Neurohormonal Balance in HFrEF



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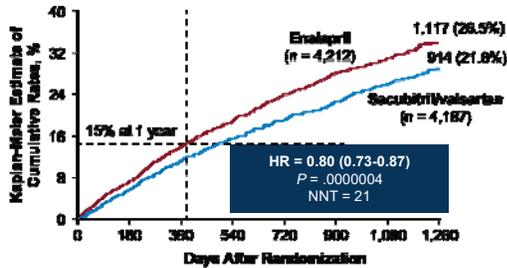
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PARADIGM-HF: CV Death or HF Hospitalization (Primary Endpoint)<sup>1</sup>

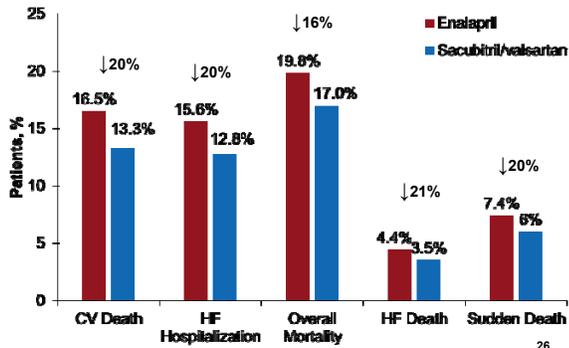


Patients at Risk

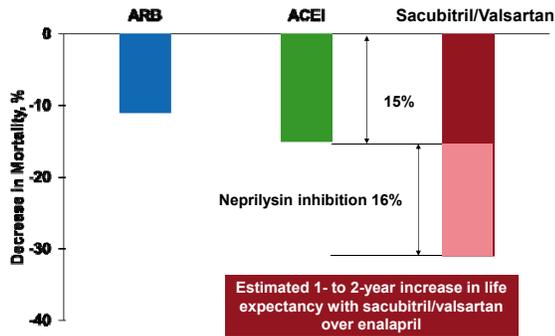
Days After Randomization	0	180	360	540	720	900	1,080	1,260
Sacubitril/Valsartan	4,187	3,922	3,863	3,018	2,267	1,614	898	246
Enalapril	4,212	3,883	3,578	2,822	2,123	1,492	853	236

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PARADIGM-HF: Other Key Endpoints<sup>1,2</sup>



Sacubitril/Valsartan: Greater Mortality Reduction Than With ACEI/ARB<sup>1,2</sup>



1. McMurray JJ et al. Eur Heart J. 2015;36:434-439. 2. Claggett B et al. N Engl J Med. 2015;373:2289-2290.

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### Ivabradine Treatment Discontinuation<sup>1</sup>

	Patients With an AE, Leading to Withdrawal		
	Ivabradine, % (n = 3,232)	Placebo, % (n = 3,260)	P
All AEs	14	13	.051
Symptomatic bradycardia	1	<1	.002
Asymptomatic bradycardia	1	<1	<.0001
Atrial fibrillation	4	3	.137
Phosphenes	<1	<1	.224
Blurred vision	<1	<1	1

1. Swedberg K et al. *Lancet*. 2010;376:875-885.




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### Guideline Update<sup>1</sup>

COR	LOE	Recommendations
Ia	B-R	Ivabradine can be beneficial to reduce HF hospitalization for patients with symptomatic (NYHA FC II-III), stable, chronic HFrEF (LVEF ≤35%) who are receiving GDMT, including a β-blocker at maximally tolerated dose, and who are in sinus rhythm with a heart rate ≥70 bpm at rest

- Incremental benefits of ivabradine are more pronounced in patients with higher resting heart rates
- Magnitude of heart rate reduction achieved with ivabradine + β blockade is the principal determinant of subsequent outcome

1. Yancy CW et al. *J Am Coll Cardiol*. 2016;68:1476-1488.




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### Practical Points on Use of Ivabradine

- Starting dose is 5 mg twice daily
- Target heart rate is 50-60 bpm

After 2 weeks	
Heart rate >60 bpm	• Increase dose to 7.5 mg twice daily (max dose)
Heart rate 50-60 bpm	• Maintain initial dose
Heart rate <50 bpm or symptomatic bradycardia	• Lower dose to 2.5 mg twice daily
Heart rate <50 bpm or symptomatic bradycardia and 2.5-mg twice daily dose	• Discontinue




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## Case 2: 73-Year-Old Male With CHF

### Option 1

- Switch from valsartan to sacubitril/valsartan
- Increase carvedilol

### Option 2

- Consider ivabradine if heart rate is persistently >70 bpm despite high-dose carvedilol

Management would be the same, even if the same patient presented and was much less symptomatic (NYHA FC II)

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## HFpEF: ACCF/AHA Guidelines<sup>1</sup>

	COR	LOE	Recommendation
<b>Class I</b> • Control hypertension • Chronotropic control • Judicious use of diuretics	I	B	Systolic and diastolic BP should be controlled according to published clinical practice guidelines
	I	C	Diuretics should be used for relief of symptoms due to volume overload
<b>Class II</b> • Revascularization • Management of AF • β-blockers, ACEI, ARBs for hypertension • Consider ARBs to reduce hospitalization	IIa	C	Coronary revascularization for patients with CAD in whom angina or demonstrable myocardial ischemia is present despite GDMT
	IIa	C	Management of AF according to published clinical practice guidelines for HFpEF to improve symptomatic HF
	IIa	C	Use of β-blocking agents, ACEIs, and ARBs for hypertension in HFpEF
	IIb	B	ARBs might be considered to decrease hospitalizations in HFpEF
	III: No benefit	C	Nutritional supplementation is not recommended in HFpEF

1. Yancy CW et al. J Am Coll Cardiol. 2013;62:e147-e239.

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## Nonpharmacologic Strategies for Heart Failure Management: Defibrillator and Cardiac Resynchronization Therapy

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## Requirements for Self-Care

### Adherence to Treatment

- Medications
- Follow-up
- Diet

### Self-Monitoring

### Preventive Behaviors

- Exercise
- Alcohol and smoking cessation
- Caution with nonprescription medications
- Weight loss

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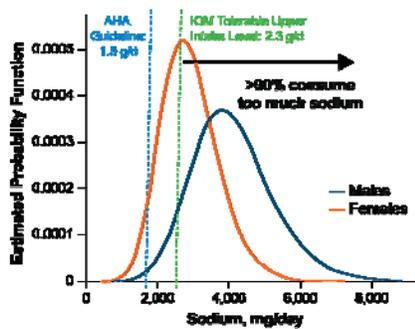
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## Adherence to Sodium Restriction Is Poor

Estimated Usual Intake of Sodium Among US Adults Aged ≥20 y (N = 12,501)<sup>1</sup>



1. Cogswell ME et al. *Am J Clin Nutr*. 2012;96:647-657. 2. Lainscak M et al. *Am J Cardiol*. 2007;99:310-37D.

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## Challenges in Adhering to Low-Sodium Diet

Lack of culturally relevant dietary guidance

Lack of knowledge of sodium content of foods

Inability to read food labels

Reliance on prepared foods

Multiple dietary restrictions;  
two-thirds of patients trying to follow ≥2 diets<sup>1</sup>

Cost/availability of low-sodium alternatives

1. Carlson B. *Heart Lung*. 2001;30:351-359.

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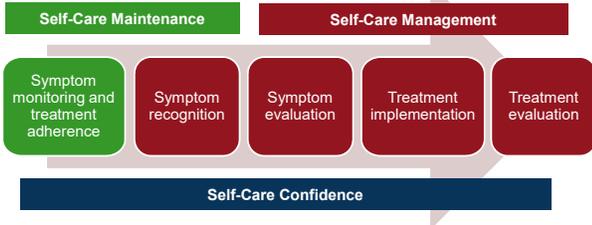
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## Self-Monitoring<sup>1</sup>



- Many patients do not recognize symptoms of worsening disease
- Fewer than 50% of HF patients report weighing themselves daily

1. Riegel B et al. *Circulation*. 2009;120:1141-1163.

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## Other Self-Care Recommendations

- Fluid restriction (1.5-2.0 L/d) only for those with refractory symptoms and hyponatremia
- Moderation of alcohol intake
  - Abstinence recommended for those with alcoholic cardiomyopathy
- Smoking cessation
- Influenza/pneumonia vaccination
- Avoidance of NSAIDs, herbal medications
- Exercise

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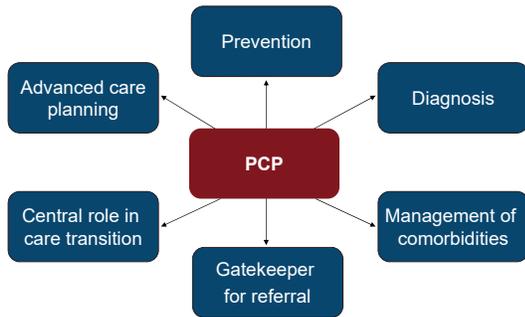
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## The Role of the PCP in Heart Failure Care



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# **An Osteopathic Approach to Low Back Pain**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***An Osteopathic Approach to Low Back Pain***

Kathleen Sweeney, DO, Margaret Wilkins, DO,  
Jacqueline Fabina, DO, and Drew Keister, MD

**Disclosures:**

The speakers have no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speakers have attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speakers indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

**\*\*SESSION HANDOUTS ARE NOT AVAILABLE  
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# **Breast Cancer Update Prevention and Screening**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Breast Cancer Update Prevention and Screening***  
Michael Brown, MD

**Disclosures:**

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## Update on Breast Disease

Michael T. Brown, MD, MBA, FACS  
Medical Director  
McGlenn Cancer Institute  
Surgical Oncology  
Reading Hospital, Tower Health

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## Disclosure

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## Breast Disease

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- Benign
- Malignant

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## Common Breast Symptoms

- Breast Pain
  - Cyclic
- Treatment
  - Medication review ---- Antidepressants, Antihypertensives
  - Symptomatic relief --- NSAID, Evening Primrose oil tablets 1500mg Qday
  - Dietary restrictions --- Caffeine, Chocolate
  - Tamoxifen

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## Breast Rash

- Cellulitis
  - Antibiotics
  - Follow up exam
- Lactating
  - Evaluate for abscess, Galactocele
- Monomial rash
  - Lotrimen, NYSTATIN powder
- Cancer
  - Biopsy Skin and Deep Tissues

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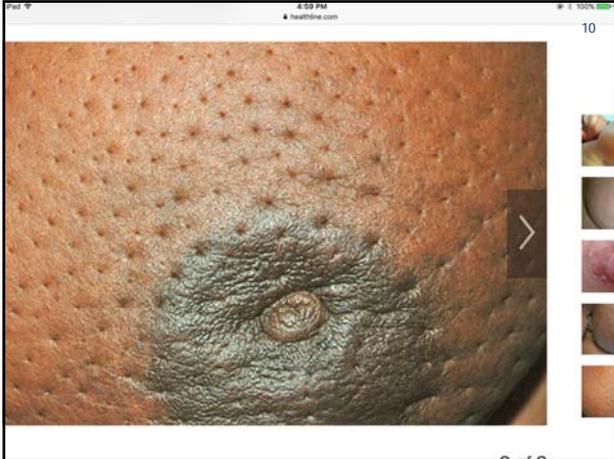
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## Breast Mass

- Fibroadenoma
  - smooth, rounded, rubbery, young women
- Breast Cyst
  - Multiple
  - Aspirate for symptom relief
  - Do not have to send the fluid
- Malignancy
  - Biopsy

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## Male Breast Masses

- Gynecomastia
  - 2 age groups 15-20, over 60
  - Alcoholism, liver or thyroid dysfunction, Medications
- Biopsy
  - May need imaging and biopsy
- Genetic Testing For Male Breast Cancer
  - BRCA 2 --- association with prostate and pancreas

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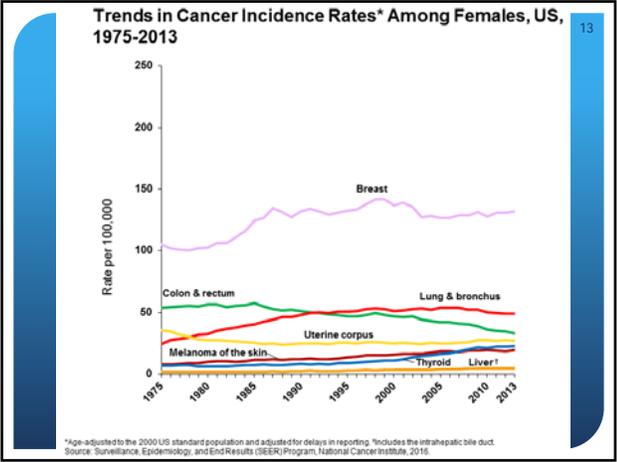
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- ## Breast cancer
- #1 cancer in women
  - Cause
  - Prevention
  - Screening
  - Treatment
  - Survivorship and Support

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- ## Cause
- 1 in 8, many women do not get breast cancer
  - Genetics BRCA 1, BRCA 2, many other genes of unknown significance
  - Radiation exposure - Treatment for Hodgkin's Disease
  - Diet - high fat
  - Exposure to estrogen
    - Earlier menstruation
    - Late pregnancy or no pregnancy
    - Hormone replacement

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# Screening

- Based on risk
- Whom to screen
- When to screen
- How to screen
- How often to screen
- When to stop screening

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# Risk - A situation involving exposure to danger

- How to assess Breast Cancer Risk for a woman
  - Use a risk assessment model
- Age
- Onset of menses
- Age at first birth
- Prior Biopsies
- Proliferative breast pathology---ADH, LCIS
- Family History
- Breast Density

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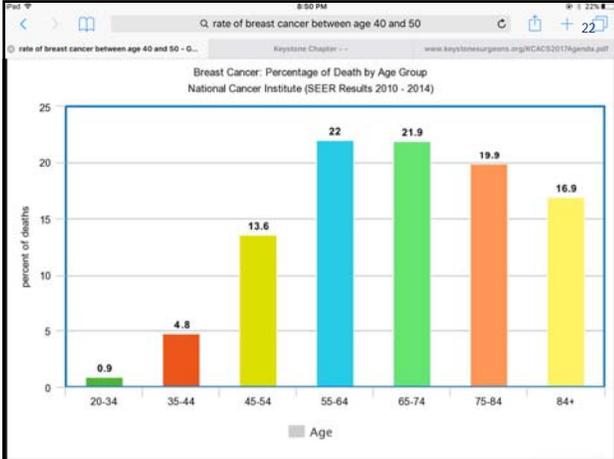
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**I. Breast density is determined through a woman's mammogram and described as one of four categories:**

(A) Fatty; (B) Scattered fibroglandular density; (C) Heterogeneously dense; or (D) Extremely dense

Breasts which are (C) Heterogeneously dense; or (D) Extremely dense are considered "dense breasts."

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**Fatty Breast**

Small cancer is easily seen

**Dense Breast**

Even a large cancer is difficult to see

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TABLE: SCREENING GUIDELINE COMPARISON 26

Breast Cancer Screening Guidelines - Comparison\*

	ACR/SBI	ACS	ACOG	AMA	NCCN	USPSTF
Age to Start Mammography	40	45 Option to start at age 40	Offer at 40, not later than 50	40	40	50
Age to Stop Mammography	When life expectancy is < 5-7 years	When life expectancy is < 10 years	Age 75, then shared decision	Not stated	Not stated	74 years
Mammography Interval	Annual	Annual 45-54, Every 1 or 2 years 55 and older	Every 1 or 2 years	Annual	Annual	Every 2 years
View on Tomosynthesis (3D) Mammography	No longer investigational, add address for breast imaging	Improvement in detection, lower chance of recall	Not stated	Not stated	Improves cancer detection, reduces callback rates	Insufficient evidence to support routine use, grade "I"

\*Adapted from <http://www.breast.org/ScreeningGuidelines/ScreeningGuidelinesComparisonChartDecember14.pdf> Dec. 2014

Resources

Have we helped you? <https://www.ama-assn.org/speical/ama-assn/2014/11/14/ama-assn-2014-11-14>

Please help us. <https://www.ama-assn.org/speical/ama-assn/2014/11/14/ama-assn-2014-11-14>

**DONATE TODAY!**

ACR/NIH <http://www.acr.org/About-Us/Health-Care/From-Research-to-Clinical-Practice/Research/2011/01/20/ACR-NIH-Immunogenomic-Screening-at-Age-40>

AMA <http://www.ama-assn.org/speical/ama-assn/2014/11/14/ama-assn-2014-11-14>

NCCN [http://www.nccn.org/clinical\\_guidelines/pdf/1.2011/2011/1/2011.pdf](http://www.nccn.org/clinical_guidelines/pdf/1.2011/2011/1/2011.pdf)

USPSTF <http://www.uspreventiveserVICES.org/USPSTF-recommendations>

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BreastScreen Australia

BreastScreen Australia is the national breast cancer screening program.

It invites women aged between 50 and 74 for a free mammogram every two years.

BreastScreen Australia aims to continue to reduce deaths from breast cancer through early detection of the disease.

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## When to start screening

- Assess risk for breast cancer
- Include family history of both mother and father
- Testing can be associated with more biopsies

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## Screening

- Average risk---(12% lifetime) mammogram every 1 to 2 years
- Slightly increased risk (12% - 19% lifetime)- mammogram every year, ultrasound may be offered for extreme density.
  - Insurance may not cover additional imaging
- High risk (>20% lifetime) 1.6% 5 year risk
  - Yearly mammogram
  - Yearly MRI
  - Genetic Testing if indicated
  - Chemoprevention with Tamoxifen or raloxifene

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## Breast Biopsy "Biopsy lesion first"

- Mammographic - Stereotactic breast biopsy
- Ultrasound guided breast biopsy
- MRI guided breast biopsy

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## Breast Biopsy Results

- Benign
  - Fibrocystic change, Fibroadenoma
- Proliferative -Atypical hyperplasia, papilloma, radial scar, LCIS
  - Open excision biopsy ( 11% chance of malignancy)
- Malignant
  - Comprehensive evaluation

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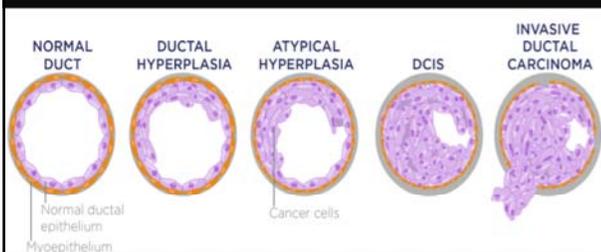
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## Proliferative Lesions

- Annual Screening
- LCIS/ ADH
  - Risk reducing strategies
    - Weight control
    - Modest use of alcohol
    - Consider Chemoprevention

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# Breast Cancer

- Size
  - <2cm
  - >2cm - consider neoadjuvant treatment
- Stage
  - Stage 1 CBC, LFT,
  - Stage 2, Lymph node involvement -Consider CT C/A/P, or CT/PET
- Molecular profile
  - Estrogen Receptor
  - Progesterone Receptor
  - HER2 overexpression

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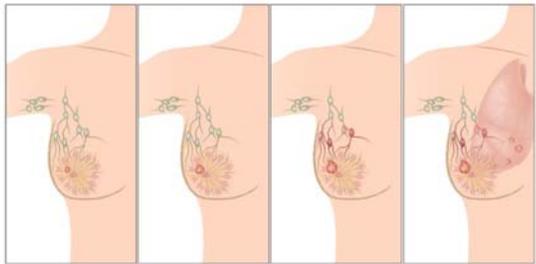
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## Clinical Staging of Breast Cancer



Stage I      Stage II      Stage III      Stage IV

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## Multidisciplinary Breast Center

- Pathology review
- Radiology Review
- Surgery, Radiation Oncology, Medical Oncology
- Nurse navigation
- Social Worker
- Genetics
- Research - Clinical protocols

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# Breast Surgery

- Lumpectomy when possible
- Mastectomy
  - Modified radical mastectomy
  - Skin sparing mastectomy
  - Nipple sparing mastectomy
- Reconstruction
  - Tissue Flaps--- TRAM, Latissimus, Free Flap
  - Tissue expander with Implants

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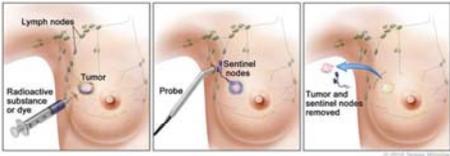
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8:30 PM anticancerfund.org 44

40 of 41

© 2014 Breast Cancer Research Foundation

Sentinel lymph node biopsy of the breast. A radioactive substance and/or blue dye is injected near the tumor (first panel). The injected material is detected visually and/or with a probe that detects radioactivity (middle panel). The sentinel nodes (the first lymph nodes to take up the material) are removed and checked for cancer cells (last panel).

**Soft tissue**  
Refers to muscle, fat, fibrous tissue, blood vessels, or other supporting tissue of the body.

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# Radiation

- After Lumpectomy or partial mastectomy
- After Mastectomy
  - Tumors > 5cm
  - Close margins
  - Lymph node involvement
- Short course 3.5 weeks
- Conventional Course 6 weeks with boost to primary site

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## Medical Therapy

- Antihormonal --Anastrozole, Letrozole, Tamoxifen
- Cytotoxic - systemic chemotherapy
- Targeted - Trastuzumab (Herceptin)
- Immune stimulating - PD 1 Inhibitor
  - Pembrolizumab (keytruda)
  - Nivolumab (Opdivo)

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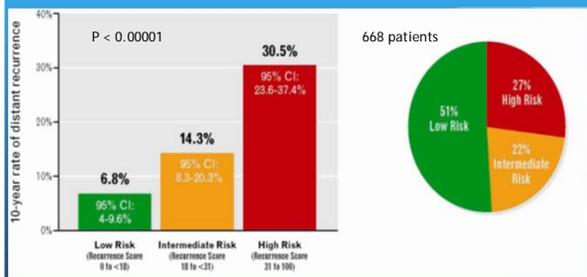
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## Oncotype DX Recurrence score



Park et al. N Engl J Med. 2004;351:2617-2626

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## Survivorship

- Encouragement
- Side Effects of treatment
- Lymphedema
- Ongoing monitoring
- Anxiety

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# **Treatment Alternatives for Substance Abuse**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Treatment Alternatives for Substance Abuse***  
Dean Drosnes, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation **WILL** include discussion of unapproved or investigational uses of products or devices.



## Treatment Alternatives for Substance Use Disorders

Dean Drosnes, MD, FASAM  
Associate Medical Director  
Director, Chronic Pain and SUD Program  
Caron Treatment Centers

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## Disclosure

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## Learning Objectives

- Understand Medication Assisted Treatment options for treatment of opioid use disorder
- Learn the medication options for relapse prevention in alcohol use disorder
- Understand the necessity for comprehensive treatment of substance use disorders.

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Medication  
Assisted for Opioid Use Disorder  
Treatment

- **Medication-Assisted Treatment (MAT)** is the use of medications, in combination with counseling and behavioral therapies, to provide a “whole-patient” approach to the treatment of substance use disorders. (SAMHSA)
- **Medication assisted Recovery (MAR)** is a transitional term to help the general public, recipients of health care services, and professional health care service providers understand that pharmacotherapy can be helpful in supporting recovery. (ASAM)
- **Medication Assisted Treatment (MAT)**, another variation on the concept of MAR, may involve pharmacotherapy alone. (ASAM)

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Medication  
Assisted for Opioid Use Disorder  
Treatment

- **Medication Assisted Treatment (MAT)** (cont.)...It is essential that addiction treatment and recovery approaches address the various aspects of biological, psychological, social and spiritual dimensions for optimum health and wellness. It is hoped that as the public and professionals recognize that recovery and treatment need to be holistic, appropriate pharmacotherapy would be well accepted as part of treatment and recovery, *such that the terms MAR and MAT would be deemed unnecessary.* (Italics added)

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Pharmacotherapy Options for OUD

- Methadone
- Buprenorphine
- Naltrexone
- Naloxone
- N.B. – The  $\alpha$ -adrenergic agonist clonidine is not FDA approved for treatment of opioid withdrawal per se, but is widely accepted as a pharmacotherapy for opioid withdrawal.

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## Goals of MAT

- Improve patient survival
- Increase retention in treatment
- Decrease illicit opiate use and other criminal activity among people with substance use disorders
- Increase patients' ability to gain and maintain employment
- Improve birth outcomes among women who have substance use disorders and are pregnant

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## Methadone



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## Methadone

August 23, 1965

### A Medical Treatment for Diacetylmorphine (Heroin) Addiction: A Clinical Trial With Methadone Hydrochloride

Vincent P. Dole, MD; Marie Nyswander, MD  
Author Affiliations

From the Rockefeller Institute, and Manhattan General Division of Beth Israel Hospital, New York.

JAMA. 1965;193(8):646-650. doi:10.1001/jama.1965.03090080000002  
Full Text

#### Abstract

A group of 22 patients, previously addicted to diacetylmorphine (heroin), have been stabilized with oral methadone hydrochloride. This medication appears to have two useful effects: (1) relief of narcotic hunger, and (2) induction of sufficient tolerance to block the euphoric effect of an average illegal dose of diacetylmorphine. With this medication, and a comprehensive program of rehabilitation, patients have shown marked improvement: they have returned to school, obtained jobs, and have become reconciled with their families. Medical and psychometric tests have disclosed no signs of toxicity, apart from constipation. This treatment requires careful medical supervision and many social services. In our opinion, both the medication and the supporting program are essential.

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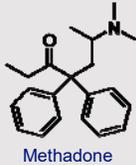
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## Metadone

- Full agonist at  $\mu$ -opioid receptor



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## Metadone

- Slow acting oral formulation
- Available through Opioid Treatment Programs (OTPs)
  - Methadone is the most highly regulated drug in existence
- Goals of methadone treatment
  - (1) To suppress opioid withdrawal.
  - (2) To block the effects of illicit opioids.
  - (3) To reduce opioid craving and stop or reduce the use of illicit opioids.
  - (4) To promote and facilitate patient engagement in recovery oriented activities including psychosocial intervention.

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## Metadone

- Induction
  - Federal law limits first day's dose to 30mg.
- Dose escalation
  - No faster than 5 mg every 2<sup>nd</sup> day
    - Due to drug accumulation and AE risk
    - **Start low; Go slow**
- Maintenance dose usually 60-120mg/day



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## Methadone

- Split dosing may be necessary for rapid metabolizers
- Higher doses associated with QT prolongation and possible arrhythmia (Torsade de Pointes).
- Half-life 8-59 hours (or longer).
- Hepatic metabolism. Cytochrome P450 enzymes, primarily CYP3A4, CYP2B6, and CYP2C19 and to a lesser extent CYP2C9 and CYP2D6.
- Multiple drug interactions and pharmacogenomic determinants of effectiveness.

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## Methadone

- Initial doses must be observed. Take-home doses earned by negative UDS and participation in programming.
- "A narcotic treatment program may permit a patient to reduce attendance at the narcotic treatment program for observation to one time weekly and receive no more than a 6-day take-home supply of medication when in the reasonable clinical judgment of the narcotic treatment physician, which is documented in the patient record." [28 PA Code 715.16]
- If weaning: reduce dose by 5-10% every 2 weeks.

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## Buprenorphine



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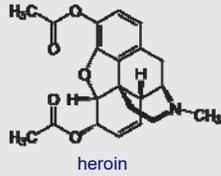
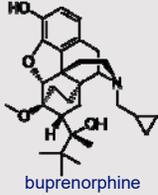
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## Buprenorphine

- Partial  $\mu$ -opioid receptor agonist



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## Buprenorphine

- High affinity for the MOR.
  - First dose usually >12 hours after short-acting opioid (heroin, fentanyl), >24 hours after other (or unknown) opioid.
  - May cause precipitated withdrawal.
  - Ceiling effect enhances “user friendliness”



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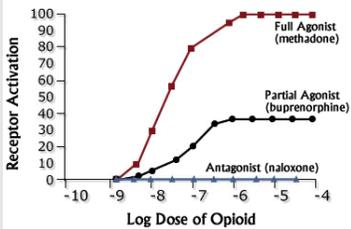
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## Full vs. Partial MOR Agonists

Receptor Activation:  
Full Agonist, Partial Agonist, Antagonist



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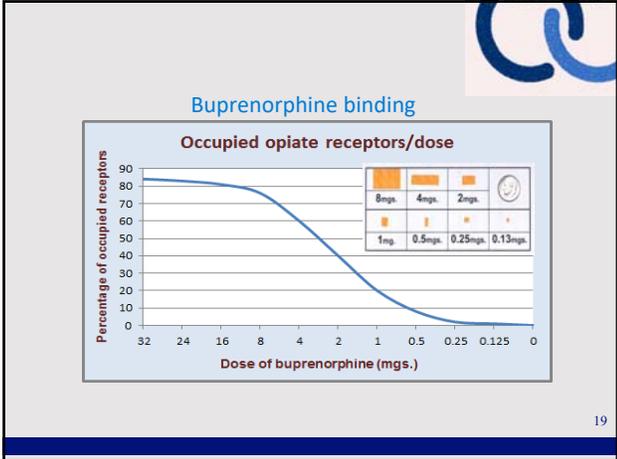
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- ### Buprenorphine
- Induction: 2-4mg day 1
    - Mono- or combination product (Suboxone)
      - Concern for misuse (IV administration)
  - Increase dose 4-8mg/day to eliminate withdrawal symptoms and minimize cravings.
  - Well tolerated.
    - Few adverse reactions
    - Few drug-drug interactions
    - Well-suited to out-patient management
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- ### Buprenorphine
- Diversion is a concern
  - Duration of treatment is not standardized
  - Implantable formulation
    - Probuphine approved May 2016
    - Indicated for patients stable on sublingual buprenorphine
    - 80 mg per 4 implants.
    - Duration of action = 6 months, then remove.
    - Can be supplemented with s.l. formulation.
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## Buprenorphine regulations

- To prescribe or dispense buprenorphine, providers must qualify and apply for a waiver under DATA 2000.
- Nurse practitioners (NPs) and physician assistants (PAs) can now train and apply to become DATA waived practitioners.
- Prescribing limits: 30 patients year 1, 100 patients year 2, then some providers are eligible for 275 if criteria are met.

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## Agonists Compared

Buprenorphine	Metadone
Partial mu agonist	Full mu agonist
36–48 hour half-life	24–36 hour half-life
Daily or alternate day dose frequency	Daily dose frequency
Less abuse potential	More abuse potential
Ceiling effect limits overdose risk	No protective overdose factors
Limited to mild–moderate dependence	More effective for severe dependence
Mild withdrawal symptoms	Moderate/severe protracted withdrawal
Tablet preparation—risk of injection	Oral liquid*—less risk of injection
	Tablet preparation is available
Moderately expensive	Inexpensive

\*Metadone is sometimes prescribed as an intravenous preparation

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## XR-Naltrexone



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## XR-Naltrexone

- Vivitrol FDA approved 2010 for “the prevention of relapse to opioid dependence following opioid detoxification.”
  - Was approved for AUD 2006
- $\mu$ -opioid receptor antagonist (No intrinsic activity at MOR)
- Reduces cravings for opioids and alcohol.
- Monthly IM injection, 380mg dose.
- No special training or licensure required.

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## XR-Naltrexone-Adverse Reactions

- Hepatotoxicity – avoid in advanced liver disease
- Injection site reactions
- Depression and suicidality
- Precipitated withdrawal
- Potential opioid overdose risk
- Opioid ineffectiveness



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## Candidates for XR-Naltrexone

- Those with occupational considerations, e.g. HCPs
- Failed agonist therapy or opposed to agonist therapy
- High motivation for abstinence-based recovery model
- Currently abstinent with high relapse risk
- Do not want physical dependence
- Stigma, regulations, family concerns
- ? Younger +/- shorter duration of use



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## XR-Naltrexone

JAMA Psychiatry | Original Investigation

### Effectiveness of Injectable Extended-Release Naltrexone vs Daily Buprenorphine-Naloxone for Opioid Dependence: A Randomized Clinical Noninferiority Trial

Lars Tjønnum, MD, DMSc; Kristin Klemmetsby Sjøll, MSc; Zill-e-Huma Latif, MD; Jirata Sahytleer Benth, PhD; Arif Oghuzen, MSc; Kamran Sharma-Haase, MD; Peter Krings, MD, PhD; Nikolaj Kjaer, MSc, PhD

- First head to head study of XR-naltrexone vs. buprenorphine-naloxone published online October 18, 2017.

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Exhibit 1: Key Differences Between Medications Used To Treat Patients With Opioid Dependence

Prescribing Considerations	Extended-Release Injectable Naltrexone	Buprenorphine	Metadone
Frequency of Administration	Monthly	Daily	Daily
Route of Administration	Intramuscular injection in the gluteal muscle by healthcare professional.	Oral tablet or film is dissolved under the tongue. Can be taken at a physician's office or at home.	Oral (liquid) consumption usually witnessed at an OTP, until the patient receives take-home doses.
Restrictions on Prescribing or Dispensing	Any individual who is licensed to prescribe medicine (e.g., physician, physician assistant, nurse practitioner) may prescribe and order administration by qualified staff.	Only licensed physicians who are DEA registered and either work at an OTP or have obtained a waiver to prescribe buprenorphine may do so.	Only licensed physicians who are DEA registered and who work at an OTP can order methadone for dispensing at the OTP.
Abuse and Diversion Potential	No	Yes	Yes
Additional Requirements	None; any pharmacy can fill the prescription.	Physicians must complete limited special training to qualify for the DEA prescribing waiver. Any pharmacy can fill the prescription.	For opioid dependence treatment purposes, methadone can only be purchased by and dispensed at certified OTPs or hospitals.

Sources: Adapted from 15, 16, 18

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## Pharmacotherapy for AUD

- Naltrexone (oral or IM) (ReVia, Vivitrol)
- Acamprosate (Campral)
- Topiramate (Topamax)
- Baclofen (Lioresal)
- Disulfiram (Antabuse)

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## Naltrexone ( $\mu$ -opioid antagonist)

- Oral formulation
  - Once daily, dosage 50-200mg
  - Transient AEs - typically nausea, dysphoria x < 5 days
  - Witnessed dosing probably helpful
  - Duration of therapy – 6-12 months?
- IM formulation (Vivitrol)
  - 380mg IM every 4 weeks
  - Minimal G-I side effects
  - Ongoing therapy challenging



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## Naltrexone for AUD

- The Sinclair Method
  - Take 50mg oral naltrexone prior to drinking alcohol on every drinking occasion
  - Diminishes the enjoyment of alcohol
  - Modeled on classical conditioning
  - 80% abstinence or moderate drinking at 4-6 months reported

[Sinclair, J.D. Evidence about the use of naltrexone and for different ways of using it in the treatment of alcoholism. Alcohol and Alcoholism, 36: 2-10, 2001.](#)

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## Acamprosate (Campral)

- Partial NMDA agonist
- Not hepatically metabolized
- Minimal AEs reported; well tolerated
- Dose: 2x333mg tabs TID
- Dose adjust for renal impairment
- Neuroprotective effect?
- Decreases relapse to alcohol
- Effectiveness comparable to naltrexone



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## Topiramate (Topamax)

- Na-channel blocker, NMDA antagonist, GABA enhancer
- Clinical trials show decrease alcohol intake and more days abstinent compared to placebo
- Not FDA approved for treatment of AUD
- Dose: 75-300mg/day in divided doses
- AEs include cognitive impairment



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## Baclofen

- Skeletal muscle relaxant
- Mixed results in clinical trials
- Not FDA approved for AUD
- AEs include nausea, vertigo, drowsiness, abdominal pain
- More popular in EU than in US

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## Disulfiram (Antabuse)

- Acetaldehyde dehydrogenase antagonist
- N,V, flushing, tachycardia, diaphoresis, anxiety ensue when ethanol is ingested
- Clinical trials show effectiveness in some studies, insufficient evidence in others
- Compliance is a limitation; ingestion under supervision most effective

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### Duration of treatment

- Large individual variation
  - More is usually better!
- <90 days treatment is ineffective.
- Treatment outcomes are similar between those remanded to treatment and those who willingly engage, given a similar duration of participation.

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### Duration of treatment

- Minimum of 12 months methadone maintenance appears to necessary for successful outcome.
- Duration of buprenorphine therapy for OUD:
  - **UNKNOWN!**
- Duration of XR-naltrexone therapy for OUD:
  - **UNKNOWN!**
- Duration of pharmacotherapy for AUD:
  - Minimum 6 months, probably 1 year is better.

  
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### Common co-occurring disorders

- Chronic pain
- Mood Disorders
- ADHD
  - The psychostimulant problem
- Eating Disorders
- Other “process addictions.”
- Sleep Disorders

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### Self Help/Peer Support

- 12-step programs
  - Pros:
    - Widely available
    - Free
    - Peer Credibility
  - Cons:
    - Unsupervised
    - Limited accountability
    - Highly opinionated!



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### Comprehensive treatment

- Individual and group counseling
- Inpatient and residential treatment
- Intensive outpatient treatment
- Partial hospital programs
- Case or care management
- Medication
- Recovery support services
- 12-Step fellowship
- Peer supports



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### Comprehensive treatment

- A person accessing treatment may not need to access every one of these components, but each plays an important role.
- These systems are embedded in a broader community and the support provided by various parts of that community also play an important role in supporting the recovery of people with substance use disorders.

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# **Screening, Brief Intervention and Referral to Treatment (SBIRT)**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Screening, Brief Intervention and Referral to Treatment  
(SBIRT)***

Michael McCormick, DO

**Disclosures:**

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The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

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Michael A. McCormick, D.O., Addiction Medicine  
Pennsylvania Academy of Family Physicians  
Reading, PA  
November 17, 2017



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<sup>2</sup>



## DISCLOSURES

- Dr. McCormick does not have any relevant financial relationships with any corporate organizations to disclose regarding today's presentation.

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<sup>3</sup>



## MASBIRT

- 2006-2011 Massachusetts with SAMHSA
- Outpatient clinics
- Inpatient unit
- Emergency/Urgent Care Departments
- Specialty Areas
  - Adolescents
  - Dental
  - OB/GYN Clinics

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## MASBIRT

- 173,758 SBIRT encounters
- 81.8% Negative Screen
- 18.2% Positive Screen
  - 14.9% Brief Intervention was indicated
  - 1.4% Brief Treatment was indicated
  - 1.9% Referral to Treatment

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## “Translating SBIRT to Public School Settings: An Initial Test of Feasibility”

- Journal of Substance Abuse Treatment (2014)
- Tom McLellan, PhD and Brenda Curtis, PhD
- PENN
- 2 Urban public schools
- Feasibility and economic sustainability study

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## Demographics

- Equal numbers of middle and high school students
- Equal gender distribution
- 248 students screened over 16 weeks
- 6<sup>th</sup> - 12<sup>th</sup> grade students
- Random recruitment with parents’ consent

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## Results

- 42% reported alcohol/drug use within the past year using SBIRT
- Of note: only 28% reported use in an anonymous survey the previous year
- Alcohol use was the most widely used
- MJ use was second
- Other substance use was third
- **Feasible and Desirable**

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### SBIRT Initiative:

*Grants and Support in 3 basic avenues*

1. Colleges and Universities (12 in 2005)
2. Medical residency programs (11 in 2008) (6 in 2009)
3. State cooperative agreements (22 States and 2 Tribal Councils)

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## Madras, et al (2009) SAMHSA SBIRT Grantees Analysis

- 459,599 patients screened
- 22.7% screened positive for “risky/problematic” or “abuse/addiction”
  - ✓ 15.9% were recommended to BI
  - ✓ 3.2% were recommended to BT
  - ✓ 3.7% were recommended to RT

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## Madras, et al (2009) SAMHSA SBIRT Grantees Analysis

6 month follow-ups

**Majority of self-reported Alcohol use rates diminished from baseline for “heavy users”**

❖ Heavy Alcohol use was 38.6% lower than baseline

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- CSAT 10/03
- Public Health Initiative
- Widespread adoption w/in systems of medical care
- Widespread education
- Incentivized in the Affordable Care Act

**SBIRT Initiative:**

*Grants and Support in 3 basic avenues*

1. Colleges and Universities (12 in 2005)
2. Medical residency programs (11 in 2008) (6 in 2009)
3. State cooperative agreements (22 States and 2 Tribal Councils)

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## The Impact of SBIRT on ED Patients' Alcohol Use

- 7,751 Screened
- 2,051 (26%) exceeded NIAAA low risk limits
- 55% enrolled in the study
- 699 (62%) completed study
- Followed-up at 3 months
  - 37.2% in SBIRT arm no longer exceeded NIAAA low risk limits
  - 18.6% in control arm no longer exceeded NIAAA low risk limits

Annals of Emergency Medicine, Volume 50, Issue 6, December 2007, Pages 699-710.e6

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## “E”....asy to use

- Evidenced-based
- Early identification
- Easy to implement universal screening
- Efficient (modal time of 5-10 minutes)
- ER’s, 1° care offices, CJS, schools....
- Ease of transition between components
- Early intervention
- Effective, full continuum of services
- Experiential evidence and strong research



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## Pennsylvania

- Cohort #1 (6 states and 1 Tribal Council)
- Community Health Clinics
- Primary Care Offices
- **Cohort #1 Outcome Data:**
  - 2,210 baseline interviews were completed
  - 39% screened “positive”
  - 59% of “positives” for BI’s
  - 20% for BT’s
  - 21% referred to more intensive specialty treatment
  - Overall, there was a 27% reduction in substance use & harms



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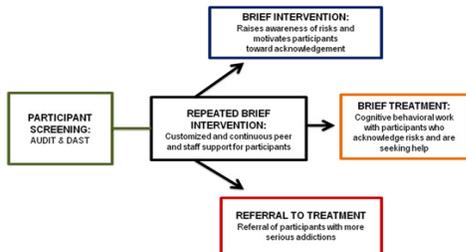
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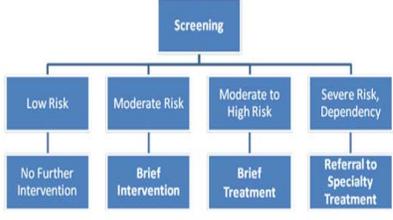
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## Screening in Action: Flexibility Helps



```

graph TD
    A[Screening] --> B[Low Risk]
    A --> C[Moderate Risk]
    A --> D[Moderate to High Risk]
    A --> E[Severe Risk, Dependency]
    B --> B1[No Further Intervention]
    C --> C1[Brief Intervention]
    D --> D1[Brief Treatment]
    E --> E1[Referral to Specialty Treatment]
  
```

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## Screening

- AUDIT (WHO) (Alcohol Use D/O's Identification Test)  
10 questions about recent alcohol use, alcohol use disorder symptoms & alcohol related problems Validated on 1° Care patients in 6 countries
- DAST (Drug Abuse Screening Test)
- ASSIST (Alcohol, Smoking and Substance Involvement Screening Test)
- CAGE (Cut Down, Annoyed, Guilty, Eye-opener)
- NIDA Drug Use Screening Tool

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## AUDIT

**SLIDE 3**  
Alcohol Use Disorders Identification Test (AUDIT)<sup>®</sup>

**Alcohol consumption:**

1. How often do you have a drink containing alcohol?
2. How many drinks containing alcohol do you have on a typical day when you are drinking?
3. How often do you have 6 or more drinks on 1 occasion?

**Drinking behavior:**

4. How often during the past year have you found that you were not able to stop drinking once you had started?
5. How often during the past year have you failed to do what was normally expected of you because of drinking?
6. How often during the past year have you needed a first drink in the morning to get yourself going after a heavy drinking session?

**Adverse reactions:**

7. How often during the past year have you had a feeling of guilt or remorse after drinking?
8. How often during the past year have you been unable to remember what happened the night before because you had been drinking?

**Alcohol-related problems:**

9. Have you or has someone else been injured as a result of your drinking?
10. Has a relative, friend, or a doctor or other healthcare worker been concerned about your drinking or suggested you cut down?

The AUDIT is scored on a scale of 0 to 40, with a score of 8 or higher considered positive and warranting further assessment. Details on scoring can be accessed at [http://www.hqibdooc.who.int/nr/2001/WHO\\_AASD\\_AASB\\_01.de.pdf](http://www.hqibdooc.who.int/nr/2001/WHO_AASD_AASB_01.de.pdf).

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### AUDIT - C

- **Q1: How often did you have a drink containing alcohol in the past year?**
  - Never, Monthly, 2-4 x month, 2-3 x week, 4 or > per week
- **Q2: How many drinks did you have on a typical day when you were drinking in the past year?**
  - None, 1 or 2, 3 or 4, 5 or 6, 7 to 9, 10 or more
- **Q3: How often did you have six or more drinks on one occasion in the past year?**
  - Never, > monthly, monthly, weekly, daily or almost daily

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### AUDIT - C

- The AUDIT-C is scored on a scale of 0-12 (scores of 0 reflect no alcohol use).
- Answers are from 0 – 4 points each
- Total score of 4 or > in men, or 3 or > in women is considered positive.

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### DAST 10

- These questions refer to the past 12 months. (Answers - No or Yes)
1. Have you used drugs other than those required for medical reasons?
  2. Do you abuse more than one drug at a time?
  3. Are you always able to stop using drugs when you want to? (If never use drugs, answer "Yes.")
  4. Have you had "blackouts" or "flashbacks" as a result of drug use?
  5. Do you ever feel bad or guilty about your drug use? (If never use drugs, choose "No.")
  6. Does your spouse (or parents) ever complain about your involvement with drugs?
  7. Have you neglected your family because of your use of drugs?
  8. Have you engaged in illegal activities in order to obtain drugs?
  9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?
  10. Have you had medical problems as a result of your drug use? (e.g., memory loss, hepatitis, convulsions, bleeding, etc.)

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## DAST 10

Score	Drug Abuse	Suggested Action
0	No Problems	None
1-2	Low level	Monitor, re-assess
3-5	Moderate level	Further Investigation
6-8	Substantial level	Intensive Assessment
9-10	Severe level	Intensive Assessment

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## CAGE

1. Have you ever felt you should **Cut** down on your drinking?
2. Have people **Annoyed** you by criticizing your drinking?
3. Have you ever felt bad or **Guilty** about your drinking?
4. Have you had an **Eye-opener** first thing in the morning to steady nerves or get rid of a hangover?

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## CAGE

- CAGE is scored with a 0 or 1 for each question – (no or yes)
- Higher Score is indicative of alcohol problems
- Total score of 2 or more is clinically significant

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## NIDA QUICK SCREEN

In the past year how often have you used the following?

- Alcohol – (Men 5 or >, Women 4 or >)
- Tobacco
- Prescription Drugs for non-medical reasons
- Illegal drugs
- **Answer** – Never/Once or Twice/Monthly/Weekly/Daily

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## Screenings in Primary Care Settings

- Allied Health Staff Implementation
  - Nurses
  - SW's
  - Health Educators
- Noted in the chart for the 1° Care provider's notification and oversight




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## Primary Care Settings

- 3 - 5% screen positive for alcohol dependence
- 8 - 18% screen positive for alcohol abuse
- 15 - 40% screen positive for hazardous/harmful drinking




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## Brief Intervention

Who?	Those Identified @ Moderate Risk for Substance Issues
How?	Single or Multiple MI Sessions (1 - 5) (5 - 60 minutes each session)
What?	Insight and Awareness
Where?	Same Sight as Screenings
Why?	15-40% Positive for Hazardous/Harmful Drinking

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## What are Brief Interventions?

**Brief intervention:** Brief counseling and patient education that can be conducted in a few minutes during almost any clinic visit. Brief interventions include **one or more** of the following:

- Further assessment of the problem
- Making a recommendation for more healthy behavior
- Suggesting a treatment approach

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## What are Brief Interventions?

- *Example:* Motivate the patient who admits having a substance use problem, but who is not seeking treatment. If successful, recommend the appropriate treatment.
- All patients that screen positively for a substance use problem should receive a brief intervention - even patients requiring referral. Healthcare providers and/or other staff members can be involved.

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### Brief Interventions are Successful

- They are successful – even a brief 3 – 6 minute intervention can make a difference!
- Repeating the brief intervention stage at each appointment can also be very effective in leading to change.

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### 7 Steps in Brief Intervention

1. Confirm your concern with the patient's responses to screening questions. (Not judging)
2. Ask patient's view of the situation, barriers to quitting, and risk factors for relapse.
3. Discuss their personal responsibility for health effects and other consequences of substance use.

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### 7 Steps in Brief Intervention

4. Provide the patient with non-judgmental advice and discuss benefits of quitting.
5. Mention treatment options when appropriate and gauge patient's reaction.
6. Encourage and support the patient. Solicit commitment to a clear goal.
7. Provide patient education and resources.

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## Motivational Interviewing

- “Collaborative, people centered, inspiring change.”
- “...is a goal-oriented, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence.”
- “...is a collaborative, goal oriented style of communication with particular attention to the language of change.”
- “...is a technique in which you become a helper in the change process and express acceptance of your client.”

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## Motivational Interviewing

This technique has been shown to be effective with helping people overcome **substance use disorders** and other changes (Miller & Rollnick, 2012).

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## Motivational Interviewing (cont.)

Four processes or areas are involved in Motivational Interviewing: **Engage, Focus, Evoke, Plan**

- **E** - Engage - openness, concern, and lack of judgment to establish rapport
- **O** - Open ended Questions
- **A** - Affirmation
- **R** - Reflective listening
- **S** - Summaries

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## Engage

“There are some signs of drug use and, because I care about your health, I'd like to explore ways I can help you. What can you tell me about it?”

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## Focus

- Collaboratively selecting a target behavior to focus on.
- **ASK** - Ask permission to provide information or advice
- **TELL** - Provide information that relates to patient's concerns
- **ASK** - Pay attention to and ask for patient's reaction and understanding
- “How ready are you to quit -- on a scale of 1 to 10?”

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## Evoke

- Involves directing the interaction toward increasing the patient's readiness for change
- Chart of advantages vs disadvantages
- Open ended questions and reflective listening
- “**How is drinking affecting your life?**”

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## Plan

- The patient comes up with his or her own plan!!
- Plan for the next 30 – 90 days
- Doesn't have to be quitting, but rather changing (decreasing). Depends where the patient currently is.
- **Attainable and objectively measured**

“What steps, if any, can you do in the next month to move in the direction of thinking about quitting?”

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## Motivational Interviewing (cont.)

- Asking rather than telling?  
“Tell me what you already know about the health problems associated with smoking.”
- Affirmations – build their confidence  
“I think you have it in you to do this with enough support”
- Use of pauses...pause and wait patiently  
“That sounds difficult. (Wait after asking the question. Try counting five breaths.) What do you think? (Count five more breaths.)”

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## Motivational Interviewing in Teens

- **Effectiveness:** Motivational Interviewing is also an effective intervention for substance use problems with teens. (Jensen et al., 2011) It can be well suited for adolescents who are rebellious because it avoids confrontation

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## Motivational Interviewing in Teens

- Reflective listening in combination with a non-judgmental approach gives teens a sense of being heard.
- Their typical craving for autonomy is met through the process of eliciting their opinions.
- Finally, their often shaky sense of identity and self-esteem is calmed by meeting them where they are, developing rapport, and providing positive feedback, such as admiring their resourcefulness or expressing your faith in them.

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## Limitations with Teens

- Complete autonomy in determining drinking cannot be achieved, because drinking is illegal for people under age 21.
- Minors are subject to more social restrictions on drinking than adults. For example, by parents and school.
- Confidentiality may need to be broken if the teen's safety is at stake - see guidelines below from the AAP for when to consider breaking confidentiality.
- The goals teens set need to consider safety. Because they are still developing, they may need assistance in use of good judgment.

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## Other Factors

- Include parents and other family in the education and process.
- Discuss risk and a safety plan around driving or being a passenger.
- Other worrisome issues: hospital visits, IV use, alcohol poisoning, mixing substances.
- Very important to establish rapport!

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### Bad Doctor Example



<https://www.youtube.com/watch?v=hwlgc8S818&feature=youtu.be>

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### Teen Alcohol Use Case – Screening:



[https://www.youtube.com/watch?v=2c\\_uddHJbwg&feature=em-share\\_video\\_user](https://www.youtube.com/watch?v=2c_uddHJbwg&feature=em-share_video_user)

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### Good Screening - Continued



<https://www.youtube.com/watch?v=fX90j4jD9Sc&feature=youtu.be>

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## Brief Treatment (1° Care)

- AKA....Brief Intensive Intervention
- Systematic
- Focused
- Relies on assessment
- Requires patient engagement
- Utilizes implementation of change strategies
- GOALS:
  1. Δ immediate and future risky behaviors
  2. Address long standing problems w/harmful ETOH misuse
  3. More intensive care for higher levels of d/o



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## Brief Treatment (continued)

- Assessment
- Limited # of clinical sessions (6-20)
  - Evidenced-based
  - Highly focused
  - Structured
    - CBT
    - Solution-focused
    - Motivational enhancement
- Usually referred to specialty SUD provider outside program or somewhere else w/in the medical system



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## ASAM Criteria

1. Larger amounts over longer time?
2. Desire or efforts to cut down?
3. Time spent in obtaining, using, or recovering?
4. Craving?
5. Missed work, school or home obligations?
6. Social or interpersonal problems caused by use?
7. Given up or reduced other activities?
8. Use in hazardous situations?
9. Medical or psychological problems caused or worsened by use?
10. Tolerance?
11. Withdrawal?

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## ASAM criteria

- Severity: Use Disorder
- Mild: 2-3 symptoms
- Moderate: 4-5 symptoms
- Severe: 6 or more symptoms.
- **\*\*Emphasis placed on Tolerance and Withdrawal\*\***

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## Level of Care

- Intensive Outpatient Program
  - 3 Hours per day, 3 x week (not >10 hrs week)
- Partial Hospitalization – Day Program
  - 9 AM – 3 PM every day, go home at night
- Inpatient Residential Program
  - Caron

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## Level of Care

- Most times patients must start at IOP – insurance will want a failure at IOP before paying for residential treatment
- Outpatient usually includes weekly group therapy and individual therapy

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### Detox – What level?

- Medically Managed – Hospital
- Medically Monitored - Caron
- The goal is to have a system of care that matches patient’s clinical needs with the appropriate care setting in the least restrictive and most cost-effective manner. (ASAM)

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### SBIRT Goals

- The goal of SBIRT is to discover those who are “at risk”
- We can then do certain things, including brief interventions or treatment to change their course. To prevent the use disorder, severe diagnosis.

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### SBIRT Benefits



- Upstream approach
- Identifies and intervenes in substance misuse
- Before SUD develops
- Puts substance use “on the table”
- Gives medical professionals a sense of agency re: Substance Use D/O’s
- Brief Interventions have been shown to:
  1. Reduce risky/harmful alcohol/drug use in 1° Care pts
  2. Identified pregnant ♀ at risk for alcohol/drug use while screening for smoking

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### Referral to Treatment

- Patients needing more than Brief Intervention
- Referred to a specialty SUD provider
- Proactive and collaborative effort needed
- Best if 1° Care provider establishes a relationship w/ a specialty SUD provider/facility that can determine and facilitate entry into multiple levels of care
- Strong Linkages are CRITICAL
- Referral to Treatment is recommended when a patient meets the diagnostic criteria for substance use disorder (DSM V)

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### WHAT NOW?




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**[Return to Top](#)**

## **Diagnosing and Managing CDK to Avoid Complications and Dialysis**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Diagnosing and Managing CDK to Avoid Complications and  
Dialysis***

Adam Rubin, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

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# Diagnosing and managing CKD to avoid complications and Dialysis

ADAM M. RUBIN, M.D.  
READING NEPHROLOGY, LTD.

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## Disclosure

- ▶ The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

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## Overview

- ▶ Abbreviations
- ▶ Definitions
- ▶ Methods of determining Kidney function
- ▶ Risk factors for kidney disease
- ▶ Therapeutic Interventions
- ▶ Summary Points

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## Key to Abbreviations

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- ▶ ACE-I : Angiotensin converting enzyme inhibitor
- ▶ ARB: Angiotensin receptor blocker
- ▶ CKD: chronic kidney disease
- ▶ eGFR : estimated glomerular filtration rate
- ▶ CCB: calcium channel blockers
- ▶ ESRD: End stage renal disease

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## How to measure kidney function

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- ▶ Creatinine?
- ▶ GFR?
- ▶ Inulin?
- ▶ Cystatin C?

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## Creatinine

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- ▶ A waste breakdown product of creatine phosphate
  - ▶ Generated by muscle metabolism
  - ▶ Generated by diet
  - ▶ Excreted in small amount by the GI tract
  - ▶ Generation is determined by age, sex, race and weight
  - ▶ There is proximal tubular secretion of creatinine
- ▶ Its value in determining kidney function is limited due to these factors

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## The GFR

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- ▶ The GFR is only one measurement of kidney function
  - ▶ Excretory Function (filtration, reabsorption and secretion)
  - ▶ Endocrine Function (renin, EPO, Vitamin D)
  - ▶ Metabolic Function (breakdown of low molecular weight proteins and drugs)

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## The true GFR

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- ▶ GFR is a physiological property that cannot be measured directly
- ▶ Variables include body size, diet and even time of day
- ▶ No method to directly measure
  - ▶ Estimated from filtration markers or clearance measurements

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## Calculation of eGFR

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- ▶ Urinary excretion is the GFR times the plasma concentration (filtered load) - tubular reabsorption plus tubular secretion
- ▶ In steady state generated marker - non renal excretion equals the GFRx Plasma concentration -tubular reabsorption plus the tubular secretion
- ▶ GFR equals the generation of the marker from cells and diet plus tubular reabsorption minus tubular secretion minus non kidney excretion all divided by plasma level
- ▶ There is an inverse relation between plasma concentration and GFR
- ▶ For Creatinine the eGFR =  $(G-E-TS)/\text{serum Cr}$

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## Filtration Markers

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- ▶ Ideal marker is freely filtered
- ▶ Non protein bound
- ▶ Not reabsorbed
- ▶ Not secreted
- ▶ Molecular weight <20000 dalton

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## Filtration Markers

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- ▶ Gold standard is IV inulin clearance
- ▶ Homer Smith's protocols to measure GFR by inulin clearance were very complicated utilizing catheters and bladder washing, and continuous infusions
- ▶ 24 hour urine creatinine clearance is easier to measure but less accurate than inulin due to tubular secretion of creatinine in the proximal tubule. Also as the kidney function deteriorates the amount of secretion can increase
- ▶ Collection errors

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So how do we use these markers to classify CKD?

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**Table 11. Definition of Chronic Kidney Disease**

**Criteria**

1. Kidney damage for  $\geq 3$  months, as defined by structural or functional abnormalities of the kidney, with or without decreased GFR, manifest by *either*:
  - Pathological abnormalities; or
  - Markers of kidney damage, including abnormalities in the composition of the blood or urine, or abnormalities in imaging tests
2. GFR  $< 60$  mL/min/1.73 m<sup>2</sup> for  $\geq 3$  months, with or without kidney damage

Methods to estimate GFR are discussed in Guideline 4. Markers of kidney damage are discussed in Guidelines 5–6.

KDOQI workgroup operational definition of chronic kidney disease

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Definitions

- ▶ More Simply stated
  - ▶ A decreased eGFR of less than 60 for greater than 3 months
  - ▶ Structural kidney disease
  - ▶ Proteinuria
  - ▶ Hematuria

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KDIGO Recommendation

- ▶ We recommend using a serum creatinine and a GFR estimating equation for initial assessment
- ▶ We suggest using additional tests for confirmatory testing in specific circumstances when eGFR based on serum creatinine is less accurate
- ▶ Recommend using a GFR estimating equation to derive GFR from serum creatinine rather than relying on serum creatinine alone

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19

## Diabetic Nephropathy

- ▶ Structural changes
  - ▶ Mesangial expansion
  - ▶ Glomerular basement membrane thickening
  - ▶ Podocyte injury
  - ▶ Glomerular sclerosis
    - ▶ Nodular glomerulosclerosis
    - ▶ Kimmelstiel-Wilson lesion

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## Clinical Features of Diabetic Nephropathy

- Albuminuria
- Hematuria
- Glomerular Hyperfiltration

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21

## Diabetic Nephropathy

- ▶ Glomerular Hyperfiltration and Hypertension
- ▶ A GFR increase of 25-50% is seen in about half of patients with type 1 diabetes and also occurs in type 2 diabetics
  - ▶ Increased after a protein load

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## Diabetic Nephropathy

22

- ▶ Effects of Hyperglycemia
  - ▶ Increase mesangial matrix expansion and injury.
  - ▶ Increased advanced glycation end products that accumulates and cross link collagen and cause fibrosis

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## Diabetic Nephropathy

23

- ▶ Afferent arteriolar dilatation increases the intraglomerular pressure and the renal blood flow
- ▶ Causative factors likely include:
  - ▶ Glycosylated proteins, sorbitol accumulation, increased tubular sodium reabsorption due to increased sodium glucose cotransport and increased ECF volume.
  - ▶ Hyperinsulinemia and hyperglycemia cause increased sodium reabsorption
  - ▶ Sex hormones, insulin like growth factor, Atrial natriuretic peptide
  - ▶ Glomerular hypertension appears to be mediated by angiotensin II and induces fibrosis. RAAS inhibition seems to counter these profibrotic effects

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## Who is at risk developing Diabetic Nephropathy

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African Americans and Mexican Americans have an increased incidence and worse outcomes compared to Caucasians

Smokers

Increased BMI is associated with increased risk of developing CKD in patients with Diabetes

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## Treatment of Diabetic Nephropathy

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- ▶ Glycemic Control
  - ▶ Efficacy in slowing progression is a factor of both the degree of control and the time at which the control is achieved
- ▶ Renin Angiotensin Aldosterone system Inhibition
  - ▶ ACE inhibitors and ARB, mineralocorticoid receptor antagonists
- ▶ Blood Pressure Control
- ▶ Diet

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## Blood Pressure control in Diabetic Kidney Disease

26

- ▶ United Kingdom Prospective Diabetes Study
  - ▶ Intensive blood glucose control and blood pressure management decreased diabetic complications
    - ▶ 20% reduction in death related to diabetes
    - ▶ 40% reduction in eye, kidney and nerve complications
    - ▶ 40% decrease in development of lower extremity arterial disease
    - ▶ 15% decrease in heart attack
  - ▶ Risk of death from diabetes, end organ damage and heart attack decreased 12% for every decrease of 10mmHg in systolic pressure

Efficacy of atenolol and captopril in reducing risk of macrovascular and microvascular complications in type 2 diabetes. UKPDS 39. UK Prospective Diabetes Study Group. BMJ. 1998;317(7175):977-90.

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## Type 1 Diabetics and ACE-I

27

- ▶ Benefits are both early and late
- ▶ Have been shown to decrease progression from increased albuminuria to overt diabetic nephropathy
- ▶ ACE Inhibition has been shown to result in both remission of albuminuria or delay the rate of decline by up to 50%
- ▶ Shown in patients with overt diabetic nephropathy to delay the rate of rise in creatinine
- ▶ Effect is not limited solely to the control of blood pressure

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# Type 2 Diabetes and ARB

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- ▶ More data exists for ARB than ACE-I in this population
- ▶ 2 important trials IDNT and RENAAL demonstrate the benefits of ARB therapy in type 2 diabetes

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# Type 2 Diabetes and ARB

29

- ▶ Irbesartan Diabetic Nephropathy Trial
  - ▶ Patients with Hypertension and diabetic nephropathy were randomized to Irbesartan, amlodipine or placebo
  - ▶ At 2.6 years time the irbesartan group had a lower risk of the combined end points of doubling serum creatinine, development of end stage renal disease or death from any cause
  - ▶ 23% lower than amlodipine and 20% less than placebo
  - ▶ The reduction in doubling the creatine alone was 37% less than amlodipine and 30% less than placebo

Levine EJ, et al. "Prospective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes". *The New England Journal of Medicine*. 2001; 345(12):861-869.

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# Type 2 Diabetes and ARB

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- ▶ RENAAL Trial
  - ▶ 1513 patients with type 2 diabetes and diabetic nephropathy were randomized to losartan or placebo both in addition to conventional therapy
  - ▶ The losartan arm was found to have a 25 % reduction in doubling of the serum creatinine, and a 28% reduction in risk of development of ESRD at over 3 years
  - ▶ The risk of death or ESRD increased by 6.7 percent for every increase in SBP of 10mmHg
  - ▶ Cardiovascular risk was decreased by 18% for every 50% reduction in proteinuria

Berry M, Brenner M.D., Mark E. Cooper, M.D., Ph.D., David Zee Douma, M.D., Ph.D., William J. Evans, M.D., William E. Mitch, M.D., Hans-Henrik Parving, M.D., Giuseppe Remuzzi, M.D., Steven M. Sedorin, Ph.D., Zoran Stankovic, Ph.D., and Richard Workalembo, M.D. for the RENAAL Study Investigators. *N Engl J Med* 2001; 345:861-869. doi:10.1056/NEJMoa011161

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## ACE and ARB dual therapy

31

- ▶ Either class of agent alone is associated with benefits in reduction of proteinuria and reduction of rate of decline in renal function
- ▶ Both agents together are not recommended as the rate of adverse events is increased and there is not a reduction in death or deterioration in renal function

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## ACE and ARB dual therapy

32

- ▶ VA NEPHRON D
- ▶ RCT with 1448 patients on Losartan randomized to either the addition of lisinopril or placebo
- ▶ Primary endpoint was a composite of a 50% reduction in eGFR, ESRD, or death
- ▶ At just over 2 years the trial was stopped as AKI requiring hospitalization and severe hyperkalemia were significantly increased (18 vs 11% and 9.9 vs 4.4)
- ▶ The rate of reaching primary endpoints was similar (18.2 vs 21)

N Engl J Med 2013; 369:1992-2003. doi:10.1056/NEJMc1303154

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## ACE and ARB dual therapy

33

- ▶ ONTARGET trial
- ▶ 3163 patients with diabetic nephropathy had higher rates of acute kidney injury requiring dialysis, hyperkalemia and hypotension
- ▶ 1.4 vs 0.8, 11.3 vs 7.3, and 2.8 vs 1.9
- ▶ Combination therapy was not associated with any reduction in development of ESRD or doubling of creatinine and in fact had non statistically significant increases in those endpoints

Yusuf S, et al. "Telmisartan, ramipril, or both in patients at high risk for vascular events". *The New England Journal of Medicine*. 2008; 358(15):1547-1559.

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## Direct Renin Inhibitor

34

- ▶ Aliskiren, direct renin inhibitor Aliskiren Trial in Type 2 Diabetes Using Cardiorenal Endpoints ALTITUDE trial
- ▶ 8561 diabetic patients with preexisting renal or cardiovascular disease were randomized to 300mg per day of Aliskiren or placebo
- ▶ At about 33 months the Aliskiren group reached the composite end point of ESRD, doubling of serum creatinine, renal death, cardiovascular death, cardiac arrest, heart failure, non fatal MO or stroke at an increased rate over placebo 18.3 vs 17.1
- ▶ Adverse events were more frequent with Aliskiren.
- ▶ Trial was stopped due to futility

N Engl J Med 2012; 367:2204-2213. doi:10.1056/NEJMOA1205799  
Shaw

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## Bardoloxone methyl

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- ▶ An anti oxidant inflammatory modulator that was shown in animal models to decrease ischemic or drug induced acute kidney injury
- ▶ BEAM trial randomized 227 patients with eGFR between 20 and 45 to placebo or Bardoloxone methyl
  - ▶ At 1 year the eGFR was increased in all dosage arms of the trial
- ▶ BEACON
- ▶ 2185 patients with diabetes and eGFR off 15-30 were randomized to baroxolone methyl or placebo. All patients were on ACE or ARB
- ▶ Trial was halted due to safety concerns
- ▶ Bardoloxone methyl was associated with an increased rate of adverse cardiovascular outcomes including death, hospitalization for heart failure, non fatal stroke or MI
- ▶ GFR was increased but so was blood pressure and proteinuria

Journal of the American Society of Nephrology 2013; 24(1):149-158. doi: 10.1093/ajkd/kfs444

Perpitiu PE, Roden P, Tiao RD, et al. Bardoloxone methyl and kidney function in CKD with type 2 diabetes. N Engl J Med 2011; 365:327-36.

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## Non Dihydropyridine CCB

36

- ▶ Diltiazem and Verapamil
  - ▶ Maybe as effective in lowering proteinuria as an ACE or ARB
  - ▶ In combination shown to be even more effective than either alone
  - ▶ May be due to reduction in intraglomerular pressure
  - ▶ Lack definitive studies to show the same improvement in outcomes as ACE ARB

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## Blood Pressure and CKD

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- ▶ In patients with non diabetic CKD the focus of therapy is to treat any underlying cause of CKD, control blood pressure and limit proteinuria
- ▶ Increased amounts of proteinuria are associated with more rapid decline in eGFR
- ▶ Blood pressure control to less than 130/80 has been associated with longer renal survival

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Not all agents are equal

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## Antihypertensives that do not decrease proteinuria

39

- ▶ Alpha blockers
- ▶ Diuretics
- ▶ Beta blockers
- ▶ Methyl dopa
- ▶ Guanfacine

Antiproteinuric effect of blood-pressure-lowering agents: a meta-analysis of comparative trials.  
Gauerres RT, Shultz WJ, Himmelfarb JM, de Zeeuw D, de Jong PE.  
Nephrol Dial Transplant. 1995;10(11):1963.

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## Antihypertensives and non diabetic CKD

40

- ▶ ACE seem to decrease proteinuria by about a third.
- ▶ ARB has less data in non diabetic CKD but the antiproteinuric effect of ARB in CKD was similar to that of ACE
- ▶ Non dihydropyridine calcium channel blockers have been shown to decrease proteinuria
- ▶ Mineralocorticoid receptor antagonists have been shown to reduce proteinuria when added to an ACE or ARB but were associated with increased risk of hyperkalemia

Abstracts submitted for presenting the progression of chronic kidney disease: a systematic review and meta-analysis.  
Nephrology 15(10):1045-1054, October 2010  
Choi J, Anon Nephrol. 2009;15(10):1045-1054. Epub 2009 Nov 4. Meta-analysis: effect of monotherapy and combination therapy with inhibitors of the renin-angiotensin system on proteinuria in renal disease.  
Kane R, Frischholz C, Winkler M, Mann JF.  
Ann Intern Med. 2008;149(11):81-9.  
Differential effects of calcium antagonist subclasses on markers of nephropathy progression.  
Bakris GL, Weir MR, Sica M, Campbell R, Wauson-Kelley A.  
Kidney Int. 2004;65(1):109.

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## Dietary Modification

41

- ▶ High salt intake can negate the benefits of ACE/ARB
- ▶ CKD Patients with high sodium intake of greater than 6grams per day was associated with increased cardiovascular risk
- ▶ The antiproteinuric effects of ACE/ARB and nondihydropyridine CCB was diminished by increased sodium intake
- ▶ 2 gram sodium restriction is recommended

Relation between ACE inhibition and progression to ESRD.  
Vague P, Paine A, Paganin M, Verstra C, Bannister G, Baggett P.  
J Am Soc Nephrol. 2012;23(11):1941-1948. Epub 2012 Dec 10. See comment. In: Pharmacological Research, Center for Human Health, Science and Technology Park, Kilmarnock, East Ayrshire, Scotland, UK. PMID: 23222222  
Modulation of dietary sodium intake on the renal and antiproteinuric effects of angiotensin receptor blockers.  
Lambert E, Wang J, Himmelfarb J, Paganin M, Verstra C, Bannister G, Baggett P, et al.  
Kidney Int. 2012;82(1):100-107. Epub 2012 Mar 21.  
Urinary sodium excretion and kidney failure in nondiabetic chronic kidney disease.  
Park J, Tighiouar H, Lavey AS, Buhki GJ, Sarnak MB.  
Kidney Int. 2014;85(1):102-108. Epub 2013 Mar 18.

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## ACE and ARB in advanced CKD

42

- ▶ Is it ever too late to start an ACE inhibitor or ARB?
- ▶ Technically no
- ▶ Chinese study utilizing benazepril with patients with CKD and a creatinine as high as 3, showed a risk reduction of 43 percent in reaching ESRD, doubling of serum creatinine level or death
- ▶ But this was non diabetics and patients with hyperkalemia during a run in period were disqualified

Efficacy and safety of benazepril for advanced chronic renal insufficiency.  
Hsu FY, Zhang Y, Zhang GH, Yao JS, Chen PY, Zhang WB, Jiang JF, Liang M, Wang GH, Liu ZH, Gong KW.  
N Engl J Med. 2006;354(2):133.

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## ACE and ARB in advanced CKD

43

- ▶ REIN trial (Ramipril efficacy in nephropathy) showed a 20% decrease in rate of decline of GFR and a 33% reduction in incidence of ESRD in the group of patients with a starting eGFR between 11 and 33

Randomised placebo-controlled trial of effect of ramipril on decline in glomerular filtration rate and risk of terminal renal failure in proteinuric, non-diabetic nephropathy. The GISEN Group (Gruppo Italiano di Studi Epidemiologici in Nefrologia)  
Lancet. 1993;346(9001):1137.

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## KDIGO guidelines

44

- ▶ For patients with CKD without Diabetes and urine albumin excretion of less than 30mg per 24 hours the goal is less than or equal to 140/90
- ▶ For all other non diabetic patients with CKD and albuminuria of greater than 30mg of proteinuria the goal blood pressure is less than or equal to 130/80 and it is recommended that an ACE or ARB is utilized

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## For diabetic CKD patients

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- ▶ For diabetic CKD patients with urinary albumin excretion of less than 30mg the blood pressure goal is less than or equals to 140/90
- ▶ In all other diabetic CKD patients the goal is less than or equal to 130/80
- ▶ Use of an ACE or ARB is recommended
- ▶ KDIGO clinical practice guideline for the management of blood pressure in Chronic kidney disease published in Kidney International volume 2 issue 5 December 2012

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## Summary

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- ▶ For all patients with CKD without albuminuria, the KDIGO recommended blood pressure goal is less than or equal to 140/90
- ▶ For all patients with CKD and albuminuria of greater than 30mg per 24 hours the goal blood pressures are less than or equal to 130/80
- ▶ ACE for type 1 diabetics and ARB for type 2 diabetics
- ▶ Glycemic control with a goal hemoglobin A1C of less than 7
- ▶ Low salt diet

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**[Return to Top](#)**

## **Intro to the Top 10 Easy to Use Wellness Apps for Your Patients**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Intro to the Top 10 Easy to Use Wellness Apps for Your  
Patients***

Drew Keister, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation **WILL** include discussion of unapproved or investigational uses of products or devices.

LEHIGH VALLEY HEALTH NETWORK

# The Top 10 Wellness Apps For You or Your Patients: an Intro

Drew Keister, MD, FAAFP

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LEHIGH VALLEY HEALTH NETWORK

## Disclosures

- I have no conflicts of interest to disclose
- I will be talking about specific apps in this presentation
  - I have no personal interest in any of the apps or the companies that sponsor/created them

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LEHIGH VALLEY HEALTH NETWORK

## Objectives

- Identify components of fitness regimens that might be assisted by digital apps;
- Discuss the pros and cons of the most popular fitness/wellness apps;
- Show patients how to download and use the most popular fitness/wellness apps

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## Introduction

- In 2015, a study by IMS Institute for Healthcare Informatics identified more than 165,000 health-related mobile apps on Google Play and iTunes stores
- Our patients use them
- What do we know? What should they use?

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## Audience Poll

- Show of hands:  
Who has used what you would consider a fitness app?



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## What types of fitness apps do you know about?



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## Our survey says...

- Informal survey of residents and faculty
- Google searches
- My personal experience



www.clipartof.com - 1048749

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## Types of apps

- Activity trackers (includes wearables)
- Workout guides
- Food/calorie Counters
- Emotional Support & Mindfulness
- Shopping

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## Evidence for effectiveness

- Overall, apps are promising
  - Generally contain good information
  - Need improvement in user interface and content
  - Part of a systematic approach
- More studies are needed to determine the benefits
  - Barrier: Rapid evolution of tech & culture

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## Activity Trackers

- Allow user to monitor activity/calorie burning
- Sometimes tied in to Calorie Counters
- Sometimes include wearables



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## MapMyRun

- AKA “ MapMyWalk”, “MapMyRide”, “MapMyFitness”
- Tracks distance, pace (with GPS) and time
  - Follows Trends
  - Maps your route
- Share with friends feature

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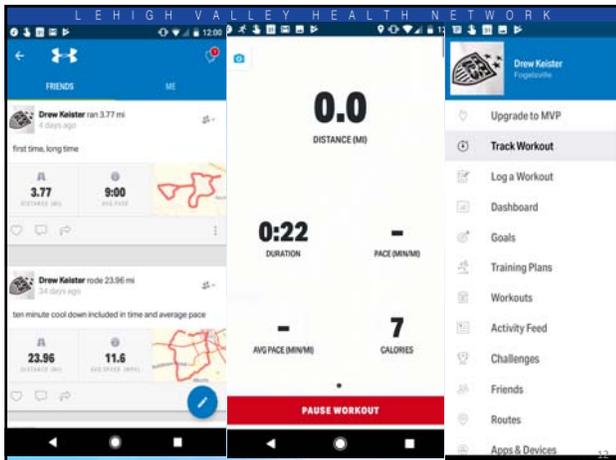
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## A Word on Wearables

### Monitoring movement:

- Most SmartPhones
- Apple Watch
- FitBit



- Monitor Pulse, BP, Temp, EtOH lvl, etc...
- Major challenge for FM in the future:  
**How do we use the data??**

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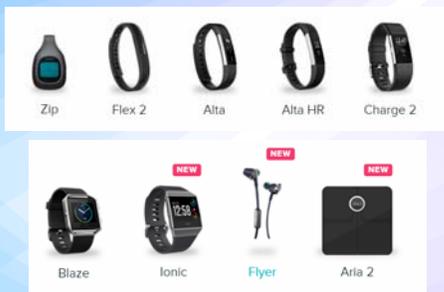
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## FitBit



<https://www.fitbit.com/app>

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## Day & Night

The Fitbit app has a purpose for every part of your day.



### All-Day Activity

View progress towards your daily goals for steps, distance, calories burned and active minutes, and see your trends over time.

### Sleep Goals & Tools

Use a Fitbit tracker to record your sleep at night. Then, use the sleep tools in the app to set a weekly sleep goal, create bedtime reminders and wake targets, and review your sleep trends over time.

### MobileTrack

If you want to track your activity but don't have a Fitbit tracker, you can use your smartphone to record basic stats like steps, distance and calories burned.

### Multi-Tracker Support

Connect multiple trackers to one account and the Fitbit app will automatically detect when you switch between them. So you can wear Fitbit Charge during workouts and use Fitbit One to discreetly track your day.

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LEHIGH VALLEY HEALTH NETWORK

## Workout Guides

- Give user advice about exercise
- Exist for all types of exercise (e.g. running, weights, yoga, pilates, etc)
- Often have a free component, then option to purchase more
  - Some have a subscription; Some link to live workouts

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LEHIGH VALLEY HEALTH NETWORK

## Couch to 5K (C25K)

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LEHIGH VALLEY HEALTH NETWORK

## Nike Training Club

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## Food/Calories Counters

- High-tech food journal
- Include calorie calculators based on weight goals
- Often contain items from menus of chain restaurants
- Sometimes a part of activity tracking apps, as well

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## MyFitnessPal

The screenshot shows the MyFitnessPal app interface. On the left, the 'Diary' screen displays a summary for 'Today' with a goal of 2,960 calories, 292 food calories, 0 exercise calories, and 2,668 remaining calories. Below this is a list of meals: Breakfast (292), Lunch (0), and Dinner (0). The Breakfast section lists items like Peppers, Hard Boiled Eggs, and Bacon. On the right, the 'Breakfast' log shows a search for 'red pepper' and a list of recent items including Peppers, Sweet, Red, Raw; Peppers - Sweet, Red, Sautéed; Red Pepper Hummus; Pepper Red Roasted; Red Bell Pepper; and Bell Pepper, Red.

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## Emotional Support & Mindfulness

- All sorts of apps
  - E.g. Meditation, interactive, resources
  - Varying quality and cost
  - Some very specialized
- Some evidence to support their benefit in various conditions
- Anxiety and Depression Association of America Ratings:
  - <https://adaa.org/finding-help/mobile-apps>

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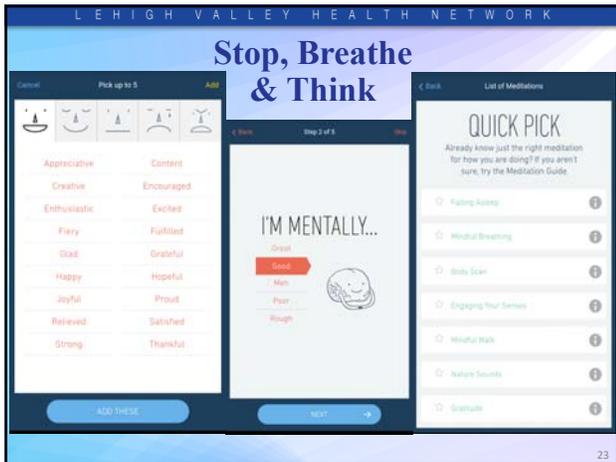
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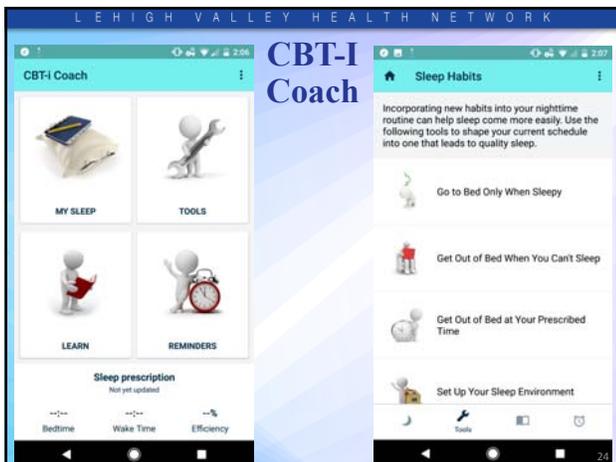
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## Shopping

- Have someone else shop for the user
  - Simplify life
  - Avoid impulse purchases (esp food)
- Often have associated cost
- Some don't like giving up control

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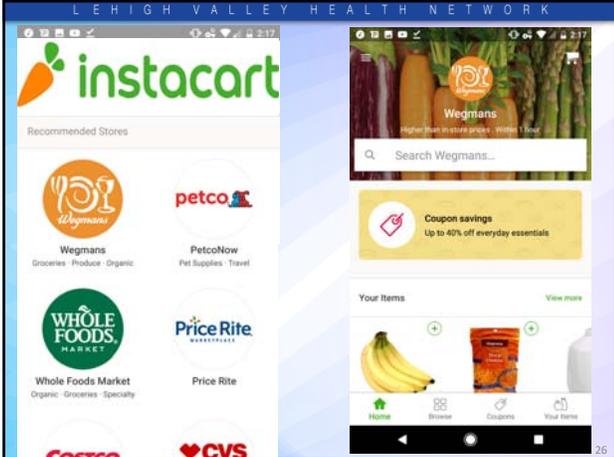
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## Summary

- Lots of apps
  - Varying Quality
  - Limited Evidence
  - Great Potential
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- Explore, Learn with your patients, and have fun!

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## Questions?

Contact Information:

Drew Keister, MD  
LVHN FM Residency Director  
Vice Chair for Education  
[Drew M.Keister@lvhn.org](mailto:Drew.M.Keister@lvhn.org)



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**[Return to Top](#)**

**ABFM's Family Medicine Certification  
(FMC)...Recent Enhancements Which  
Favorably Impact You Now**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***ABFM's Family Medicine Certification (FMC)...Recent  
Enhancements Which Favorably Impact You Now***

Joseph Tollison, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.



The American Board of Family Medicine

**ABFM's Family Medicine Certification (MOC/FMC): Recent Enhancements Which Favorably Impact You Now**

**Joseph W. Tollison, M.D.**  
**Senior Advisor to the ABFM President**

**DISCLOSURE:** Dr. Tollison has no financial conflicts related to his presentation.

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The American Board of Family Medicine

**MODIFIED/ENHANCED (NEW) REQUIREMENTS  
(PER 3-YEAR STAGE)**

**2017**

- 1) **\*\*EXAM CHANGES!\*\***
- 2) CKSA (Continuous Knowledge Self-Assessment)
- 3) New Performance Improvement (PI) activity modifying PPM
- 4) PRIME Registry – Advantages for Family Physicians

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# Cognitive Examination

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## 2017 Changes-Cognitive Exam

- **320** multiple choice questions; previously **370** items
- Total exam time **unchanged**
- Select **one** module from eight options; previously **2** modules required
- Pooled flexible break time; previously, break time fixed
- Enhanced computer-based exam experience
- Reduced Exam sections from five to four

Ambulatory Family Medicine	Maternity Care
Child & Adolescent Care	Emergent/Urgent Care
Geriatrics	Hospital Medicine
Women's Health	Sports Medicine

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## 2017 Cognitive Exam

- **All** candidates (Certification & Continuous Certification) take the **same** examination
- **All** candidates will choose **1** module of 45 questions each over which to be tested during the morning exam session

Ambulatory Family Medicine	Maternity Care
Child & Adolescent Care	Emergent/Urgent Care
Geriatrics	Hospital Medicine
Women's Health	Sports Medicine

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 The American Board of Family Medicine

**CKSA (CONTINUOUS KNOWLEDGE SELF-ASSESSMENT)**  
 AVAILABLE as of January 2017

CONCEPTS: (1) Twenty-five (25) questions per quarter; 2.5 points; 2.5 CME credits  
 (2) Rationale for correct answer provided  
 \*(3) Performance Report available (optional)  
 (4) New CKSA app available  
 (5) Optional Completion Method for KSA

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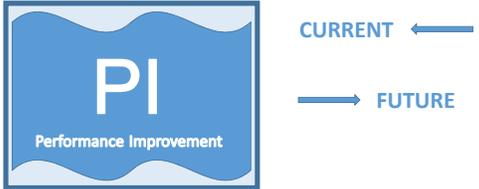
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 Performance Improvement



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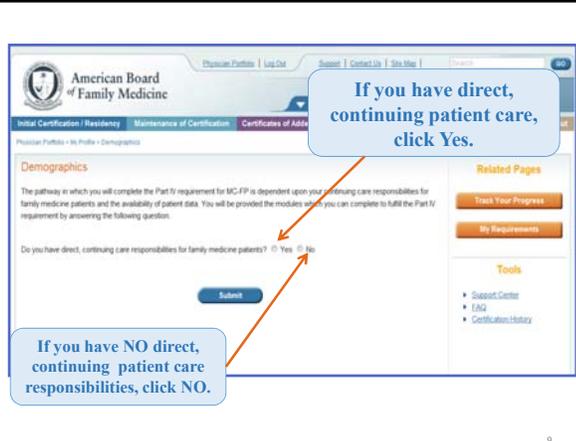
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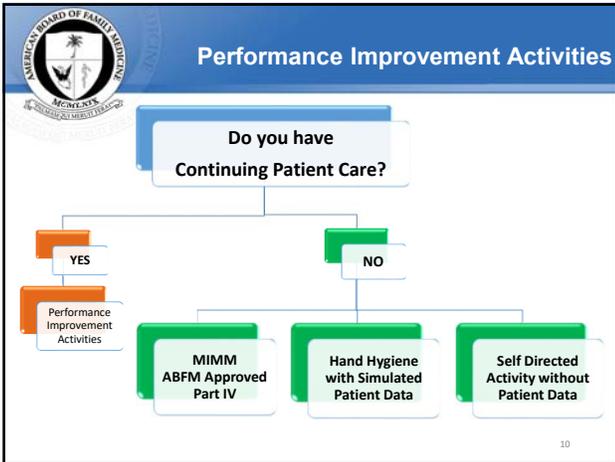
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**Performance Improvement Activities**

NO Access to Continuing Patient Care?

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**Methods in Medicine Activities (MIMMs)**

**ABFM Products**  
no additional charge beyond the cost of Family Medicine Certification

**Current Topics:** Cultural Competency MIMM, Hand Hygiene PPM (with simulated patient data), ABFM Self-Directed Activity

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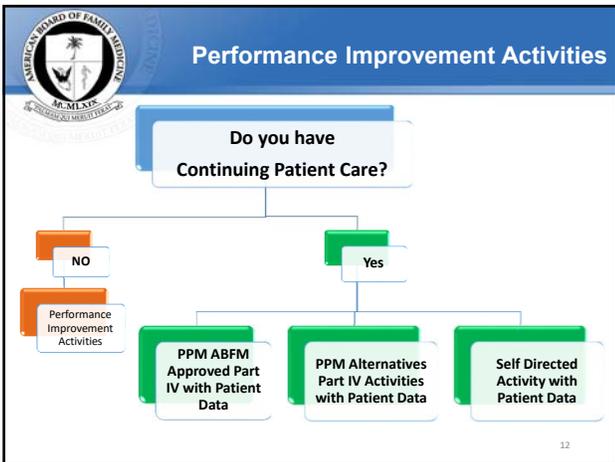
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## Performance Improvement Activities

### PPM Alternatives

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## Performance Improvement Activities

**Approved Performance Improvement Alternatives**

*(Examples of Approved Performance Improvement Alternatives)*

- American Academy of Family Physicians (METRIC)
- Multi-Specialty Portfolio Approval Program (MSPP) Sponsor organization activities
- New Jersey Academy of Family Physicians (NJAFP) Activity Performance in Practice Colorectal Cancer Screening
- National Committee for Quality Assurance (NCQA)
  - Physician Recognition Programs (PRPs)
  - Approved PRPs include: Diabetes, Heart Disease/Stroke, and Patient Centered Medical Home (PCMH)
  - Individual-level certificates of recognition in Diabetes, Heart Disease/Stroke, or PCMH can be submitted for Performance Improvement credit
  - Organization-level certificates of recognition require additional physician attestation to be considered for Performance Improvement credit

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## Performance Improvement Activities

Visit the ABFM website for the complete current list of

**Approved External Activities**

**[www.theabfm.org](http://www.theabfm.org)**

*(listed under the Family Medicine Certification Section—click Performance Improvement)*

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## Performance Improvement Alternatives Support

- **Kevin Graves, Program Manager Alternatives Activities**
  - Email: [kgraves@theabfm.org](mailto:kgraves@theabfm.org)
  - Phone: 877-223-7437, ext 1100
- **Support Center**
  - Phone: 877-223-7437
  - Email: [help@theabfm.org](mailto:help@theabfm.org)
  - Live Chat

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## PI – Future Considerations

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## PRIME Registry

PRIME Registry is a patient data tool developed by the American Board of Family Medicine (ABFM) for clinicians and practices that extracts patient data from your electronic health record (EHR) and turns it into **actionable measures, presented in an easy to use dashboard that brings your EHR data to life.**

The goal: to Reduce Burden, Assure Competence, Improve Quality, and Enhance Professionalism for family physicians.

**HOW IT WORKS:**

1. Following enrollment, data are extracted from practice EHR (over 100 supported EHRs)
2. EHR data extraction is refined to follow clinician documenting practices—so you don't have to change the way you chart
3. Data are transformed into actionable quality measures presented in a **personalized dashboard**

visit [www.primenavigator.org](http://www.primenavigator.org) email [PRIME@theabfm.org](mailto:PRIME@theabfm.org) call **877-223-7437**

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## PRIME Registry

**PRIME DASHBOARD**

Your PRIME dashboard:

- Displays 40+ electronic Clinical Quality Measures (eQCMs) at clinician level, practice level, and individual patient level
- Simplifies ability to track patient care, target opportunities for improvement and follow up
- Includes integrated MIPS and PI Activity modules
- Supports reporting for CPC+ Track 2 and other quality programs

*The PRIME Registry is a federally certified Qualified Clinical Data Registry (QCDR), an approved reporting vehicle under MACRA.*

As a QCDR, PRIME is authorized to propose more meaningful quality measures to CMS.

visit [www.primenavigator.org](http://www.primenavigator.org) email [PRIME@theabfm.org](mailto:PRIME@theabfm.org) call 877-223-7437

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## PRIME Registry

**NEW: PERFORMANCE IMPROVEMENT (PI) ACTIVITY MODULE**

New PI Activity Module simplifies Performance Improvement Activity requirement for ABFM Continuous Certification

- Integrated tool in PRIME Dashboard - no manual submission of data
- Allows ABFM Diplomates who are part of the PRIME Registry to seamlessly use their measures data to create and implement a quality improvement plan in their practice
- Each activity completed awards 20 points toward diplomate's Performance Improvement Activity requirement for ABFM Continuous Certification

visit [www.primenavigator.org](http://www.primenavigator.org) email [PRIME@theabfm.org](mailto:PRIME@theabfm.org) call 877-223-7437

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## PRIME Registry

**WHO MAY ENROLL IN PRIME**

- All primary care clinicians including **family medicine**, general internal medicine, general pediatrics, and OB/GYN, as well as NPs, PAs, and any other Eligible Providers.
- Practice must be using an Electronic Health Record (EHR) to participate.
- Practice/physician must be able to sign two agreements: A PRIME Registry agreement (Business Associate Agreement, Registry Participation Agreement and Data Release Consent Form) and Tech partner FIGmd agreement (Data Warehouse Agreement, Business Associate Agreement, and Data Release Consent).

**COST**

ABFM is currently offering the PRIME Registry **FREE for the first THREE years to the first 2000 ABFM Diplomates who enroll**. After that, subscription rates are only \$295 per clinician/year for ABFM Diplomates. For all other clinicians, PRIME is \$360/clinician/year.

visit [www.primenavigator.org](http://www.primenavigator.org) email [PRIME@theabfm.org](mailto:PRIME@theabfm.org) call 877-223-7437

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## PRIME Registry

FOR MORE INFORMATION:  
 Join one of our bi-weekly interactive dashboard demonstrations:  
 Visit <http://primenavigator.org/primereqdemo> for dates and dial in information  
**TO ENROLL**  
 Visit [www.primenavigator.org](http://www.primenavigator.org) to enroll  
 Sign up portal video: <https://youtu.be/bc-h77qSFdl>

visit [www.primenavigator.org](http://www.primenavigator.org) email [PRIME@theabfm.org](mailto:PRIME@theabfm.org) call 877-223-7437

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## The American Board of Family Medicine

### MODIFIED/ENHANCED (NEW) REQUIREMENTS (PER 3-YEAR STAGE)

**2016**

- 1) Unlinking of SAMs
  - KSA (Knowledge Self-Assessment)
  - CSA (Clinical Self-Assessment)
- 2) 50 points
- 3) Discount (50%) – Age 70 and over

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## What Exactly are the Family Medicine Certification Requirements?

<b>2003-2010</b> <i>(7 Year Option)</i>	<del>7-Year Certification Requirements (Certification Examination in Year 7) Minimum of 3 KSAs, CSAs <i>Optional</i> Minimum of 1 Performance Improvement (PI) Activity Minimum of 110 Points</del>
<b>2003-2010</b> <i>(10 Year Option)</i>	10-Year Certification in three 3-year stages (Exam in Year 10) Minimum of 1 Knowledge Self-Assessment Activity (KSA) Per 3-Year Stage Minimum of 1 Performance Improvement (PI) Activity Per 3-year Stage Additional Activities to reach 50 points per 3-Year Stage
<b>2011-Beyond</b> <i>(Continuous)</i>	Continuous Process in 3-Year Stages Minimum of 1 KSA = 10 Points Per 3-Year Stage Minimum of 1 Performance Improvement (PI) Activity = 20 Points Per 3-Year Stage Minimum of 50 Points from SA & PI Activities per 3-Year Stage

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**ABFM Officers**

May 2017 – April 2018



Elizabeth Baxley, M.D.  
Chair



Jerry Kruse, M.D.  
Chair-Elect



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Treasurer



Joseph Gravel, Jr., M.D.  
Member-At-Large



Keith Stelter, M.D.  
Immediate Past Chair

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**2017 New ABFM Directors**



Beth Bortz  
Richmond, Virginia



Lauren Hughes, M.D., M.P.H., M.Sc.  
Philadelphia, Pennsylvania



John Mellinger, MD  
Springfield, Illinois



Daniel Spoggin, MD  
Sparks, Nevada

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Wendy Diggs, M.D.  
Overland Park, KS



John Brady, M.D.  
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Colleen Conry, M.D.  
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**The American Board of Family Medicine**



**ABFM's OVERARCHING APPROACH**

**ALIGNMENT**

**REDUNDANCY**




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**RESOURCES**



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**The Phoenix**



**THE PHOENIX**  
A Diplomates' Newsletter

**A Message from the President**

James C. Poffo, MD

- Summer & Winter Edition Each Year
- Mailed and Emailed to All Diplomates
- PDF Available on ABFM Website

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# CME

Awarded by the American Academy of Family Physicians

KSA = 8  
CME Credits

CSA = 4  
CME Credits

PPM = 20  
CME Credits

MIMM = 20  
CME Credits

Cultural  
Competency  
MIMM = 9  
CME Credits

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# CKSA App



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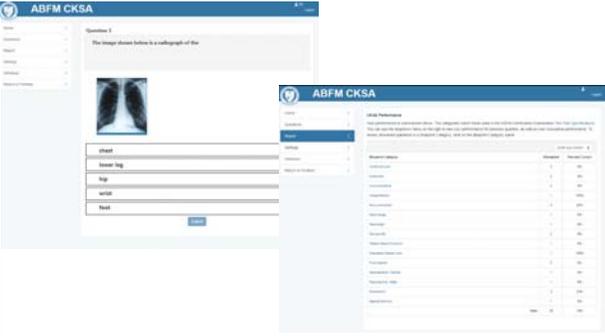
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# ABFM CKSA App



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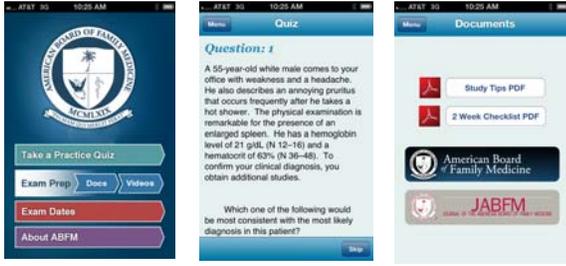
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# ABFM Exam Prep App



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# Exam Preparation Assistance

## Exam Preparation Tools Available on ABFM Website:



- Videos Outlining Study Plans
- Study Tips
- 2-Week Checklist
- Exam Tutorial

Access these tools on the ABFM website [www.theabfm.org](http://www.theabfm.org)

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# Support Center Assistance



**877-223-7437**

**Extended Hours Available!**  
(Eastern time)

**8:00 am - 9:00 pm**  
13 hours!  
Monday - Friday  
&  
**9:00 am - 5:00 pm**  
8 hours!  
Saturday  
N/A Sunday

- Manned by ABFM Staff located **IN** the ABFM home office
- Able to answer questions regarding all phases of ABFM business

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Live chat available from  
ABFM Home page




**2 Minute Rule**  
Have a Question after 2 minutes?  
Contact our Support Center!!

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**Outreach Resources**

**RESOURCES INCLUDE:**

- SUPPORT CENTER
- LIVE CHAT ("LIVE HELP")
- THE PHOENIX
- WEBSITE
- EMAILS (PERIODIC)
- APP (EXAM PREP)
- KSA STUDY GROUP SUPPORT
- PRIME SUPPORT
- BOOTH @ AAFP FMX
- PUBLICATIONS
- YOUTUBE CHANNEL
- PRESENTATIONS
  - Latest Family Medicine Certification Info
  - On-site Discussion
  - Invitations Welcome
  - State Chapter & Review Courses

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**Avoid Late Fees**

**BEGIN the formal application prior to the deadline to avoid late filing fees**

- to be able to access the application, all required activities must be paid for/and or started  
(completion of the Certification Activities is not required to start the application but all Activities must be complete by the deadline for clearing deficiencies)
- **IMPORTANT!!!** Advance beyond the payment page of the application
- go back to the application to choose a test date and test center as soon as all deficiencies are cleared (including completion of all Certification Activities)

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## Exam Deadlines

### 2018 Spring Exam Deadlines

Spring 2018 Exam Deadline	Date
Registration Begins	December 1, 2017
*Deadline to submit application without a late fee	January 19, 2018
Final Deadline to submit application with a \$100 late fee	February 23, 2018
Exam Dates	April 5, 6, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19
Exam Results	June 15 (tentative)

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## Continuous Certification

### Timetable (not required but helpful)

**Set a Goal of 15-20 Points Per Year!**

**Year 1:**  
15-20 Points

**Year 2:**  
15-20 Points

**Year 3:**  
15-20 Points



**50 Points Total**

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## It's Not Too Late!

**2014** Diplomates must complete the Continuous Certification Requirements.  
The deadline for 2014 Diplomates to complete Family Medicine Certification requirements in Stage I is **December 31, 2017!**

**2011** Diplomates who have completed Stage I, may still qualify for the 3-year extension to their certificate.  
The deadline for 2011 Diplomates to complete Family Medicine Certification requirements in Stage II is **December 31, 2017!**

**2008** Diplomates who received extension to 10-year certificate.  
Need to complete Stage III this year. Prerequisite to be approved for Family Medicine Certification Examination. Certification Examination application opens **December 2017.**

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## How Can We Help?

HOW CAN WE HELP  
YOU DO WHAT YOU  
NEED TO DO NOW?

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## Contact the ABFM

- **Support Center**
  - Phone: 877-223-7437
  - Email: [help@theabfm.org](mailto:help@theabfm.org)
  - Live Chat
- **Website**
  - [www.theabfm.org](http://www.theabfm.org)
- **ABFM**
  - Phone: 888-995-5700
  - Fax: 859-335-5701

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## ABFM Goal:



LEAVE  
*NO*  
DIPLOMATE  
BEHIND...

**EVER!**

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**[Return to Top](#)**

# **Evaluation and Differential Diagnosis of Syncope**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Evaluation and Differential Diagnosis of Syncope***  
Andrew Waxler, MD

**Disclosures:**

The speaker is a Consultant/Speaker for Sanofi/Regeneron, Zoll, CardioDx.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

**\*\*SESSION HANDOUTS ARE NOT AVAILABLE  
ONLINE.\*\***

**[Return to Top](#)**

# **Managing Meds During a Problem Pregnancy**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Managing Meds During a Problem Pregnancy***  
Christine Stabler, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

Medical Management of  
the Pregnant Patient

Christine Stabler, MD

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Disclosure

- The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

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Objectives

- Be able to recognize and act on evidence-based recommendations for the evaluation and management of common medical problems in pregnancy.
- Confidently prescribe appropriate medications during pregnancy.

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## Managing Medical Illness in Pregnancy

- Great need for primary providers to manage medical illness in pregnancy
- Management before, during and after pregnancy
- Preconception counseling and patient education
- Collaboration with subspecialists and MFM's

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## Managing Medical Illness in Pregnancy

- You will need an understanding of the physiologic changes of pregnancy and how they affect disease
- A basic knowledge of pregnancy specific illnesses
- A strategy for evaluating drug safety in pregnancy

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- Hypertension
- Diabetes
- Depression
- Thyroid disease
- Epilepsy
- Asthma
- Hepatic Disease
- Drugs in Pregnancy

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## Pregnancy – a Stress Test for Life

- Pregnancy likely to unmask occult chronic disease
  - Glucose intolerance
  - Renal dysfunction
  - Hypercoaguable states
  - Valvular heart disease
  - Cerebral aneurysm

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## Predictor of Disease Later in Life

- Increased rates of postpartum chronic disease
  - Women with GDM have up to 75% likelihood of developing Type II DM in subsequent five years
  - Women with preeclampsia more likely to develop CAD and stroke later in life
- Higher rates of hypertension, insulin resistance, dyslipidemia and inflammatory markers
- Primary prevention could play an important role – Knowledge is power.

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Pregnancy in women over 40 increased 65% in the previous decade



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## Medication in Pregnancy

The FDA has used five categories (A, B, C, D, and X) to describe a drug's potential for causing adverse effects during pregnancy.

Based upon the results of animal studies, human data, and consideration of whether the benefit of the drug's use during pregnancy outweighs the risk.

The FDA has begun the phase-out of risk categories from prescription drug labeling -now requires information from available human and animal studies about (1) known or potential maternal or fetal risks, (2) dose adjustments needed during pregnancy and the postpartum period, and (3) benefit/risk considerations.

Process of updating existing medications will likely take several years. In the interim, it is useful to have an understanding of the various categories.

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## Case #1

- 24 y/o G1P0 at 16 weeks gestational age who you have managed for the past 6 years with Mild Intermittent Asthma.
- She reports increasing nighttime cough and is using her rescue inhaler 2-3 times a day.
- Her FEV 1 is 65% of predicted value, increasing to 88% after a nebulized beta agonist.
- What should you do?

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## Management Options

- No change in management
- Add inhaled steroid
- Add LABA
- Add oral montelukast
- When do you see her back? What teaching is necessary?

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## Asthma

- Commonest chronic medical illness to complicate pregnancy
- Occurs in up to 3-8% of women of childbearing age
- Often undiagnosed or undertreated
  - A significant increase in complications of pregnancy in asthmatic women.
  - The largest study to date shows a 15 to 20 percent increased risk of perinatal mortality, preeclampsia, preterm delivery, or low birth weight infants compared to non-asthmatic women
  - Patients with more severe asthma have a 30 to 100 percent increased risk

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## Physiologic Changes in Pregnancy

- 20% increased oxygen demand
- Tidal Volume increases
- Inspiratory capacity, expiratory reserve and residual volume decrease
- Marked reduction in functional residual capacity
- FEV1 and Peak Flows are unchanged
- Breathlessness can be a normal sx of pregnancy so objective assessment is important

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## Asthma

- Careful follow-up by clinicians experienced in managing asthma is essential.
- The optimal frequency of asthma evaluations is not known-should be based on the prepregnancy degree of asthma control.
- In an observational study, visits every four weeks improved adherence to controller medication and asthma control.
- All pregnant patients should understand the symptoms of asthma and have ready access to their clinician should their symptoms change or increase.

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## Monitoring

- Measurement of peak expiratory flow (PEF) or forced expiratory volume in one second (FEV<sub>1</sub>) using a portable device offers the advantages of less expense and greater ease of serial measurements at home.
- The frequency of measurement should be individualized - patients with more severe asthma may need to measure their PEF twice a day
  - upon awakening
  - 12 hours later.

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## Management

- Primary goals of asthma management
  - prevention of acute exacerbations
  - optimization of ongoing asthma control
- Prevention – avoidance of triggers, no smoking
- Optimize pre-pregnancy control and tailor treatment to objective symptoms
- Management is no different than non-pregnant – beta agonists, inhaled steroids are mainstays of therapy

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## Medications

- Albuterol is recommended as the short-acting beta agonist of choice.
- For patients with mild persistent or more severe asthma, inhaled glucocorticoids reduce exacerbations during pregnancy.
- Budesonide is the preferred inhaled glucocorticoid for use during pregnancy, as more published gestational human data are available for that medication. However, other inhaled glucocorticoids could be continued if the patient was well-controlled on one of these medications prior to pregnancy, and data for fluticasone have been reassuring regarding low birth weight, small for gestational age, preterm birth, and major congenital malformations.

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## Medications

- Salmeterol has been recommended as the inhaled long-acting beta agonist of choice in the. Retrospective cohort studies provide reassuring data for both salmeterol and formoterol.
- Montelukast or zafirlucast could be considered as alternative but NOT preferred therapy for mild persistent asthma or as add-on therapy to inhaled glucocorticoids.

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## Specific Medication Safety Information

SABA use is a marker for poorly-controlled asthma and more frequent exacerbations, which may independently contribute to the development of congenital anomalies.

Some studies only have access to data about prescriptions filled and not the frequency of actual use. Even if the statistical associations for relative risk are valid, the anomalies mentioned above are infrequent.

Therefore, the absolute increase in risk is very small and, as noted earlier, less than the risk of poorly-controlled maternal asthma.

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## Systemic Steroids

- Systemic glucocorticoids have been used fairly extensively during pregnancy to treat asthma exacerbations.
- For each pregnant woman, the potential risks of gestational oral glucocorticoids must be balanced against the risks to the mother or infant of inadequately treated asthma.
- Risks of severe uncontrolled asthma include maternal or fetal mortality, these risks are considered to be greater than the potential risk of systemic glucocorticoids.
- Oral glucocorticoids should be used during pregnancy when indicated for the management of severe asthma.

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## Inhaled Corticosteroids

- Use of inhaled budesonide during early pregnancy was assessed in a registry-based cohort study of 2014 Swedish women.
- The rate of congenital malformations was not different from that of the general population (3.8 versus 3.5 percent). Additional data from the Swedish Medical Birth Registry reported no clinically significant effects of inhaled budesonide on fetal mortality, gestational age, or fetal growth
- Budesonide is currently the only inhaled glucocorticoid with a pregnancy category B rating

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## Leukotriene Inhibitors

- The first prospective, controlled study of the use of leukotriene receptor antagonists in pregnancy followed 96 women taking these medications, 122 women taking SABAs only, and 346 women without asthma.
- No increase in major birth defects or adverse outcomes was detected in the offspring of patients receiving these medications.
- A subsequent study with similar design described 180 montelukast-exposed pregnancies compared to 180 disease matched controls and 180 pregnancies in non-asthmatic women with no increase in the rate of major malformations

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## Managing Acute Exacerbations

- Hydration, O<sub>2</sub> and positioning in a seated or lateral decubitus position.
- Monitoring with continuous pulse ox titrated to >95%
- The changes in blood gases that occur secondary to acute asthma during pregnancy are superimposed on the "normal" respiratory alkalosis of pregnancy.
- A PaCO<sub>2</sub>>35 mmHg or a PaO<sub>2</sub><70 mmHg associated with acute asthma represent more severe compromise during pregnancy than in the non-gravid state.

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## Acute Exacerbations

- Fetal heart rate monitoring is the best available method for determining whether the fetus is adequately oxygenated.
- After 23 to 24 weeks of gestation, noninvasive fetal heart rate monitoring is appropriate during asthma exacerbations requiring emergency department treatment or hospitalization.
- The fetal heart rate tracing should be evaluated by a clinician experienced in fetal heart rate assessment.

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## Acute Management

- Systemic corticosteroids – same dose as non-pregnant
- Parenteral beta-agonists –rarely needed. Theoretic concerns that the alpha-adrenergic effects might cause vasoconstriction in the uteroplacental circulation - recommended that epinephrine generally be avoided during pregnancy except in the setting of anaphylaxis.
- For the rare patient who requires use of a systemic beta-agonist to treat asthma, subcutaneous administration of terbutaline is a reasonable choice

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## Acute management

- IV magnesium sulfate –may be beneficial in acute severe asthma as an adjunct to inhaled beta agonists and intravenous glucocorticoids
- Ipratropium can be used to treat severe acute asthma exacerbations. It is felt to be safe during pregnancy
- Most respiratory infections that trigger an exacerbation of asthma are viral rather than bacterial and do not require antibiotic therapy.
- Testing for and treatment of influenza may be appropriate, depending on the time of year and symptom pattern.

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## Case #2

- 26 y/o G1P0 at 6 weeks EGA just found out she is pregnant and wants information about smoking during pregnancy. She smokes about 15 cigarettes a day for the past 8 years and has never tried to quit before.
- What do you tell her?
- What are her options?

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## Smoking in Pregnancy

- Cigarette smoking is the most important modifiable risk factor associated with adverse pregnancy outcomes.
- In 2002 in the US, 5 to 8 % of preterm deliveries, 13 to 19 % of term infants with growth restriction, 5 to 7 % of preterm-related deaths, and 23 to 34 % of sudden infant death syndrome (SIDS) deaths were attributable to prenatal smoking.
- In addition, smoking and secondhand smoke exposure increase the risk of infertility, placental abruption, preterm premature rupture of membranes (PPROM), and placenta previa.

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## Prevalence

- Study of United States birth certificate data from 2014 noted that 10.9 percent of American women reported smoking cigarettes in the three months before pregnancy. Of those, nearly one-quarter did not smoke during pregnancy.
- The highest rates of smoking during pregnancy were seen in women ages 20 to 24 years (13%), unmarried women (15%), women of non-Hispanic American Indian or Alaska Native ethnicity (18%), and women living in West Virginia (27%).
- The highest rates of smoking cessation were reported in women with the highest educational levels, private insurance, and non-Hispanic Asian and Hispanic race and ethnicity.

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## Mechanisms of Risk

- Impaired fetal oxygenation
- Altered fetal development – growth restriction, abnormal lung development
- Toxin exposure - >2500 other directly toxic substances are found in cigarettes, such as ammonia, polycyclic aromatic hydrocarbons, hydrogen cyanide, vinyl chloride, and nitrogen oxide.
  - May cause direct damage to fetal genetic material - increased incidence of structural chromosomal abnormalities among women who smoked regularly (12 vs 3.5%). Most of these abnormalities were the result of deletions or translocations, and many were localized to the 11q23 region, which is also associated with several hematologic malignancies.

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## Effects on Pregnancy and the Neonate

- Miscarriage - OR 1.23
- Premature ROM – OR 1.9-4.2
- Placental abruption - OR 1.4-2.5
- Placenta previa - OR 1.4-4.4
- Neonatal effects –
  - Irritability, Hypertonicity, impairment of functions associated with the frontal lobe and cerebellar, such as emotion, impulse control, and attention
- Neonatal Death/IUFD – OR 1.46
- Low birth weight – OR 1.5-3.5
- Preterm delivery - OR 1.3-2.5
- Anomalies
- SIDS – OR 2.0-4.0
- Behavioral prob/ADHD/Tourett's
- Cognitive reduction

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## Smoking Cessation in Pregnancy

Pregnancy provides a unique opportunity for medical intervention for smoking cessation -women in prenatal care see their physicians frequently.

Multiple opportunities to assess and reinforce abstinence.

Concerns over the dangers of cigarette smoking for the fetus serve as an additional motivator to stop smoking.

Pregnancy also provides an opportunity to educate the woman's partner or family members on the benefits of smoking cessation for themselves, the woman, and the baby.

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## Smoking Cessation

- 35 to 75 % of pregnant smokers completely stop smoking by the end of pregnancy.
- Most women who are able to quit smoking by themselves during pregnancy stop smoking prior to their first prenatal visit.
- In the absence of intervention, women still smoking after their first prenatal visit are likely to continue smoking during pregnancy.
- Risk factors for continued smoking include lower education status (less than high school level), heavy smoking (>10 cigarettes per day), a partner or other household member who smokes, public insurance, poor coping skills, multiparity, and coexisting emotional or psychiatric problems .

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## Smoking Cessation

- There is expert consensus that pregnant women who use tobacco should be identified early in pregnancy and provided augmented, pregnancy-tailored counseling on smoking cessation.
- RCTs show that healthcare provider-initiated interventions can lead to significant reductions in the number of women smoking during pregnancy.
- Counseling alone is associated with only modest improvement in continued abstinence 6 to 12 months after the quit date.
- Examples of brief interventions include information about smoking-related risks from the physician and frequent follow-up to assess patient progress, as well as use of a pregnancy-specific or other self-help manual, one or more sessions with a health educator, and video tapes on smoking risks and cessation

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## Five A's

- **Ask** - Ask about and document smoking status (current and past) at every patient encounter (including smoking status of household members) and whether anyone smokes in the woman's home or car. Among current smokers, document number of cigarettes smoked per day.
- **Advise** – Advise smokers to stop smoking. Women advised to quit rather than just cut down are more likely to stop smoking.
- **Assess** – Assess the patient's readiness to quit smoking in the next month. Accept a patient's decision to continue to smoke non-judgmentally.

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## Five A's

### • Assist –

- Connect the smoker to pregnancy-specific, structured, smoking cessation support, which is available in a variety of formats that include written material, videos, computer websites, telephone calls, or in-person counseling in individual or group settings.
- Offer a direct referral to a smoker's quit line to provide ongoing telephone counseling and support (eg, in the United States: 1-800-QUIT NOW)
- Provide financial incentives, if available. The odds of quitting with the use of incentives are three times the odds of quitting in the absence of incentives, holding all other interventions constant.
- Offer pharmacotherapy

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## Five A's

- **Arrange** – Address tobacco use at every subsequent prenatal visit to track progress, reinforce success, and provide ongoing assistance to women who continue to smoke. Lack of ongoing follow-up and support decrease the chance of successful smoking cessation.

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## Pharmacotherapy

- Practice guidelines by the Agency of Health Care Policy and Research, and the American Psychiatric Association (APA), advocate the use of adjunct pharmacotherapy for all smokers unless contraindicated
- United States Preventive Task Force (USPSTF) and others have found inadequate evidence to evaluate the safety or efficacy of pharmacotherapy during pregnancy .

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## Pharmacotherapy

- Offer pharmacotherapy to pregnant women who are otherwise unable to quit or who are at high risk for continued smoking: heavy smokers (>10 cigarettes per day); those smoking later in pregnancy; and those who have previously attempted to stop. For these women, we feel the benefits of quitting with pharmacotherapy outweigh the potential risks of pharmacotherapy and the risks of continued smoking.
- When pharmacotherapy for smoking cessation is utilized, general principles of prescribing drugs during pregnancy should be followed.
  - These include using the lowest dose necessary to achieve success in order to minimize fetal exposure and, if possible, delaying therapy until the second trimester in order to avoid the period of embryogenesis when the fetus is most sensitive to teratogens.

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## Nicotine Replacement

- ACOG states the use of NRT can be undertaken with close supervision and after a thorough discussion about the risks of continued smoking and the possible risks of replacement therapy. This statement, acknowledges both the significant negative impact of smoking on fetal outcomes and the benefit of adjunct pharmacotherapy on smoking cessation in nonpregnant individuals.
- Proponents of using NRT during pregnancy argue that blood levels of nicotine are lower than those achieved during active smoking. In addition, use of NRT avoids exposure to the other potentially toxic chemicals found in cigarettes.

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## Nicotine Replacement

- NRT does not appear to be harmful and may be associated with lower rates of prematurity and SGA infants.
- Even if NRT cannot entirely reduce all of the risks associating with smoking during pregnancy, maternal smoking cessation results in less exposure to secondary smoke for the baby.
- Assessment of the impact of NRT during pregnancy does not typically evaluate postnatal outcomes such as URIs, asthma, hospital admission, otitis media and SIDS, and therefore the effect of NRT may be underestimated.

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## NRT

- Electronic nicotine delivery systems (ENDS) are used by some pregnant women for smoking reduction.
- At least one health organization states data on benefits and risks of ENDS are insufficient to recommend using these devices in pregnant women. Although data are lacking, many pregnant women believe ENDS are safer in pregnancy.
- In one survey study of 326 pregnant women, nearly 75 percent of the ENDS ever-users believed these products to be less harmful compared with traditional cigarettes. More data are needed on the physiologic impact of ENDS on the mother and fetus and the role of these devices in smoking cessation.

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## Bupropion

- In one of the first prospective, matched, controlled observational studies among pregnant women, pregnant smokers receiving bupropion were significantly more likely to quit than pregnant controls (45 versus 14%).<sup>1</sup>
- In a subsequent questionnaire study that included over 1200 pregnant smokers, bupropion use was associated with much higher rates of smoking cessation compared with no bupropion use (81 versus 0%).
- Sixty percent of bupropion users did not smoke again during pregnancy or the first postpartum year. In addition, bupropion use was associated with an 88 percent reduced risk of prematurity, although the study only included data on live-births and did not include women with fetal deaths.

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## Bupropion

- Two small studies reported the prevalence of left ventricular outflow tract obstruction was increased in infants exposed to bupropion in the first trimester (alone or in conjunction with other antidepressants) compared with infants exposed to other antidepressants, but the small number of cases precluded making a clear conclusion about this association.
- Some women may choose to wait until the second trimester before beginning bupropion.

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## Varenicline

- There is no information on the safety of varenicline use in human pregnancy
- Teratogenic effects have not been observed in animal studies.
- Given the lack of information and the availability of alternative drugs, avoid using it for smoking cessation in pregnant women.

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## Case #3

- 32 year old G1P0 presents with a positive pregnancy test. You have managed her acquired hypothyroidism for the past 4 yrs. She has been maintained on a stable dose of 100 mcg of levothyroxine daily. How will her pregnancy affect your management?

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## Hypothyroidism

- Common in pregnancy with an estimated prevalence of 2-3% and 0.3-0.5% for subclinical and overt hypothyroidism respectively.
- Endemic iodine deficiency accounts for most hypothyroidism in pregnant women worldwide while chronic autoimmune thyroiditis is the most common cause of hypothyroidism in iodine sufficient parts of the world.
- The presentation of hypothyroidism in pregnancy is not always classical and may sometimes be difficult to distinguish from the symptoms of normal pregnancy. A high index of suspicion is therefore required especially in women at risk of thyroid disease e.g. women with a personal or family history of thyroid disease, goiter, or co-existing primary autoimmune disorder like DM 1.

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## Risk Factors- Who to Screen

- Living in an area of moderate to severe iodine insufficiency
- Symptoms of hypothyroidism
- Family or personal history of thyroid disease
- Personal history of:
  - Thyroid peroxidase (TPO) antibodies
  - Goiter
  - Age >30 years
- Type 1 diabetes
- Head and neck irradiation
- Recurrent miscarriage or preterm delivery
- Multiple prior pregnancies (two or more)
- Morbid obesity (body mass index [BMI]  $\geq 40$  kg/m<sup>2</sup>)
- Infertility
- Prior thyroid surgery
- Use of amiodarone, lithium, or recent administration of iodinated radiologic contrast agents

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## Hypothyroidism

- The demand for thyroid hormones is increased during pregnancy due to an increase in thyroxine binding globulin, an increase in placental type 3 deiodinase and the placental transfer of maternal thyroxine to the fetus.
- The necessary increase in thyroid hormone production is facilitated by high human chorionic gonadotropin (hCG) concentrations, which bind the TSH receptor and stimulate the maternal thyroid to increase maternal thyroid hormone concentrations by roughly 50%.
- If the necessary increase in thyroid function cannot be met, pregnancy and fetal compromise can occur.
- Currently, there is not enough evidence to suggest that screening for thyroid dysfunction is beneficial.

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## Hypothyroidism

- Uncorrected thyroid dysfunction in pregnancy has adverse effects on fetal and maternal well-being.
- Can affect neurointellectual development in the early life of the child. Due to an increase in thyroxine binding globulin, an increase in placental type 3 deiodinase and the placental transfer of maternal thyroxine to the fetus, the demand for thyroid hormones is increased during pregnancy. The necessary increase in thyroid hormone production is facilitated by high human chorionic gonadotropin (hCG) concentrations, which bind the TSH receptor and stimulate the maternal thyroid to increase maternal thyroid hormone concentrations by roughly 50%.
- If throxine demand is unmet, this may cause a previously unnoticed thyroid disorder to worsen and become evident as gestational thyroid disease. Currently, there is not enough evidence to suggest that screening for thyroid dysfunction is beneficial.

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## Hypothyroidism

- Hypothyroidism is diagnosed by noting a high TSH associated with a subnormal T4 concentration.
- Subclinical hypothyroidism (SCH) is present when the TSH is high but the T4 level is in the normal range but usually low normal.
- SCH is the commonest form of hypothyroidism in pregnancy and is usually due to progressive thyroid destruction due to autoimmune thyroid disease. Prior to pregnancy, the damaged gland may be able to maintain adequate production.

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## Maternal Complications

- Spontaneous loss
- Preeclampsia
- Anemia
- Placental abruption OR 3.0
- Post Partum Hemorrhage
- Preterm delivery
- Treatment of hypothyroidism reduces the risks of these adverse obstetric and fetal outcomes; a retrospective study of 150 pregnancies showed that treatment of hypothyroidism led to reduced rates of abortion and premature delivery.

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## Fetal Outcomes

- Neurointellectual impairment has now been shown in iodine sufficient (USA) where a study showed that the IQ scores of 7-9 year old children, born to mothers with undiagnosed and untreated hypothyroidism in pregnancy, were seven points lower than those of children of matched control women with normal thyroid function in pregnancy.
- Another study showed that persistent hypothyroxinaemia at 12 weeks gestation was associated with an 8-10 point deficit in mental and motor function scores in infant offspring compared to children of mothers with normal thyroid function.
- Maternal thyroid peroxidase antibodies were shown to be associated with impaired intellectual development in the offspring of mothers with normal thyroid function. (maternal FT4 levels that are associated with child IQ and brain morphological outcomes, as opposed to maternal TSH levels)

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## Of Note

- In pregnancy, iodide losses through the urine and the fetoplacental unit contribute to a state of relative iodine deficiency.
- Pregnant women require additional iodine intake. A daily iodine intake of 250 µg is recommended in pregnancy but this is not always achieved even in iodine sufficient parts of the world.

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## Hypothyroidism

- Assessment of antibody status is important. Women with subclinical hypothyroidism and positive anti-thyroid peroxidase (TPO) antibodies tend to have the highest risk of adverse pregnancy outcomes, and adverse outcomes occur at a lower TSH than in women without TPO antibodies.
- In the American Thyroid Association (ATA) systematic review (ATA guidelines on thyroid disease during pregnancy), the risk of pregnancy-specific complications was apparent in TPO-positive women with TSH >2.5 mU/L but was not consistently apparent in TPO-negative women until TSH values exceeded 5 to 10 mU/L.

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## Hypothyroidism Management Goals

- Ideally preconception management will prevent the risks of infertility and spontaneous pregnancy loss.
- Immediately increase Levothyroxine by 25 - 50% - double dose 2-3 days per week
- Keep TSH < 2.5 through the second trimester (< 3.0 later)
- Check TSH q4weeks until mid pregnancy, then at 32 weeks
- Post partum resume pre-pregnancy dose.

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## Case #4

- 30 y/o G3P2 presents at the time of a positive pregnancy test with concerns of her history of moderately severe depression during and after her last pregnancy 5 years ago. She wants to know what is safe and how to manage her symptoms so she can enjoy this pregnancy and her 2 children.
- What is your advice?

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## Managing Depression in Pregnancy

- Information about the risks of antidepressant drugs during pregnancy comes from low to moderate quality studies.
- No randomized trials have been conducted; the evidence is based upon observational studies that can yield associations confounded by measured and residual (unmeasured) factors.
- Observational studies include retrospective case-control studies, which carry the risk of recall bias. In addition, population based registry studies typically rely upon prescription databases that may misclassify exposure, given that women may not take a prescribed drug.
- Some studies did not precisely define outcomes, or grouped together different types of malformations across a range of severity from mild to severe.
- Other studies did not specify the antidepressant dose or timing of use during the antenatal period. Some observed associations between exposure and outcome are based upon a small number of exposed and affected infants, and some associations may occur by chance due to an excessive number of comparisons.

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## SSRI's

- The adverse pregnancy risks of antidepressants have been more widely studied in SSRIs than other antidepressant drugs; in one study of women who used antidepressants during the first trimester (n >64,000), SSRIs were prescribed for 72 percent.
- Although SSRIs differ in their pharmacologic properties, the pregnancy outcomes observed for the different drugs (usually from underpowered analyses) are comparable, suggesting that the impact of SSRIs is likely a class effect of the SSRI drugs. Thus, composite data on SSRIs are generally used for the primary analyses of outcomes.

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## SSRI's and Teratogenicity

- Most studies indicate that SSRIs as a group are not major teratogens and are not associated with birth defects.
- In studies that have observed an association between SSRI exposure and congenital anomalies, the **magnitude of the increased risk was small.**
- A meta-analysis of 12 studies compared infants of mothers who used antidepressants during pregnancy (n >50,000; largely SSRIs) with infants who were not exposed (n >1,200,000). The risk of congenital malformations was comparable for the two groups

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## Observational studies – conflicting data

- A meta-analysis of 13 studies compared infants of mothers who used antidepressants (n >20,000; largely SSRIs) during pregnancy with infants who were not exposed (n >1,500,000). The risk of congenital cardiac malformations was increased in the group that was exposed to antidepressants (relative risk 1.4, 95% CI 1.1-1.7). Given that the baseline risk for cardiovascular malformations in unexposed infants is approximately 5 in 1000, a relative risk increase of 1.4 would result in an absolute risk of 7 in 1000 live births.

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## Other side of the coin

- A national registry study (nearly 1,300,000 births) compared infants who were exposed to SSRIs in early pregnancy (n >10,000) with infants not exposed.
- After adjusting for potential confounds, the analyses found that the specific risk of cardiovascular defects was comparable for the two groups.

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## Effects on Pregnancy

- Two independent meta-analyses each used the same set of observational studies, but found contradictory results, suggesting that the association between antenatal exposure to SSRIs and spontaneous abortion was small or nonexistent.
- Incidence of preeclampsia – identical
- Post partum Hemorrhage – Increased OR <2.0

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## Preterm Delivery

- The effect of SSRIs upon preterm delivery may be related to the timing of exposure.
- In a meta-analysis of 41 observational studies (n >5,000,000 pregnant women) that controlled for potential confounding factors (eg, maternal age, smoking, alcohol use, and history of prematurity), first trimester exposure to antidepressants (mostly SSRIs) was not associated with preterm birth.
- Third trimester exposure was associated with premature delivery (odds ratio 2.0, 95% CI 1.6-2.4); controlling for depression did not eliminate the effect. However, heterogeneity across studies was large.

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## Effects on the Baby

- When depressed mothers who took antidepressants during pregnancy were compared with depressed mothers not exposed to antidepressants (six studies), the association between antidepressant exposure and lower birth weight was not statistically significant.
- Compared outcomes in offspring exposed to SSRIs during the second and/or thirds trimester with offspring who were not exposed. After adjusting for potential confounding factors, the risk of five-minute Apgar scores <7 was greater in the exposed neonates than unexposed neonates (odds ratio 2.2, 95% CI 1.7-2.7).

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## Perinatal Death

- Multiple studies suggest that SSRIs are not associated with an elevated risk of perinatal death.
- As an example, a study of national registries from five countries (n >1,600,000 births) included more than 29,000 mothers who filled an SSRI prescription during pregnancy; among the births, there were more than 6000 stillbirths, 3600 neonatal deaths, and 1500 postnatal deaths.
- After controlling for potential confounding factors (eg, maternal age, smoking, diabetes, and psychiatric illness), the analyses found that the risks of stillbirth, neonatal death, and postnatal death were each comparable for women who used or did not use SSRIs.

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## Safety of SSRI's

- No one SSRI is "safer" or "less safe" to use during pregnancy than another, with the possible exception of Paroxetine. Several studies have found that paroxetine was associated with a small increased risk for congenital cardiovascular malformations; however, other studies have found no such risk.
- Few studies have had sufficient power to evaluate the risks associated with specific SSRIs, including the more widely studied medications, (citalopram, fluoxetine, sertraline)
- Even across studies that have assessed individual SSRIs, there is substantial inconsistency in the type and magnitude of adverse events reported, which may suggest that the observed associations are less likely to represent a true effect .

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## Citalopram

- Teratogenicity -NO
- Spontaneous loss -NO
- Hypertensive disorders -NO
- PP Hemorrhage -YES RR 1.5

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## Escitalopram

- Teratogenicity - NO
- Spontaneous loss - NO
- Hypertensive disorders - NO
- PP Hemorrhage – YES RR 1.6

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## Fluoxetine

- Teratogenicity – Possible RR 1.2-1.3 cardiac
- Spontaneous loss - NO
- Hypertensive disorders - NO
- PP Hemorrhage – NO

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## Paroxetine

- Teratogenicity – Small increase noted – RR 1.4-1.7
- Spontaneous loss - NO
- Hypertensive disorders - conflicting
- PP Hemorrhage - YES

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## Sertraline

- Teratogenicity – conflicting data most studies say no
- Spontaneous loss - NO
- Hypertensive disorders - NO
- PP Hemorrhage - YES

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## Depression as a Cause

- Untreated depression in the mother is associated with worse pregnancy outcomes.
- There is also evidence that what happens *in utero*, while the fetus is developing, may predispose a child to certain illnesses later on in life. <sup>1</sup>
- It has been hypothesized that dysregulation of the maternal hypothalamic-pituitary-adrenal (HPA) axis — as a result of exposure to stressful life events or the experience of anxiety or depressive symptoms during pregnancy — may lead to long-standing alterations in the fetal HPA axis, making the child more susceptible to depression or anxiety as an adult.

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## Conflicting Studies Published

- Two large international trials yielded different outcomes for SSRI- exposed children at age 14.
- Taking both of these studies into consideration, it is still not clear if the increased prevalence of depression in the children can be attributed to exposure to the medication or to the underlying psychiatric illness.
- The Good News- There was no observed association between prenatal SSRI exposure and risk for autism spectrum disorders, ADHD, or anxiety disorders.

Mahn H, et al. Gestational Exposure to Selective Serotonin Reuptake Inhibitors and Offspring Psychiatric Disorders: A National Register-Based Study. J Am Acad Child Adolesc Psychiatry. 2016; 55(5):359–366.

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## Summary

- Although most Family Physicians are not providing maternity care, they all will care for women of childbearing age and be faced with medical management of pregnant patients.
- The Family Physician is ideally prepared to provide this care from Primary prevention, to preconception planning through pregnancy and into the post partum period.

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## **Is Heart Disease Different in Women?**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Is Heart Disease Different in Women?***  
Agnieszka Mochon, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

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# Is Heart Disease Different in Women?

Agnieszka Mochon, MD, FACC  
Tower Health Medical Group -  
Cardiology

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## Disclosure

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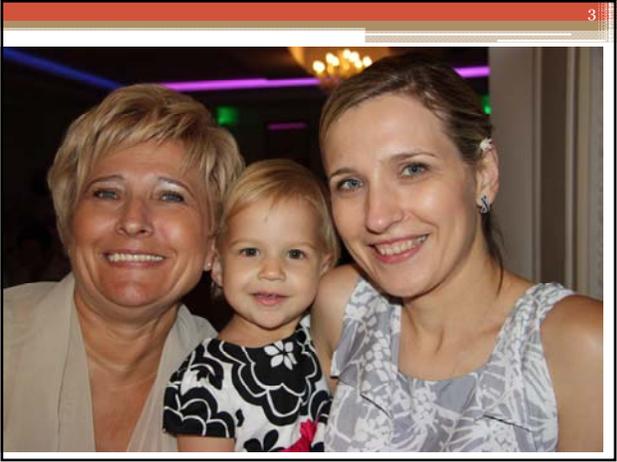
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### Is heart disease different in women?

- Epidemiology
- Awareness
- Risk factors
- Heart disease
  - Presentation
  - Management
  - Outcomes
- Cardiovascular conditions more common in women

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### Epidemiology of CVD in women

- **Heart disease is the No. 1 killer of women**
  - 1 in 3 women's deaths each year
  - 43 million women in the U.S. are affected by heart disease
  - 90% of women have at least 1 risk factor
- Increased risk of stroke
- Women develop CV disease later in life

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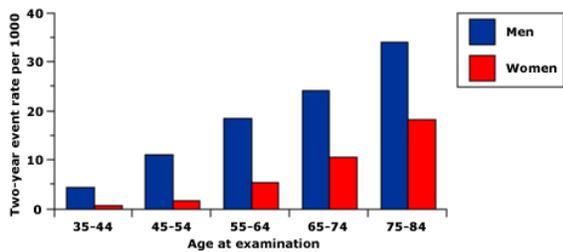
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### Epidemiology of CVD in women




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## Awareness




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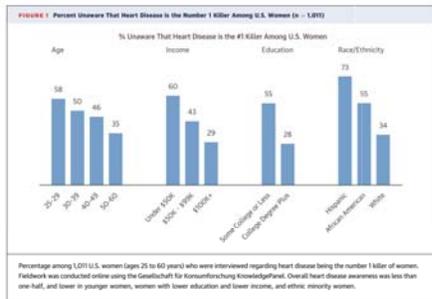
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## Women's Heart Alliance campaign




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## Women's Heart Alliance campaign

- 73% did not know a woman that had heart disease
- 71% never raised issue of heart disease with their physician
- 38% reported having a moment when they thought something was wrong with their heart
  - 50% told someone
  - 30% seeked medical help

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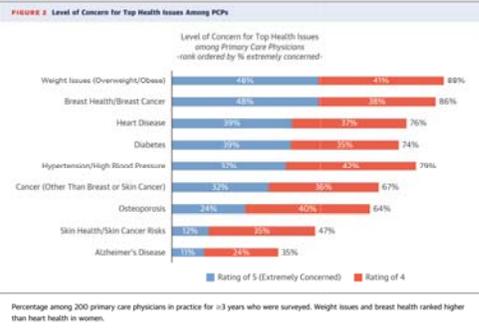
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## Women's Heart Alliance campaign




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## Cardiovascular risk factors

- Risk factors in common with men
  - Personal history of atherosclerotic vascular disease
  - Age over 55
  - Family history of premature CVD
  - Hypertension
  - Dyslipidemia
  - Diabetes mellitus
  - Metabolic syndrome
  - Chronic kidney disease
  - Smoking
  - Obesity

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## Cardiovascular risk factors

- Risk factors unique for women
  - Post-menopausal status
  - Pregnancy related complications
  - Psychological stress (eg, depression, post-traumatic stress disorder, etc)
  - Inflammatory/rheumatic diseases
  - Other: early menarche, PMS, preterm labor and spontaneous pregnancy loss

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### Family history of heart disease

- CVD in a first-degree relative prior to age 55 years (males) or 65 years (females)
- Found more commonly in women than in men with CVD

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### Hypertension

- 70 to 80% in women above age 70
- HTN is more common in women than man after the age of 65
- 10 fold increase in coronary mortality in premenopausal women
- Increases the risk of cardiovascular events in women who have known CVD
- Associated with diastolic dysfunction, stroke and heart failure

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### Dyslipidemia

- Low HDL, rather than high LDL cholesterol
- Lipoprotein(a) is a determinant of CVD in premenopausal women and postmenopausal women under age 66 and independent of other risk factors
- Triglycerides appear to uniquely influence coronary risk in older women

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## Dyslipidemia

- Treat high-risk women in the same fashion as men
- Reduction in cardiovascular events in similar in women when compared to men in primary prevention trials

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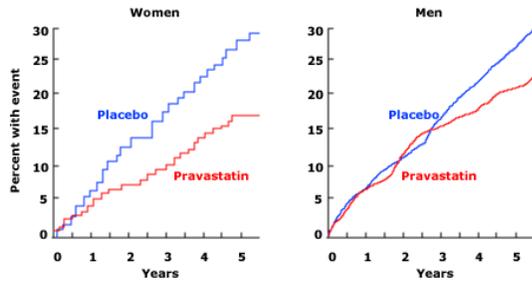
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## CARE trial




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## Diabetes mellitus

- The increase in CVD risk in patients with diabetes is **greater in women than in men**
- Risk of CVD increases 3-7 times for women with DM compared to women without DM (2-4 times in diabetic men)

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### Smoking

- Associated with 50% of all coronary events in women
- Women who smoke die 14.5 years earlier than non-smokers (compared to 13.2 years for men)
- Increased risk for adverse events post ACS (2.5 times greater compared to men who smoke)
- Cessation of smoking in women is associated with a rapid reduction in the risk of MI

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### Postmenopausal status

- ACC/AHA Guidelines recognize the postmenopausal state as a risk factor for CVD
- Early natural menopause ( $\leq 44$  years of age) has been associated with an increase in the risk of CVD
- Does type of menopause (natural or surgical) matter in prediction of CVD?
- Postmenopausal women who develop CVD have an increased burden of risk factors compared with those who do not

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### Pregnancy related complications

- Eclampsia and pre-eclampsia
- Gestational hypertension
- Gestational diabetes
  - Gestational diabetes increases a woman's risk for DM 35-60%

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### Other women unique risk factors

- Menarche
- Premenstrual syndrome
- Spontaneous pregnancy loss
- Preterm birth

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### Heart disease in women

- CAD
- Atrial fibrillation
- Valvular heart disease
- CVD more prevalent in women
  - Stress induced cardiomyopathy
  - Spontaneous coronary artery dissection
  - Peripartum cardiomyopathy

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### Coronary artery disease

- Symptoms
  - chest pain most common
  - more likely to have associated symptoms
- Delay in seeking medical advice
- Physician's delay in evaluation
- Greater burden of risk factors
- Women younger than age 45 years have a worse prognosis than men

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## Coronary artery disease

- ACS
  - Less likely to receive adequate medical therapy/cardiac rehab
  - Higher rate of depression
  - Higher rate of vascular complication, bleeding and mortality.

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## Coronary artery disease

- More women than man will
  - die within first year after MI
  - suffer another MI within 5 years,
  - develop HF after MI,
  - suffer CVA within 5 years of MI

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## Atrial fibrillation

- Higher thromboembolic risk
- Stroke mortality W>M
- More symptomatic

Criteria	Yes	No	Pass. Point
<b>C</b> ongestive heart failure Symptoms of heart failure confirmed with objective evidence of cardiac dysfunction	<input type="checkbox"/>	<input type="checkbox"/>	+1
<b>H</b> ypertension Sustaining BP > 160/90 mmHg on at least 2 occasions on current antihypertensive pharmacologic treatment	<input type="checkbox"/>	<input type="checkbox"/>	+1
<b>A</b> ge 75 years or older	<input type="checkbox"/>	<input type="checkbox"/>	+2
<b>D</b> iabetes mellitus Fasting glucose > 126 mg/dL, or treatment with oral hypoglycemic agent and/or insulin	<input type="checkbox"/>	<input type="checkbox"/>	+1
<b>S</b> troke, TIA, or TE Includes any history of cerebral ischemia	<input type="checkbox"/>	<input type="checkbox"/>	+2
<b>V</b> ascular disease Prior MI, peripheral arterial disease, or aortic plaque	<input type="checkbox"/>	<input type="checkbox"/>	+1
<b>A</b> ge 65 to 74 years	<input type="checkbox"/>	<input type="checkbox"/>	+1
<b>S</b> ex Category (female) Female gender confers higher risk	<input type="checkbox"/>	<input type="checkbox"/>	+1

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### TAVR

- Electronic search for studies reporting TAVR outcomes (17 studies)
- All cause mortality and major CV events at 30 days and > 1 year follow up
- 47188 patients – 49.4% women
- Women were older but with fewer comorbidities

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### TAVR

- At 30 days
  - more bleeding (p < 0.001)
  - vascular complications (p < 0.001)
  - stroke/transient ischemic attack (p = 0.02)
  - No difference in all-cause (p = 0.19) or cardiovascular mortality (p = 0.91)
- At 1 year
  - lower all-cause mortality (p < 0.001)
  - less moderate/severe aortic insufficiency (p = 0.001)
  - lower cardiovascular mortality (p = 0.009)

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### Stress-induced cardiomyopathy

- Acute ST changes syndrome in the absence of critical CAD
- Cardiac biomarker levels usually mildly elevated
- Postmenopausal women
- Precipitated by psychological stress
- Mechanisms include
  - catecholamine excess
  - coronary artery spasm
  - microvascular dysfunction
- Management
  - Supportive
  - At least the short-term use of standard medications for heart failure due to systolic dysfunction

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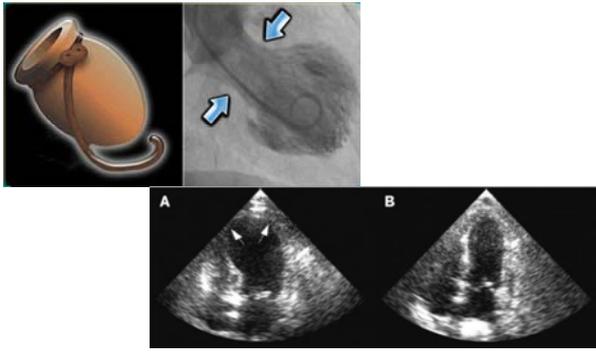
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### Stress-induced cardiomyopathy




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### Spontaneous coronary artery dissection

- Younger women
- No risk factors for CAD
- Risk factors:
  - Underlying arteriopathy
  - Systemic inflammation
  - Pregnancy - increased hemodynamic stress or hormonal effects on the arterial wall
  - Family history
- Triggers
  - Severe stress
  - Intense exercise

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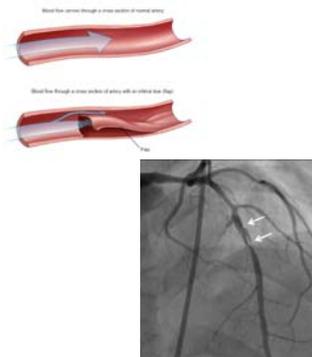
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### Spontaneous coronary artery dissection

- Mechanism
  - intimal tear vs
  - bleeding of vasa vasorum with intramedial hemorrhage
- 10-year recurrence rate 29.4 percent




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## Peripartum cardiomyopathy

- EF <45%
- 36 week of gestation – 5 months after delivery
- ≈1 in 1000 to 4000 live births
- The incidence is increasing
  - increased awareness and diagnosis
  - rising maternal age
  - changing demographics
  - rising multifetal pregnancies




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## Peripartum cardiomyopathy

- Risk factors
  - Age > 30
  - Multiparity
  - Multifetal pregnancy
  - African descent
  - Hypertension and Preeclampsia
  - Prior toxin exposure (eg, cocaine)
  - Long-term (>4 weeks) oral tocolytic therapy
  - Others: anemia, malnutrition, obesity, DM

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## Peripartum cardiomyopathy

- Prognosis
  - High rate of LV EF recovery (20-60%)
  - Increased risk of reoccurrence with future pregnancies
  - Mortality rate of 10% in 2 years

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Thank you!



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**Update in Obstetrics for Primary  
Care...from A to Zika...What Every FP  
Who Doesn't Do OB Needs to Know**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Update in Obstetrics for Primary Care...from A to Zika...What  
Every FP Who Doesn't Do OB Needs to Know***

Stacey Milunic, MD

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Update in Obstetrics  
for Primary Care...  
from A to Zika!  
(What every FP who doesn't do  
OB needs to know)

Stacey Milunic, MD

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Objectives

- o Discuss the evaluation and management of common non-obstetric acute complaints in a pregnant patient
- o Identify the impact of updated prenatal care guidelines on primary care of the pregnant patient
- o Demonstrate appropriate preconception counseling about Zika Virus and other significant diseases

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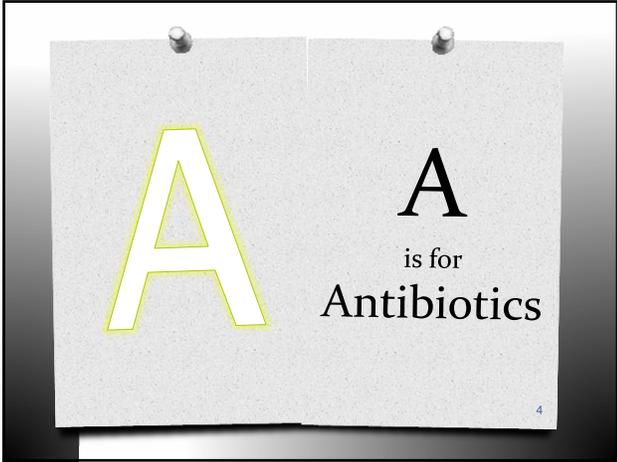
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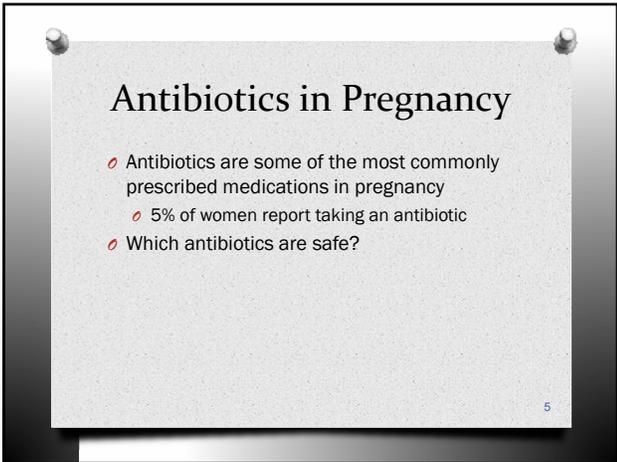
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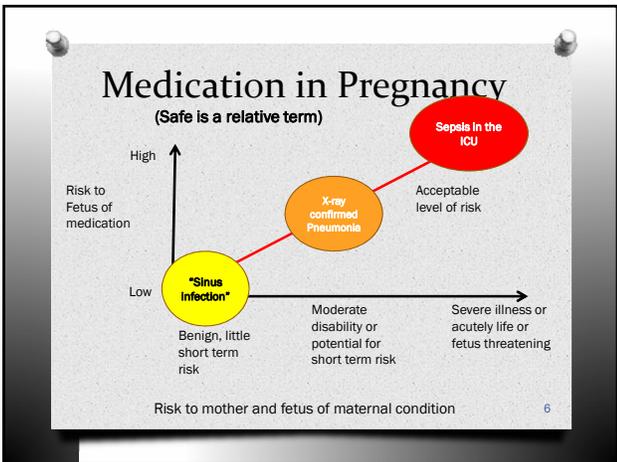
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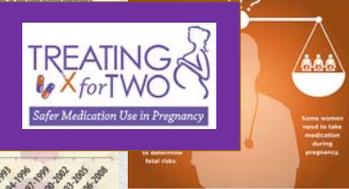
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## Medication in Pregnancy

### Medication Use During Pregnancy



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## Antibiotics in Pregnancy

- Antibiotics are some of the most commonly prescribed medications in pregnancy
  - Which antibiotics are safe?
- Which outcomes?  Which trimester? Which antibiotic?

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## Antibiotics: The Great

- Penicillins
- Cephalosporins
- Erythromycin
- 2009 National Birth Defects Prevention Study showed no association with major malformations
- 2017 Quebec Pregnancy Cohort case-control study showed no association with pregnancy loss
- Supported by older data

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## Antibiotics: The Good

- Macrolides (azithromycin/clarithromycin)
  - Possible association with SAB (1<sup>st</sup> trimester)
- Nitrofurantoin
  - Better than being sick... especially after the 1<sup>st</sup> trimester!
- Fluoroquinolones
  - Animal studies showed damage to developing cartilage
  - Human cohort studies have not shown an association with major malformations
  - Possible association with SAB

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## Antibiotics: The Avoid

- Sulfonamides (trimethoprim-sulfoxamide)
  - Associated with birth defects in first trimester
  - Associated with hyperbilirubinemia near term
- Aminoglycosides
  - Associated with fetal ototoxicity
- Tetracyclines
  - Birth defects, fetal tooth discoloration
  - Associated with SAB

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**B** **B**  
is for  
Betamethasone

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## Steroids for Lung Maturity

- Previously betamethasone (or dexamethasone) recommended for women at risk of delivery <34 weeks
- 2016 ACOG recommends a single course of steroids for women 34-36 5/7 weeks at risk of delivery within 7 days who have not had one previously (but no tocolysis)
  - Multicenter blinded RCT, outcome was need for respiratory support in first 72 hours
- Increased risk of neonatal hypoglycemia in the betamethasone group (25% vs. 17%)

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# C

C  
is for  
Carrier  
Screening

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## Carrier Screening

- Options for carrier screening have expanded dramatically
  - Now possible to "pan-screen" – one panel includes 274 genetic conditions
- Ideally carrier screening is done prior to conception
- ACOG recommends offering all women screening for cystic fibrosis, spinal muscular atrophy and hemoglobinopathies, regardless of ethnicity
- Additional screenings should be offered based on family history, ethnicity, and patient preference

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## Cystic Fibrosis

- Autosomal recessive disease characterized by pulmonary disease and pancreatic insufficiency
  - 1:2500 non-Hispanic Caucasians
  - Median life expectancy 41 years
- Standard 23-mutation panel appropriate for average risk individuals
- Consider expanded panels for non-Caucasians
- CF gene sequencing is usually unnecessary
- Consult a genetic counselor if a family history
- Now on the newborn panels for all 50 states

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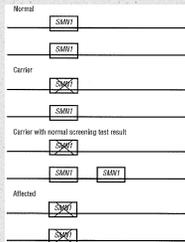
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## Spinal Muscular Atrophy

- Autosomal recessive disease of spinal motor neurons; presents as generalized weakness and death from respiratory failure, often by age 2
- 1/6000 - 1/10,000 births
- Leading genetic cause of infant death
- No effective treatment
- Carrier testing requires a measurement of the SMN1 copy number
- 3-4% of the population are carriers with normal screening tests



Carrier screening for genetic conditions. Committee Opinion No. 691. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;129:e41-55.

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## Hemoglobinopathies

- Includes both sickle-cell diseases and thalassemia
  - Wide range of presentations from intrauterine death (alpha-thal major) to asymptomatic
- Initial screening is CBC with indices
  - Also screens for iron deficiency anemia
- Add hemoglobin electrophoresis if at risk for hemoglobinopathy based on ethnicity OR if low MCV/MCH
- Included in PA Newborn screening

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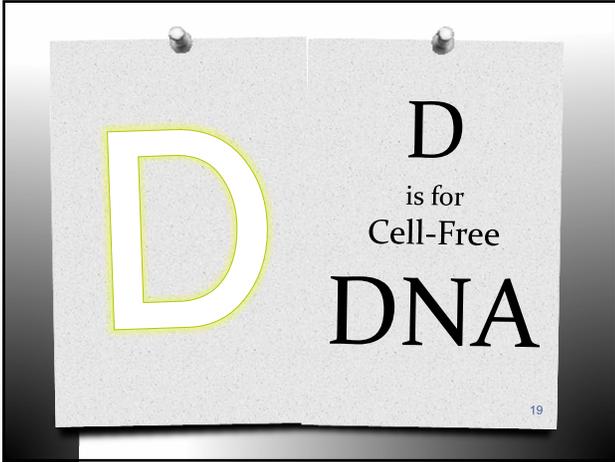
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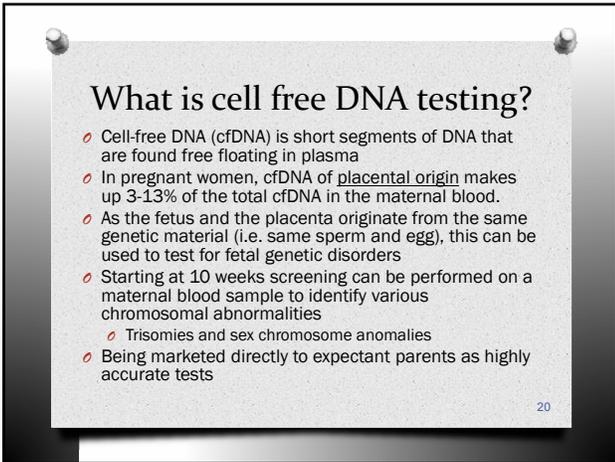
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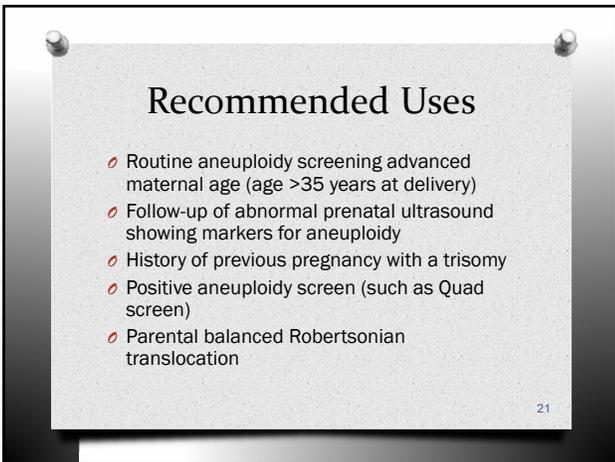
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## Potential Uses

(not currently recommended)

- o Determination of fetal sex
- o Screening for sex-chromosome abnormalities
- o Screening for paternally derived autosomal dominant genetic abnormalities
- o Paternity testing
  - o Being offered commercially online
- o Determining Rh status of fetus
- o Screening for microdeletions

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## How accurate are these?

	Sensitivity	Specificity	PPV	NPV
Trisomy 21	100%	99.9%	81%	100%
Trisomy 18	90%	100%	90%	100%
Trisomy 13	100%	99.9%	50%	100%

Based on an (industry funded) study of 15,841 women in a "routine prenatal population" with an average age of 30.7 years

Caveat: 3% had an invalid cell free DNA test, and there was a much higher rate of aneuploidy in this group

NEJM. Cell-free DNA analysis for Noninvasive Examination for Trisomy. April 23, 2015. 23

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## Reasons to be cautious:

- o Test results can be affected by multiple gestation, placental mosaicism, maternal mosaicism or translocation
- o Cell-free DNA testing is screening and NOT diagnostic
- o Failed cell-free DNA testing is an indication for genetic counseling as it confers a higher risk of aneuploidy. It is more likely to fail in obese women.
- o Cell-free DNA testing does not screen for neural tube defects or other structural abnormalities that are not due to aneuploidy
- o Screening for microdeletions with cfDNA has not been validated in clinical trials and is not recommended
- o Tests are being transitioned from high-risk to low-risk populations which will increase the false-positive rate

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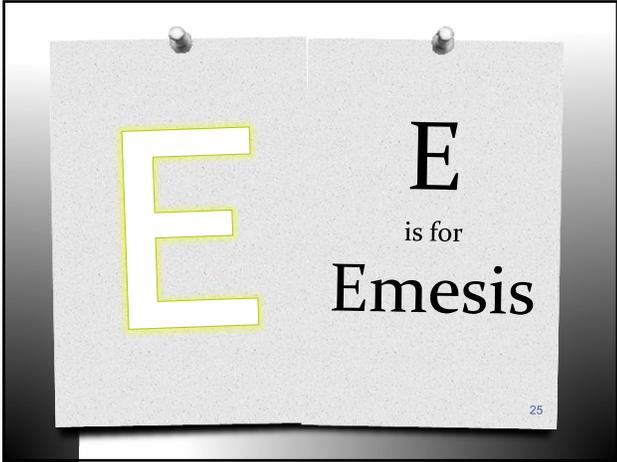
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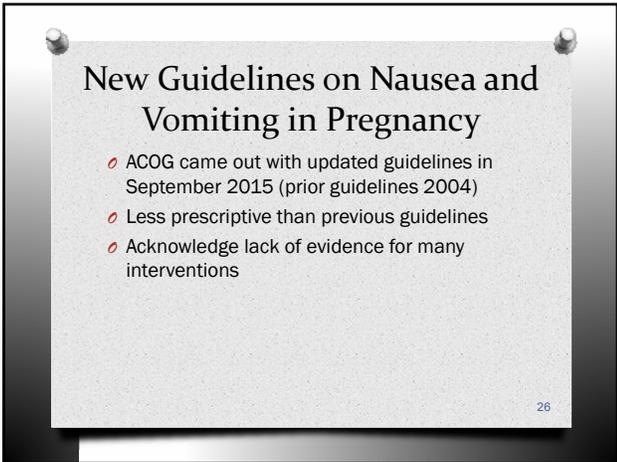
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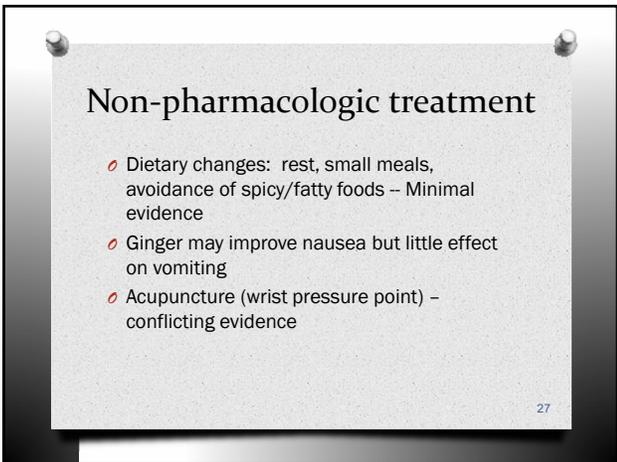
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## Pharmacologic Therapy

- Vitamin B6 alone or plus doxylamine is first line pharmacotherapy
  - RCTs have shown it to be better than placebo
    - Both delayed release and short acting
    - No study of short vs long acting
  - Extensive safety data
- Considered safe but less direct evidence of efficacy
  - Prochlorperazine, chlorperazine, metoclopramide, scopolamine

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## Pharmacologic Therapy

- Ondansetron
  - May be more effective than doxylamine-pyridoxine (small study)
  - 1st trimester use associated with cardiac anomalies (1.62 odds ratio) though absolute risk low
  - Not first line
- Methylprednisolone
  - Mixed evidence regarding efficacy in prevention of re-hospitalization in severe cases
  - 1<sup>st</sup> trimester use associated with cleft palates
  - Limit to severe cases and taper once improved

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is for

Fluconazole

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## Is Oral Fluconazole Safe?

- 4/26/2016 – FDA released a Drug Safety Communication stating they were reviewing study results linking oral fluconazole to increase risk of miscarriage
- Cohort study looking at 3315 women exposed to fluconazole at 7-22 weeks and 13,246 matched controls
- Spontaneous Abortion: HR 1.48 [95% CI 1.23-1.77] in fluconazole exposed women
- Absolute risk 4.43% in exposed versus 4.25% in unexposed

31

04/26/2016 Drug Safety Communications - FDA Available at FDA.gov  
Association B...  
Study: Fluconazole Use During Pregnancy and Risk of Spontaneous Abortion and Stillbirth. JAMA. 2016;315(1):58-67.  
doi:10.1001

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## So if not Fluconazole, what?

- Per CDC 2015 Guidelines, “only topical azole therapies, applied for 7 days, are recommended for use among pregnant women”
  - Clotrimazole 1% cream
  - Miconazole 2% cream
  - Miconazole 100 mg vaginal suppository
  - Terconazole 0.4% cream
- Take home point: Only use oral fluconazole in pregnant patients that have failed topical treatments

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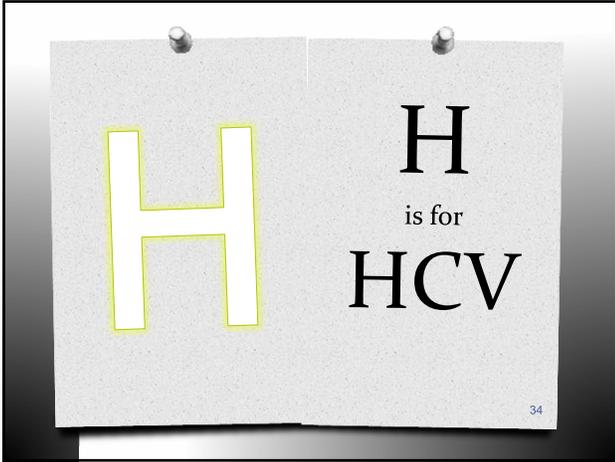
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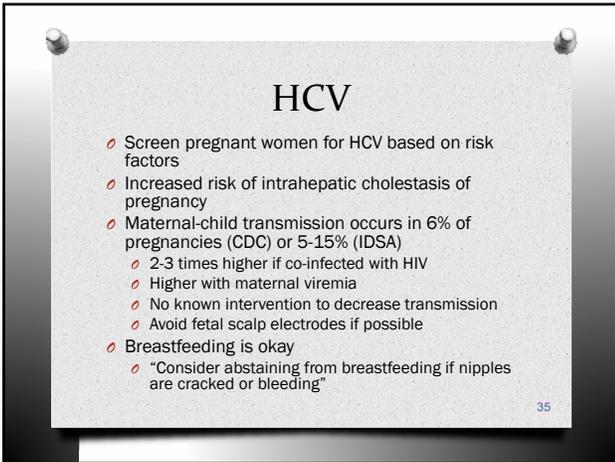
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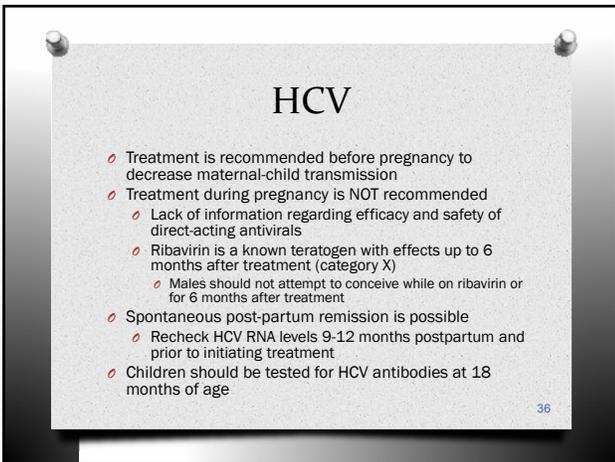
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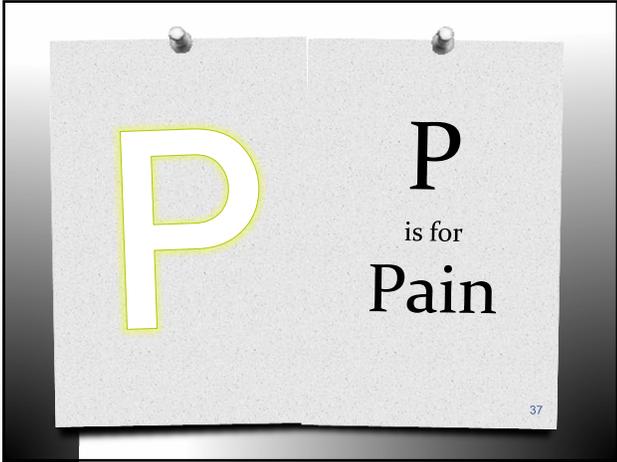
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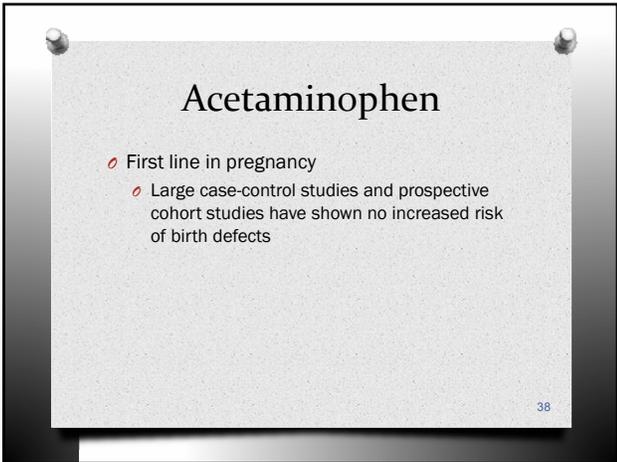
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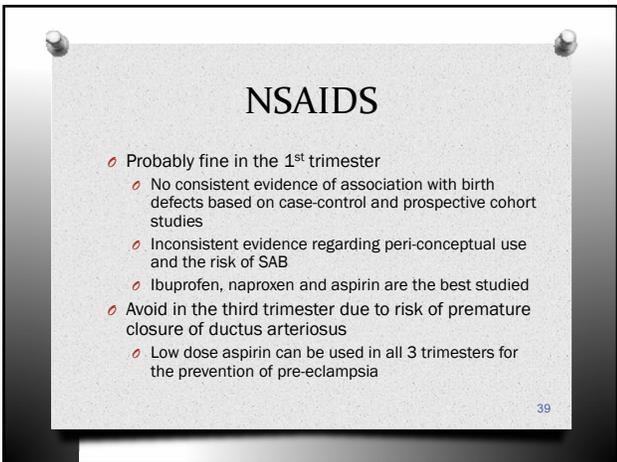
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## Opiates

### Opiate Use Disorder

- Lots of studies
- Medication-assisted treatment is the standard of care
  - Buprenorphine
  - Methadone
- Good evidence that MAT is preferable to relapse or continued use
- High relapse rate with supervised withdrawal

### Opiate Use

- Few studies
- Few recommendations

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## Opiates

- Probably fine in the 1<sup>st</sup> trimester
  - Inconsistent evidence regarding association with neural tube defects
- Risk for Neonatal Abstinence Syndrome
  - Cohort study of 290,605 women who filled an opiate Rx during pregnancy
  - Overall rate of NAS 6 per 1000 deliveries
  - ↑ risk with use >30 days (23.7 vs 3.3 per 1000)
  - ↑ risk with 3<sup>rd</sup> trimester use (7.8 vs 4.2 per 1000)
  - Increased risk with h/o opiate use disorder, h/o other drug use, tobacco use, and use of psychotropic medications

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## What about opiate withdrawal in pregnancy?

- Traditionally discouraged
- Cohort study of 301 pregnant women with opiate use disorder detoxified during pregnancy
  - Various forms of detoxification occurred
  - 2 pregnancy losses occurred however remote from detoxification events
  - 17% delivered <37 weeks
  - 31% rate of NAS (all with evidence of relapse)
  - 41% NICU admission rate
  - No fetal monitoring done during detoxification
  - No long term follow-up

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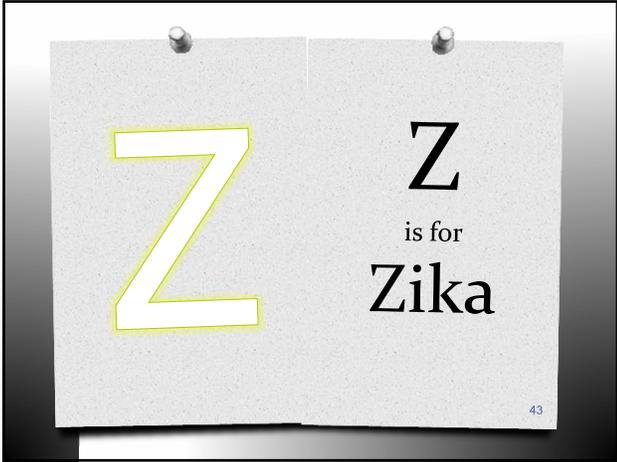
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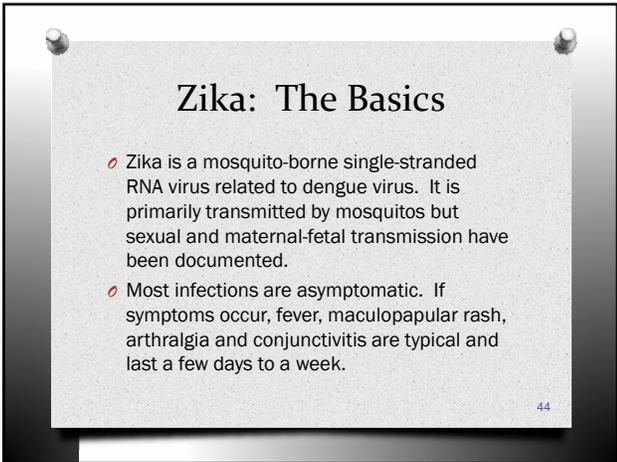
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## Zika and Pregnancy

**Congenital Zika syndrome is a pattern of birth defects in babies infected with Zika during pregnancy**



- There is evidence of maternal-fetal transmission during all trimesters
- There is limited information regarding peri-conceptional infection (infection within the 8 weeks prior to conceiving)

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## US Zika Pregnancy Registry Data (reported June 2017)

- Prior to the registry, the frequency with which Zika caused an adverse event was unknown
- Registry followed 2549 completed pregnancies with reported outcomes
- 5% rate of Zika-associated birth defects with "possible" infection
- 8%, 5% and 4% rate in pregnancies with confirmed Zika RNA testing in the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> trimesters
- Only 52% of infants from pregnancies possibly affected by Zika reported postnatal neuroimaging
- No difference between maternal symptomatic and asymptomatic infections

47

Weekly Update: After Maternal Zika Virus Infection During Pregnancy — U.S. Territories, January 1, 2016–April 25, 2017. Weekly Report. <https://www.cdc.gov/mmwr/preview/mmwrhtml/ww4115a421.htm>

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## Zika: Preconception Counseling

- No evidence that conception after resolution of Zika infection has an effect on pregnancy
- Men and women visiting areas with Zika transmission should delay attempts at conception even if they are asymptomatic
  - Women should wait 2 months symptoms/possible exposure
  - Men should wait 6 months after symptoms/possible exposure due to the persistence of Zika RNA in the semen
    - Zika RNA detected in semen up to 188 days after symptom onset
  - If both members of a couple are possibly exposed, they should wait 6 months to attempt conception
- It is recommended to use condoms or not have sex during the waiting period.

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<https://www.cdc.gov/zika/hc-providers/reproductive-age/patient-counseling.html>

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## Zika: Pregnancy Counseling

- Travel to areas with risk of Zika should be avoided during pregnancy.
- If a pregnant woman must travel to an area with Zika, she should be counseled to strictly follow steps to prevent mosquito bites and sexual transmission of Zika during the trip.
- If the male partner of a pregnant women is possibly exposed to Zika, they should abstain or use condoms throughout the remainder of the pregnancy to prevent transmission during pregnancy.

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<https://www.cdc.gov/zika/hc-providers/pregnant-women/patient-counseling.html>

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## Zika: Preconception Testing

- Zika IgM testing is no longer recommended in asymptomatic women as part of preconception counseling or prenatal care
  - IgM can persist beyond 12 weeks after infection
  - Difficult to distinguish recent infection from prior infection
- Testing of men prior to attempting conception is not recommended as it is unclear whether blood test results accurately reflect the presence of Zika RNA in semen

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CDC Health Advisory, May 5 2017. <https://emergency.cdc.gov/han/han00402.asp>

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smilunic@pennstatehealth.psu.edu

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## Recommended References

- **A** – Crider KS, Cleves MA, Reefhuis J, Berry RJ, Hobbs CA, Hu DJ. Antibacterial Medication Use During Pregnancy and Risk of Birth Defects National Birth Defects Prevention Study. *Arch Pediatr Adolesc Med.* 2009;163(11):978–985. doi:10.1001/archpediatrics.2009.188
- Sulfonamides, nitrofurantoin, and risk of birth defects. Committee Opinion No. 717. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2017;130:e150–2.
- **B** -. Gyamfi-Bannerman C, Thom EA, Blackwell SC, Tita AT, Reddy UM, Saade GR, et al. Antenatal betamethasone for women at risk for late preterm delivery. NICHD Maternal–Fetal Medicine Units Network. *N Engl J Med* 2016;374:1311–20. doi:10.1056/NEJMoa1512311
- **C** – Carrier screening for genetic conditions. Committee Opinion No. 691. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2017;129:e41–55.

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- **E** – ACOG Practice Bulletin #153. Nausea and Vomiting of Pregnancy. *Obstet Gynecol* 2015; 126:e12-24.
- **F** – 04/26/2016 - Drug Safety Communication - FDA. Available at FDA.gov
- **H** - <https://www.hcvguidelines.org/unique-populations/pregnancy>
- <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>

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*Obstet Gynecol.* 2010;115(1):109-115. Feldkamp ML, Meyer RE, Krikov S, Botto LD.
- **Nonsteroidal antiinflammatory drug use among women and the risk of birth defects**  
*Am J Obstet Gynecol.* 2012;206(3):228 e221-228. Hernandez RK, Werler MM, Romitti P, Sun L, Anderka M, National Birth Defects Prevention Study.
- **BMJ.** 2015 May 14;350:h2102. doi: 10.1136/bmj.h2102. **Exposure to prescription opioid analgesics in utero and risk of neonatal abstinence syndrome: population based cohort study.** Desai RJ<sup>1</sup>, Huybrechts KF<sup>2</sup>, Hernandez-Diaz S<sup>3</sup>, Mogun H<sup>4</sup>, Paterno E<sup>4</sup>, Kallenbach K<sup>4</sup>, Kerzner LS<sup>5</sup>, Bateman BT<sup>6</sup>.
- *Am J Obstet Gynecol.* 2016 Sep;215(3):374.e1-6. doi: 10.1016/j.ajog.2016.03.015. Epub 2016 Mar 17. **Detoxification from opiate drugs during pregnancy.** Bell J<sup>1</sup>, Towers CV<sup>2</sup>, Hennessy MD<sup>3</sup>, Heitzman C<sup>4</sup>, Smitin B<sup>5</sup>, Chatwin A<sup>4</sup>.

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## Recommended References

- o Z - [www.cdc.gov/zika](http://www.cdc.gov/zika)
- o <https://www.cdc.gov/zika/hc-providers/reproductive-age/patient-counseling.html> (accessed 10/29/2017)
- o <https://www.cdc.gov/zika/hc-providers/pregnant-women/patient-counseling.html>
- o Oduyebo T, Polen KD, Walke HT, et al. Update: Interim Guidance for Health Care Providers Caring for Pregnant Women with Possible Zika Virus Exposure – United States (Including U.S. Territories), July 2017. MMWR Morb Mortal Wkly Rep 2017;66:781-793. DOI: <http://dx.doi.org/10.15585/mmwr.mm6629e1>

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**[Return to Top](#)**

## **When Does an Ill Child Become An Emergency?**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***When Does an Ill Child Become An Emergency?***  
Chris Valente, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

## The Ill-Appearing Infant: Emergencies in the Early Months of Life

Chris Valente, MD  
Chief, Section of Pediatric Emergency Medicine  
Department of Emergency Medicine  
The Reading Hospital  
17 November 2017

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## Disclosure

- The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

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## One Hour Into Your Shift...

Bed #	Vi.	Patient	Age	CC/Current L.	A	Arrival	WSGInfo	C.	RevAPP	Fel.	AMP/ED
ED19		Blue, Baby-boy (M)	7 day ...	Poor feeding		00:03					
ED20											
ED21											
ED22											

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## Goal and Objectives

### Goal:

- Develop a thoughtful approach to emergencies in the first months of life

### Objectives:

- Discuss key components of the history and physical exam to consider when an ill-appearing neonate presents to care
- Describe the differential diagnosis for an ill-appearing neonate
- Discuss the initial management of a neonate in shock

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## Why Do Babies Scare Us?



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## Why Do Babies Scare Us?

- Neonates often present with non-specific signs and symptoms
- Guardians may not appreciate the severity of presentation
- Rapid deterioration
- Most in shock have sepsis, **but we must consider other possibilities...**
  - ....And there are many other possibilities!

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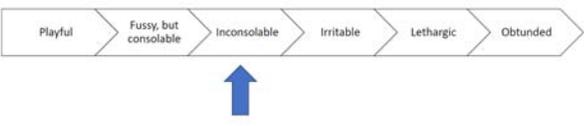
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 Scientific Assembly  
 WASHINGTON, DC 17

### AVPU and speaking the language

- Alert, responds to Voice, responds to Pain, Unresponsive



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### Differential Diagnosis of the Ill- Appearing Infant

- Infection – sepsis, meningitis
- Trauma (non-accidental)
- Cardiac disease
- Neurologic disorders
- Metabolic and electrolyte disorders
- GI disorders
- Endocrine disorders
- Feeding failure/problems

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### The Ill-Appearing Neonate: “The Misfits”

- T – Trauma
- H – Heart disease, Hypovolemia
- E – Endocrine
- M – Metabolic
- I – Inborn errors of metabolism
- S – Sepsis
- F – Formula dilution/overconcentration
- I – Intestinal catastrophes
- T – Toxins
- S – Seizures

Sharieff GQ, McCollough M, Emerg Med Clin North Am, 2002

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## The Ill-Appearing Neonate: "Neo-secrets"

- N – \*N-born errors of metabolism
- E – Electrolyte abnormalities
- O – Overdose
- S – Seizure
- E – Enteric emergencies
- C – Cardiac
- R – Renal, Recipe errors
- E – Endocrine
- T – Trauma
- S – Sepsis

Kim O, Brousseau D, Clin Ped Emerg Med, 2008

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## History: Key Considerations

- Prenatal care
- Birth history
  - Prematurity, NICU course, maternal GBS status
- Feeds
  - If formula fed, how is it mixed?
- Wet diapers, bowel movements
- Activity level



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## History: Key Considerations



- Fever OR hypothermia
  - Lack of fever does not exclude infection!
- Associated symptoms
- Newborn screen
  - May not be available
- Family history
- Social history
  - All caregivers, exposures

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## Physical Examination: Key Considerations

- Vital signs
  - 4-extremity BP's
  - Pre-/post-ductal SpO<sub>2</sub>
- Respiratory
  - Signs of distress often subtle
  - Usually no crackles
- Cardiovascular
  - +/- murmur
  - Gallop, pulses, perfusion; liver edge



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## Yale Observation Score

Table 1. Yale Observation Scale.

Observation item	Normal (1 point, each item)	Moderate impairment (1 point, each item)	Severe impairment (5 points, each item)
Quality of cry	Strong or none	Whimper or sob	Weak or moaning, high-pitched, or hardly responds
Parental stimulation	Cries briefly or no cry and content	Cries off and on	Persistent cry with little response
State variation	Stays awake or awakens quickly	Eyes close briefly then wakes or awakens with prolonged stimulation	No arousal and falls asleep
Color	Pink	Pale extremities or acrocyanosis	Pale, cyanotic, mottled, or ashen
Hydration	Skin/eyes normal and moist membranes	Mouth dry	Skin doughy or tented and/or sunken eyes
Response to social overtures	Smiles or alerts	Brief smiles or alerts	No smile, anxious, dull, no alerting

The total of these items corresponds as follows:  
 Appears well (score, 6-10)  
 Moderately ill (score, 11-15)  
 Toxic appearing (score, >15)

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## Febrile Infant ≤ 28 days – “No-brainer” Workup 100% of the time

- Higher risk of serious bacterial infection (SBI) overall at 15-20%
- Unpredictable clinical appearance
- Unreliable observation scales (e.g. Yale)
  - Even “low-risk”, well-appearing infants may have SBI 5-11% of the time
    - Baker: SBI present in 5/109 low risk infants < 4 weeks (NPV of 95% good but not good enough)
    - Replicated by Chiu 1994 and Schwartz (6% SBI rate, NPV 94%)

Schwartz. Arch Dis Child. 2009  
 Baker MD. Arch Pediatr Adolesc Med. 1999  
 Baker. Pediatrics. 1990  
 Jaskiewicz. Pediatrics. 1994

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## My Version of Ill-Appearing

- 1) Inconsolable while I am in the room
- 2) Anything beyond inconsolable  
(lethargic = inappropriate/lack of response to people and pain)
- 3) Paradoxical irritability
- 4) Septic (perfusion impairment)

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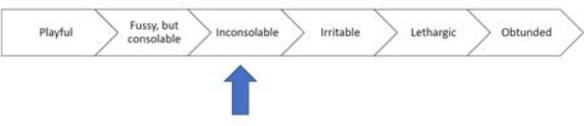
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 Scientific Assembly  
WASHINGTON, DC 17

### AVPU and speaking the language

- Alert, responds to Voice, responds to Pain, Unresponsive



Playful → Fussy, but consolable → Inconsolable → Irritable → Lethargic → Obtunded

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## Case

- 2 week old M with increased fussiness over the past two days
- Not feeding well
- Two small episodes of emesis
- Last bowel movement was 3 days ago
- T<sub>39.1</sub> P 196 RR 64 BP 84/52 SpO<sub>2</sub> 97%
- Slightly pale, eyes closed/crying moaning
- No murmurs, CR 4 seconds
- Tachypnea, grunting, clear lungs
- Decreased tone, weak suck

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## Case

Summary: 2 week old fussy, febrile infant with poor perfusion

- Had full workup including LP and meningitic dosing of antibiotics < 60 minutes
- 80cc/kg of fluid
- Intubated
- Admitted to the ICU
- Blood culture + for Gram Positive Cocci in Chains at 8hrs
- CSF also positive
- Multiple septic emboli on neuroimaging → hydrocephalus
- Continued to deteriorate and ultimately expired

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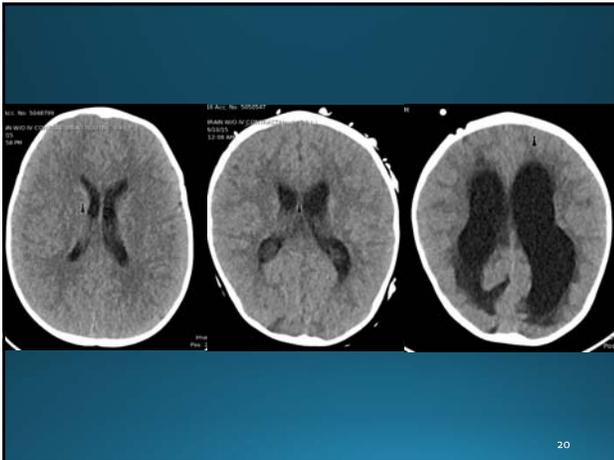
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## Our Task

- “With increased attention to rapid recognition, aggressive fluid administration, and early administration of antibiotics and vasoactive agents, pediatric mortality from severe sepsis and shock have decreased markedly.”
- Han 2003: Prospective cohort of 91 patients with septic shock
  - Each hour delay in appropriate resuscitation (OR = 1.5) or persistence of hemodynamic abnormalities (OR = 2.3) associated with increased risk of death

Goldstein B, et al. International Consensus Conference on Pediatric Sepsis. *Pediatr Crit Care Med.* 2005  
Odetola FO. *Pediatrics.* 2007  
HanYY. *Pediatrics.* 2003

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## Pediatric Septic Shock

- Two or more SIRS criteria
- Signs of inadequate tissue perfusion
- Suspected or proven infection

Kleinman. *Pediatrics*. 2010

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## Detection Challenges

Pediatric systemic inflammatory response syndrome criteria

Age group	Heart rate (beats/minute)		Respiratory rate (breaths/minute)	Leukocyte count (leukocytes x 10 <sup>3</sup> /mm <sup>3</sup> )	Systolic blood pressure (mmHg)
	Tachycardia	Bradycardia			
Newborn (0 days to 1 week)	>180	<100	>50	>34	<59
Neonate (1 week to 1 month)	>180	<100	>40	>19.5 or <5	<79
Infant (1 month to 1 year)	>180	<90	>34	>17.5 or <5	<75
Toddler and preschool (>1 to 5 years)	>140	NA	>22	>15.5 or <6	<74
School age (>5 to 12 years)	>130	NA	>18	>13.5 or <4.5	<83
Adolescent (>12 to <18 years)	>110	NA	>14	>11 or <4.5	<90

From UTD 2017

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## Detection Challenges

- SIRS CRITERIA NOT HELPFUL!!
  - Hard to remember ranges
  - Most kids with fever have tachycardia and tachypnea

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## Detection Challenges

- Most kids with fever have tachycardia and tachypnea
- KEY PRINCIPLES:
  - Low index of suspicion
  - Listen to the parent
  - Spend time with the patient

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## Detection: It's Really All About Perfusion

- 1) Altered mental status
  - irritable/inconsolable OR lethargic/somnolent/obtunded
- 2) Distal perfusion
  - mottled or cool extremities with decreased pulses/delayed cap refill OR "flash" cap refill
- 3) Oliguria
- 4) Hypotension = SBP < 5% for age\*
  - \*60mmHg < 1mo; 70 + (age x 2) for 1mo – 10 years; 90mmHg for > 10 years



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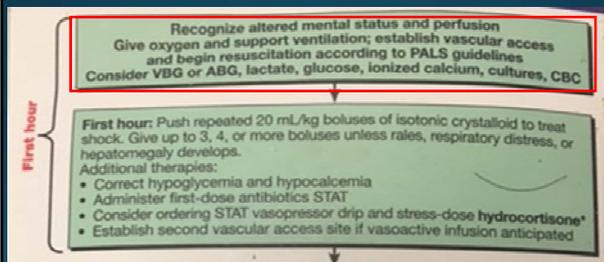
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## Pediatric Septic Shock Algorithm



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## Lab Workup

- Blood glucose
- VBG (or ABG) with lactate
- CBC with differential
- Electrolytes with ionized calcium
- Hepatic function tests
- PTT/PT/INR, fibrinogen, d-dimer
- Inflammatory markers
- CULTURES

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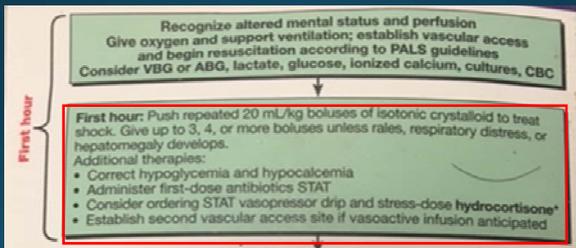
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## Pediatric Septic Shock Algorithm



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## Management



- “Early Goal Directed Therapy”: Access, fluid resuscitate, antibiotics
- KEY QUESTIONS LEFT UNANSWERED:
  - When to intubate?
  - What RSI drugs to use?
  - How much fluid?
  - What if access is difficult?
  - When to start pressors?
  - Which pressor?
  - What antibiotics?

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## RSI in Children with Sepsis

- In patient with shock, converting to PPV (increased intrathoracic pressure) often precipitates cardiac arrest
  - Optimize fluid status first, if possible
  - Start pressors prior to intubation

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## RSI in Children with Sepsis

- In patient with shock, converting to PPV (increased intrathoracic pressure) often precipitates cardiac arrest
  - Optimize fluid status first, if possible
  - Start pressors prior to intubation
- Avoid etomidate

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## What? No Etomidate???

- Etomidate inhibits 11- $\beta$ -hydroxylase  $\rightarrow$  impairs response to ACTH
- den Brinker. One single dose of etomidate negatively influences adrenocortical performance for at least 24 hours in children with meningococcal sepsis. *Intensive Care Med* 2008.
  - 60 kids with meningococcal sepsis
  - If received etomidate  $\rightarrow$  3-fold lower cortisol, 4-fold higher ACTH, higher lactate, 7/8 deaths in intubated patients

Lipner-Friedman. *Corticoid Study Group. Crit Care Med.* 2007  
Schenarts. *Acad Emerg Med.* 2001  
Birnly. *Crit Care Med.* 2009

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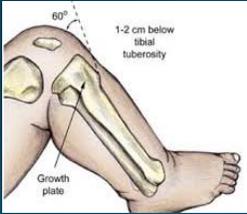
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## The IO is your friend...use the IO



- Tibial plateau is preferred
- Distal femur or proximal humerus are also options
- Low infection risk (0.6%)
- Can draw blood
- Safe for rapid infusion
  - Can give anything you would give IV
- Cheaper than central lines

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## Take Advantage of the IO Route

- 78-90% first time success rate vs 43-60% for peripheral IV
- Success rate in 60 dehydrated children within 5 minutes 100% vs. 67% for IV
- Some studies suggest IO placement after 3 IV attempts or 90 seconds
  - In arrest situation, put in IO immediately as IV attempted
  - **At a minimum, convert to IO if no access in 5 minutes**

Banerjee. *Pediatrics*, 1994  
Kleinman. *Circulation*, 2010

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## Fluid administration

- 20mL/kg NS or LR infused as quickly as possible\*
  - Manual "push-pull" setup
  - Gravity/pressure-bag/pump too slow
  - Must continually reassess
- Additional fluid boluses until tissue perfusion, oxygen delivery and BP adequate (use cap refill time, urine output, lactate, radial arterial BP or SvO<sub>2</sub>/ScO<sub>2</sub>)
  - 60mL/kg in first hour
  - Up to 120mL/kg first several hours
- Colloid not routinely recommended

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## When is aggressive fluid resuscitation a bad thing?

- Third world countries
  - FEAST (Fluid Expansion as Supportive Therapy) trial
  - Increased 48 hr mortality in population of Sub-Saharan African children 60 days – 12 years when albumin or saline boluses given
    - 57% malaria
- First world countries
  - Heart failure
  - DKA
  - Severe anemia

Maitland. NEJM 2011

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## Importance of Antibiotics

- Kumar. Crit Care Med. 2006
  - Each hour delay → 8% increase in mortality (adults)
- Weiss. Crit Care Med. 2014
  - If not administered within three hours increased mortality (OR = 4, 95% CI 1.3 -12.1)
- **DO NOT DELAY ANTIBIOTICS FOR URINE OR CSF CULTURES!**

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## Which Antibiotics?

- Cefotaxime 100mg/kg or Ceftriaxone 75-100mg/kg
  - Cefepime 50mg/kg if immunosuppressed to cover Pseudomonas
  - Gentamicin if affected by cefotaxime shortage
- Vancomycin 15mg/kg (MRSA coverage)
- Add anaerobic coverage for intra-abdominal source
  - Piperacillin-tazobactam or metronidazole
- Cover for herpes in neonates

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## Vasopressors

- When? If no improvement after 40-60mL/kg crystalloid
- What?
  - Warm shock:
    - Norepinephrine
  - Cold shock:
    - Traditionally Dopamine 5-10mcg/kg/min
    - BUT we are moving toward Epinephrine 0.05-0.3mcg/kg/min
- How? Peripheral IV or IO administration acceptable

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## Epi vs. Dopa

- Ventura. Crit Care Med. 2014
  - Single center double-blinded prospective RCT involving 120 children 1 month - 15 years of age
  - Fluid refractory shock in ICU
  - Trial stopped early

### Results:

- 1) Higher mortality associated with dopamine (21% vs. 7%)
- 2) Greater rate of nosocomial infections with dopamine (29% vs 2%)

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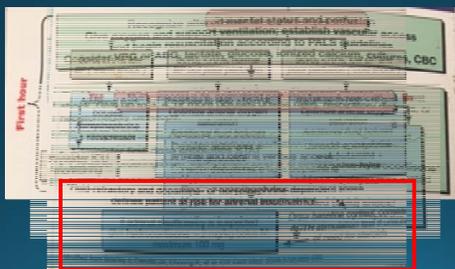
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## Pediatric Septic Shock Algorithm



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## Don't forget steroids in the right setting

- H/o adrenal insufficiency or chronic steroid use
  - Some studies show adrenal insufficiency common in critically ill children
    - Menon 2010: Prospective multicenter study
      - 30% of 381 ICU patients met criteria within 24 hours
      - 43% if receiving catecholamines
- Consider hydrocortisone for pressor-refractory shock

Repeat fluid challenge of NSS<sup>a</sup>  
20 mL/kg IV/IO  
Up to total of 60 mL/kg IV/IO  
**OR**  
to SBP > 70 + (2 x age in years)

If history of Congenital Adrenal Hyperplasia (CAH) or daily steroid use, check glucose and give Hydrocortisone (if available or if carried by patient)  
0 – 3 y/o = 25 mg IV/IO  
3 – 12 y/o = 50 mg IV/IO  
≥ 12 y/o = 100 mg IV/IO  
Or patient's prescribed dose, if known

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## Causes of Neonatal Emergencies: SEPSIS, SEPSIS, SEPSIS

By far the most common, and you should (almost) ALWAYS treat an ill-appearing neonate for potential sepsis  
<https://www.youtube.com/watch?v=O6kRqnfBEc>

BUT - keep an open mind and remember the mnemonics

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## Case

- 7 day-old male brought in by parents for poor feeding
- Mom was initially breast-feeding → switched to formula 2 days ago
- Taking < 1 ounce at a time, fussy and needing frequent breaks
- No fevers, no vomiting
- Normal prenatal course, birth weight 3320g
- Saw PCP 2 days ago, weight 3090g
- Vitals: T 96.4F HR 192 RR 68 BP 68/36 SpO<sub>2</sub> 92% Wt 2875g
- Sunken fontanel, tacky MM
- Tachypnea with grunting, flaring, moderate retractions
- No murmur or gallops, 2+ brachial pulse, 1+ femoral pulse, CR 3 seconds
- Abdomen soft, non-distended, liver 3cm below costal margin

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## Causes of Neonatal Emergencies: Cardiac Disease

### Cyanotic and Obstructive Lesions

- Usually present within first week
- Precipitous deterioration as PDA closes

### Coronary artery abnormalities

- ALCAPA

### Arrhythmias

- SVT



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## Causes of Neonatal Emergencies: Cardiac Disease

### Cyanotic Lesions

- Tricuspid atresia
- Pulmonic atresia
- Transposition of the great arteries

### Obstructive Lesions

- Hypoplastic left heart
- Critical aortic stenosis
- Critical coarctation of the aorta or interrupted aortic arch



\*Most other congenital heart disease patients present at several months of age in heart failure\*

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## Causes of Neonatal Emergencies: Cardiac Disease



### Presentation:

- Slow feeding, *tachypnea* and *tachycardia*, murmur, gallop, *hepatomegaly*, cyanosis, shock

### Workup:

- ECG
- CXR
- 4-extremity blood pressures/sats
- Labs: ABG, CBC, electrolytes
- ECHO

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## Causes of Neonatal Emergencies: Cardiac Disease

### Management:

- Supplemental oxygen
- Fluid boluses (small 10cc/kg) → reassess after each one
- Early discussion with pediatric cardiologist
- **Prostaglandin E. may be life-saving**
  - May cause apnea, bradycardia, hypotension

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## Case

- 3 month-old presenting with decreased responsiveness
- Seemed fine earlier in the day, went down for a nap, hard to arouse 4 hours later
- Emesis x 1, NB/NB
- Vitals: T 94.4F HR 90 RR 18 BP 112/74 SpO<sub>2</sub> 98%
- GCS 7 (E2, V1, M4), intermittent stiffening of upper extremities
- Pupils 7mm → 4mm, symmetric
- Normal heart sounds, 2+ pulses, CR brisk
- Lungs clear, breath sounds symmetric
- Abdomen soft, non-distended, no hepatomegaly
- Bruise on R flank

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## Case cont.

Summary: 3 month-old unresponsive (sudden change), hypothermia, status epilepticus, bruise

- Difficult access → IO placed in right tibia, IV established
- 20 cc/kg 0.9% NaCl pushed through line
- Ativan 0.1mg/kg x 2, fosphenytoin and levetiracetam
- Cultures obtained, vanc/ceftriaxone/acyclovir ordered
- Intubated for respiratory failure and placed on vent
- Transported to CT

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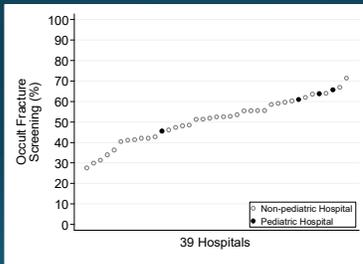
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## Skeletal Survey Use in Infants <1 year with Femur Fractures



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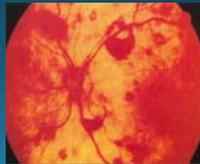
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## Causes of Neonatal Emergencies: Trauma

- Have a high index of suspicion
- May see a bulging fontanel or increased head circumference
- Retinal hemorrhages usually pathognomonic, but not always present
- If hemodynamically unstable → look for sources of bleeding



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## Clues About Increased Intracranial Pressure

- If infant - large or bulging fontanel
- Irritability, vomiting, altered mental status
- Cushing's Triad:
  - 1) Bradycardia (or tachycardia)
  - 2) Hypertension
  - 3) Disordered respirations
- Anisocoria, dilated and sluggish/"blown" pupils
  - Fundoscopic and ocular ultrasound unreliable acutely
- Hemiplegia or posturing
- Mass effect or cerebral edema on CT
  - BUT CT often does not show findings of ↑ ICP in first 24 hours

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# "BRAIN CODE"

Neurocrit Care. Author manuscript; available in PMC 2016 Jun 1.  
Published in final edited form as:  
Neurocrit Care. 2015 Dec; 23(Suppl 2): S76-S82.  
doi: 10.1097/NEU.0000000000000168

PMCID: PMC4791176  
NIDMSID: NIDMS780973

## Emergency Neurological Life Support: Intracranial Hypertension and Herniation

Robert D. Stevens<sup>1</sup>, Michael Shaykhet<sup>2</sup> and Rhonda Cadena<sup>3</sup>

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# Impending Herniation in the ED

- Neurosurgical consult
- General Principles: Avoid hypoxia, hypercarbia, hypotension, hyperthermia, hypoglycemia
  - Provide supplemental oxygen
  - Secure airway
    - Lidocaine with unproven benefit but if given 1mg/kg, allow 3-5 minutes to take effect
  - Maintain perfusion
  - Once intubated, monitor end tidal CO<sub>2</sub>
    - Hyperventilation probably just as bad as hypoventilation; causes ischemia
    - Aim for 35mmHg

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# Impending Herniation in the ED

- Elevate head of bed
- Head in midline position
- Anti-emetics
- Anticonvulsants
- Proper sedation
- Consider dexamethasone 0.5mg/kg (max 10mg) if vasogenic edema present
- Hyperosmolar therapy

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## Causes of Neonatal Emergencies: In-born Errors of Metabolism

### Subtle findings:

- Abnormal tone
- Irritability
- Poor feeding
- FTT
- Vomiting
- Unusual odor to urine

### Overt findings:

- **Acidosis**
- Temperature instability
- Dehydration
- Shock
- Persistent **hypoglycemia**
- Seizures
- **Hepatomegaly**, jaundice
- *May see gram-negative (E. coli) infections in Galactosemia*

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## Causes of Neonatal Emergencies: In-born Errors of Metabolism

### Workup:

- Blood glucose
- Electrolytes
- Blood gas
- Ammonia
- Lactate
- Urine ketones
- Specific testing can be sent, but rarely helpful in the ED
  - Urine organic acids
  - Plasma amino acids
  - Urine reducing substances

### Management:

- Fluid resuscitation
- Often, large amounts of glucose needed to turn off catabolism (D10)
- Early metabolism specialist or pediatric referral center



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## Causes of Neonatal Emergencies: Gastrointestinal Disease

### Malrotation with midgut volvulus

- 90% cases in first 3 months
- Consider in any neonate with emesis that does not look like digested milk
- Often do not have significant abdominal distention

### Duodenal atresia

- Also with bilious emesis
- Look for "double bubble" on x-ray

### Necrotizing enterocolitis

- Suspect in premies but 10% cases occur in full term infants
- Irritability or lethargy, +/- fever, abdominal distention, vomiting or diarrhea
- Look for pneumatosis intestinalis on x-ray

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## Causes of Neonatal Emergencies: Malro with volvulus



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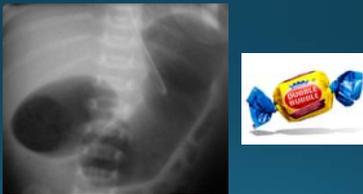
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## Causes of Neonatal Emergencies: Duodenal Atresia



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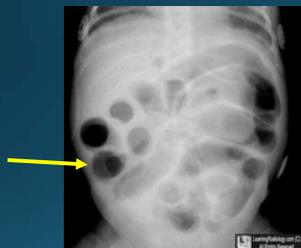
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## Causes of Neonatal Emergencies: Necrotizing Enterocolitis



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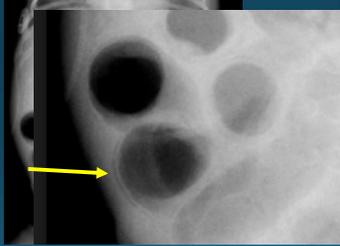
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## Causes of Neonatal Emergencies: Necrotizing Enterocolitis



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## Case

- 2 week old M presenting with vomiting and lethargy
- Sleeping more, parents having to wake him to feed
- Vitals: T 97.6 HR 190 RR 56 BP 59/34 Sat 95%
- Lethargic, cries in response to pain
- Moving all extremities
- No murmurs, rubs, gallops; 1+ pulses throughout; O<sub>2</sub> same upper and lower extremities
- Lungs clear and symmetric
- Abdomen soft, non-tender, no hepatomegaly
- Fingertstick glucose 46

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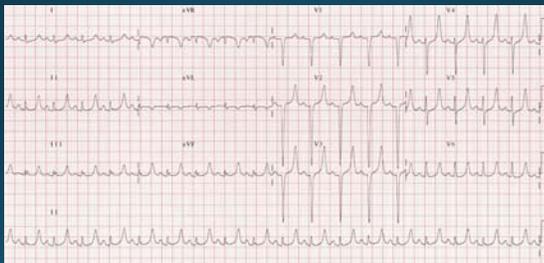
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## Case continued



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## Causes of Neonatal Emergencies: Neurologic Disorders – Seizure

- In first days of life → commonly due to hypoxic-ischemic events
- Often subtle
- Check glucose early

### Other considerations:

- Hypocalcemia, sodium derangements, in-born errors, congenital brain anomalies (CMV, toxo), infection, drug withdrawal, pyridoxine deficiency
  - Give pyridoxine if seizures refractory to benzos, (fos)phenytoin, barbiturates

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## Bonus Case

- 4 month-old with increased sleep over the past three days
- No fever, vomiting or diarrhea
- Last bowel movement was 3 days ago (baseline is daily BM)
- T<sub>37.5</sub> P 136 RR 42 BP 86/52 SpO<sub>2</sub> 97%
- Slightly pale, decreased tone
- Normal heart and lung exam, normal perfusion
- Weak suck and gag

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## Causes of Neonatal Emergencies: Neurologic Disorders - Infant Botulism

- Clostridium botulinum
- Approximately 110 cases/year (72% infant botulism)
- Most from ingestion of environmental dust and soil containing spores



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## Causes of Neonatal Emergencies: Neurologic Disorders - Infant Botulism

- Clostridium botulinum
- Approximately 110 cases/year (72% infant botulism)
- Most from ingestion of environmental dust and soil containing spores



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## Causes of Neonatal Emergencies: Neurologic Disorders - Infant Botulism

- Clostridium botulinum
- Approximately 110 cases/year (72% infant botulism)
- Most from ingestion of environmental dust and soil containing spores



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## Causes of Neonatal Emergencies: Neurologic Disorders - Infant Botulism

- Clostridium botulinum
- Approximately 110 cases/year (72% infant botulism)
- Most from ingestion of environmental dust and soil containing spores



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## Causes of Neonatal Emergencies: Neurologic Disorders - Infant Botulism

### Presentation:

- Can look ill, but generally well perfused and normal hemodynamics
- Afebrile
- **Constipation, feeding difficulties, poor suck, weak cry**, descending or global hypotonia, drooling, respiratory failure

### Management:

- Botulinum toxin recovered from stool
- Call California Department of Health Services
  - Botulism immune globulin (BabyBIG)
- May need intubation and critical care services
- Avoid aminoglycosides



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## Bonus Case

- 5 week-old with 2-3 days of vomiting and diarrhea
- No fever
- Had previously been well
- T<sub>37.4</sub> P 176 RR 42 BP 75/43 SpO<sub>2</sub> 87%
- Ill-appearing and dusky, sunken anterior fontanel
- Dry mucous membranes
- 1/6 systolic murmur upper sternal border radiating to back
- Soft, non-tender abdomen, liver edge at costal margin

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## Case

- Differential:
  - Shock (sepsis, cardiogenic, hypovolemic)
  - Pneumonia, bronchiolitis
  - Congenital heart disease (R → L shunting)
  - Methemoglobinemia

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What is the most important next intervention?

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What is the most important next intervention?

- Administration of 100% FiO<sub>2</sub> via non-rebreather leads to no change in pulse ox reading
- This makes pulmonary etiology less likely

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Next steps?

- 4 extremity BPs, 4 extremity O<sub>2</sub> Sat, EKG, CXR, labs

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## What is the diagnosis?

- EKG sinus tachycardia
- Labs normal
- Fluids are administered
- O<sub>2</sub> still 88%



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## What is the diagnosis?

### Methemoglobinemia

- Ferrous iron (Fe<sup>2+</sup>) oxidized to ferric (Fe<sup>3+</sup>) state which cannot bind oxygen
- Causes: infections/diarrhea/acidosis, well-water contaminated with nitrates, medications (**benzocaine**, lidocaine, sulfonamides)
  - Particular susceptibility due to lower cytochrome B<sub>5</sub> reductase, ease of oxidation of HbF and increased nitrate → nitrite converting intestinal flora
- Diagnosis: MetHb level by co-oximetry
  - Chocolate brown blood may be a clue
- Treatment: Methylene blue 1mg/kg when levels > 30%

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## Summary

- Think broadly for reasons why a neonate may appear ill (THE MISFITS; NEO SECRETS)
- Keep in mind key components of the history and physical examination to help differentiate etiologies of septic-appearing newborns
- Address signs of shock early as neonates often decompensate quickly

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The End



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Thank you!

Questions?

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**AAFP Highlight on  
Vaccinations 4 Teens**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***AAFP Highlight on Vaccinations 4 Teens***

Madalyn Schaeffgen, MD

Robbin Thibodeaux

**Disclosures:**

The speakers have no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speakers have attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speakers indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

***This program is provided through the AAFP Foundation's Family Medicine Philanthropic Consortium with support from Sanofi Pasteur.***



*Highlight on*  
**VACCINATIONS 4 TEENS**

Reading CME Conference  
November 18, 2017  
Madalyn Schaeffgen, MD, FAAFP




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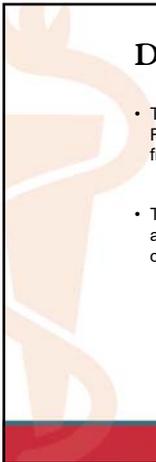
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## Program Overview

- Despite CDC recommendations, millions of teens remain under-vaccinated<sup>1,2</sup>
- *Highlight on VACCINATIONS 4 TEENS* provides support for family physicians and care teams to help see that more teen patients are up-to-date on vaccinations, using the 16-year visit as a prime opportunity
- A variety of program materials are available for your practices here:  
[www.aafpfoundation.org/vaccinations4teens](http://www.aafpfoundation.org/vaccinations4teens)

1. Centers for Disease Control and Prevention. (2016). National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2015. Retrieved from [http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6103a1.htm?\\_id=mm6103a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6103a1.htm?_id=mm6103a1_e)  
2. United States Census Bureau. (2013). Age and Sex Composition in the United States. Retrieved from <http://www.census.gov/popest/data/totals/2013/comp.html>. Accessed October 16, 2016.

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## Agenda and Speakers

**Know the Facts: Under-vaccination Among Teens in the U.S. and Pennsylvania**

**The Day My Life Changed Forever: Robbin Thibodeaux**

**Make an Impact, One Patient at a Time: Madalyn Schaeffgen, MD, FAAFP**

**How to Make a Difference: Q&A Session**

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## KNOW THE FACTS

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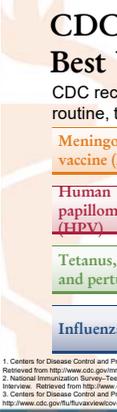
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## CDC Considers Vaccination the Best Way to Help Protect Teens

CDC recommends that teens receive four vaccinations, as a matter of routine, to help protect against serious infectious diseases:

<b>Meningococcal vaccine (MenACWY)</b>	Only 33.3% of eligible adolescents (by the time they were interviewed at 17 years of age) received the recommended second dose of MenACWY vaccine in 2015 <sup>1</sup>
<b>Human papillomavirus (HPV)</b>	In 2015, only 41.9% of girls and 28.1% of boys completed the HPV vaccine series <sup>2</sup>
<b>Tetanus, diphtheria and pertussis (Tdap)</b>	86% of teens received the Tdap booster in 2015 <sup>1,2</sup>
<b>Influenza (flu)</b>	Just 46.8% of teens were vaccinated against flu in 2015 <sup>3</sup>

<sup>1</sup> Centers for Disease Control and Prevention. (2016). National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years — United States, 2015. Retrieved from [http://www.cdc.gov/mmwr/volumes/65/wr/mm6533a4.htm?\\_id=mm6533a4\\_a](http://www.cdc.gov/mmwr/volumes/65/wr/mm6533a4.htm?_id=mm6533a4_a).  
<sup>2</sup> National Immunization Survey-Teen (NIS-Teen), United States (2015). Estimated Vaccination Coverage with Selected Vaccines and Doses among Adolescents aged 13-17\* Years, by Age at Interview. Retrieved from [http://www.cdc.gov/mmwr/volumes/65/wr/mm6533a4.htm?\\_id=mm6533a4\\_a#f1\\_down](http://www.cdc.gov/mmwr/volumes/65/wr/mm6533a4.htm?_id=mm6533a4_a#f1_down).  
<sup>3</sup> Centers for Disease Control and Prevention. (2015, September 29). Flu Vaccination Coverage, United States, 2015-16 Influenza Season. Retrieved from <http://www.cdc.gov/flu/avac/viewcoverage-1516csmates.htm>.

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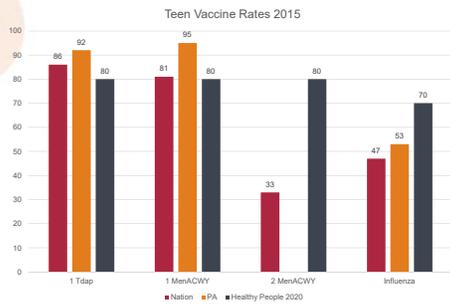
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## Where Do We Stand In Pennsylvania?



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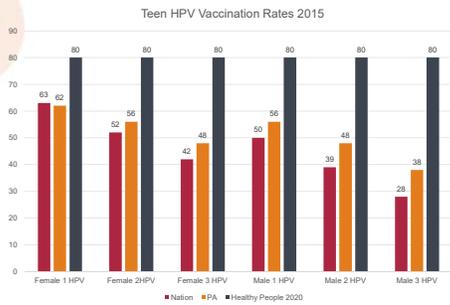
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## Where Do We Stand In Pennsylvania?



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## Pertussis

- 48,277 cases in USA in 2012, the most reported since 1955
- 2012 outbreaks of Pertussis in CA and MI
- In PA
  - 2010 – 979
  - 2011 – 742
  - 2012 – 1945
  - 2013 – 633
  - 2014 – 691

[http://www.pennlive.com/midstate/index.ssf/2014/12/whooping\\_cough\\_pertussis\\_outbr.html](http://www.pennlive.com/midstate/index.ssf/2014/12/whooping_cough_pertussis_outbr.html)

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## HPV

- 24,600 cases each year in the US of newly diagnosed cancer attributable to two high risk HPV types.
- Plus 3,800 more cancer cases attributable to 5 additional high risk HPV types

• <https://www.cdc.gov/mmwr/volumes/65/wr/mm6533a4.htm>

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## Influenza

- 2016-2017 influenza season
  - 71,272 Total cases in PA
  - 149 deaths in PA alone

- [http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/L-L/Documents/2016.17\\_Flu\\_Season.pdf](http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/L-L/Documents/2016.17_Flu_Season.pdf)

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## 2017 Pennsylvania School Vaccination Requirements for Attendance

- All grades –
  - 4 doses of tetanus, diphtheria and acellular pertussis (one on or after 4<sup>th</sup> birthday) – usually DTaP
  - 4 doses of polio (one on or after 4<sup>th</sup> birthday and at least 6 months since previous dose, or 3 doses if the 3<sup>rd</sup> dose is on or after 4<sup>th</sup> birthday and at least 6 months since previous dose)
  - 2 doses of measles, mumps and rubella (usually MMR)
  - 3 doses of hepatitis B
  - 2 doses of varicella or evidence of immunity

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## 2017 Pennsylvania School Vaccination Requirements for Attendance continued...

- 7<sup>th</sup> grade
  - One dose of Tdap
  - One dose of meningococcal vaccine (MCV)
- 12<sup>th</sup> grade
  - One dose of meningococcal vaccine (MCV) after age 16
- Exemptions include medical reasons, religious beliefs, philosophical/strong moral or ethical conviction. Children may be excluded from school during an outbreak of vaccine preventable disease.

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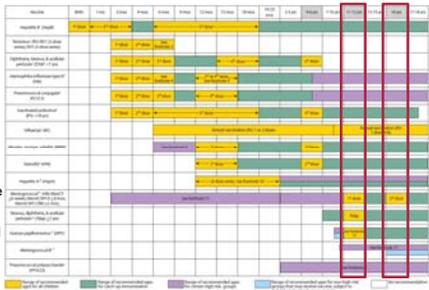
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## Important Visits for Teen Vaccination

- Teenage years are critical times for vaccines; two key visits are the 11-12-year-old and 16-year-old visits
- If a child misses or delays the 11-12-year-old visit, the schedule for some adolescent vaccinations may be thrown off
- 2017 Childhood and Adolescent Immunization Schedule calls out both of these important visits<sup>1</sup>



1. Centers for Disease Control and Prevention (2017). Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017. Retrieved from <https://www.cdc.gov/vaccines/schedules/downloads/0920-18yrs-combined-schedule-bw.pdf>

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## Demystifying the Immunization Schedule

- <https://www.youtube.com/watch?v=qcR8tQaD3HE&feature=youtu.be>

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## Highlight on VACCINATIONS 4 TEENS

Features a robust Resource Library of materials for family physician offices, including:

- Back-of-office materials
  - Q&A to address questions from teen patients and parents/guardians
  - Three educational videos from Dr. Margot Savoy, MD, MPH, FAAFP and AAFP liaison to ACIP, on:
    - The value of the immunization platforms and making the most out of the 11-12 and 16-year-old visits
    - Tips for using the schedule
    - Standing orders and activating staff as champions
  - Links to other educational videos on meningococcal and HPV vaccination
  - A fact sheet on the importance of addressing under-vaccination



Visit [www.aafpfoundation.org/vaccinations4teens](http://www.aafpfoundation.org/vaccinations4teens) to download these resources.

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## Highlight on VACCINATIONS 4 TEENS, cont.

- Front-of-office materials
  - Reminder communications for parents/guardians
    - Letters/emails
    - Postcards
    - Text messages
  - Teen vaccination overview poster/handout
  - Template digital and social media content directed to teens and parents/guardians
  - Personal testimonials



Visit [www.aafpfoundation.org/vaccinations4teens](http://www.aafpfoundation.org/vaccinations4teens) to download these resources.

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## THE DAY MY LIFE CHANGED FOREVER

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# Meningococcal Meningitis: A Parent's Perspective



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## The Purpose for My Presentation

- To Tell My Son's Story
- To Bring Awareness to Meningitis
- To Get the People We Love – Vaccinated!
- To Help Save a Life!



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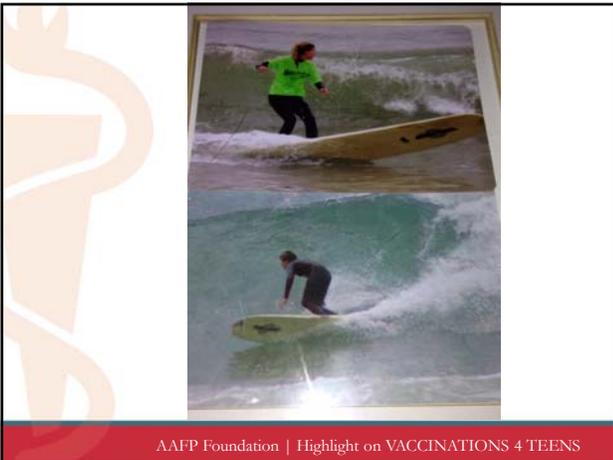
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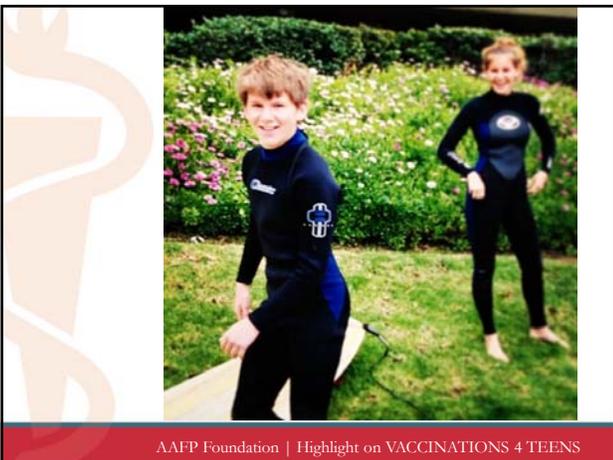
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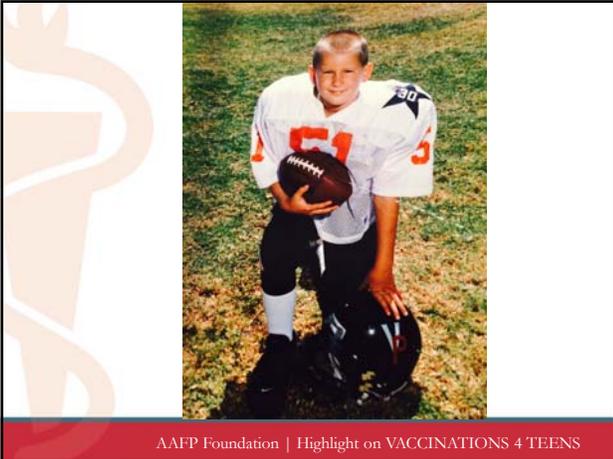
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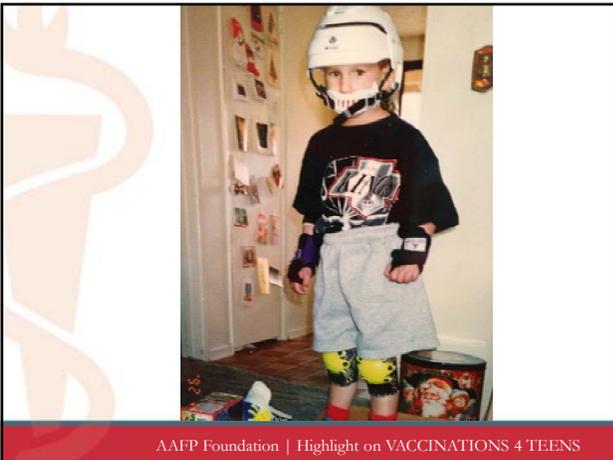
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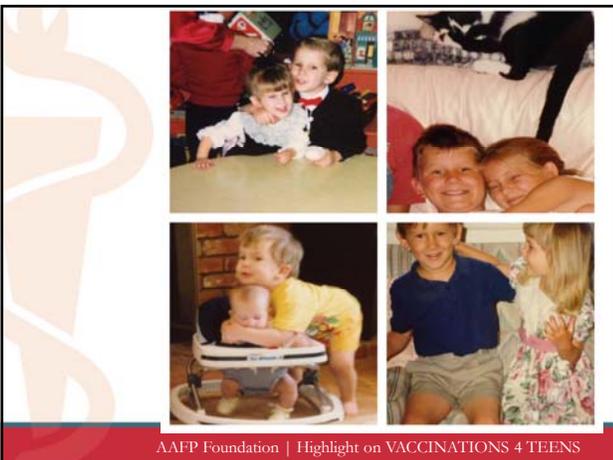
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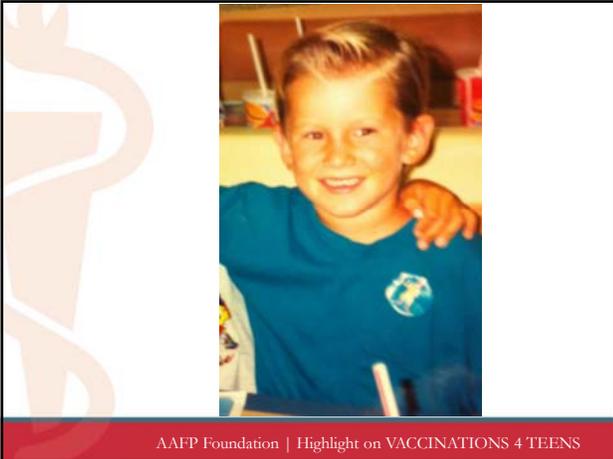
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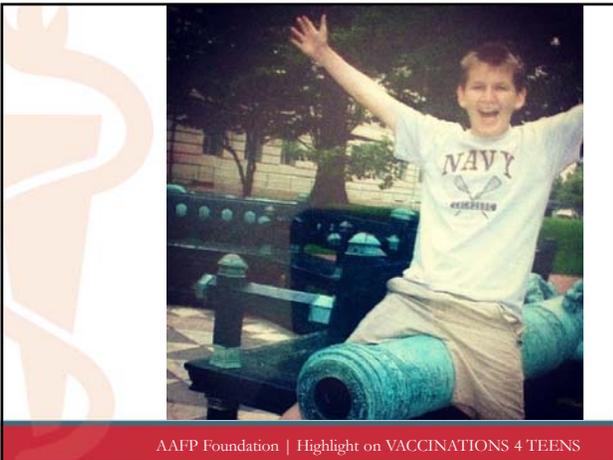
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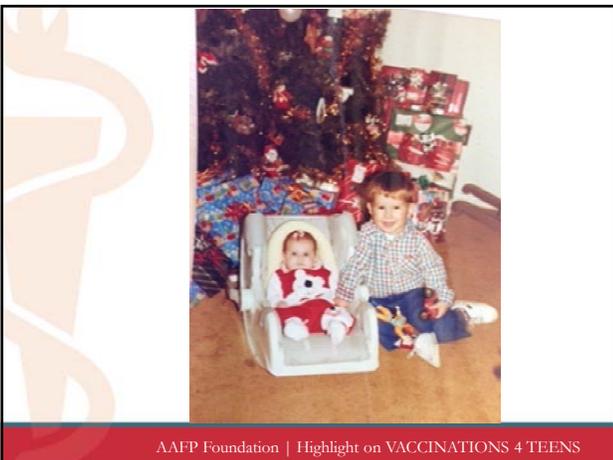
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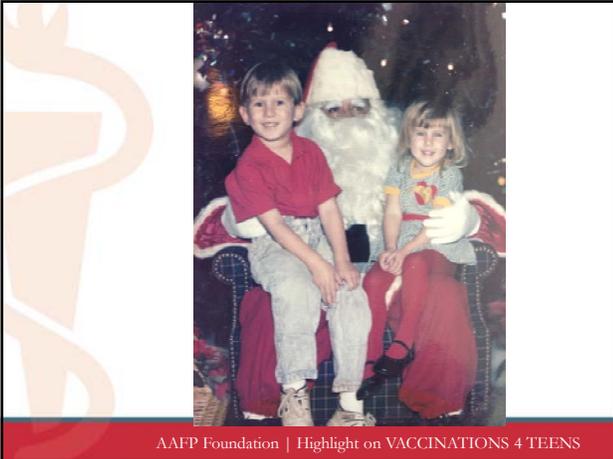
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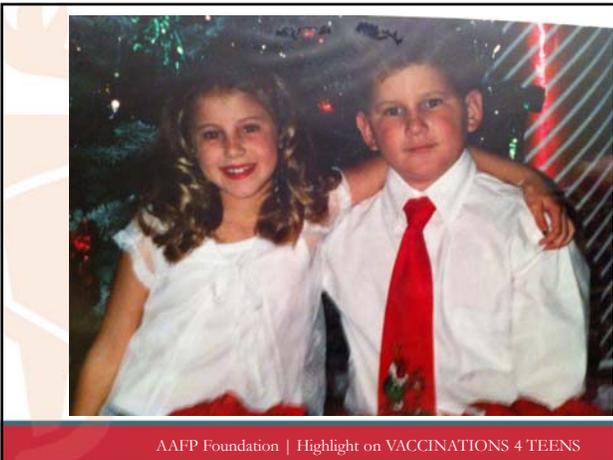
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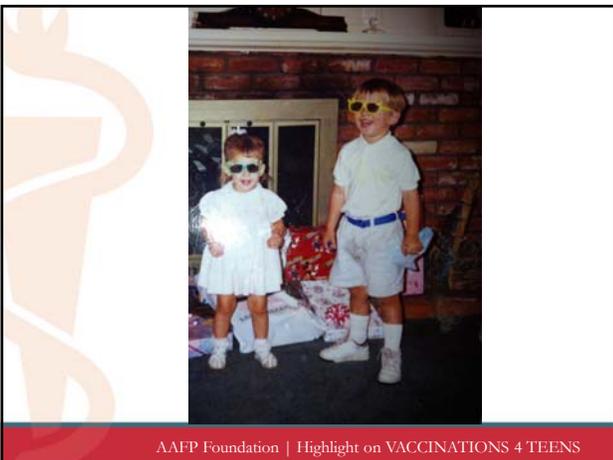
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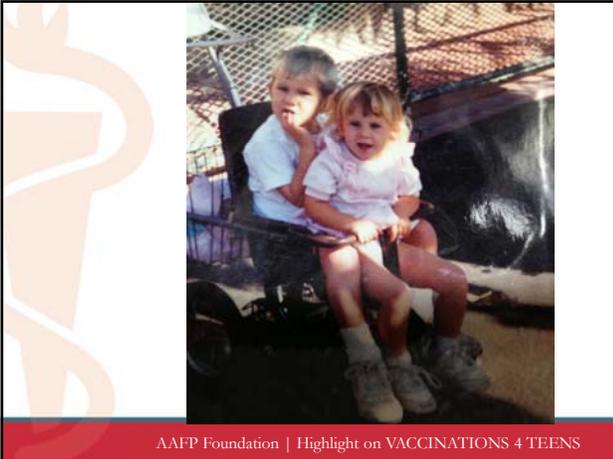
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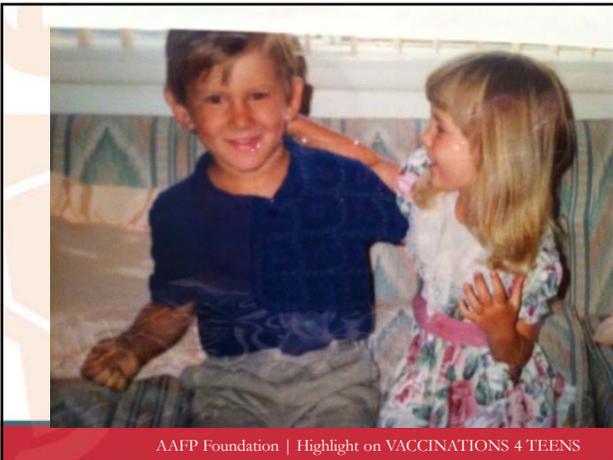
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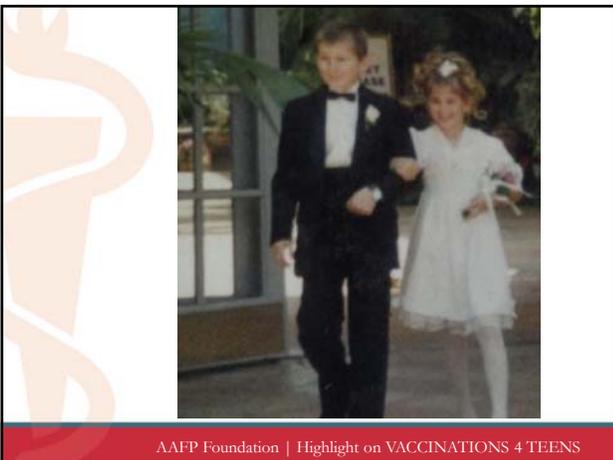
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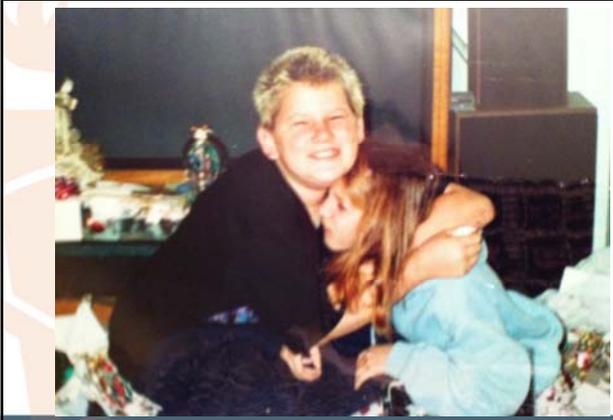
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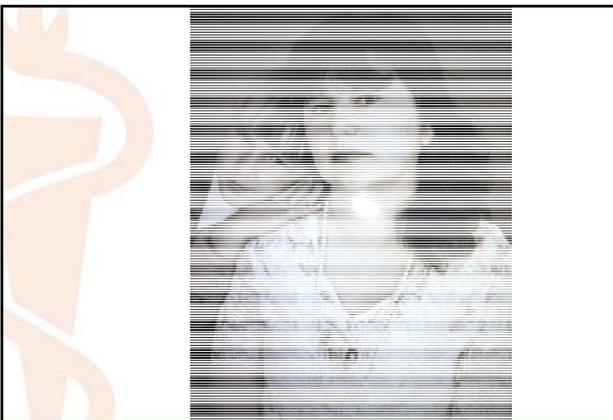
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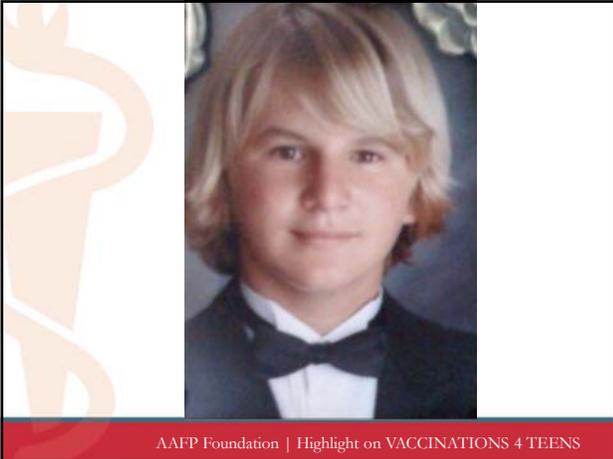
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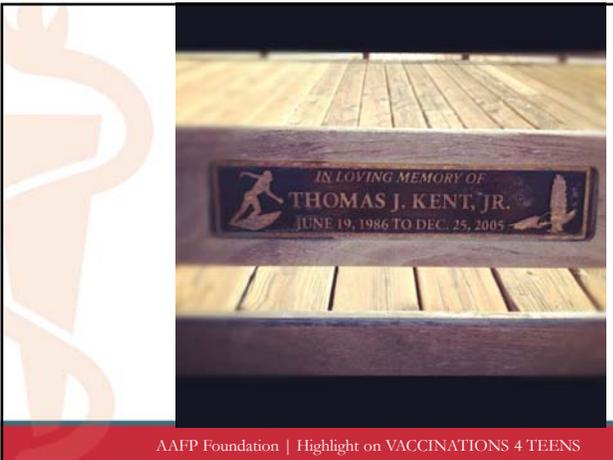
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### HPV Patient and Caregiver Testimonials

- Compelling patient and caregiver testimonial videos are available from the National HPV Vaccination Roundtable (American Cancer Society):
  - ["HPV Survivor Stories"](#) (Individual patient video links also listed below)
  - ["HPV Survivors – Christine Baze"](#)
  - ["HPV Stories – Christine Baze and Dr. Linda Duska"](#)
  - ["HPV Survivor – Scott Vetter"](#)
  - ["HPV Stories – Scott Vetter and Dr. Cherie Ann Nathan"](#)
  - ["HPV Survivor – Tamika Felder"](#)
  - ["HPV Survivor – Frank Summers"](#)
  - ["HPV Caregiver – Justine Almada"](#)

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MAKE AN IMPACT,  
ONE PATIENT AT A TIME

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### Strategies for Increasing Teen Vaccination Rates

- There are ways to address vaccine hesitancy<sup>1</sup>
  - **Discuss vaccine safety and benefits** in a nonjudgmental way
  - **Understand your patient and their concerns:** Cultural pressure, misinformation and fear of harm are reasons for vaccination hesitation
  - **Give a strong recommendation:** Open the conversation with a presumptive approach and remember that persistence matters
  - **Live to fight another day:** Despite best efforts, a small percentage of patients will refuse one or more vaccines; preserve the relationship with the patient and table the conversation for another day

1. Loeber J. and Savoy M. Strategies for Addressing and Overcoming Vaccine Hesitancy. Am Fam Physician. 2016 Jul 15;94(2):94-96. Retrieved from <http://www.aafp.org/afp/2016/0715/94.html>.

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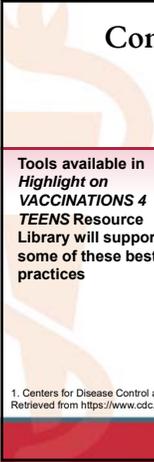
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### Common Key Best Practices

**Tools available in Highlight on VACCINATIONS 4 TEENS Resource Library will support some of these best practices**

- **Know the vaccine schedules** (or where to find them) and educate your staff
- **Strongly recommend** adolescent vaccines to patients aged 11 through 18 years and parents/guardians<sup>1</sup>
- **Use every opportunity** to vaccinate adolescent patients<sup>1</sup>
- **Use patient reminder and recall systems** such as automated postcards, phone calls and text messages<sup>1</sup>

1. Centers for Disease Control and Prevention (2016). Preteen and Teen Vaccines: For Health Care Professionals/Clinicians. Retrieved from <https://www.cdc.gov/vaccines/who/teens/for-hcp.html>.

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## Common Key Best Practices cont'd

- **Educate parents/guardians** about the diseases that can be prevented by adolescent vaccines<sup>1</sup>
- **Implement standing orders policies** so that patients can receive vaccines without a physician examination or individual physician order<sup>1</sup>
- **Remember to work with staff** to check patients' vaccination records and update the state immunization registry

1. Centers for Disease Control and Prevention (2016). Preteen and Teen Vaccines: For Health Care Professionals/Clinicians. Retrieved from <https://www.cdc.gov/vaccines/who/teens/for-hcp.html>

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## AAFP Adult Immunization Office Champion Project

- Research into ways to improve immunization rates in adults in the US with plans to disseminate the processes that work to other family medicine offices across the country.
- A 3 year project
  - Started with gathering in June 2016
  - Phase 1 trial, Phase 2 sustainability
- Involves 25 family medicine practices across the country

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LEHIGH VALLEY HEALTH NETWORK

## AAFP Adult Immunization Office Champion Project

LVPF Family Medicine at Cetronia

**Madalyn Schaeffgen, MD, FAFP**

© 2015 Lehigh Valley Health Network

A PASSION FOR BETTER MEDICINE.™ 610-402-CARE LVHN.org




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### 3 Year Project: August 2016 – July 2019

- Patient education in the waiting room – posters, handouts
- Staff and provider education
  - Standing orders
  - Quick texts
  - Pre-visit planning
  - Need to check immunization status at every visit.
  - Strong recommendations from all staff/providers
- Access –
  - decrease financial barriers (use VFC, discuss ACA coverage for ACIP A & B recommended vaccines, stock enough vaccine)
- Documentation
  - Increase data collection through SIIS
  - Pharmacies
  - employee health
  - flu clinics
  - Health Bureau
- Increase Rates
  - Incentives/rewards for staff –
    - Clerical – most scheduled vaccines
    - Clinical – most increased rate
  - Recall/reminder systems – pre-visit planning, use health maintenance
  - Use standing orders
  - Provider Feedback monthly on performance rates

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### First Year

- 8/22/2016 Seasonal influenza vaccinations began
- 9/2/2016 Staff meeting with education and review of the following:
  - Adult immunizations, schedules – resource guides placed at immunization refrigerators and pocket cards given to staff
  - Standing orders
  - Need to be proactive
  - Discussion of addressing barriers and ways to improve immunization rates
  - Trifold poster of adult immunizations placed in waiting room, Pneumonia vaccine posters placed on entrance and exit doors
  - Handouts from AAFP given to patients regarding benefits of the vaccines if patient declined the vaccine at the end of the visit.
- 12/1/2016 Sent bulk letters to patients to encourage to come in for flu vaccines

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### AUGUST 2016 POSTER



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# ENTRANCE/EXIT POSTERS




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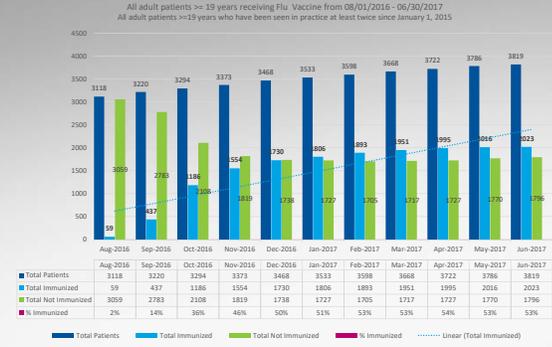
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## Cetronia Practice - Influenza Vaccine Tracking




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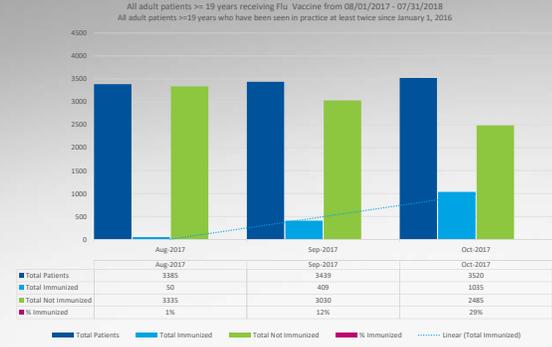
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## Cetronia Practice - Influenza Vaccine Tracking




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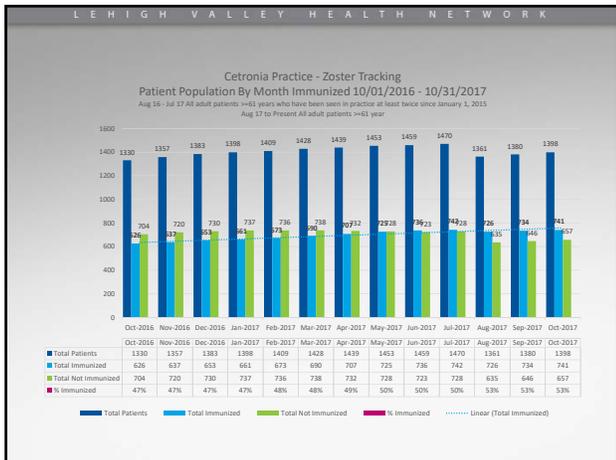
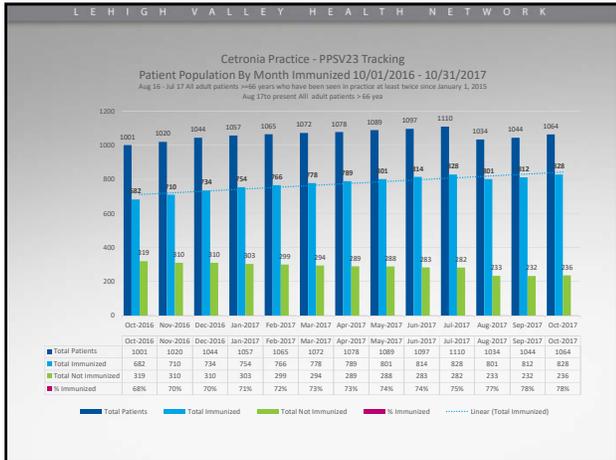
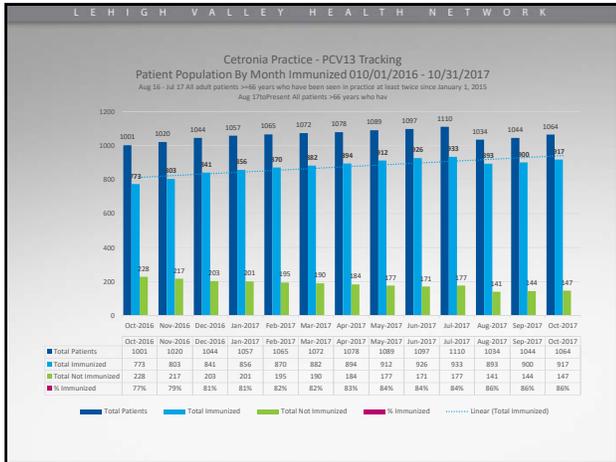
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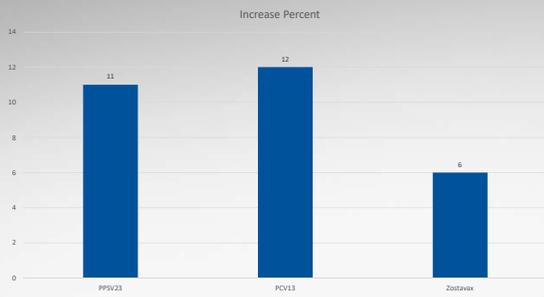
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## August 2016 to October 2017 Increase in Immunization Rates



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HOW TO MAKE A DIFFERENCE:  
Q&A

AAFP Foundation | Highlight on VACCINATIONS 4 TEENS

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Thank You!

*This program provided through the AAFP Foundation's  
Family Medicine Philanthropic Consortium  
with support from Sanofi Pasteur.*

 **AAFP** | **Highlight**  
FOUNDATION ON VACCINATIONS 4 TEENS

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**[Return to Top](#)**

**KEYNOTE - "The Three P's: Pride,  
Passion, and Purpose"**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***KEYNOTE - "The Three P's: Pride, Passion, and Purpose"***  
Steve Gilliland

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

**\*\*SESSION HANDOUTS ARE NOT AVAILABLE  
ONLINE.\*\***

**[Return to Top](#)**

## **Panel on Burnout and Discussion Groups**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

***Panel on Burnout and Discussion Groups***

Steve Gilliland, Donald Beckstead, MD,  
Michael Gaudiose, MD, and Lynn Rogers, LCSW

**Disclosures:**

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Physician Wellness

Lynn M. Rogers, LCSW  
Don Beckstead, MD, FAAFP

UPMC Altoona Family Physicians  
Altoona, PA

11/18/17

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Disclosure

\* The speakers have no conflict of interest, financial agreement, or working affiliation with any group or organization.

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Is it *really* a problem?

Shanafelt, et. al. surveyed 6,880 physicians in 2011 and again in 2014

They surveyed the participants using the Maslach Burnout Inventory (MBI)

MBI is rigorously validated assessment tool which is considered to be the gold standard for measuring burnout

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## Burnout

- 54.4% indicated they experienced at least 1 symptom of burnout.
- 40.9% said they were satisfied with their Work/Life balance.
- 46.9% scored high for emotional exhaustion

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## Burnout and Depression

- 39.6% reported high levels of emotional exhaustion.
- 37.7% reported high levels of depersonalization
- 51.4% scored high for burnout.
- 40% screened positive for depression**
- 6.3% admitted to suicidal ideation in the previous 12 months.**

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## Yes, It *really* is a problem!

- Relationship problems
- Patient safety
- Legal problems
- Substance Use
- Depression
- Anxiety
- Traffic Violations
- Impaired Memory
- Medical Errors
- Sleep problems

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We know it's a  
problem.  
What can we do  
about it?

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Burnout- Top 10 causes per 2017  
Medscape poll of physicians

- \* 1. Too many bureaucratic tasks
- \* 2. Work too many hours
- \* 3. Feeling like a cog in a wheel
- \* 4. Increased computerization of practice
- \* 5. Income too low
- \* 6. Difficult patients
- \* 7. Insurance issues
- \* 8. MOC requirements
- \* 9. Lack of professional fulfillment
- \* 10. Threat of malpractice

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AAFP Position Paper- Burnout Causes

- \* Medicolegal issues
- \* Frustrations with referral networks
- \* Finding work-life balance
- \* Frequent on-call
- \* Reimbursement issues
- \* Feeling undervalued

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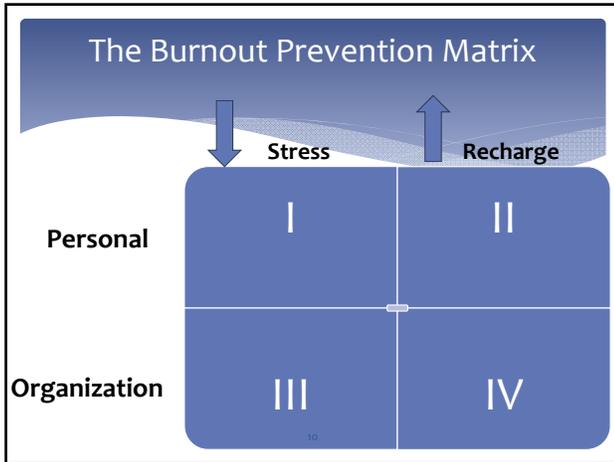
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### Quadrant I: Personal Tools to Decrease the Stress & Energy Drain

- Journaling
- Improve skills to handle difficult patients
- Systematize your practice
- Design your ideal practice, then plan strategies to align with your practice
- Improve your organizing/filing
- Work less hours?
- Understand your finances
- Learn Mindfulness Stress Reduction
  - meditation, take moments to “just be present”
  - stress release breathing techniques

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### Quadrant II: Personal Recharge Activities

- Create, schedule and execute your personal exercise and nutrition programs
- Prioritize and schedule time for your important relationships
- Prioritize and schedule time for hobbies, interests, charities, or creative pursuits
- Prioritize and schedule ‘DOWN TIME’ with NOTHING TO DO!  
Corollary= “Scheduled Spontaneity”

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### Quadrant III: Organizational Support to Decrease Stress and Energy Drain- loy in Practice Article

- \* Pre-visit planning
- \* Labs before upcoming visits
- \* Extended team care/ PCMH
- \* Standing orders/order entry
- \* Scribing
- \* Rx renewal protocols
- \* Verbal vs electronic messages; clerical tasks
- \* Periodic staff meets to assess the week/processes

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### Quadrant IV: Organizational Recharge Activities

- \* Onsite exercise facilities and exercise classes
- \* Walking groups at lunch
- \* Onsite programs to teach healthcare stress management and burnout prevention
- \* Onsite programs to teach and allow the practice of mindfulness, meditation and other stress relief tools (Yoga, Tai Chi, etc.) to physician and staff during work days

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### Next Steps

Choose a couple of suggestions from each quadrant and commit to **follow through** with them!

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## UPMC Altoona FM Residency

- \* Wellness program during orientation
- \* Monthly resident support group
- \* Wellness curriculum
- \* Individual resident “check-in” sessions
- \* Text/e-mail “check-ins w/ individuals/groups
- \* Monthly resident dinners
- \* Resident retreats
- \* Holiday parties/picnics throughout the year
- \* Mindfulness presentations/exercises
- \* Partnership with local wellness/fitness center

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## UPMC Altoona FM Residency

- \* Altoona Curve baseball tickets
- \* Resident recognition program
- \* Cultural stipend
- \* Sports jersey Fridays
- \* Lend-A-Hand program
- \* UPMC Life Solutions
- \* UPMC Resident/Fellow Assistance Program
- \* Physician wellness = weekly fac. meeting agenda item
- \* “Open-door” policy --- culture of caring
- \* Flexibility in rotations/esp. <sub>17</sub>electives

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## MISCELLANEOUS

- \* Technology/Connectivity
  - EHR @ home
  - e-mails
  - Facebook/Twitter etc.
- \* Expectation of 24/7 availability
- \* Understand what work/life issues deplete you
- \* Recurrent mundane tasks
- \* Martyr syndrome
- \* Learn to say “No”
- \* “Staycations”

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[www.healthleadersmedia.com](http://www.healthleadersmedia.com), [www.medscape.com](http://www.medscape.com) 19

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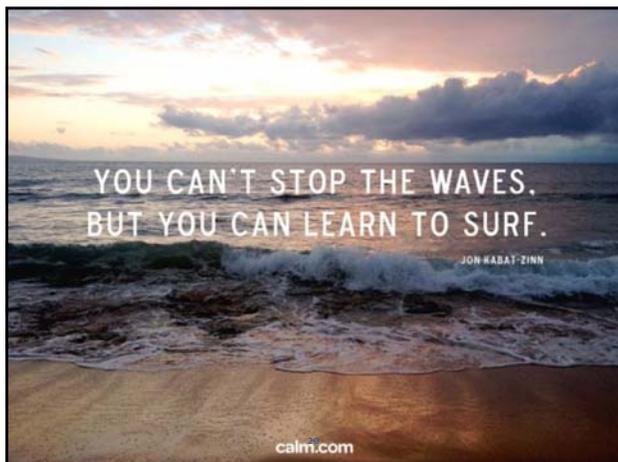
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**Marijuana for Medical Use –  
Just the Facts M'aam**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

Marijuana for Medical Use – Just the Facts M'aam  
Sarah Mullins, MD

**Disclosures:**

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# Medical Cannabis: Lessons Learned by a Family Doctor

Sarah Mullins MD  
Delaware Family Physician of the Year 2016  
Delaware Academy of Family Physicians, Assistant Secretary  
Epilepsy Foundation of Delaware  
AAFP Tobacco Cessation Advisory Committee

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# Disclosure: These experiences and views are my own!

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

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# Where do you work?

- 1) Primary Care Family Medicine
- 2) Primary Care Internal Medicine
- 3) Geriatrics
- 4) Hospice
- 5) Other

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Where do you work?

- 1) Delaware
- 2) Pennsylvania
- 3) New Jersey
- 4) Maryland
- 5) Other



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Have you certified a patient for cannabis?

- 1) Yes
- 2) No
- 3) Not available in my state



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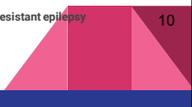
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## Policy

- **Medical Cannabis legal in 46 states, Puerto Rico, Guam and DC, Schedule 1 by federal law**
- **AAFP Policy Statement**
  - Recognizes that there is support for the medical use of marijuana
  - Does not endorse state laws approving medical use
  - Supports federal reclassification and funding of high quality research
- **Epilepsy Foundation**
  - "Not unreasonable" to consider compassionate use in drug resistant epilepsy
  - Actively advocating for federal rescheduling of cannabis



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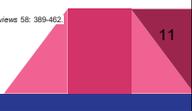
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## The Issues

- **Prohibition has limited research access and funding**
- **Diverse strains with different ratios of > 60 cannabinoids**
- **Societal concerns regarding increased access**
  - MVAs, opioid OD decreases
- **Concerns about long term effects**
- **Public pressure, anecdotal cases**

Fischer et al. 2006. [The endocannabinoid system as an emerging target of pharmacotherapy](#). *Pharmaceutical Reviews* 58: 389-402.



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## Current Research



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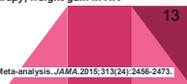
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## A Systematic Review and Meta-analysis

- Cannabinoids for Medical Use published in JAMA 2015
- Analyzed 79 RCTs of cannabinoids for:
  - nausea and vomiting due to chemotherapy, appetite stimulation in HIV/AIDS, chronic pain, spasticity due to multiple sclerosis or paraplegia, depression, anxiety disorder, sleep disorder, psychosis, glaucoma, or Tourette syndrome
- 6462 patients, studied patient-relevant/disease-specific outcomes
- Results
  - Moderate-quality evidence: Chronic pain and spasticity
  - Low-quality evidence: nausea and vomiting due to chemotherapy, weight gain in HIV infection, sleep disorders, and Tourette syndrome
  - Increased risk of short term side effects

Whiting PF, Wolff RF, Deshpande S, et al. Cannabinoids for Medical Use: A Systematic Review and Meta-analysis. JAMA. 2015;313(24):2456-2473.



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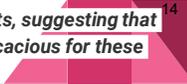
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## Pain and Cannabis

- MEDLINE review of 28 RCT on cannabis JAMA 2015
- Use of marijuana for chronic pain, neuropathic pain, and spasticity due to multiple sclerosis is supported by high-quality evidence
- Six trials that included 325 patients examined chronic pain, 6 trials that included 396 patients investigated neuropathic pain, and 12 trials that included 1600 patients treated on multiple sclerosis

Medical Marijuana for Treatment of Chronic Pain and Other Medical and Psychiatric Problems: A Clinical Review. Kevin P. Hill, MD, MHS. JAMA. 2015;313(24):2474-2483. doi:10.1001/jama.2015.6199

Several of these trials had positive results, suggesting that marijuana or cannabinoids may be efficacious for these indications



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### CBD in Dravet Syndrome

- Phase 3 multicenter, double-blind RCT, 120 2-18 year olds
- Orphan drug and Fast Track Designation by FDA
- On average, age 10, taking 4 AEDs, 13 convulsive seizures per month
- Results
  - 39% reduction in monthly seizures (placebo 13%, p <0.001)
  - Well tolerated
    - somnolence, diarrhea, decreased appetite, fatigue, pyrexia, vomiting, lethargy, upper respiratory tract infection and convulsion
    - 84% rated side effects mild or moderate
    - 8 patients discontinued treatment
  - Similar results with Lennox-Gastaut atonic seizures, plan to trial infantile spasms, tuberous sclerosis complex

GW Pharmaceuticals Announces Positive Phase 3 Pivotal Study Results for Epidiolex (cannabidiol) 14 March 2016, Press Release accessed 12 Sept 2016.

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### Long-Term Safety

- Lack of correlation with lung cancer, anxiety, depression
- Increased risk of psychosis, respiratory irritation
- Impaired Cognitive Function
  - Basic motor coordination
  - Complex executive function tasks
    - ability to plan, organize, solve problems, make decisions, remember, and control emotions and behavior

**Many studies apply to smoked, whole plant preparations**

An Evidence Based Review of Acute and Long-Term Effects of Cannabis Use on Executive Cognitive Functions. Rebecca B. Gray, Ph.D., 1 | Natalie A. Clancy, B.S., 1 and Barbara J. Meisler, Ph.D., 1 *J Addict Med*. 2013; 16(1):1-5  
 Moore, T. H., S. Zammit, et al. (2007). "Cannabis use and risk of psychotic or affective mental health outcomes: a systematic review." *Lancet* 370(9564): 210-23.  
 Mohr, R., B. A. Moore, et al. (2006). "The association between marijuana smoking and lung cancer: a systematic review." *Arch Intern Med* 166(13): 1359-67.

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- 599 current studies on Clinicaltrials.gov
- What can we do about conditions not well studied?

## Clinical Trials

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Delaware's Medical Marijuana Program

- Law passed July 1 2012
- First State Compassion Center opened July 2015
- Application fee \$125, average monthly meds for chronic pain ~\$200
- Currently, over 1500 cardholders, certified by ~300 physicians

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First State Compassion Center



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Adult Qualifying Conditions

- **Cancer**
- **Positive status for Human Immunodeficiency Virus (HIV Positive)**
- **Acquired Immune Deficiency Syndrome (AIDS)**
- **Decompensated cirrhosis**
- **Amyotrophic Lateral Sclerosis (ALS / Lou Gehrig's Disease)**
- **Agitation of Alzheimer's disease**
- **Post-traumatic Stress Disorder (PTSD) \*Note: MUST be a licensed psychiatrist to certify this condition**
- **Intractable epilepsy**
- **Autism with self-injurious or aggressive behavior**

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### Adult Qualifying Conditions

- **A chronic or debilitating disease or medical condition or its treatment that produces one or more of the following**
  - Cachexia or wasting syndrome
  - Severe, debilitating pain that has not responded to previously prescribed medication or surgical measure for more than three months, or for which other treatment options produced serious side effects.
  - Intractable nausea
  - Seizures
  - Severe and persistent muscle spasms, including but not limited to those characteristic of Multiple Sclerosis

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### Pediatric Qualifying Conditions

- Intractable epilepsy
- A chronic or debilitating disease or medical condition where they have failed treatment involving one or more of the following symptoms
  - Cachexia or wasting syndrome
  - Intractable nausea
  - Severe, painful and persistent muscle spasms

*Must be a peds GI, onc, neuro or palliative care*

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PHYSICIAN CERTIFICATION	
I have made or confirmed a diagnosis of a debilitating medical condition, as defined in Title 16, Chapter 49A of the Delaware Code (4902A(3)), for the qualifying patient.	_____ <small>Physician Initials</small>
I have established a bona fide physician-patient relationship with _____ (patient) beginning _____ (date of first patient visit to your office). This qualifying patient is under my care, either for primary care or the debilitating medical condition listed on this form.	_____ <small>Physician Initials</small>
I have conducted an in-person physical examination of the qualifying patient within the last 90 calendar days. I completed an assessment of the qualifying patient's current medical condition, including presenting symptoms related to the debilitating medical condition I diagnosed or confirmed.	_____ <small>Physician Initials</small>
I have completed an assessment of the qualifying patient's medical history, including medical records from other treating physicians for the qualifying condition. I have established a medical record of the qualifying patient with regards to the medical condition, continued treatment under my care, and will document follow-up to determine efficacy of the medical marijuana treatment.	_____ <small>Physician Initials</small>
I have explained the potential risks and benefits of the medical use of marijuana to the qualifying patient.	_____ <small>Physician Initials</small>
<b>Physician's Attestation</b> I, _____ (physician), hereby certify that I am a physician duly licensed to practice medicine. It is my professional opinion that the qualifying patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient's qualifying debilitating medical condition or symptoms associated with the debilitating medical condition. Further, it is my professional opinion that the potential benefits of the medical use of marijuana would likely outweigh the health risks for this patient. I attest that the information provide in this written certification is true and correct.	

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## Strain Benefits

### Benefits of Indica:

- 1. Relieves body pain
- 2. Relaxes muscles
- 3. Relieves spasms, reduces seizures
- 4. Relieves headaches and migraines
- 5. Relieves anxiety or stress

### Benefits of Sativa:

- 1. Feelings of well-being and at-ease
- 2. Up-lifting and cerebral thoughts
- 3. Stimulates and energizes
- 4. Increases focus and creativity
- 5. Fights depression

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## Menu examples

### Hollywood Haze

With a spicy scent accented by hints of citrus and earthy sweetness, this hybrid provides a high-energy, happy and creative buzz. This strain is best suited to help with stress, depression, pain, insomnia and nausea.

### 818 Headband

818 Headband aka Sour OG is a hybrid with earthy and sweet flavors to compliment its uplifted, euphoric and relaxed effects. Best suited for those suffering from stress, pain, depression, lack of appetite and nausea.

### 401 Gasband

Gas is a type of sativa-dominant strain that possesses a strong fruity smell with the happy, dreamy and talkative effects it provides. Those suffering from cancer related symptoms such as lack of appetite and nausea might find this strain beneficial.

### Pineapple Fields

A hybrid strain that encompasses intense tropical flavors those of pineapple and diesel. Best for stress and pain relief, anti depression, nausea and insomnia.

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Case Examples

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Jane

- 34yo social worker chronically disabled with “double crush” of severe cervical spinal stenosis, carpal tunnel syndrome complicated by MCTD
  - Unable to type, write, knit
  - Failed cervical fusion, bilateral carpal tunnel releases
  - Side effects and incomplete relief of neuropathic pain from NSAIDs, gabapentin, lycrica, amitriptyline, nortriptyline, tramadol, oxycodone, hydrocodone, fentanyl patch
- Certified for cannabis, titration down and off opioids
- Now working at the Compassion Center, counseling patients
  - Offers to help my other neuropathic pain patients

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Jane

- At time of certification, no FH seizures
- 1 year after certification, sister started workup for “spacing out”
  - Dx with complex partial seizures
- 3 episodes after smoking cannabis, witnessed jerking, unawareness

*Current eval for seizures, hold cannabis, remember like all AEDs seizures may worsen for some*

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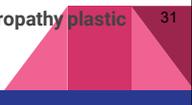
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Cheri

- 72yo WF with severe peripheral neuropathy, pain uncontrolled with maximally dosed gabapentin, nortriptyline; oxycodone dose increasing
- Did not tolerate lyrica, nucynta, morphine, opana, fentanyl, hydrocodone, codeine, NSAIDs
- Failed an experimental peripheral neuropathy plastic surgery release



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Cheri

- Unfamiliar with products, Cheri brings packages to my office
- Counseling session with staff at the Compassion Center arranged
- Patient overwhelmed, and decides not to use  
*May need to arrange extra education for some patients*



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Nick

- 29yo s/p TBI with skull fractures, chronic migraines, vomiting, bipolar d/o
- Asks for recertification of his current cannabis card
  - Approved by his neuro and psych to do so
- Intolerant/lack of effect with topamax, amitriptyline, propranolol, rizatriptan, sumatriptan, NSAIDs, ondansetron, promethazine, compazine
- Able to eat, care for self with mother's and state home health aide's assistance while using cannabis
  - Per mother "it keeps away Atilla the Hun"



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Nick

- Pt self-discontinues psych meds, and continues cannabis (unknown to caregivers)--gets arrested due to delusions and forfeits cannabis card
- Back to vomiting, migraines
  - Recommended to have marinol, which helps somewhat, but suboptimal results

*If uncomfortable with psych issues, consider psych certification*

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Maria

- 36yo F disabled therapist with lupus, fibromyalgia
- Severe pain flares despite plaquenil, benlysta, prednisone, flexeril, tylenol with codeine, PT
  - Cause her to be unable to wear clothes, leave bed
- Unwilling to escalate narcotics, due to experience counseling for addiction
- Since starting cannabis, has returned to part-time work

*Alternates T#3 with cannabis due to cost, although she is more functional on cannabis*

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Mark

- 69yo M recently diagnosed with ALS, seen at multidisciplinary clinic
- On Riluzole, starting advanced planning
- I discussed Compassion Center as another option in the future
- Later, received letter of thanks from patient for including this topic in our discussion of palliative care

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Walter

- 86y M with metastatic pancreatic cancer, not a Whipple candidate
- Seen in Philly, referred to me by oncologist for cannabis
- Enjoying time with grandchildren, good appetite, amused that adult children and grandchildren had to be educated about his therapy

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Common Sense Criteria

- Condition with clinical trials that show efficacy for cannabis
- Failed first- and second-line noncannabinoid therapies (?marinol)
- No known substance abuse, psychotic disorder, unstable mood disorder

Strouse Thomas B. Cannabis and Cannabinoid Research. January 2016, 1(1): 38-43. doi:10.1089/can.2015.0010.

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Common Sense Criteria

- Good evidence for chronic pain, neuropathic, MS spasticity
- Acceptance for HIV and cancer-caused cachexia, chemo-induced N/V
  - However, science is weaker
- Consider variability of product
- Not a panacea

***Be aware, discuss openly with patients, conventional options don't work for everyone***

Strouse Thomas B. Cannabis and Cannabinoid Research. January 2016, 1(1): 38-43. doi:10.1089/can.2015.0010.

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**Quick Hits Panel – Q & A – Obstetrics  
for Board Review**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

Quick Hits Panel – Q & A – Obstetrics for Board Review  
Christine M. Stabler, MD, and  
Stacey Milunic, MD

**Disclosures:**

The speakers have no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speakers have attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speakers indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

Quick Hits Panel – Q & A –  
Obstetrics for Board Review

Christine M. Stabler, MD  
Stacey Milunic, MD

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Disclosure

- The speakers have no conflict of interest, financial agreement, or working affiliation with any group or organization.

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Which statement regarding uterine  
fibroids in pregnancy is false?

- A. Significantly increases risk of cesarean delivery
- B. Increases risk of breech presentation
- C. Increases risk of fetal death
- D. Increases length of gestation by 7 to 10 day

(AFP January, 15, 2017 Volume 95, Number 2 p. 100)

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Fetal Alcohol Spectrum Disorders, (FASD), affect an estimated 2% to 5% of children born in the United States. Which statement is false?

- A. FASDs have a lifelong impact on behavior, intellect and physical abilities.
- B. It is safe but not recommended to drink in the second trimester
- C. Physicians should counsel women who discontinue contraception in their reproductive years to cease alcohol use
- D. Screening for alcohol use begins with asking women about their drinking habits at any primary care visit

• (AFP January, 1, 2017 Volume 95, Number 1 p. 6)

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Zika virus was first reported in Brazil in 2015. It has spread rapidly to over 61 countries and territories worldwide including the United States. All but one of the following statements are true:

- A. Routes of transmission are limited to bites from an infected Aedes mosquitoes and maternal-fetal transmission
- B. Testing for Zika is recommended for pregnant women with possible exposure whether symptomatic or asymptomatic
- C. Congenital Zika Syndrome is associated with infection in the first and early second trimesters of the pregnancy
- D. Congenital Zika Syndrome includes severe microcephaly, scalp rugae, intracranial calcifications, brain and eye abnormalities, club foot, joint contractures and neurological sequelae

• (AFP April 15, 2017 Volume 95, Number 8 p. 507)

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Preterm labor is the leading cause of neonatal morbidity and the most common reason for hospitalization during pregnancy. All of the following statements are true except:

- A. Diagnosis of preterm labor requires the presence of regular contractions associated with cervical changes
- B. A woman with a history of preterm delivery is 1.5 to 2 times more likely to have a subsequent preterm delivery
- C. The incidence of preterm delivery has been increasing since 2007
- D. A course of corticosteroids is the only antenatal intervention that improves post-delivery neonatal outcomes.

• (AFP March 15, 2017 Volume 95, Number 6 p. 366)

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Postpartum hemorrhage occurs in 3% to 5% of obstetric patients.  
Which statement is incorrect?

- A. Complications may include Sheehan Syndrome and dilutional coagulopathy
- B. Oxytocin is preferred over misoprostol for the prevention of uterine atony due to fewer side effects
- C. Multiparity is a risk factor for postpartum hemorrhage
- D. Causes of postpartum hemorrhage include poor uterine tone, trauma, retained tissue, and low thrombin

• (AFP April 1, 2017 Volume 95, Number 7 p. 442)

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A French study published in the British Medical Journal in 2016 looked at cardiovascular risk in 5 million women using oral contraceptives and found a risk of 6 events (MI, PE, ischemic CVA) per 10,000 women years of use. Based on information in this study, what recommendation would you give to a woman wishing to initiate the safest oral contraceptive regimen?

- A. Standard estrogen dose with a desogestrel
- B. Low dose estrogen with gestodene
- C. Low dose estrogen with levonorgestrel
- D. Low dose estrogen with desogestrel

• (AFP May 1, 2017 Volume 95, Number 9 p. 577)

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You discover while reviewing her medical records, that a patient who presents for preconception counseling did not receive MMR as a child due to parental concerns regarding autism. Which statement is false?

- A. The AAFP vaccination exemption policy includes medical contraindications and allergic reactions only
- B. In Pennsylvania, the School Vaccination exemptions include medical, religious and personal belief refusals
- C. There is a risk of MMR producing autism in those immunized as children
- D. It is strongly recommended that she receives MMR before attempting pregnancy

• (AFP June 15, 2017 Volume 95, Number 12 p. 786)

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USPSTF has reviewed available clinical evidence and based on that review issued recommendations regarding the use of Folic Acid supplementation for the prevention of neural tube defects. Which of the following statements is incorrect?

- A. The critical period for supplementation is 1 month prior to conception and through the first two trimesters of pregnancy
- B. Studies confirm that dosages between 400 to 800 micrograms decrease the risk of neural tube defects
- C. Risk factors for neural defects include: maternal diabetes, obesity, anticonvulsants (valproic acid and carbamazepine), personal or family history of neural tube defects
- D. USPSTF recommends a Folic Acid supplement dose of 1 mg

- (AFP May 15, 2017 Volume 95, Number 10 Online content)
- (Online content: <http://www.aafp.org/afp/2017/0515>)

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True statements regarding iron deficiency anemia in pregnancy are the following except:

- A. USPSTF found inadequate evidence to support the practice of routinely screening pregnant women for iron deficiency anemia
- B. USPSTF found no evidence to support the practice of routine iron supplementation to improve Apgar scores or length of gestation
- C. It is estimated that 18.6% of pregnant women in the United States have iron deficiency and 16.2 % have iron deficiency anemia
- D. According to the Institute of Medicine, the RDA for iron in pregnancy is 60 mg of elemental iron

- (AFP January 15, 2016 Volume 93, Number 2 p. 133)

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True statements regarding peripartum depression include all but one of the following:

- A. DSM 5 classifies peripartum depression as a major depressive disorder identified during pregnancy or within the first 4 weeks postpartum
- B. It is short in duration, with minimal symptoms and minimal impact on function
- C. Sertraline is safe to use during both pregnancy and lactation
- D. Occurs in one of seven women

- (AFP May 15, 2016 Volume 93, Number 10 p.852)

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True statements regarding hypertension during pregnancy include all the following except:

- A. Gestational hypertension appears after 20 weeks of gestation
- B. HELLP Syndrome is a pre-eclampsia related coagulopathy
- C. Low dose aspirin provides a small to moderate benefit in the prevention of pre-eclampsia
- D. Systolic blood pressures of at least 140 mm Hg or diastolic blood pressures of at least 90 mm Hg plus proteinuria are required for the diagnosis of pre-eclampsia

• (AFP January 15, 2016 Volume 93, Number 2 p.121)

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USPSTF has made the following recommendations on screening pregnant women for STI's except:

- A. Screen all pregnant women for syphilis and HIV infection
- B. Screen pregnant women at their first prenatal visit for HBV
- C. Screen for chlamydia and gonorrhea in all pregnant women 24 years old or younger and older women who are at increased risk
- D. Screen for HSV at any time using serologic testing

• (AFP December 1, 2016 Volume 94, Number 11 p.907)

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The AAFP Position Paper on Preconception Care recommends all the following except:

- A. Immunization status should be reviewed annually and updated as needed
- B. All women of reproductive age should be screened for alcohol, tobacco and drug use
- C. Women with hypertension should be treated with ACEI or ARB anti-hypertensives
- D. All women and their partners should be assessed for STI risk and provided with testing and treatment as needed

• (AFP September 15, 2016 Volume 94, Number 6 p.508)

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Which of the following is not a contraindication to vaginal delivery:

- A. Prodromal symptoms of herpes simplex infection
- B. Prolonged latent labor
- C. Previous vertical cesarean section scar
- D. Complete placenta previa

• (AFP August 1, 2015 Volume 92, Number 3 p. 202)

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True statements regarding antenatal dietary education and use of dietary supplements include all the following except:

- A. Use of high protein supplements improve fetal outcomes
- B. Decreases the rate of preterm birth
- C. Increases infant birth weight among undernourished women
- D. Does not affect maternal outcomes

• (AFP April 1, 2016 Volume 93, Number 7 p. 557)

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# **An Overview of Lymphomas**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

An Overview of Lymphomas  
Erik Rupard, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

# LYMPHOMA FOR THE NON-ONCOLOGIST

Erik Rupard, MD  
Chief, Hematology/Oncology  
McGlinn Cancer Institute



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## DISCLOSURE

- The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

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## OLD JOKE IN MEDICINE

How many psychiatrists  
does it take to change a  
light bulb?

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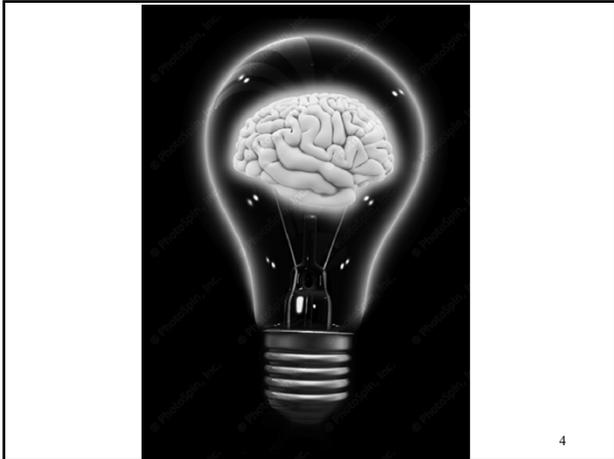
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## WHAT I WON'T DO

- Throw lots of stats at you
- Directly quote articles
- Impress you with my massive knowledge base
  - ◆ (which does not exist)
- Bore you
  - ◆ THIRD day
  - ◆ Sunday = MERCY

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## WHAT I WILL OFFER

- A practical review of common lymphomas
- 3 actual cases from my own clinic
  - ◆ Discussion of diagnostic modalities
  - ◆ Treatment options, including newer therapies
- Staging of the disease
- Long-Term Consequences
- BONUS: "Bust" A Few Cancer "Myths"

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**MYTH #1:  
PEOPLE WHO GET  
CANCER WILL DIE OF  
CANCER**

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**KIND OF REMINDS  
ME OF...**

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## REALITY

- Of the people who walk into my office:
  - ◆ 33% - 50% will be cured
  - ◆ > 90 % of breast cancer
    - 5-year survival stage I/II = 100% (!)
  - ◆ Vast majority of
    - Thyroid, Testicular, Lymphoma
  - ◆ Another 33% with die WITH, not OF
    - Prostate, colon
    - chronic leukemias
- BUT: some will succumb to their disease
  - ◆ One = too many
  - ◆ We do not need to feel helpless

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## CASE # 1

- 56 y/o male with cough in Feb 2016
  - ◆ Azithromycin > no relief
  - ◆ CXR = right-axillary mass
  - ◆ CT confirmed chest/neck abnormalities
  - ◆ April 2016: Rupard ordered PET scan
- BASICS: To know how to treat a cancer patient, we only need to know two things

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## # 1: WHAT IS IT?

### MEDICAL TERM = DIAGNOSIS

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## DIAGNOSIS

- In 2017, must be VERY specific
  - ◆ Type of cancer (lymphoma, lung) not enough
  - ◆ Sub-type (Hodgkin's, NHL)
  - ◆ Mutations (variable according to tissue type)
    - BCL-2, BCL-6, c-MYC mutations
    - "double" or "triple-hit" NHLs
  - ◆ Micro-satellite instability ("MSI")
  - ◆ Mutations: genomic sequencing
- DRIVES TREATMENT DECISIONS

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## #2: WHERE IS IT?

### MEDICAL TERM = STAGE

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## STAGING IN A NUTSHELL

T = Tumor  
 N = Nodes  
 M = Metastases

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## STAGING IN A NUTSHELL

- Stage I: small tumor, in one place (T1N0M0)
- Stage II: either larger tumor, or small positive lymph nodes (T2N0, T1N1)
- Stage III: more lymph nodes involved
  - “locally-advanced” (T2N3)
- Stage IV: involving another organ
  - “metastatic” (TxNxM1)

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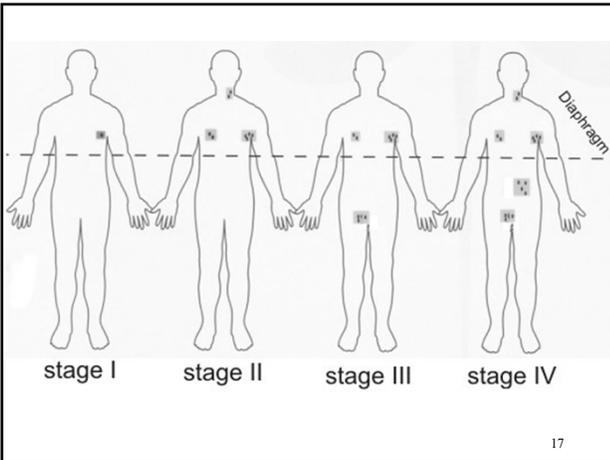
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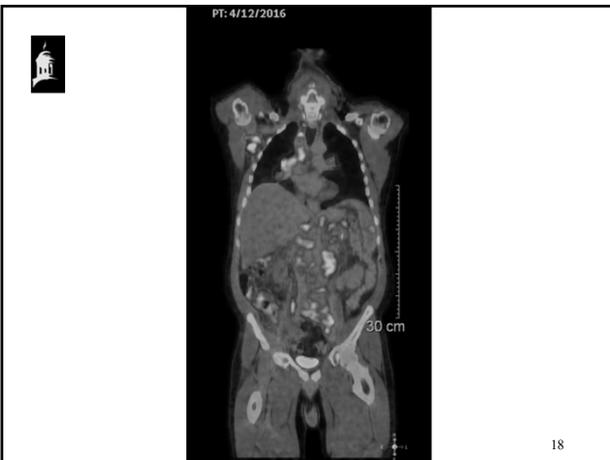
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### CASE CONT'D

- Biopsy by General Surgery (R axillary)
  - ◆ Excisional biopsy required
  - ◆ Flow cytometry and cytogenetics
- Bone marrow biopsy as well
  - ◆ Per NCCN guidelines (NCCN.org)
  - ◆ A free resource for all providers
  - ◆ Very helpful in workup/staging

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NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

# B-cell Lymphomas

Version 5.2017 — September 26, 2017

NCCN.org

Continue

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## NCCN Guidelines Version 5.2017 Diffuse Large B-Cell Lymphoma

NCCN Guidelines Index Table of Contents Discussion

### DIAGNOSIS<sup>a,b</sup>

**ESSENTIAL:**

- Hematopathology review of all slides with at least one paraffin block representative of the tumor. Rebiopsy if consult material is nondiagnostic.
- An FNA or core needle biopsy alone is not generally suitable for the initial diagnosis of lymphoma. In certain circumstances, when a lymph node is not easily accessible for excisional or incisional biopsy, a combination of core biopsy and FNA biopsies in conjunction with appropriate ancillary techniques for the differential diagnosis (immunohistochemistry, flow cytometry, PCR for IGH and TCR gene rearrangements, and FISH for major translocations) may be sufficient for diagnosis.
- Adequate immunophenotyping to establish diagnosis and GCB versus non-GCB origin<sup>c</sup>
- IHC panel: CD20, CD3, CD5, CD10, CD45, BCL2, BCL6, Ki-67, IRF4/MUM1, MYC with or without
- Cell surface marker analysis by flow cytometry: kappa/lambda, CD45, CD3, CD5, CD19, CD20

**USEFUL UNDER CERTAIN CIRCUMSTANCES:**

- Additional immunohistochemical studies to establish lymphoma subtype
- IHC panel: Cyclin D1, kappa/lambda, CD30, CD138, Epstein-Barr virus in situ hybridization (EBER-ISH), ALK, HHV8, SOX11
- Karyotype or FISH: MYC, BCL2, BCL6 rearrangements<sup>d</sup>

### SUBTYPES

**Subtypes included:**

- DLBCL, NOS
- DLBCL, coexistent with follicular lymphoma of any grade
- DLBCL, coexistent with gastric MALT lymphoma
- DLBCL, coexistent with nasopharyngeal MALT lymphoma
- Follicular lymphoma grade 3<sup>e</sup>
- Intravascular large B-cell lymphoma
- DLBCL associated with chronic inflammation
- ALK-positive DLBCL<sup>f</sup>
- EBV-positive DLBCL of the elderly
- T-cell-histocyte-rich large B-cell lymphoma

**Subtypes not included:**

- Primary cutaneous B-cell lymphomas (See NCCN Guidelines for Primary Cutaneous B-Cell Lymphomas)
- Primary DLBCL of the CNS (See NCCN Guidelines for CNS)
- Primary Mediastinal Large B-Cell Lymphoma (PMBL), see BCEL-B.1 of 4.
- Grey Zone Lymphoma, see BCEL-B.2 of 4.
- Double Hit Lymphomas, see BCEL-B.3 of 4.
- Primary Cutaneous B-cell Lymphomas, Leg type, see BCEL-B.4 of 4.

See  
Workup  
(BCEL-2)

<sup>a</sup>Burkitt lymphoma intermediate histology or DLBCL, CD10+ tumors with very high proliferation >95% with or without Burkitt lymphoma-like features might be considered for more aggressive treatment as per BULBCL.

<sup>b</sup>See International Diagnostic Index (BCEL-4).

<sup>c</sup>Typical immunophenotype: CD20+, CD45+, CD3-, other markers used for subclassification.

<sup>d</sup>Note: All recommendations are category 2A unless otherwise indicated.

<sup>e</sup>Clinical Trials: NCCN believes that the best management of any patient with cancer is a clinical trial. Participation in clinical trials is especially encouraged.

<sup>e</sup>See Use of Immunophenotyping/Genetic Testing in Differential Diagnosis of Mantle Cell and T(11;22) Cell Neoplasms (BCEL-2).

<sup>f</sup>Cases with double expression of MYC and either BCL2 or BCL6 by IHC having a GCB-like immunophenotype should undergo FISH testing for MYC, BCL2, and BCL6 rearrangement.

<sup>g</sup>Germlinal center (or follicle center) phenotype is not equivalent to follicular lymphoma and can occur in DLBCL and Burkitt lymphoma. Monoclonality is required to establish diagnosis.

<sup>h</sup>Concomitancy exists regarding management of FL grade 3. Some may treat FL grade 3a as follicular lymphoma and others may treat it as DLBCL.

<sup>i</sup>These are most often CD20 negative and rituximab is not necessary.

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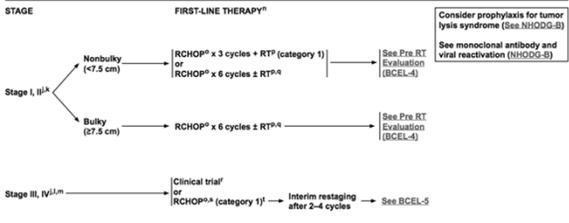
2 | BCEL-1



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## NCCN Guidelines Version 5.2017 Diffuse Large B-Cell Lymphoma

NCCN Guidelines Index Table of Contents Discussion



<sup>a</sup>In testicular lymphoma, after completion of chemotherapy, scrotal RT should be given (25-30 Gy).

<sup>b</sup>No patients who are not candidates for chemotherapy, involved-site radiation therapy (ISRT) is recommended.

<sup>c</sup>In selected cases (4-6 factors according to prognostic model, HIV lymphoma, testicular, double hit lymphoma), there may be an increased risk of CNS events. The optimal management of these events is uncertain, but CNS prophylaxis can be considered with 4-8 doses of intrathecal methotrexate and/or cytarabine, or systemic methotrexate (3-5 gm/m<sup>2</sup>) during the course of treatment. Recent data regarding stage II DLBCL of the breast have been suggested as a potential risk for CNS. In selected cases, RT to initially bulky sites of disease may be beneficial (category 2B).

<sup>d</sup>For systemic disease with concurrent CNS disease, see BCEL-C.

<sup>e</sup>Recommendations are for HIV-negative lymphoma only.

<sup>f</sup>For HIV-positive DLBCL, see AUC-2.

<sup>g</sup>See BCEL-C for regimens used in patients with poor left ventricular function and patients >80 years of age with comorbidities.

<sup>h</sup>See Principles of Radiation Therapy (NHOOG-2).

<sup>i</sup>RT is not used, interim staging after 3-4 cycles of RCHOP is appropriate to confirm response.

<sup>j</sup>May include high-dose therapy.

<sup>k</sup>Based on current clinical trials, RCHOP is preferable due to reduced toxicities, but other comparable anthracycline-based regimens are also acceptable (see BCEL-C).

<sup>g</sup>Note: All recommendations are category 2A unless otherwise indicated.

<sup>h</sup>Clinical Trials: NCCN believes that the best management of any patient with cancer is a clinical trial. Participation in clinical trials is especially encouraged.

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2 | BCEL-3





## DIFFUSE LARGE B-CELL

- Back To Basics:
- **Diagnosis** = diffuse large B-cell lymphoma
  - ◆ BCL-2 positive, BCL-6 and c-MYC negative
  - ◆ “single-hit”
- **Stage** = IVa
  - ◆ A = fevers, chills, night sweats, or weight loss
  - ◆ B = none of the above
- Prognosis?

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## IPI (INT’L PROG INDEX)

- A point each for:
  - ◆ Age > 60 (0 points)
  - ◆ Performance Status > 2 (0 points)
  - ◆ LDH higher than ULN (+1)
  - ◆ Extranodal disease > 2 (+1)
  - ◆ Stage III or IV (+1)
- Patient = 3 out of 5
- High-Intermediate = 78% 5-year survival

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## TREATMENT

- R-CHOP
  - ◆ Rituximab = immune therapy
  - ◆ Cyclophosphamide = chemo
  - ◆ Doxorubicin (“Hydroxydaunocin”) = chemo
  - ◆ Vincristine (“Oncovin”) = chemo
  - ◆ Prednisone 100 daily x 5
- Every 3 weeks
- 2 cycles > PET > 4 more cycles

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## SIDE EFFECTS

- Rituximab
  - ◆ MAB = “Monoclonal Antibody”
  - ◆ Tricks immune system
  - ◆ “Tags” cancer as infection
- Can cause severe infusion reaction
  - ◆ “Infusion-related cytokine release syndrome”
  - ◆ Like severe flu, can be deadly
  - ◆ NO: hair loss, nausea/vomiting, neutropenia
  - ◆ MILD: myelosuppression

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## SIDE EFFECTS

- C, H, O = chemo
  - ◆ Kills rapidly-dividing cells
  - ◆ Messes with DNA
- Action on rapidly-dividing cells
  - ◆ Source of chemo’s activity against cancer
  - ◆ Source of side effects
    - Myelosuppression, infectious risk
    - Hair loss, GI issues (N/V, constipation)
  - ◆ Doxo = cardiac; Vincas = neuropathies

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## SIDE EFFECTS

- And don’t forget the steroids!
  - ◆ Huge dose (100 mg daily x 5d every 3 weeks)
  - ◆ Diabetes exacerbation or unmasking
  - ◆ Visual changes, cataracts
  - ◆ Decreased lymphocytes
    - Viral/fungal infections
    - Can be deadly
  - ◆ Psychological (insomnia, lability, psychosis)

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# RESPONSE?

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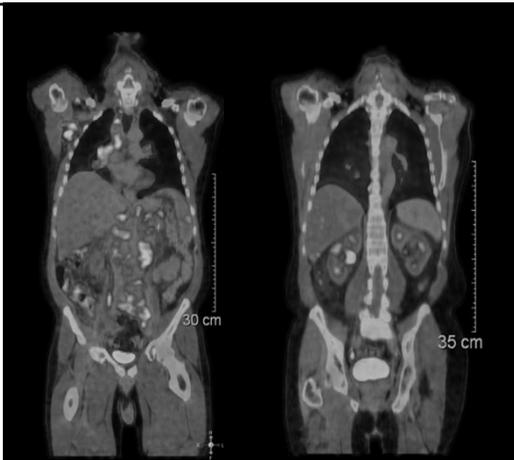
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# MYTH #2: MORE AND MORE PEOPLE ARE DYING OF CANCER

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## FOUR GROUPS

- National Cancer Institute
- American Cancer Society
- Centers For Disease Control
- National Association of Cancer Registries
  - ◆ MCI is a member of the latter
  - ◆ Denise Williams submits all data
- Each group has shown decline in cancer deaths over past decade

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## DECLINE

- Down 1.7% in men
- 1.3% in women
- 1.5% in children
- Why?
  - ◆ Fewer people are smoking
  - ◆ Better and more accessible cancer screening
    - ◆ Mammograms, colonoscopies
  - ◆ Improved treatments

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## NO MISUNDERSTANDINGS:

We still have a long,  
long way to go

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## CASE #2

- 57 y/o male
  - ◆ Massive deformity of neck
  - ◆ Pt reports “grew overnight”
    - wife: “3-4 weeks”
    - Not painful, but some “fullness”
  - ◆ No cytopenias, normal LDH
- CT and PET scan ordered
- Sent for biopsy

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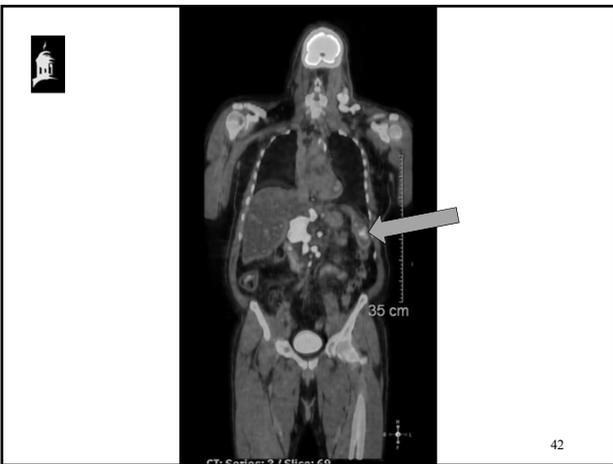
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**BACK TO BASICS**

- Diagnosis (neck biopsy)
  - ◆ Hodgkin's Disease (Mixed Cellularity)
- Stage: IIIAS
  - ◆ Involved neck nodes (obviously)
  - ◆ Hilum/Medistinum
  - ◆ Retroperitoneal nodes
  - ◆ Spleen (= "S")

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**HODGKIN'S LYMPHOMA**

- NOT a "good cancer"!!
- Bimodal Age Distribution
- > 45 year-olds, advanced stage greatly diminish survival
- Stage I/II = 95% 5-year
- Stage III/IV – 80% and 50% 5-year
- SURVIVORS: Tough treatment x 6 months

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## TREATMENT

- ABVD
  - ◆ Doxorubicin (“Adriamycin”)
  - ◆ Bleomycin
  - ◆ Vinblastine
  - ◆ Dacarbazine
- All-chemo regimen
  - ◆ Every 2 weeks x 2 = one cycle
  - ◆ 6 cycles total
- Growth Factor Required (Neulasta)

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## LONG-TERM ISSUES

- Doxorubicin (Adria)
  - ◆ Heart failure
  - ◆ May manifest late
- Bleomycin
  - ◆ Lung toxicity at 18% rate
  - ◆ Not subtle: hypoxia, fevers, interstitial
  - ◆ Reduces 5-year survival by 30%
  - ◆ Permanently decreases QOL

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## BUT: IT WORKS

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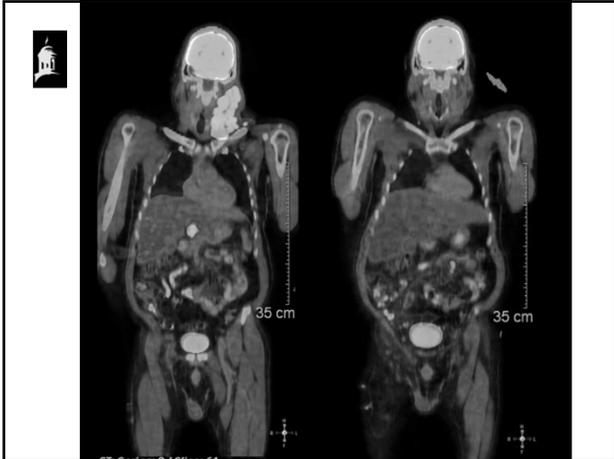
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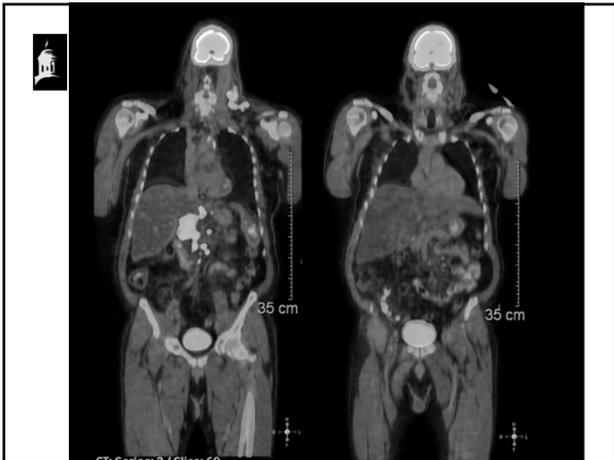
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**MYTH #3:  
NEUTROPENIC  
PATIENTS REQUIRE  
“PRECAUTIONS”**

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## Neutropenic Precautions

**VISITORS** VISITANTES: FAVOR DE ANUNCIARSE A LA ENFERMERIA DE PISO ANTES DE ENTRAR AL CUARTO  
**REPORT TO NURSES' STATION BEFORE ENTERING ROOM**  
 VISITEURS: VEUILLEZ VOUS ADRESSER AU BUREAU DES INFIRMIERES AVANT D'ENTRER DANS LA CHAMBRE



**STRICT  
HAND  
WASHING  
BEFORE  
PATIENT  
CARE**

1. Rubize hands with 4 broad strokes
2. Handwashing is required upon entering the room
3. No gloves or aprons are required
4. No high heels, scapulars, or flowers may be taken into the room



**NO SICK  
VISITORS OR  
PERSONNEL**



**NO PLANTS  
OR FRESH  
FRUIT OR  
VEGETABLES**

5. No visitors or staff with infectious illnesses may enter the room  
 6. No open ill prescriptions must be taken with articles leaving the room

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 HHS VIS Care, 3315 South 27th East • SLC, UT 84106  
 © 2007 MCKA, Inc.

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## REALITY

- “Neutropenic Precautions” do not exist
- CDC did away with them in 2007

**2007 Guideline for Isolation Precautions:  
Preventing Transmission of Infectious  
Agents in Healthcare Settings**

Jane D. Siegel, MD; Emily Rhinehart, RN MPH CIC; Marguerite Jackson, PhD; Linda Chiarello, RN MS; the Healthcare Infection Control Practices Advisory Committee

Acknowledgement: The authors and HICPAC gratefully acknowledge Dr. Larry Strausbaugh for his many contributions and valued guidance in the preparation of this guideline.

Suggested citation: Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. <http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf>

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## EVIDENCE

- Gowns/Gloves do NOT help
  - ◆ ...and probably hurt (Duquette 1999, Kenny 2000, Larson 2004)
- Flowers/plants
  - ◆ Again: not a single reported case
  - ◆ Park, 2008:
    - ◆ Appendectomy patients (N = 90)
    - ◆ Flowers = lower BP, heart rate
    - ◆ Lower pain and anxiety scores

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## EVIDENCE

- Neutropenic Diet
  - ◆ The most maddening of the myths
  - ◆ No fresh fruits and veggies?!?
  - ◆ Literally dozens of studies
  - ◆ Absolutely NO benefit
- REMEMBER: We want these patients to eat!
- I have smuggled in all sorts of goodies

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## WHAT DOES WORK?

- Hand washing
- Washing hands
- Cleaning distal upper extremities
- Lavando las manos
- You get the point...



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### CASE #3

- 52 y/o male
  - ◆ Bilateral cervical and supraclavicular nodes
  - ◆ Not painful, but unsightly; no F/C/NS
  - ◆ Pt reports "grew overnight"
  - ◆ Wife: "since Bush Administration"
- PCM orders labs:
  - ◆ WBC 985,000, Hgb 13, Plts 156,000
  - ◆ Differential: 99% lymphs, 1% grans

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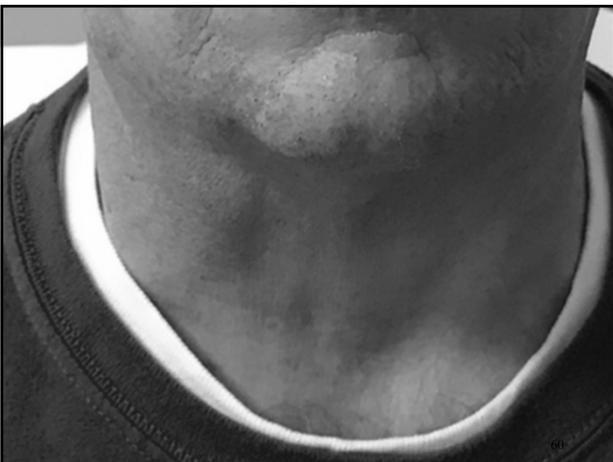
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# WORKUP

- Flow Cytometry of Peripheral Blood
  - ◆ Put cells in “buckets” according to proteins
  - ◆ CD-5, CD-10, CD-20, CD-23, etc
- Useful in most lymphomas/leukemias
- Generates a report:

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## PHENOTYPING REPORT (LY)

SAMPLE DESCRIPTION (ESTIMATED PERCENTS OF NORMAL CELLS PRESENT)

Normal lymph phenotype (% of all cells)			
% Myeloid	1	CD3	2.5
% Monocytes	1	CD4	1.1
% RBC precursors	0	CD8	1.0
% Lymphoid	98	CD56	0.2

95% ABNORMAL LYMPHOCYTE POPULATION ESTIMATED TO BE PRESENT

PHENOTYPIC DESCRIPTION OF ABNORMAL CELLS

Antibody	+/-	INTERP	Antibody	+/-	INTERP	Antibody	+/-	INTERP
<b>B-related</b>			<b>T-related</b>			<b>Myeloid/Other</b>		
CD10	Neg		CD2	Neg		CD11b		
CD11c			CD3	Neg		CD13		
CD19	Pos	Dim	CD4	Neg		CD14		
CD20	2+	Dim	CD5	Pos	Dim	CD15		
CD22	Pos	Dim	CD7	Neg		CD33	Neg	
CD23	Pos	Het	CD8	Neg		CD34	Neg	
CD38	3+	Dim	CD25			CD45	Pos	Mod
CD103			CD56	Neg		CD61		
Kappa	Neg		TCRaB			CD64		
Lambda	Pos	Dim	TCRgd			CD71	Neg	
FMC7	Neg					CD117		
						HLA-DR	Pos	Het
						CD16		

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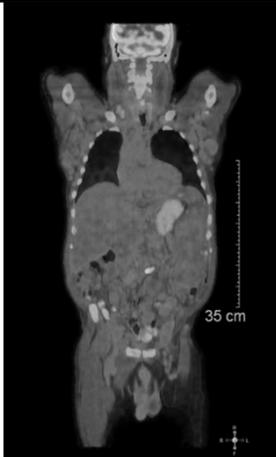
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## CLL TREATMENT

- No symptoms = no treatment
- Symptoms or progressive cytopenias:
  - ◆ Rituximab (anti-CD-20 antibody)
  - ◆ “gentle” chemo (chlorambucil, bendamustine)
  - ◆ Ibrutinib (Bruton’s kinase inhibitor)
  - ◆ R-CHOP
- This patient got bendamustine/rituximab
  - ◆ Relapse @ 7 months > ibrutinib

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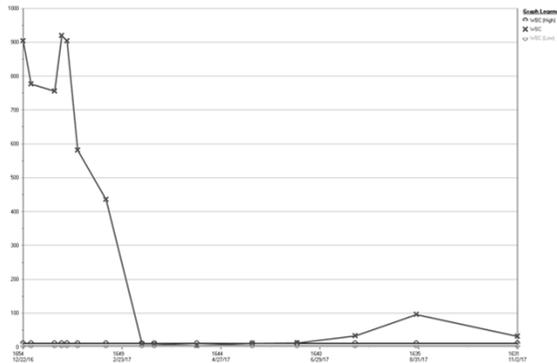
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## CLL/SLL

- CLL = mostly in blood, SLL = mostly nodes
- An indolent form of NHL
- Favors older, whiter, males
- Benign disease course
- Complications
  - ◆ Infections
  - ◆ Richter Transformation
  - ◆ Other cancers...

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**MYTH #4:  
CANCER PATIENTS ALL  
NEED CHEMOTHERAPY,  
AND CHEMO MAKES  
EVERYONE SICK**

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**REALITY**

- Majority of cancer patients will not require or receive chemotherapy
- Those who do are less likely than ever to have
  - ◆ Nausea/Vomiting (most gain weight!)
  - ◆ Hair loss (only 5 agents cause this)
  - ◆ Neutropenia (thank you, Neulasta!)
  - ◆ Hospitalization
- Again: too many will have one or more...

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# “I DON’T KNOW HOW YOU CAN PRACTICE IN YOUR SPECIALTY”

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# I SAW PATIENT # IN SEPTEMBER

Dr. Ryland,  
Once again, I wanted  
to thank you for my  
excellent care. In April  
2016 I had some doubts  
that I would see this  
day. By God's grace and  
Thru your hand it was  
granted to ME. To walk  
my little girl down the  
aisle was priceless.  
Thank you,  
[Redacted]

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9/2/2017



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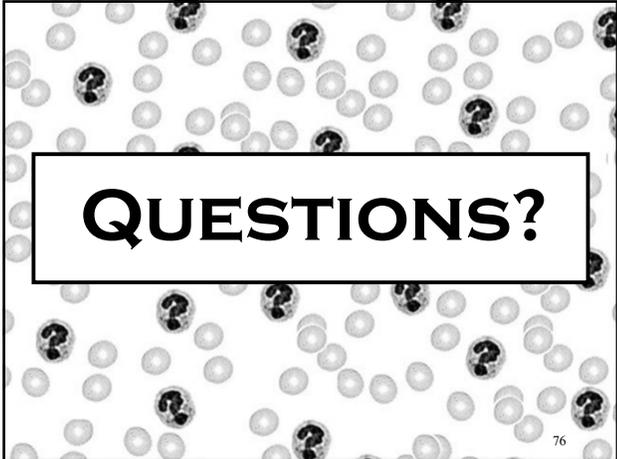
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**[Return to Top](#)**

## **Fever and Rash**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

Fever and Rash  
Michael Gaudiose, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

***This educational activity is funded in part by an educational grant from Novartis Pharmaceuticals Corporation, which has no control over its content.***

# FEVER WITH RASH

*John H. Snyce, MD, FFAFP  
 Retired Medical Director, 2nd Joint First*

*Michael C. Gaudioso, MD, FFAFP  
 US Army War College, D. Scott Clinic*




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# FEVER WITH RASH



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# OBJECTIVES

- ❖ Develop a detailed history
- ❖ Perform a comprehensive examination of the skin, describing primary and secondary lesions
- ❖ Utilize appropriate laboratory studies
- ❖ Recognize those lesion that represent significant or life-threatening diseases
- ❖ Initiate timely treatments and currently approved treatments

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**CHILDHOOD ILLNESSES**

- ❖ Measles (Rubeola)
- ❖ German Measles (Rubella)
- ❖ Mumps (Parotitis)
- ❖ Chickenpox (Varicella-Zoster)
- ❖ Erythema Infectiosum [Fifth Disease] (B 19 Parvovirus)
- ❖ Roseola Infantum [Sixth Disease] (Human Herpes Virus 6) (HHV-6)

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**CHILDHOOD ILLNESSES**

- ❖ Enterovirus (Echovirus and Cocksackievirus)
- ❖ Hand, Foot, and Mouth Disease (Cocksackie virus)
- ❖ Kawasaki Syndrome (?)
- ❖ Scarlet Fever (S. pyogenes, erythrogenic toxin)

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**OTHER ILLNESS**

- ❖ Herpes Zoster (Varicella-Zoster)
- ❖ Infectious Mononucleosis (Epstein-Barr Virus, Cytomegalovirus)
- ❖ Toxic Shock Syndrome (Staphylococcal aureus enterotoxins)  
(Streptococcal pyrogenic exotoxins)
- ❖ Meningococemia (Neisseria meningitidis)
- ❖ Gonococemia (Neisseria gonorrhoeae)
- ❖ Lyme Disease (Borrelia burgdorferi)
- ❖ Rocky Mountain Spotted Fever (Rickettsia rickettsia)

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## MEASLES

MEASLES: OVERVIEW

**KEY FACTS**

- Measles is one of the leading causes of death among young children even though a safe and cost-effective vaccine is available.
- In 2008, there were 164 000 measles deaths globally – nearly 450 deaths every day or 18 deaths every hour.
- More than 95% of measles deaths occur in low-income countries with weak health infrastructures.
- Measles vaccination resulted in a 78% drop in measles deaths between 2000 and 2008 worldwide.
- In 2008, about 83% of the world's children received one dose of measles vaccine by their first birthday through routine health services – up from 72% in 2000.

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## MEASLES



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## MEASLES



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# MEASLES

Measles

Mottled rash



Black dot Koplik Spot



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# MEASLES

## COMPLICATIONS

- Diarrhea 8%
- Otitis media 7%
- Pneumonia 6%
- Encephalitis 0.1%
- Seizures 0.6-0.7%
- Death 0.2%

(Based on 1985-1992 surveillance data)

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# MEASLES

## Measles-Prevention

**Isolation**- from 7 days after exposure to 4-6 days after the onset of rash

**Vaccine or immunoglobulin**- vaccine is effective in prevention or modification of measles only if given within 72 hr of exposure. Immune globulin may be given up to 6 days after exposure to prevent or modify infection.

**Immune globulin**- for susceptible household contacts younger than 6 months of age, pregnant women & immunocompromised persons

**Immunization during an outbreak**-immunize infant as young as 6 months of age; additional dose at 12-15 months of age

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## ATYPICAL MEASLES

- ❖ At risk: Recipients of killed measles vaccine 1963 to 1967 in USA
- ❖ Occurs when exposed to natural measles
- ❖ Prodromal symptoms similar to natural disease
- ❖ Eruptive phase differs
- ❖ Mildly pruritic maculopapular rash begins on wrist and ankles with high fever
- ❖ Spreads centripetally to extremities and torso but spares face
- ❖ Evolves to vesicular, purpuric and hemorrhagic rash followed by desquamation of palms and soles

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## RUBEOLA OR RUBELLA



Measles vs. Rubella

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## RUBELLA

- ❖ Incubation: 18 days (range 14- 21 days)
- ❖ Prodromal: Lymphadenopathy (post auricular, suboccipital, and cervical) begins 4-7 days before rash and peaks at eruption of rash  
Mild malaise and headache with moderate fever 1 day or less before rash
- ❖ Eruptive: Begins on face or neck and spreads to trunk and extremities within hours fading within 3 days with fine desquamation

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# RUBELLA

## Rubella (German Measles)



- Mild fever, sore back of neck/ear lymph nodes
- Faint Pink/Red Spots merge to itchy blotches on face, more noticeable after warm shower
- Patches leave face, may peel, will fade as it spreads head to toe
- Older children: Pink eyes, headache, loss of appetite, joint pain
- CRS: Fetus of unexposed 1<sup>st</sup> trimester moms: deafness, cataracts, heart defects, mental retardation

(kidshealth.org)

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# RUBELLA

Rubella





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# RUBELLA

## Fetal abnormalities associated with maternal rubella infection:

- Encephalitis;
- Hepatomegaly;
- Bone defects;
- Mental retardation;
- Cataracts ;
- Thrombocytopenic purpura;
- Cardiovascular defects
- Splenomegaly;
- Microcephaly

Abetal syndrome



Microcephaly   Hip   Cataracts

advm.com

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**ROSEOLA**

- ❖ Incubation: 12 days (range 5-15 days)
- ❖ Prodromal: Explosive onset of high fever (103- 106)  
Suboccipital lymphadenopathy for 7 days
- ❖ Eruptive: Begins on day 4 as fever resolves  
Faint pink macules appear on trunk and neck  
Lesions coalesce then fade within hours to 2 days

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**ROSEOLA**



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**ROSEOLA**



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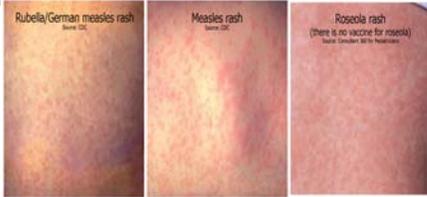
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## EXANTHEM CONFUSIUM



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## ERYTHEMA INFECTIOSUM

- ❖ Incubation: 13-18 days
- ❖ Prodromal: Absent in 90% of cases  
Mild in 10% of cases with malaise, sore throat, pruritis, low grade temperature
- ❖ Eruptive: 3 overlapping stages (Facial erythema, Net pattern erythema and Recurrent phase)
- ❖ Late: Pruritis and symmetric polyarthritits as IgG titers rise (women)

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## ERYTHEMA INFECTIOSUM



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## ERYTHEMA INFECTIONOSUM



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## VARICELLA

- ❖ Incubation: 14 days (range 9- 21 days)
- ❖ Prodromal: Children: absent or mild malaise, headache and low grade fever just before or at onset of the rash  
 Adult: more severe with headache, malaise, chills, and fever 2 to 3 days before the rash
- ❖ Eruptive: Macular-papulo-vesicular rash begins on the trunk, spreads to face and extremities, appearing in crops, resolving in stages

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## VARICELLA

**Symptoms/ Contagiousness**

- Red, itchy rash that looks like blisters
- Fever (100-102 F)
- Abdominal Pain
- Sore Throat
- This virus is contagious two days before the actual rash appears until all of the blisters are crusted over.
- Chickenpox is extremely contagious. Often times, those who are infected are asked to stay home until healthy.
- It is an airborne disease. It can be spread by sneezing, coughing, and direct contact with the actual rash.
- One will develop chickenpox 10-21 days after contact with the infected person.

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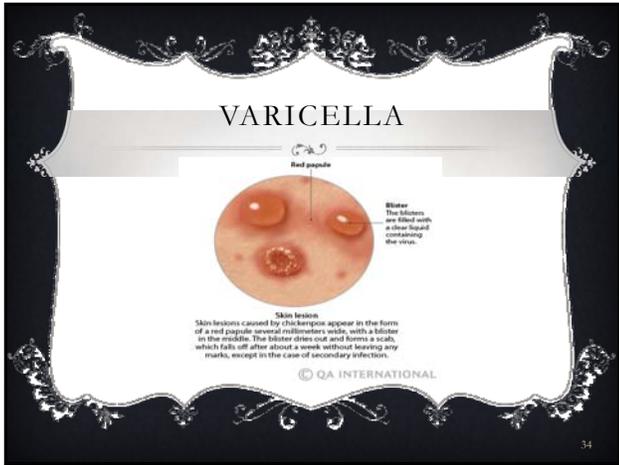
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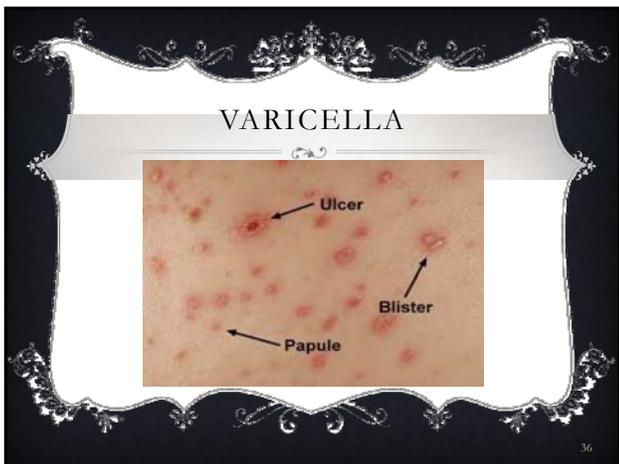
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# VARICELLA

Chickenpox - summer 2007  
The same spot over 15 days.

Day 1 - a.m.	Day 1 - p.m.	Day 2	Day 3	Day 4
Day 5	Day 7	Day 10	Day 11	Day 15

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# VARICELLA

**Varicella: Complications**

- Secondary bacterial infection of skin lesions
- Central nervous system manifestations (meningoencephalitis, cerebellar ataxia)
- Pneumonia (viral or bacterial)
- Hepatitis, hemorrhagic complications, thrombocytopenia, nephritis occur less frequently
- Certain groups at increased risk for complications
  - Adults
  - Immunocompromised persons
  - Pregnant Women
  - Newborns

CDC. Prevention of Varicella. MMWR 2007; 56(No. 10): 4). *Am J Clin Med* May 10

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# VARICELLA

**Prevention and control:**

- No specific treatment for chicken pox. The usual control measures are notifications, isolation of cases and disinfection of articles
- Varicella Zoster immunoglobulin (VZIG)- for immunosuppressed and newborns.
- Vaccine- live attenuated vaccine.



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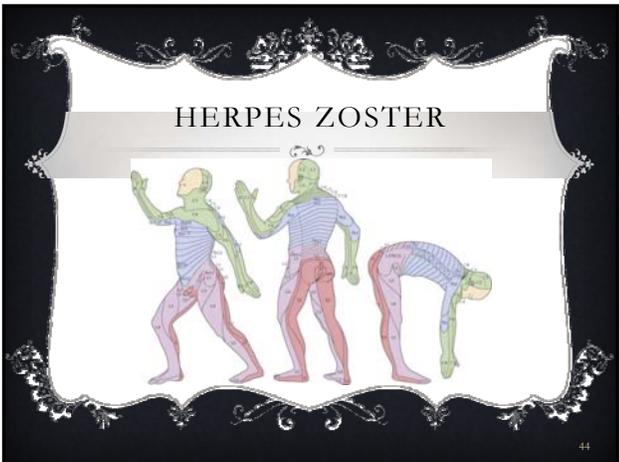
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## HERPES ZOSTER

### Complications of VZV



#### Oticus

- Zoster infection of ear without neuropathies
- Tx: Antivirals + Steroids
- ENT consult
- Limit tactile stimulation
- Audiogram if hearing affected
- May require canal debridement after vesicles resolve

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## HERPES ZOSTER

**TABLE 1. Impact of acute herpes zoster and postherpetic neuralgia on quality of life**

Life factor	Impact
Physical	Chronic fatigue Anorexia and weight loss Physical inactivity Insomnia
Psychological	Anxiety Difficulty concentrating Depression, suicidal ideation
Social	Fewer social gatherings Changes in social role
Functional	Interferes with activities of daily living (e.g., dressing, bathing, eating, travel, cooking, and shopping)

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## HERPES ZOSTER

### Herpes Zoster Vaccine: Hypothesis

- Because zoster is more frequent and is associated with more complications in older populations;
- Because declining CMI is associated with an increased risk of zoster;
- Because VZV-specific CMI declines with aging;
- If we could boost the declining CMI with a vaccine, perhaps we could prevent or attenuate herpes zoster

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## HERPES ZOSTER

### CDC Recommends Herpes Zoster Vaccination for Adults

- October 2007 – CDC includes zoster vaccine in adult immunization schedule for adults  $\geq 60$  years of age
- May 2008 – For the prevention of herpes zoster, the CDC recommends that the zoster vaccine be given to all people  $\geq 60$  years of age who have no contraindications, including:
  - Patients who have had a previous episode of herpes zoster
  - Patients with chronic medical conditions

† Centers for Disease Control and Prevention. MMWR. 2007;157:1-10

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## HERPES ZOSTER

### Zoster Vaccine: Contraindicated in Immunocompromised Patients

- ACIP guidance on what constitutes an "immunocompromised patient":
  - Corticosteroids—a dose equivalent to either  $\geq 2$  mg/kg of body weight or 20 mg/day of prednisone for  $\geq 2$  weeks raises concern about the safety of vaccination with live-virus vaccines
  - Persons receiving chemotherapy or radiation for leukemia and other hematopoietic malignancies, solid tumors
- Live, attenuated vaccines should not be administered for at least 3 months after such immunosuppressive therapy or chemotherapy

*However, many other "gray areas" remain where physicians must use clinical judgment*

ACIP. Herpes Zoster Vaccination in Immunocompromised Patients. 2008

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## HERPES ZOSTER

### Zoster Treatment

- Antivirals: Acyclovir, valacyclovir, famciclovir
- Prednisone in certain cases
- Pain Control: Narcotics, gabapentin, pregabalin, amitriptyline



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# HERPES ZOSTER

## Antiviral Therapy for Herpes Zoster

Medication	Typical Dosing
Acyclovir (Zovirax®)	800 mg 5x/day, 7-10 days
Famciclovir (Famvir®)	500 mg 3x/day, 7 days
Valacyclovir (Valtrex®)	1000 mg 3x/day, 7 days

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# ENTEROVIRUS

**Table 1. Clinical Manifestations Of Enteroviral Disease**

Mild infections	Poliovirus Serous infection
Fever of rash	Menigitis
Hand, foot, and mouth syndrome	Encephalitis
Herpangina	Acute paralysis
Rhinopharyngitis	Neonatal sepsis
Pharyngitis	Meningoencephalitis
Cardiomyopathy	Myocarditis
Chorea	Chronic infection in immunocompromised patients

(Reprinted with permission from Dawson, Table 1 clinical manifestations of major EV infections, Clin Opin Pediatr Feb 2001.)

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# ENTEROVIRUS

## Rhinoviruses

- Rhinoviruses (from the Greek (gen.) "nose") are the most common viral infective agents in humans and are the predominant cause of the common cold. Rhinovirus infection proliferates in temperatures between 33–35 °C (91–95 °F), and this may be why it occurs primarily in the nose. Rhinovirus is a species in the genus Enterovirus of the **Picornaviridae family of viruses.**

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## ENTEROVIRUS

**Coxsackie virus infection  
present with**

- Both group A and group B Coxsackievirus can cause nonspecific febrile illnesses, rashes, upper respiratory tract disease, and aseptic meningitis



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## HAND FOOT MOUTH DISEASE

- ❖ Incubation: 4 to 6 days
- ❖ Prodromal: Mild fever, malaise, and sore throat for 1- 2 days  
20% submandibular and/or cervical lymphadenopathy
- ❖ Eruptive: Oral lesions (enanthems) in 90% appear first  
67% develop 3 to 7 mm red macules next day  
These evolve into pale, white, oval vesicles with red border on palms, soles and dorsum of digits

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## HAND FOOT MOUTH DISEASE



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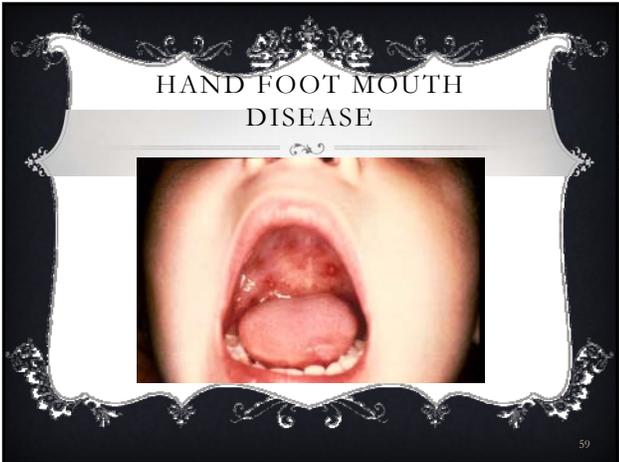
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## INFECTIOUS MONONUCLEOSIS

- ❖ Incubation: 4 to 14 days (range 33 to 49 days)
- ❖ Prodromal: Headache, malaise followed in 1 day by 101 to 104 F
  - Day 2 Exudative tonsillitis and lymphadenopathy
  - Day 5 Petechiae on hard and soft palate
- ❖ Eruptive: Day 4 to 6 Exanthem on trunk and upper arms
  - Macular or maculopapular morbilliform

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## INFECTIOUS MONONUCLEOSIS

**Infectious mononucleosis (IM) and Epstein-Barr virus (EBV)**

IM is an acute viral illness characterised by **fever, pharyngitis, cervical lymphadenopathy, and lymphocytosis.** **Whereas - 90% of cases of IM are due to EBV, 5-10% of cases are due to Cytomegalovirus (CMV).** CMV is the most common cause of **heterophile-negative mononucleosis.** **Less common causes rubella, Toxoplasma, HIV, herpesvirus 6, hepatitis viruses and drug reactions.**

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## INFECTIOUS MONONUCLEOSIS

**Main symptoms of infectious mononucleosis**

**Cervical lymphadenopathy**  
 - Pharyngitis  
 - Tonsillitis  
 - Exanthem  
 - Splenomegaly  
 - Heterophile antibody

**Respiratory**  
 - Cough

**Systemic**  
 - Fever  
 - Malaise

**Visual**  
 - Heterophile antibody

**Other**  
 - Splenomegaly  
 - Heterophile antibody  
 - Exanthem

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**INFECTIOUS  
MONONUCLEOSIS**

**General Symptoms**

- High fever
- Severe sore throat
- Swollen glands and tonsils
- Weakness and fatigue
- Rash
- Pink and purple spots in mouth



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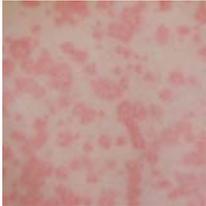
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**INFECTIOUS  
MONONUCLEOSIS**



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**INFECTIOUS  
MONONUCLEOSIS**



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# SCARLET FEVER

**Diseases caused by group A streptococcus**

- Pharyngitis
- Impetigo/pyoderma
- Pneumonia, Necrotizing fasciitis
- **Rheumatic fever**
- Glomerulonephritis
- Osteomyelitis
- Scarlet fever & erysipelas
- Toxic shock syndrome

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# SCARLET FEVER

**Scarlet Fever**

**CLINICAL FEATURES**

- 2-4 incubation period
- Headache and tonsillitis appear after
- Rash develops within 2 hours
- Spreads rapidly over trunk and neck
- With increased density in the neck, axillae and groin.

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# SCARLET FEVER

**Differential diagnosis**

◆ **Scarlet fever**

Red rash blanches with pressure, which is diffuse but spares the palms, soles, and face. The face appears flushed. The skin rash fades in a week and is followed by extensive desquamation. Patient has good response to PG.

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### RASH OF SCARLET FEVER




Exanthem is red, punctate & finally papular (goose flesh texture or coarse sand paper). Red Strawberry tongue is a typical feature of this disease.

DR. HARIVANSH CHOPRA  
www.dharmajournal.com

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### SCARLET FEVER




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### SCARLET FEVER

NHS

#### Scarlet Fever

**Scarlet fever is a germs**

<p><b>Causes</b></p> <p>Scarlet fever is caused by the bacteria <i>Streptococcus pyogenes</i>. This bacteria is often found in the throat and skin.</p> <p><b>Signs and symptoms</b></p> <p>Scarlet fever usually starts with a sore throat, a fever and a red, bumpy rash. The rash is often described as feeling like coarse sandpaper.</p> <p><b>Diagnosis</b></p> <p>Scarlet fever is usually diagnosed by a doctor who examines the throat and skin.</p> <p><b>Prevention</b></p> <p>Scarlet fever can be prevented by good hygiene, such as washing hands regularly.</p>		<p><b>Complications</b></p> <p>Scarlet fever can lead to complications such as kidney problems, ear infections, and skin infections.</p> <p><b>Treatment</b></p> <p>Scarlet fever is treated with antibiotics. It is important to finish the course of antibiotics.</p>
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# KAWASAKI SYNDROME

- ❖ Mucocutaneous Lymph Node Syndrome
- ❖ Etiology is unknown
- ❖ One of the vasculidities of childhood

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# KAWASAKI SYNDROME

**Kawasaki disease - AHA diagnostic criteria**  
Fever of ≥ 5 days duration + four of five criteria

1  Oropharyngeal changes (90%+ of cases)	3  Bilateral non-purulent conjunctival injection (90%+ of cases)
2  Changes in peripheral extremities (90%+ of cases)	4  Polymorphous rash (95%+ of cases)
	5  Cervical lymphadenopathy (75%+ of cases)

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# KAWASAKI SYNDROME

Child usually presents with fever




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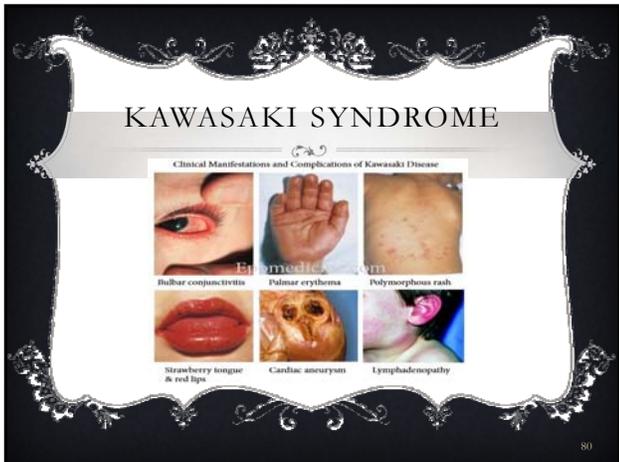
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## KAWASAKI SYNDROME

### Treatment

<b>Several symptoms present</b>	<b>Aspirin therapy</b>	<b>Gamma globulin IV</b>	<b>Possible aneurysm detected</b>
Blood work done Kawasaki diagnosis confirmed	To reduce blood clots	Given within 10 days Decreases heart problems	EKG given periodically Further medical treatment

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## TOXIC SHOCK SYNDROME

- ❖ Two Types: Menstrual and Non-menstrual
- ❖ Two Bacterial Agents: Staphylococcal (MSSA and MRSA)
- ❖ Incubation: Menstrual: 2-3 days after onset of menses  
 Non-menstrual: 2- 65 days after surgical wounds, postpartum, mastitis, septorhinoplasty, sinusitis, osteomyelitis, burns, arthritis, enterocolitis, post influenza respiratory infection, abscesses
- ❖ Due to enterotoxins TSST-1, Staph enterotoxin B, C, D, E, H

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## TOXIC SHOCK SYNDROME

Table 5. Toxic Shock Syndrome: Case Definition

1. Fever greater than 38.3°C
2. Diffuse macular erythroderma
3. Desquamation one to two weeks after onset of illness, especially on palms and soles
4. Hypotension (systolic blood pressure less than 90th percentile)
5. Involvement of three or more organ systems:
  - Gastrointestinal (vomiting or diarrhea)
  - Muscular (severe myalgia or CPK greater than two times normal)
  - Mucous membranes (vaginal, oropharyngeal, or conjunctival hyperemia)
  - Renal (BUN or creatinine greater than two times normal)
  - Hepatic (total bilirubin, SGOT or SGPT greater than two times normal)
  - Hematologic (platelets less than 100,000)
  - Central Nervous System (altered mental status without focal neurologic signs)
6. Negative results on the following tests:
  - Throat, CSF cultures
  - Serologic tests for Rocky mountain spotted fever or measles

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## TOXIC SHOCK SYNDROME



**Toxic Shock Syndrome**

**Signs & Symptoms of Toxic Shock Syndrome**

- 1) High fever which comes on suddenly is one of the many symptom of toxic shock syndrome.
- 2) Hypotension or low blood pressure.
- 3) Diarrhea or vomiting.
- 4) Patient suffering from toxic shock syndrome develops a rash which looks like a sunburn, especially on the palms and soles.
- 5) Disorientation.
- 6) Muscle pains/aches.
- 7) Redness in the eyes, mouth and throat.
- 8) Headaches.
- 9) Seizures.

ePainAssist.com

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## TOXIC SHOCK SYNDROME

**Toxic Shock Syndrome (TSS)**

- Staphylococcus aureus
- Streptococcus pyogenes
- Clostridium sordellii
- Signs & Symptoms
  - High fever, chills, tenderness, diarrhea, hypotension, hyperemia, disorientation, headache
- Treatments
  - IV fluids, IV oxacillin, nafcillin, methicillin, dopamine, dobutamine, O2



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## TOXIC SHOCK SYNDROME

### Treatment

- Prehospital Care
- Oxygen should be provided.
- Aggressive fluid resuscitation should begin in the field, especially for the severely hypotensive patient.
- Rapid transport to a hospital capable of managing severe shock is definitive prehospital management.

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## TOXIC SHOCK SYNDROME

- ❖ Treatment for MSSA: Clindamycin 900mg IV q 8 hours (adult) or 25 to 40 mg/kg IV per day q 8 hours (pediatrics)  
Oxacillin or Nafcillin 2 Grams IV q 4 hours (adult) or 100 to 150 mg/kg IV per day q 6 hours (pediatrics)
- ❖ Treatment for MRSA: Clindamycin doses as above for adults or pediatrics + Vancomycin 15- 20 mg/kg IV q 8 to 12 hours limit of 2 grams per day(adult) or 40 mg/kg IV per day q 6 hours (pediatrics)

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## TOXIC SHOCK SYNDROME

- ❖ Treatment for GAS: Clindamycin 900 mg IV q 8 hours (adult) + Imipenem 500 mg IV q 6 hours or Meropenem 1 Gram IV q 8 h
- ❖ Alternatively: Clindamycin 900 mg IV q 8 hours (adult) + Ticarcillin/Clavulanate 3.1 Gram IV q 4 hours or Piperacillin/Clavulanate 4.5 Gram IV q 6 hours
- ❖ Check literature for current pediatric treatment

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## TOXIC SHOCK SYNDROME

**Table 3. Differential Diagnosis of Toxic Shock Syndrome**

Feature	Staphylococcal Toxic Shock Syndrome	Streptococcal Toxic Shock Syndrome	Enterococcal Toxic Shock Syndrome	Non-infectious Toxic Shock Syndrome	Systemic Lupus Erythematosus
Age	Infants to elderly	Infants to elderly	Infants to elderly	Infants to elderly	Infants to elderly
Onset	Acute	Acute	Acute	Acute	Chronic
Exposure	Wound, surgery, tampons, menstruation, contact with nasal or genital mucosa	Wound, surgery, contact with nasal or genital mucosa	Wound, surgery, contact with nasal or genital mucosa	None	None
Course	Acute	Acute	Acute	Acute	Chronic
Diagnosis	Positive culture of staphylococci from wound, tampon, or genital tract	Positive culture of streptococci from wound, tampon, or genital tract	Positive culture of enterococci from wound, tampon, or genital tract	None	None
Response to treatment	Improvement with antibiotics	Improvement with antibiotics	Improvement with antibiotics	No improvement	No improvement

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## MENINGOCOCCEMIA

- ❖ Incubation: 2- 10 days
- ❖ Begins with acquisition of meningococci in the nasopharynx
- ❖ Prodromal: Fever alone to fulminant septic shock within 3- 4 days of acquisition. Can include severe headache, nausea, vomiting, stiff neck and rash (70% of cases)
- ❖ Eruptive: Purpura (60%), Erythematous papules (32%), faint macules (28%) and conjunctival petechiae (10%)

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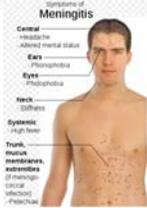
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## MENINGOCOCCEMIA



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## MENINGOCOCCEMIA

### Meningococemia

- *Neisseria meningitidis*
- Gram-negative diplococci
- Strains are grouped based on a polysaccharide capsule
- A, B, C, Y and W135



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# MENINGOCOCCEMIA

**Meningococemia**

- *N. meningitidis*
- Skin lesions occur with acute disease
- Petechia
- Ecchymosis and ischemic necrosis usually follow
- Occasionally fulfous hemorrhagic lesions occur
- Trunk and extremities



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# MENINGOCOCCEMIA

**MENINGOCOCCEMIA**



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# MENINGOCOCCEMIA




Figure 3 - The rash on this patient's buttocks shows the ischemic necrosis of meningococemia.

Figure 4 - This is a closer view of the ischemic necrotic lesions of meningococcal infection.

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# MENINGOCOCCEMIA

## Meningococemia – Prophylaxis

- Persons who have had "intimate contact" w/ oral secretions prior & during 1<sup>st</sup> 24 h of antibiotics
- "Intimate contact" – 300-800x risk (kissing, eating/ drinking utensils, mouth-to-mouth, suctioning, intubating)

Treat within 24 hours of exposure

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# MENINGOCOCCEMIA

## Meningococemia – Prophylaxis

- Rifampin
  - Urine, tears, soft contact lenses orange; OCP's ineffective
  - <1 mo 5 mg/kg PO Q 12 x 2 days
  - >1 mo 10 mg/kg (max 600 mg) PO Q 12 x 2 days
- Ceftriaxone
  - ≤12 y 125 mg IM x 1 dose
  - >12 y 250 mg IM x 1 dose
- Ciprofloxacin
  - ≥18 y 500 mg PO x 1 dose

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# MENINGOCOCCEMIA

- ❖ Initiate treatment with a 3<sup>rd</sup> generation cephalosporin such as Ceftriaxone or Cefotaxime
- ❖ If cultures show organism sensitive to penicillin may switch to Penicillin G 300,000 units/kg IV or IM q 4 hours

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# GONOCOCCEMIA

- ❖ Incubation: 2- 5 days with a range of 2- 14 days
- ❖ Rate of Infection: Males 20% to 50% vs Females 60% to 90%
- ❖ Disseminated Gonococcal Infection occurs in 1% to 3% cases
- ❖ Coexisting Chlamydia infection 45 % females vs 25 % males
- ❖ Most common form of infectious arthritis
- ❖ Problem is initial symptoms are mild or vague especially in females

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# GONOCOCCEMIA



### Gonorrhea Symptoms

- Some men with gonorrhea may have no symptoms at all. However, common symptoms in men include a burning sensation when urinating, or a white, yellow, or green discharge from the penis that usually appears 1 to 14 days after infection. Sometimes men with gonorrhea get painful or swollen testicles.
- Most women with gonorrhea do not have any symptoms. Even when a woman has symptoms, they are often mild and can be mistaken for a bladder or vaginal infection. The initial symptoms in women can include a painful or burning sensation when urinating, increased vaginal discharge, or vaginal bleeding between periods. Women with gonorrhea are at risk of developing serious complications from the infection, even if symptoms are not present or are mild.
- Symptoms of rectal infection in both men and women may include discharge, and itching, soreness, bleeding, or painful bowel movements. Rectal infections may also cause no symptoms. Infections in the throat may cause a sore throat, but usually cause no symptoms.



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# GONOCOCCEMIA

### Gonococemia

<b>Mode of Transmission</b>  Person to person via sexual contact  	<b>Clinical Manifestations</b>  -Fever -Chills, malaise -Joint pain either single or multiple joints (knee pain, wrist pain, ankle pain) -Joint swelling (knees, wrists, ankles)  	<b>Dermatologic Manifestations</b>  -Skin rash, begins as flat, pink-to-red macules that evolve into pustular papules and pustules -Painful tendons of wrists, digits, heels -A combination of skin rash and aching, swollen tendons  
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## GONOCOCCEMIA



Disseminated  
Gonococcal Infection

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## GONOCOCCEMIA

### Treatment

<p><b>Uncomplicated Gonococcal infection of cervix, urethra and rectum</b></p> <ul style="list-style-type: none"> <li>• Single dose of Tab. cefixime 500mg, Inj. Ceftriaxone 500 mg IM, tab. Ciprofloxacin 500mg, tab. Ofloxacin 400mg, or tab. Levofloxacin 250mg PLUS</li> <li>• If chlamydial infection is not ruled out- tab. Azithromycin 1 g single dose or tab. Doxycycline 100mg BID x 7days.</li> </ul>	<p><b>Uncomplicated Gonococcal infection of pharynx</b></p> <ul style="list-style-type: none"> <li>• Single dose of Inj. Ceftriaxone 125 mg IM, or tab. Ciprofloxacin 500mg PLUS</li> <li>• If chlamydial infection is not ruled out- tab. Azithromycin 1 g single dose or tab. Doxycycline 100mg BID x 7days</li> </ul>
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## GONOCOCCEMIA

- ❖ Treatment for DGI
- ❖ Ceftriaxone 1 Gram IV or IM q 24 hours + Azithromycin 1 Gram po single dose (adult) or Cefotaxime or Ceftriaxone 1 Gram IV q 8 hours (adult)
- ❖ Ceftriaxone 50 mg/kg/day IV (max 2 Grams) for 7 days (child < 45 kg) or if sensitive to Penicillin give Penicillin G 150,000 units/kg/day IV for 7 days (child < 45 kg)

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## TICK BORNE DISEASES

**tick removal**  
 Remove ticks immediately. They usually need to attach for 24 hours to transmit Lyme disease. Consult a physician if you remove an engorged deer tick.

**Using a tick spoon**  
 Place the wide part of the spoon on the skin near the tick. Push skin flat if necessary. Applying slight pressure downward on the skin, slide the remover forward so the small part of the tick is facing the tick. Confine the sliding motion of the remover to the tick.

**Using tweezers**  
 Grasp the tick close to the skin with tweezers. Pull gently until the tick lets go.

800-828-8228  
[www.mnmapublichealth.gov](http://www.mnmapublichealth.gov)

**tick ID**  
 KNOW THEM. PREVENT THEM.

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## TICK BORNE DISEASES

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## LYME DISEASE

- ❖ Incubation: 48 hours after bite by tick introducing a spirochete
- ❖ Prodromal: Variable from no symptoms to mild symptoms to abrupt systemic symptoms
- ❖ Eruptive: Stage 1 (EM rash) within 1 month
- ❖ Stage 2 (Annular rash) days or weeks after onset EM but may occur without preceding EM
- ❖ Stage 3 can develop months to years after bite
- ❖ Seasonal exposure in > children during summer and early autumn

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## LYME DISEASE

### Signs of Lyme Disease



**Erythema migrans**  
A red, circular rash with a white border, often called a "bull's-eye" rash. It typically appears 3 to 30 days after a tick bite.



**Facial Lyme disease**  
A facial rash consisting of three red spots on one side of the face, often around the eye.

**Other signs of Lyme disease**

- Joint pain and swelling
- Headache
- Stiff neck
- Memory loss
- Flu-like symptoms (fever, chills, fatigue)

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## LYME DISEASE



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## LYME DISEASE



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## ROCKY MOUNTAIN SPOTTED FEVER

- ❖ Vector: Dermacentor variabilis (East); Amblyomma americanum (West South Central); Dermacentor andersoni (West)
- ❖ Rickettsia present in salivary glands infect within 6 to 10 hours
- ❖ Seasonal peak begins April 1 to early summer ending September 30
- ❖ Risk Factors: Age < 4 and >60; Male; Native Americans and Blacks; chronic alcoholism; G6PD deficiency

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## ROCKY MOUNTAIN SPOTTED FEVER

The transmission cycle in Rocky Mountain spotted fever. Dog ticks and wood ticks are the principal vectors

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## ROCKY MOUNTAIN SPOTTED FEVER

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## ROCKY MOUNTAIN SPOTTED FEVER

**Identification**

- Classic Triad
  - Fever
  - Rash
  - History of tick bite
- Laboratory Tests
  - Thrombocytopenia
  - Hyponatremia
  - Elevated liver enzyme levels
  - Indirect immunofluorescence assay (IFA)
  - Reference standard



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## ROCKY MOUNTAIN SPOTTED FEVER



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## ROCKY MOUNTAIN SPOTTED FEVER



© 2003 Fowler - Bologna, Jarrico and Rapini: Dermatology - www.dermnet.com

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## ROCKY MOUNTAIN SPOTTED FEVER



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## ROCKY MOUNTAIN SPOTTED FEVER

**FIGURE 18.** Digital necrosis affecting the toes of a patient, occurring late in the course of Rocky Mountain spotted fever



Photo G.S. Marshall, University of Louisville School of Medicine, Louisville, KY

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## ROCKY MOUNTAIN SPOTTED FEVER

- ❖ Treatment: Drug of choice is Tetracycline, followed by Doxycycline or Chloramphenicol at full doses.
- ❖ Children < 8 and pregnant women should be treated with Chloramphenicol

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## TICK BITE PARALYSIS

- ❖ Occurs predominantly in young girls with thick long hair
- ❖ Seen in Pacific Northwest
- ❖ Due to a neurotoxin after prolonged 5 day feeding by the tick, *Dermacentor andersoni*
- ❖ Begins with fatigue, irritability and leg paresthesias followed by lost coordination, and ascending paralysis. Death from respiratory failure
- ❖ Treatment: find and remove tick with recovery in 24 hours

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## ZIKA VIRUS RASH



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## OBJECTIVES

- ❖ Develop a detailed history
- ❖ Perform a comprehensive examination of the skin, describing primary and secondary lesions
- ❖ Utilize appropriate laboratory studies
- ❖ Recognize those lesion that represent significant or life-threatening diseases
- ❖ Initiate timely treatments and currently approved treatments

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### QUESTION 1

The causative agent is correctly matched to the disease it produces except: (select the one best answer)

- ❖ A. Erythema Infectiosum- B19 Parvovirus
- ❖ B. Rocky Mountain Spotted Fever- Borrelia burgdorferi
- ❖ C. Hand Foot Mouth Disease- Coxsackie Virus
- ❖ D. Roseola- Human Herpes Virus 6 (HHV6)

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### QUESTION 2

Vesicular rashes that are less than 0.5 cm in diameter are associated with the following diseases except: (select the one best answer)

- ❖ A. Varicella
- ❖ B. Hand foot Mouth Disease
- ❖ C. Kawasaki's Disease
- ❖ D. Herpes Zoster

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### QUESTION 3

Characteristics of the Scarlet Fever rash include all of the following except: (select the one best answer)

- ❖ A. Does not blanch with pressure
- ❖ B. Has a goose flesh or sand paper texture
- ❖ C. Fades after one week and then desquamates extensively
- ❖ D. Spares palms, soles and face

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### QUESTION 4

American Heart Association criteria for Kawasaki's Disease may include any of the following except: (select the one best answer)

- ❖ A. Fever for five days or longer
- ❖ B. Elevated ASO titer
- ❖ C. Polymorphous rash
- ❖ D. Non-purulent bilateral bulbar conjunctivitis

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### QUESTION 5

A similarity between Lyme Disease and Rocky Mountain Spotted Fever is: (select one best answer)

- ❖ A. Both are caused by *Borrelia burgdorferi*
- ❖ B. Both occur in the same geographic regions
- ❖ C. Both produce digital necrosis
- ❖ D. Both have seasonal peaks

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**[Return to Top](#)**

**Intimate Partner Violence (IPV)...  
Screening as a Step to Healing**

**Pennsylvania Academy of Family Physicians  
and the Reading Hospital CME  
November 17 – 19, 2017**

Intimate Partner Violence (IPV)...Screening as a Step to Healing  
Wanda Filer, MD

**Disclosures:**

The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

The speaker has attested that their presentation will be free of all commercial bias toward a specific company and its products.

The speaker indicated that the content of the presentation will not include discussion of unapproved or investigational uses of products or devices.

## Intimate Partner Violence: Screening as a Step to Healing

Wanda D Filer, MD, MBA  
Strategic Health Institute

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## Disclosure

- The speaker has no conflict of interest, financial agreement, or working affiliation with any group or organization.

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**37% of women who seek  
emergency care in a hospital, for  
violence-related injuries, were  
injured by a current or former  
partner**

US Dept of Justice

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### According to the AMA, battered women account for

- 22-35% of women seeking care in ED
- 19-30% of injured women seen in ED
- 14% of women in ambulatory clinics
- 25% of women who attempt suicide
- 25% of women using emergency mental health care
- 45-59% of mothers of abused children

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### Your Patients and Mine

- 25-31% of American women, and 39% of Native American women, report being physically or sexually abused by an intimate partner at some point in their lives
- An estimated 10 million children witness that abuse each year
- Children may also experience the abuse firsthand

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### Prevalence and Chronicity

- American Journal of Preventive Medicine June 2006
- Random telephone survey of 3429 women ages 18-64, HMO enrollees
- Predominantly white, educated, employed
- 44% suffered some form of IPV in adult life
- 34% from physical and/or sexual abuse
- 35% from nonphysical abuse

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### Prevalence and Chronicity (cont)

- 45% of the abused women suffered more than one type
- 11-21% abused by more than one partner
- Median duration of abuse was <1-5 years
- 5-13% abuse lasted over 20 years!
- Repeated abuse episodes very common
- Younger, lower income, single mothers, child abuse survivors had highest rates

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### Health Effects of IPV

- American Journal Preventive Medicine June 2006: Dramatic health decline
- Abuse within past 5 years increased depression 2.4 fold and severe depression 2.7 fold
- Women with most recent physical/sexual assault had substantially lower physical, social, mental health functioning scores

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### Chronic Diseases: both survivors and witnesses

- Lung Diseases e.g. Asthma and COPD
- Heart disease and hypertension
- Ulcers and other GI diseases
- Diabetes
- Neurologic and Musculoskeletal Diseases
- Lack of Healthy Diet and Exercise
- Autoimmune Disorders

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### Chronic Diseases (continued)

- Depression and Anxiety
- PTSD
- High risk health decisions and behaviors
- Sleep disorders
- Substance Abuse
- Aggressive or violent behavior disorders

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Women who experience Intimate Partner Violence are 3 times more likely to display symptoms of depression, 4 times more likely to have PTSD, and 6 times more likely to have suicidal ideation (Prevention Institute)

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### Electronic Health Records and IPV

- Archives of Internal Medicine, June 2006
- Computer-based health risk assessment completed by female patients who could self-disclose IPV
- Physician prompt to discuss IPV based on patient answers
- Computer prompt improved, did not guarantee that IPV would be discussed.

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## EHR and IPV (cont.)

- 26% urban and 21% suburban women in study were at risk for IPV
- Suburban women, white, private insurance and more educated women least likely to be asked about IPV
- Only 48% of computer prompts led to physician discussions
- For patients with IPV discussed, patient satisfaction with care was higher

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## Integrating IPV Assessment & Intervention into Healthcare in the US

- USPSTF recommends IPV screening & counseling
- Requires health system integration: EHR, quality incentives, supportive resources, clinician knowledge, varying approaches and patient populations, cultural issues
- [Ncbi.nlm.nih.gov/pmc/articles/PMC4302956/](http://Ncbi.nlm.nih.gov/pmc/articles/PMC4302956/)
- J Womens Health(Larchmt).2015 Jan 1; 24(1):92-99

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## Common Comorbid Conditions

- Chronic Pain Syndromes: migraine, pelvic, fibromyalgia, CFS, arthritis
- STD' s including HIV
- Morbid Obesity
- Difficulty controlling chronic diseases
- Compliance with recommended care
- Delayed Prenatal Care/ Teen Pregnancy

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## Other Barriers

- Low Literacy due to educational challenges
- Language and cultural barriers
- Financial resources constrain access
- Multigenerational issues
- Aging perpetrators and survivors
- Disabled patients: 20% of US population in some definitions, very high risk

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**Pregnancy is a time when violence often begins or escalates**

**Pregnant women need to be screened at EVERY visit**

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**Pregnant or recently delivered women are more likely to die of homicide than any other cause.**



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## Financial Impacts

- One managed care plan experienced costs that were 92% higher for women who were victims of partner abuse than their general female enrollee-Journal of Family Practice 1999
- Direct medical and mental health care costs for victims exceed \$5.8 billion annually –CDC 2004

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## Financial Impact

- Minnesota health plan study revealed that abused women incur \$1775 more health care service dollars annually than general enrollees.
- Early identification and treatment was deemed most beneficial
- May have extensive and lifelong needs

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## Quality Care Includes Screening

- Most Americans say they could tell a physician if they had been a victim or a perpetrator!!
- 81% of all patients wish their provider would privately ask them.
- 57% of Americans personally know a victim of domestic violence

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## Forms of Abuse

- Physical Abuse
- Mental Abuse
- Sexual Abuse
- Property or economic abuse

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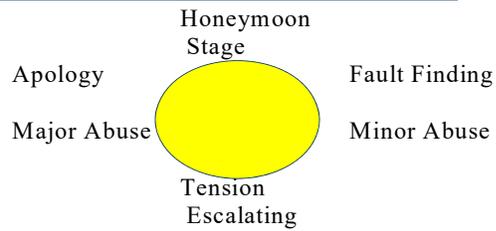
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## Cycle of Violence



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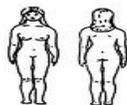
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## Patterns of Injury



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## RADAR Screening Tool

- R- Routinely Ask
- A- Ask Direct Questions
- D- Document Findings
- A- Assess Safety
- R- Referral

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## RADAR

- Routinely ask
- Non-judgmental, open ended
- Health system and office protocols
- Interview patients ALONE
- Engage staff in process
- Consider cards in rest rooms
- Staff may have own personal issues

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## RADAR

- ASK direct question?
- Do you feel safe at home?
- What happens when you argue?
- Do you ever feel unsafe in your relationship?
- I notice bruises, who did this to you?
- Are you ever forced/coerced to perform sexual acts?

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## RADAR

- DOCUMENT your findings
- Use patients own words and name of assailant
- Consider use of body map or photos
- Tell patient that this information is in records and record physical findings
- If DV suspected but not confirmed by patient, consider for differential dx list

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## RADAR

- ASSESS safety
- Is there a pattern of abuse? Escalating severity and/or frequency?
- Death threats against patient or family?
- Injury/death of pet?
- Weapon in the home?
- Is she afraid to go home?
- Who controls medications?

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## RADAR

- REFERRAL –be selective!
- Know local resources e.g. shelters
- Consider protective admission
- Respect patient as an adult capable of own decisions, set follow-up with YOU
- Offer brochures and use of private phone

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### **RADAR: Other points**

- State reporting requirements variable
- Office staff confidentiality
- AVOID “Just Leave” advice
- Children often victimized -mandated reporters
- Comorbid issues e.g. mental health, substance abuse, injuries, pregnancy/STD’ s
- Protection From Abuse Order -PFA

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**Remember : Women are more likely to be killed at the time they are leaving a relationship and for the next year.**

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**If a weapon is involved, you must report this to police in most areas.**

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- 33% of homeless persons identify domestic violence as the cause
- 21-30% of American college students report at least one occurrence of physical assault by a dating partner
- In homes with DV, children are abused or neglected at a 1500% higher rate than the national average

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### BEFORE the violence

- Ask family, friends and others for help
- Make a list of people who can give you shelter, rides and money
- Make a list of phone numbers: police, hospital, hotline
- Have an emergency kit with money, ID for self and kids, checkbook, spare keys, meds, pay stubs, food stamps, toys (easy access)

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### DURING the violence

- Call police or have someone else call
- Grab emergency kit if you can
- GET OUT! Take your children with you!

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## AFTER the violence

- Get medical help and tell them what happened
- Have the doctor, nurse, or friend take pictures
- Save any ripped or bloody clothes
- Talk to someone about your options -call a 24 hour hotline

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## Sexual Assault

- 1 in 4 females, 1 in 5-6 males: lifetime risk
- 60% before age 18
- Know state laws
- Sexual Assault forensic examiner programs in ED's, expanding community programs nationwide
- Immediate and survivorship issues impact health long term
- Comorbid issues extensive

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## Messages of Collusion or Blame

- When we advise a victim to be more assertive or accommodating to stop the violence
- When we fail to ask direct questions about injuries
- When we fail to hold the perpetrator accountable and engage in victim blaming

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## Community Action Steps

- Fatality Review Team
- Sexual Assault Response Teams
- Family Violence Task Force
- Hospitals developing emergency housing backup if shelters full
- Batters Treatment Programs
- Involving Public Health
- Blame placed on abuser and NOT the victim

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## National Domestic Violence Hotline

1-800-799-SAFE (7233)

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## Pennsylvania Coalition Against Domestic Violence

- **\*National Resource Center**
- 3605 Vartan Way #101  
Harrisburg,  
PA 17110
- [www.pcadv.org](http://www.pcadv.org)

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## Resources

[FuturesWithoutViolence.org](http://FuturesWithoutViolence.org)

- [PreventionInstitute.org](http://PreventionInstitute.org)
- [ACESTooHigh.com](http://ACESTooHigh.com)
- [DomesticViolenceResearch.org](http://DomesticViolenceResearch.org)

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## PA Coalition Against Rape

- National Sexual Violence Resource Center
- [www.nsvrc.org](http://www.nsvrc.org)
- [www.pcar.org](http://www.pcar.org)

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## Wanda D. Filer, MD, MBA FAAFP

- Strategic Health Institute  
510 Aqua Court  
York, PA 17403
- 717-873-8258

[drfiler@comcast.net](mailto:drfiler@comcast.net)  
[@DrWandaFiler](https://twitter.com/DrWandaFiler)



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