57th Annual Family Medicine Seminar

July 31 - August 3, 2014
Sagebrush Inn & Suites - Taos, New Mexico

Karen Phillips, M.D., Scientific Program Chair

This activity has been reviewed and is acceptable for up to 23 Prescribed credits by the American Academy of Family Physicians
All speakers have indicated they have nothing to disclose except for the following:


**Larry Leeman, MD, MPH** - content of presentation will include use of Mirena IUD in nulliparous women and all IUDs in immediate postpartum period

**Fernando Martinez, MD, MS** - Research Support - Bayer, Forest, GSK, Gilead, Janssen, Promedior; Consultant - Abil, Axon, BI, CSA Medical, Forest, GSK, Ikaria, Merck, Pfizer, Carden, Jennings; Speakers Bureau - CME Incite, Innova Health System, NACE, NCME, Takeda/Nycomed Peer Voice, Projects in Knowledge, St. John's Hospital, St. Mary's Hospital; Other - UpToDate, Stromedix (DSMB); Presentation will reference unlabeled/unapproved drug - Azithromycin

**Lori Heim, MD** - CME Advisory Board - LabCorp - General medicine - development of CME topics not content

**George Bakris, MD** - Research Grants & Consultant for Fee - Takeda, AbbVie, Medtronic, Relysis, Daiichi-Sankyo - Kidney Disease Progression/Hypertension; Novartis, Lilly - Kidney Disease Progression

**Marlin Hoover, PhD, MS** - Financial relationship with Marlin Hoover PhD, PC - a clinical psychology private practice professional corporation
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THURSDAY, JULY 31, 2014

8:00 a.m.  Registration, Exhibits Open
Breakfast - Exhibit Hall

8:50 a.m.  Introduction & Welcome
Karen Phillips, M.D., President Scientific Program Chair

9:00 a.m.  “The Learning Connection: Physical Activity, Nutrition, Cognition and Academic Performance”
Joseph Donnelly, ED.D., FACSM

10:00 a.m.  “Special Needs Populations”
Toni Benton, MD

11:00 a.m.  “Contraception Update”
Larry Leeman, MD

12:00 p.m.  Lunch - Exhibit Hall

1:00 p.m.  “Immunizations: Big and Small Changes in Protecting our Patients”
Melissa Martinez, MD

2:00 p.m.  “Integrating Advance Care Planning Discussions into Routine Patient Care”
Lorrie Griego, Program Manager of Advanced Care Planning

3:00 p.m.  Break – Exhibit Hall

3:30 p.m.  “Congestive Heart Failure”
Bart Cox, MD

4:30 p.m.  “Professional Burnout and Resilience: Maintaining Humanity, Compassion and Excellence in an Ever More Challenging Practice Environment”
Damian Bello, MD

5:30 p.m.  At Leisure

6:00-8:00 p.m.  Welcome Reception – Barbeque Dinner on the Patio
Honored Guest - Lori Heim, MD, Past AAFP Board Chair
“The Learning Connection: Physical Activity, Nutrition, Cognition and Academic Performance”

by

Joseph E. Donnelly, ED.D., FACSM

**Joseph E. Donnelly, ED.D., FACSM** is a Professor of Internal Medicine, and Director of Energy Balance Laboratory and Center for Physical Activity and Weight Management, and Cardiovascular Research Institute at the University of Kansas Medical Center and the University of Kansas-Lawrence. His interest is the prevention and treatment of obesity and related comorbid conditions in children and adults. He is the Director of an ongoing clinical research program termed the “Weight Control Research Project” that has provided treatment to over 3,000 individuals. In the past 15 years he has been a principal investigator for 15 major NIH awards totaling over 40 million in research funding and has published over 200 scientific articles on diet and physical activity for weight management. He was the senior author for the American College of Sports Medicine position stand “Appropriate Physical Activity Intervention Strategies for Weight Loss and Prevention of Weight Regain for Adults,” and is the past chair of the NIH study section “Psychosocial risk and disease prevention.” He is currently principal investigator for a NIH funded project investigating the use of physical activity to deliver academic lessons to children in elementary schools to diminish obesity, improve fitness and to impact academic achievement.

Email: jdonnelly@ku.edu

**Learning Objectives**

At the end of this presentation, the attendee will be able to:

- Understand the connection between physical activity and fitness with behavior, cognition, and academic achievement
- Recognize the role fitness and nutrition plays in schools to enhance the learning environment
- Identify opportunities and resources for schools and students to increase access to physical activity and nutrition
The Learning Connection: Physical Activity, Nutrition, Cognition, and Academic Performance

Joseph E. Donnelly, ED.D, FACSM
Professor, Internal Medicine
Director, Energy Balance Laboratory
Director, Center for Physical Activity & Weight Management
The University of Kansas Medical Center
The University of Kansas-Lawrence

Distribution of the Metabolic Syndrome & Its Related Components

Distribution of the Metabolic Syndrome & Its Related Components By BMI Levels

Distribution of the Metabolic Syndrome & Its Related Components By Race

TOXIC ENVIRONMENT

• An environment that promotes sedentary behavior
• Few opportunities for physical activity during the course of daily living
• Almost no need to be physically active to survive
• Abundance of high density foods
• Little need to expend energy for foods

Food has never been cheaper, more available and accessible
Where has all the physical activity gone?

Theoretical Model to Improve Health & Academic Achievement

Aerobic Fitness & Achievement Test Performance

Body Mass Index & Achievement Test Performance

Schools are Sedentary

- Bus ride can be > 60 min each way
- Recess and physical education has declined to levels that cannot provide adequate stimulus (energy expenditure) for fitness or to protect against fatness
- Motor time off task is discouraged and disciplined
- Traditional teaching paradigm- sit down and be quiet
Car Loading

Schools Present Challenges

- Schools appear to be ideal intervention sites but
  - Difficult to penetrate for permission to conduct PA studies
  - Not tolerant of biological samples (i.e. blood)
  - Not tolerant of infringement on classroom time
  - Not tolerant of additional teacher time
  - Frequently have poor facilities

Schools Present Challenges

- PE class in elementary school is generally 30min X 2d/wk, facilities, equipment, teacher to student ratio vary and often are poor, especially in lower SES, ethnic schools
- Recess is frequently eliminated in order to provide more instruction time

More Challenges

- Standardized tests (i.e. No Child Left Behind)
- Special events- field trips, assembly, etc.
  - Note only 40-60% of allocated instructional time is spent in instruction
- Absenteeism
- Child and teacher transfer between schools
- Dose of intended intervention severely compromised by all the above
- Etc.

Schools Provide Opportunities

- Children go to school
- Permanent facility
- Administration can “demand” uniformity
- Educated workforce used to delivering curriculums and evaluating outcomes

Schools Provide Opportunities

- Existing in-service mechanism
- Have physical activity and nutrition (health) mandated at the state level, but have little expertise for design and implementation
- Extended contact with children at most receptive and influential age
  - 8 hours/d
  - 5d/wk
  - 9 months/yr
Approach

• Behavioral - individual changes behavior using a variety of strategies such as
  – Improving self efficacy, planning, social support, contingency planning
• Social Marketing - similar to advertising whereby behaviors are marketed as desirable, frequently using “Madison Avenue” techniques
• Environmental - restructure environment to get desired behavior, may employ behavioral economics

Energy Intake

Adequate Nutrition and AA

[Graph showing Energy Intake Adequate vs Inadequate]

Kleinman et al., Ann Nutr Metab, 2012

Energy Expenditure

Physical Activity Across the Curriculum (PAAC)

A 3-year, randomized controlled trial of physical activity and academic achievement for elementary school children in grades 2 & 3

Donnelly et al., Physical Activity Across the Curriculum (PAAC): A randomized controlled trial to promote physical activity and diminish obesity in elementary school children.

Major Aims of PAAC

- Increase physical activity by using classroom teachers to teach existing lessons with using physical activity
- Primary aim-
  - Diminish increases in BMI
- Secondary aims-
  - Determine association between physically active lessons and academic achievement
  - Characterize metabolic syndrome

The PAAC Program

- A classroom-based approach to reduce sedentary behavior while maintaining the focus on academics
- NO DECREASE in academic instruction time
- PAAC is a technique to deliver existing academic instruction through movement

The PAAC Program

Integrate 10 minute periods of physical activity within academic lessons for a total of 90 min/wk (i.e. 1 ten min lesson in morning and afternoon.

- Language art
- Math
- Science
- History

Traditional VS. PAAC Classroom

Conceptual Framework

- Minimal intervention
- Enhances learning
- No additional teacher preparation time
- No additional cost
- Easily perpetuated and replicated
- Desirable for both teacher and student (i.e., FUN)
- Students “must” participate in classroom lessons

Design

- Cluster randomized, controlled trial N=22
- 3 year intervention
- Grades 2&3
- Target 90 minutes of moderate to vigorous physical activity/wk
- Use classroom teachers to deliver existing academic lessons using physical activity
Active Lesson

Learning to Spell

Learning Math

Learning Spanish

Level of Physical Activity

Energy Expenditure of PAAC Lessons with Cosmed
- 38 boys & girls
- Grades 2-5
- PAAC lessons of ≥ 10 min duration
- Average MET = 3.4 (lower end of moderate to vigorous)
Energy Expenditure of Exercise

38 boys & girls
Grades 2-5
PAAC lessons of ≥ 10 min duration
Average MET = 3.4 (lower end of moderate to vigorous)
Homan et al., MUSE, 2008

Will more vigorous exercise provide a greater response for cognitive function (and perhaps academic achievement?) Davis et al., Health Psychol, 2011

BMI Change Across 3 Years for PAAC Schools Receiving 75+ min of PA or < 75 min PA

<table>
<thead>
<tr>
<th></th>
<th>75+ min</th>
<th>&lt;75 min</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI Change</td>
<td>2.4±0.2</td>
<td>1.8±0.1</td>
</tr>
</tbody>
</table>

P=0.0003

9 schools 75+ min
5 school <75 min

Academic Achievement- Individual Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Reading 3yr</th>
<th>Math 3yr</th>
<th>Spelling 3yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>112</td>
<td>112</td>
<td>110</td>
</tr>
<tr>
<td>3yr</td>
<td>110</td>
<td>110</td>
<td>110</td>
</tr>
<tr>
<td>9</td>
<td>114</td>
<td>114</td>
<td>114</td>
</tr>
</tbody>
</table>

Donner Adjusted t for Each Category p ≤ 0.01

Relationship Between Teacher Modeling & Physical Activity Levels in Students (Intervene with teachers to benefit students?)

<table>
<thead>
<tr>
<th>Level of Teacher Modeling</th>
<th>None</th>
<th>Some what active</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA Level by SOFIT score</td>
<td>3.5</td>
<td>4.0</td>
<td>4.5</td>
</tr>
</tbody>
</table>

P<0.0001; dose-response relationship between teacher modeling and PA level
Gibson et al., IJBNPA, 2008

Activity Level Measured by Accelerometry

<table>
<thead>
<tr>
<th>Accelerometer Period</th>
<th>Control (N=90)</th>
<th>Intervention (N=77)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-d Ave</td>
<td>744 (183)</td>
<td>851 (233)</td>
<td>0.007</td>
</tr>
<tr>
<td>Weekend Day</td>
<td>750 (219)</td>
<td>901 (279)</td>
<td>0.005</td>
</tr>
<tr>
<td>During School</td>
<td>606 (205)</td>
<td>688 (199)</td>
<td>0.01</td>
</tr>
<tr>
<td>After School</td>
<td>946 (312)</td>
<td>1,097 (360)</td>
<td>NS</td>
</tr>
<tr>
<td>Evening</td>
<td>812 (249)</td>
<td>891 (361)</td>
<td>NS</td>
</tr>
</tbody>
</table>

Values are means (SD); * Controlling for gender, race, ethnicity, and cohort.

"P<0.0001; dose-response relationship between teacher modeling and PA level" Gibson et al., UBNPA, 2008
9-Months Post Intervention Teacher Survey

Percentage Use

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
<th>70</th>
<th>80</th>
<th>90</th>
<th>100</th>
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<td>2-4 d/wk</td>
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<td>most or every</td>
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<td>did not use</td>
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</tbody>
</table>

A+PAAC Design- Emphasis on Academic Achievement

• Adequately powered, cluster randomized trial
• 17 elementary schools, (9 intervention, 8 control)
• ~ 20 children from 2nd & 3rd grades followed 3 yrs. to 4th and 5th grades (~40/school, 682 children total)
• 20 minutes of A+PAAC lessons/day

DK55317, Donnelly PI

A+PAAC Outcomes

• Academic achievement measured by Wechsler Individual Achievement Test III
• State administered achievement tests
• Cognitive function- Flanker, n-back (Hillman)
• Anthropometrics, fitness (Pacer), blood chemistry, blood pressure, attention-to-task (Mahar), energy expenditure of A+PAAC lessons (indirect calorimetry via CosMed)

TAKE 10! To Date

• 4 revisions of the program have been completed -- all with
• TAKE 10! continues to be designed with a “school system fit” orientation:
  – little change is required in an elementary school.
  – no special equipment or training is needed.
  – grade-specific linkages

www.take10.net

Energy Expenditure

• 3 Classrooms, CSA accelerometers & digital pedometers
• 10-minute sessions

<table>
<thead>
<tr>
<th>Grade</th>
<th>Avg MET levels</th>
<th>Avg kcal expenditure</th>
<th>Pedometer step counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Grade</td>
<td>5.72-7.05</td>
<td>25.6-27.8</td>
<td>644-931</td>
</tr>
<tr>
<td>3rd Grade</td>
<td>5.51-6.77</td>
<td>27.6-33.9</td>
<td>659-1376</td>
</tr>
<tr>
<td>5th Grade</td>
<td>4.98-7.19</td>
<td>29.7-42.9</td>
<td>1002-1041</td>
</tr>
</tbody>
</table>


How Does Physical Activity Influence Academic Achievement?

• Brain function
• Attention-to-task
• Body fatness
• Physical fitness
• Physical activity
• Parent characteristics, SES
Mean percentage of intervals of on-task behavior pre and post Energizers for one fourth grade class.


Comprehensive School-based Physical Activity Program (CSPAP)

Physical Activity During the School Day

- Embed physical activity in the school curriculum
- No more than 60-mins of sedentary time
- At least 10-mins of physical activity after sedentary time
- Consider activity type, intensity, and the academic task
- Measure physical activity intensity
- Become NASPE certified Director’s of Physical Activity
- Provide opportunities for:
  - Formally structured physical activity
  - Informal physical activity – play
  - Content-rich physical activity

DIRECTOR OF PHYSICAL ACTIVITY

Launch!

March 13, 2012
AAHPERD Convention
Boston, MA
NASPE DPA Certification

CDC Review

- 43 articles reporting 50 unique studies
- Coded by physical activity context
- Investigated increasing time spent in physical education or physical activity

www.cdc.gov/healthyyouth, April, 2010
Results of CDC Review

- General findings
  - Positive or no relationship between time in physical education/recess/sports and academic achievement and indicators of cognitive function
  - Positive relationships between classroom physical activity and indicators of academic achievement, classroom behavior, and cognitive function

How to Increase Physical Activity in Schools Without Decreasing Academic Instruction

- Increase time children are physically active in physical education and recess
- Provide access to physical activity before and after school
- Promote active transportation
- Provide physically active lessons

What is Needed to Promote Non-Traditional Physical Activity in Schools

- Low cost/no cost, sustainable programs through university teacher preparation
- Low teacher burden for lesson preparation
- Activity disconnected from motor skills
- Additional evidence to link physical activity/fitness & learning
  - Plausible biological model combined with evidence from well designed interventions linking to state academic achievement tests
- Policy change

Summary: Level of Evidence for Physical Activity, Nutrition & Academic Achievement

- Fitness (aerobic capacity) seems to be associated with academic achievement
- Academic lessons taught with physical activity have been shown to improve academic achievement and attenuate increases in BMI (2 for 1)
- Physically active lessons may improve attention-to-task, a behavior associated with learning, and critical to classroom management

There is no evidence that removal of physical activity programs results in greater academic achievement

Research Questions

- How much PA is needed to improve academic performance and how much can the school be expected to provide
- Are there temporal effects of PA on academic performance and are any observed improvements lasting
- Are any positive effects of PA mediated by cognitive function or are other factors equally important
- Are fitness and fatness independently associated with academic performance
- For which students will active lessons provide the greatest benefits
- Do academic lessons taught by physical activity provide greater benefits compared to fitness breaks
- Etc.
Physical Activity Across the Curriculum (PAAC): A randomized controlled trial to promote physical activity and diminish overweight and obesity in elementary school children


* The Center for Physical Activity and Weight Management, The Schiefelbusch Institute for Lifespan Studies, 1301 Sunnyside Ave, Rm 100 Robinson Center, University of Kansas, Lawrence, KS 66045, USA

ABSTRACT

Background. Physical Activity Across the Curriculum (PAAC) was a three-year cluster randomized controlled trial to promote physical activity and diminish increases in overweight and obesity in elementary school children.

Methods. Twenty-four elementary schools were cluster randomized to the Physical Activity Across the Curriculum intervention or served as control. All children in grades two and three were followed to grades four and five. Physical Activity Across the Curriculum promoted 90 min/wk of moderate to vigorous intensity physically active academic lessons delivered by classroom teachers. Body Mass Index was the primary outcome, daily Physical activity and academic achievement were secondary outcomes.

Results. The three-year change in Body Mass Index for Physical Activity Across the Curriculum was 2.0±1.9 and control 1.9±1.9, respectively (NS). However, change in Body Mass Index from baseline to 3 years was significantly influenced by exposure to Physical Activity Across the Curriculum. Schools with ≥75 min of Physical Activity Across the Curriculum showed significantly less increase in Body Mass Index at 3 years compared to schools that had <75 min of Physical Activity Across the Curriculum (1.8±1.8 vs. 2.4±2.0, p = 0.02). Physical Activity Across the Curriculum schools had significantly greater changes in daily Physical activity and academic achievement scores.

Conclusions. The Physical Activity Across the Curriculum approach may promote daily Physical activity and academic achievement in elementary school children. Additionally, 75 min of Physical Activity Across the Curriculum activities may attenuate increases in Body Mass Index.

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Introduction

Sedentary behavior is associated with increases in BMI and in turn, increased risk and comorbidities in children including the dramatic increase in type 2 diabetes (T2DM) [Daniels et al., 2005; Steinberger and Daniels, 2003]. Schools are an ideal site to intervene with children. Approximately 98% of children are enrolled in school (U.S. Census Bureau, 2006) and this provides access to children and enables repeated exposure to health promotion interventions [Goran et al., 1999; Kann et al., 2001]. School policies can be modified and teachers and other personnel can be trained to deliver health promotion interventions. Schools offer continuity, so successful interventions may be sustained after the initial intervention and may be disseminated throughout school systems.

Unfortunately, schools may be a barrier for interventions to promote physical activity (PA). Children are required to sit quietly...
for the majority of the day to receive academic lessons. In a typical school day, this represents approximately 6 h, and may be extended by 30 min or longer if the child is provided motorized transportation and does not actively commute to and from school. To increase PA in elementary school children, we designed and implemented a low cost, minimal intervention model that increased PA in the classroom. The intervention provided training for classroom teachers to deliver existing academic lessons taught through PA. In addition, we partnered with TAKE 10!, a program of the International Life Sciences Institute Research Foundation/Center for Health Promotion that promotes PA in the classroom. The combination of existing lessons from teachers and examples from Take 10 activities was termed “Physical Activity Across the Curriculum,” or “PAAC.”

The primary aim of PAAC was to increase PA sufficiently to reduce gains in BMI for PAAC compared to control schools. Secondary aims (sub-sample) were to assess changes in metabolic fitness, aerobic capacity, skinfolds, circumferences, daily PA, diet intake, and academic achievement in children who received PAAC compared to control. Results for BMI, PA and academic achievement are presented in this paper. Results for other secondary outcomes have been published elsewhere (DuBose et al., 2006, 2007, 2008; Eisenmann et al., 2007; Gibson et al., 2008).

Methods

Design

PAAC was a three-year, cluster randomized, controlled trial. Twenty-six elementary schools in Northeast Kansas were randomized to receive PAAC or to serve as control. Randomization was stratified by school size and rural versus urban location. PAAC promoted 90 min/wk of moderate to vigorous physically active academic lessons (3.0 to 6.0 METS, ~10 min each) delivered intermittently throughout the school day. Ninety minutes was chosen as the target since children were receiving 60 min of physical education per week and combined with PAAC lessons and this would total 150 min of PA per week which was consistent with recommendations from Healthy People 2010 (U.S. Department of Health and Human Services Public Health Service, 2000). The primary outcome was the difference in change in BMI from baseline to year three between PAAC and control schools. A sub-sample of volunteer participants was recruited from each school to measure the secondary outcomes.

Participants

Participants were in grades two and three at baseline and were in grades four and five at the end of the study. All students in the respective grades in the schools randomized to PAAC participated in PAAC since it was adopted as a curriculum. All students in the control schools received regular classroom instruction without physically active lessons. Written parental consent and child assent was obtained prior to participation in the sub-sample testing.

Classroom teacher training for implementation of PAAC

Training was provided to classroom teachers at each PAAC school in a six hour in-service at the beginning of each school year. Teachers who joined a school after the in-service received individual instruction. Teachers from PAAC schools who transferred to control schools were instructed not to use PAAC. The goal of in-service training was to develop competency and strategies to deliver 90 min of moderate to vigorous intensity, physically active PAAC lessons per week. Details of teacher training have been published previously (DuBose et al., 2008; Gibson et al., 2008).

Training of research assistants for teacher support and outcome testing

Research assistants (RA) were trained to support the classroom teachers in the design and delivery of PAAC, in trouble shooting, and problem solving strategies. RA who conducted testing were trained to collect valid and reliable data and had to obtain intraclass correlations of 0.90 or greater to be certified to administer each test. The exception was the academic achievement tests that were completed by a separate group of RA from a nearby university. Each RA for academic achievement was individually trained and certified by one of the investigators (JR).

Primary outcome (BMI)

Height and weight were obtained at the beginning and end of all 3 years with a stadiometer and digital scale accurate to ± 0.1 kg. Children were measured in private during the first period of the school day in t-shirts, shorts, and socks provided by the project staff. BMI percentiles were calculated using gender and age (Kuczmarski et al., 2002).

Secondary outcomes (sub-sample only)

Sub-sample measures were obtained at baseline and at 3 years. Detailed descriptions of all sub-sample evaluations have been reported previously (DuBose et al., 2008). Tests that are relevant to this paper are briefly described below.

Daily PA

From the sub-sample, a smaller sample of children (~12 children/school) was randomly selected to wear an accelerometer (ActiGraph, 7163, Pensacola, FL) in the spring semester of each year. Accelerometers were worn over four consecutive days, which included two weekdays and two weekend days.

Academic achievement

Academic achievement for reading, writing, mathematics, and oral language skills was measured using the Wechsler Individual Achievement Test-2nd Edition (WIAT-II-A; The Psychological Corporation, 2001). The standardization sample for the WIAT-II-A consisted of 5586 individuals who were representative of the U.S. population in terms of age, sex, race/ethnicity, grade, and geographic region during 1999 through 2001. The WIAT-II-A has excellent inter-scorder reliability (i.e., 0.94 to 0.98), internal consistency (i.e., by age-range from 0.89 to 0.98), and test–retest stability (i.e., for children 6 to 9 years of age, 0.92 to 0.98 over 7 to 45 days). Validity is supported via item reviews of curriculum experts and by correlations with other achievement tests (i.e., 0.52 to 0.89), measures of intelligence (i.e., 0.30 to 0.78), teacher evaluations (i.e., 0.45 to 0.64), and school grades (i.e., 0.29 to 0.57). The WIAT-II-A was individually administered during a 30-minute period. The WIAT-II-A produces an age based score that can be compared to show trends across time.

Implementation and fidelity of PAAC

Extensive process evaluation measures were collected to monitor the extent to which the teachers delivered PAAC lessons as originally planned, to track the extent to which PAAC had been implemented, and to assess the levels of student and teacher PA during PAAC lessons across the school year. A detailed description of the process measures has been published elsewhere (Gibson et al., 2008).

Direct observations of classroom PA

Intensity of classroom PA was measured by a validated time-moment sampling procedure “System for Observation of Fitness Instruction Time,” (SOFIT) (McKenzie et al., 1991). SOFIT is rated on a Likert scale from one to five anchored with lying down for one and very active (i.e. running) for five.

Blinding

RA were blinded to condition for measurement of the primary and secondary outcomes, and for data entry. RA who conducted classroom visitations were not blinded.

Randomization and power

A cluster randomized controlled design was used with school as the unit of randomization. Twenty-six schools were randomly assigned to treatment or control stratified by district and size. The primary endpoint of this study was change in BMI between the two treatments. The methods of Donner, et al. were used for sample size and power considerations (Donner and Klar, 2000).
PAAC was powered with the assumptions of (1) a moderate ICC of 0.1; (2) a two-unit increase in BMI for control children with a standard deviation of 1.5; and (3) a 1.5-unit increase in BMI for intervention children with a standard deviation of 1.5 across 3 years. The power to detect these differences was >0.80.

Statistical analysis

An adjusted t-test (Donner and Klar, 2000), which accounts for the intraclass correlation, was used to assess change in BMI from baseline to 3 years. Change in BMI was also analyzed longitudinally, using a linear mixed model with an autoregressive type 1 covariance structure for the longitudinal measurements over time and compound symmetric covariance structure for the intraclass correlation within schools, also adjusting for gender. SOFIT data were compared between treatment groups using a mixed linear model adjusting for grade, semester, and gender. The effects of teacher modeling on SOFIT scores were analyzed using ANOVA. Demographic data were summarized descriptively, using means and standard deviations for continuous data and frequencies and percentages for categorical data. Change from baseline to end of study was analyzed using an adjusted t-test (Donner and Klar, 2000) and a linear mixed model was used to analyze longitudinal data over time. Data in the sub-sample were analyzed in a similar fashion to the main outcome. All quantitative analyses were done using SAS version 9.1 (SAS Institute, Inc., Cary, NC, USA).

Results

Participants

Twenty-six elementary schools were initially randomly assigned to PAAC or control. Two schools (8%) discontinued participation; one due to closing of the school and one refused randomization to control. Twenty-four schools completed the study; 14 PAAC and ten control. At baseline, there were 1527 participants, 814 in PAAC schools and 713 in control schools. Boys comprised 48.8% and girls 51.7% of participants. Baseline, there were 1527 participants, 814 in PAAC schools and 713 in control schools. Boys comprised 48.8% and girls 51.7% of participants. At year three, there were 1490 participants for an attrition rate of 2.5%.

Twenty-four schools completed the study; 14 PAAC and ten control. At baseline, there were 1527 participants, 814 in PAAC schools and 713 in control schools. Boys comprised 48.8% and girls 51.7% of participants.

Table 1
Baseline demographics by grade, gender, and intervention group (University of Kansas, 2003–2006).

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>PAAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>17.4 (3.0)</td>
<td>17.7 (3.0)</td>
</tr>
<tr>
<td>Male</td>
<td>17.5 (3.1)</td>
<td>17.7 (3.0)</td>
</tr>
<tr>
<td>Grade 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>18.7 (3.8)</td>
<td>18.4 (3.4)</td>
</tr>
<tr>
<td>Male</td>
<td>18.6 (4.0)</td>
<td>18.1 (3.4)</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>7.8 (0.4)</td>
<td>7.7 (0.3)</td>
</tr>
<tr>
<td>Male</td>
<td>7.8 (0.3)</td>
<td>7.7 (0.4)</td>
</tr>
<tr>
<td>Grade 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8.7 (0.4)</td>
<td>8.7 (0.4)</td>
</tr>
<tr>
<td>Male</td>
<td>8.8 (0.4)</td>
<td>8.7 (0.3)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>126.6 (5.6)</td>
<td>125.6 (5.6)</td>
</tr>
<tr>
<td>Male</td>
<td>127.3 (6.4)</td>
<td>127.3 (6.2)</td>
</tr>
<tr>
<td>Grade 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>132.1 (6.5)</td>
<td>131.9 (6.2)</td>
</tr>
<tr>
<td>Male</td>
<td>132.9 (6.2)</td>
<td>132.4 (6.4)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td></td>
<td></td>
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<tr>
<td>Grade 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>28.2 (6.5)</td>
<td>28.3 (6.5)</td>
</tr>
<tr>
<td>Male</td>
<td>28.6 (7.3)</td>
<td>28.9 (6.8)</td>
</tr>
<tr>
<td>Grade 3</td>
<td></td>
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<tr>
<td>Female</td>
<td>33.0 (9.5)</td>
<td>32.2 (7.6)</td>
</tr>
<tr>
<td>Male</td>
<td>33.1 (9.1)</td>
<td>32.1 (8.3)</td>
</tr>
</tbody>
</table>

Values are means (SD). There were no significant differences between PAAC and control.

Table 2
BMI change from baseline (University of Kansas, 2003–2006).

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>PAAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-week</td>
<td>0.83</td>
<td></td>
</tr>
<tr>
<td>Change from baseline</td>
<td>2.0 (1.9)</td>
<td>2.0 (1.9)</td>
</tr>
</tbody>
</table>

Values are mean (SD).

Table 3
Mean accelerometer counts/min (University of Kansas, 2003–2006).

<table>
<thead>
<tr>
<th>Accelerometer Periods</th>
<th>Control (n = 90)</th>
<th>PAAC (n = 77)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-day average</td>
<td>744 (183)</td>
<td>851 (233)</td>
<td>0.007</td>
</tr>
<tr>
<td>Weekday</td>
<td>738 (192)</td>
<td>800 (222)</td>
<td>NS</td>
</tr>
<tr>
<td>Weekend day</td>
<td>750 (219)</td>
<td>901 (279)</td>
<td>0.001</td>
</tr>
<tr>
<td>During school (8 AM–2:59 PM)</td>
<td>606 (205)</td>
<td>688 (199)</td>
<td>0.01</td>
</tr>
<tr>
<td>After school (3 PM–5:59 PM)</td>
<td>946 (332)</td>
<td>1017 (365)</td>
<td>NS</td>
</tr>
<tr>
<td>Evening (6 PM–11 PM)</td>
<td>812 (349)</td>
<td>891 (361)</td>
<td>NS</td>
</tr>
<tr>
<td>Minutes of MVPA (≥ 4 METs)</td>
<td>72 (36.5)</td>
<td>98 (42.7)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Values are means (SD) taken from 4-day averages. NS, non-significant. MVPA, moderate-vigorous physical activity. MET, metabolic equivalent.

a Controlling for gender, race, ethnicity, and cohort.
Daily PA

A random sample \( n = 77 \) PAAC, \( n = 90 \) control from the PAAC sub-sample completed four consecutive days (Thursday–Sunday) of PA monitoring by accelerometer during the spring semester of each of the three intervention years. Results indicated that on average over the three-year intervention, children in PAAC schools had greater PA (13\%) compared to children in control schools (Table 3). Children in PAAC schools had significantly greater levels of PA during the school day (12\%) and on weekends (17\%) and also exhibited greater levels of PA on weekdays (8\%, \( p = 0.05 \)) compared to children in control schools. Children in PAAC schools also exhibited 27\% greater levels of moderate to vigorous intensity PA (\( \geq 4 \) METS) compared to children in control schools.

Academic achievement

Significant improvements in academic achievement from baseline to 3 years were observed in the PAAC compared to the control schools for the composite, reading, math, and spelling, scores (Fig. 2).

Process measures

Delivery of PAAC lessons

The majority of teachers indicated that they incorporated PA primarily into language arts and mathematics. Teacher reports of the number of minutes of PA performed each week were averaged each month and ranged from 45 min to \( \geq 75 \) min/wk. Nine of 14 PAAC schools averaged \( \geq 75 \) min/wk. The average number of minutes of PA were lowest at the beginning of each semester and increased significantly within each year, and across years from baseline to the end of year three (\( p < 0.0001 \)).

Intensity of PAAC lessons

The average scores across the intervention showed a value of 3.4 \( \pm \) 0.46 for PAAC schools compared to 2.1 \( \pm \) 0.19 in control schools (\( p = 0.0001 \)). SOFIT scores were consistent within and across school years showing little fluctuation. Average SOFIT scores were statistically different across grade level with grades four and five lower than grades two and three (\( p = 0.0001 \)), although the small differences may not have practical importance.

Teacher participation in classroom activity (modeling)

Teacher participation in classroom PA was directly related to PA levels measured by SOFIT. Teachers who themselves were more physically active had students who were also more physically active (\( p < 0.001 \)).

Discussion

We found no significant difference for change in BMI over 3 years for children in PAAC compared with control schools. Our findings are in agreement with a number of other school based trials that evaluated the impact of PA on BMI. For example, there were no significant differences found for change in BMI between intervention and control schools in either the CATCH (Luepker et al., 1996) or SPARK trials (Sallis et al., 1993). Others have used shifts in BMI categories as the choice of analysis to determine the effect of interventions on overweight and obesity (Spiegel and Foulk, 2006). Interestingly, when we compared shifts in BMI categories we found each change in a positive direction for PAAC compared to controls and the change for overweight to at-risk approached significance (\( p = 0.08 \)).

Results for change in BMI were shown to be influenced by exposure to PAAC. Schools that delivered \( \geq 75 \) min of PAAC lessons/wk had significantly smaller increases in BMI compared to schools that received <75 min. In addition to increasing the minutes of PAAC, total energy expenditure might be increased by increasing the intensity of PAAC activities.

Gutin has recently demonstrated decreases in weight and fat mass in response to higher rather than lower intensity PA in adolescents (Gutin, 2008). This strategy would not require an increase in the time devoted to PAAC activities, yet it would increase energy expenditure. Most PAAC activities were on the order of 1.4–5.2 kcal/min (avg. \( \approx 3.4 \pm 0.5 \) METS) as measured by indirect calorimetry (Honas et al., 2008). However \( \sim 61\% \) of PAAC activities are greater than 3.0 METS. The average energy expenditure of activities greater than 3.0 METS was 3.73 kcal/min (\( \sim 4.0 \) METS). The preferential use of the activities with greater energy expenditure may increase the total energy expenditure delivered in the PAAC lessons. In turn, this may increase the effectiveness of PAAC activities to attenuate increases in BMI over time.

Teachers who modeled PA by active participation in the PAAC lesson had greater SOFIT scores shown by their students compared to students with teachers at lower levels of modeling. Modeling desired behaviors by a person significant to the targeted individual is frequently associated with greater achievement of that behavior (Bandura, 1986; Smith et al., 1988). Modeling by teachers may be an important mediator of PA in children and strategies to remove classroom barriers and increased teacher modeling should be emphasized in future studies.

Daily PA was significantly increased in PAAC children compared to controls. As expected, PA was increased during the school day, due to exposure to PAAC. The weekday daily average as well as the weekend day average was significantly greater for PAAC compared to control children. Minutes of moderate to vigorous intensity PA were greater for PAAC compared to control and may be important since this level of PA is known to increase fitness and decrease risk factors for chronic disease in children (Gutin et al., 2002; Gutin et al., 2005; Owens et al., 1999). The greater weekend PA for PAAC participants compared to control is particularly interesting. This could be explained by a change in children’s attitudes and beliefs fostered by the PAAC intervention that they can be physically active anywhere and during almost any situation rather than relying on the need for a formal PA opportunity, although this is speculative and should be tested further.

Academic achievement was significantly improved with exposure to PAAC. Foremost, this finding affirms that PAAC did not interfere with learning. Carlson et al. recently reported findings from a five year cohort investigation that followed kindergarten students through fifth grade and compared the amount of physical education received to academic achievement (Carlson et al., 2008). The major conclusion was that physical education did not have adverse effects on academic achievement and limiting physical
education to avoid adverse effects on learning does not appear to be legitimate. This conclusion was corroborated in a systematic review of PA and academic performance by Trudeau and Shephard (2008). Suggested mechanisms for the association between PA and academic performance included concentration, memory, cognitive processing, and classroom behavior. For example, Davis et al. (2007), recently reported increases in executive function that resulted from 15 wk of aerobic exercise training in overweight children (85th percentile). Children who received aerobic exercise of 40 min/day showed higher scores for executive function compared to controls. Potential mechanisms for the association of PA and improvements in academic performance need further exploration in studies designed and powered for this purpose.

Most investigations of PA and academic achievement have used cross-sectional, correlational data between academic achievement and fitness tests (California Dept of Ed, 2001; Castelli et al., 2007; Coe et al., 2006). Our results are from a longitudinal, randomized, controlled trial and compared PA (not et al., 2006). Our results are from a longitudinal, randomized, cross-sectional, correlational data between academic achievement showed higher scores for executive function compared to controls. Children who received aerobic exercise of 40 min/day received favorably and supported school-wide given the current climate centered on academic performance generated by the No Child Left Behind Act of 2001.

Few research studies have the resources to ensure that their interventions can be sustained (Bull et al., 2003; Oldenburg et al., 1999). We designed PAAC to be a low burden, minimal cost intervention that would not decrease academic instruction time, would not increase teacher preparation time, and would be enjoyable for students, teachers, and staff. PAAC was well received by children, teachers, and administration according to the results from process analysis and focus groups. Importantly, the acceptance and enthusiasm for PAAC was corroborated by findings from a post intervention survey administered to PAAC teachers in an effort to determine if PAAC was continued in the absence of the investigators. Teachers were surveyed ~9 months after completion of PAAC and without any contact from our staff over the nine month period. Approximately 95% of teachers indicated that they were using PAAC lessons one day/wk or more. Approximately 55% of teachers indicated that they were using PAAC 2 to 4 days/wk, ~35% were using PAAC on most days or every day, and only 5% were not using PAAC lessons.

Although teachers indicated continued use of PAAC, these results are limited by self-report and should be objectively verified in any future studies. Additionally, twenty percent of school days were not centered on academic instruction due to assembly, field trips, etc. and this diminished the exposure to PAAC. Strategies are needed to plan for these disruptions in academic instruction to better assure the intended level of PAAC activities are delivered.

In summary, we found that greater levels of exposure to PAAC lessons were associated with smaller increases in BMI and favorable shifts in BMI percentile. Children who received PAAC were more physically active across 24 h and on weekends compared to children who did not receive PAAC. There was a positive association between teacher modeling of PAAC lessons and the level of PA achieved by the children. There was a very intriguing, positive, and important outcome for academic achievement for those children who received PAAC compared to controls. Sixty percent of PAAC schools were able to average ≥75-minute PAAC activities across the intervention period. This, combined with the observation that PAAC has been sustained by teachers without any further contact by the investigators, speaks to the overall favorable perception and acceptance for the PAAC program by both teachers and school administrators. Continued research is needed to develop and evaluate strategies to provide greater exposure to PAAC lessons since exposure was associated with attenuated increases in BMI. Furthermore, the important secondary outcomes for increased daily PA and academic achievement deserve pursuit in adequately powered and designed studies.

Conflict of interest statement
The authors declare that there are no conflicts of interest.

Acknowledgments
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“Special Needs Populations”

by

Toni Benton, MD

Toni Benton, MD is an Associate Professor with the UNM Department of Family & Community Medicine. She received her M.D. from the University of Texas Health Sciences Center in San Antonio, TX and completed her Family Practice Residency at the University of New Mexico. She completed a mini-fellowship in Developmental Disabilities at the University Texas and a one-year fellowship in Adult Developmental Medicine in Greenville, NC. Dr. Benton is also the Medical Director of the Adult Special Needs Clinic, the Adult Cerebral Palsy Clinic and the Transdisciplinary Evaluation and Support Clinic (TEASC).

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Learning Objectives

At the end of this presentation, the attendee will be able to:

- List 3 resources in New Mexico which can assist practitioners and caregivers of individuals with Intellectual and Developmental Disabilities
- Recognize 3 common behavioral presentations of pain in a nonverbal patient
- List 3 secondary conditions commonly seen in the patient with spastic quadriplegic cerebral palsy
Approach to Primary Care in Special Needs Populations

Toni Benton, MD
UNM HSC SOM
Transdisciplinary Evaluation and Support Clinic (TEASC)

Objectives

• Common behavioral presentations of pain in a nonverbal patient with I/DD.
• Secondary conditions commonly seen in the patient with spastic quadriplegic cerebral palsy.
• Complications of management of behavior with AED’s or psychotropic medications.
• Resources in New Mexico which can assist practitioners and caregivers of individuals with Intellectual and Developmental Disabilities.

Overview

• Adults with Intellectual/Developmental Disabilities (I/DD) can have different patterns of illness and complex interactions among comorbidities.
• More difficulty accessing primary care than does the general population.
• Review the general, physical, behavioral, and mental health recommendations for adults with I/DD, especially for those conditions not screened for by routine health assessments of the general population.
• Atypical manifestations of pain and distress in adults with DD and long-term use of antipsychotic medications to address behavioral issues.

Common Behavioral Presentation of Pain in a Nonverbal patient with I/DD

• Agitation
• Irritability
• Screaming/yelling
• Weight loss
• Sleep changes
• Aggression
• Self Injurious Behavior (SIB)
• Withdrawal
• Elopement
• Changes in Eating- Hyperphagia or Decreased appetite

Case 1

• Self injurious and aggressive behavior in non verbal adult
Cerebral Palsy

Goals of Spasticity Management - The PCP Perspective

• Improve Function
  – Activities of Daily Living
  – Mobility
  – Ease of Care by Caregivers
  – Sleep
  – Overall Functional Independence
• Prevent Medical and Orthopedic Complications
• Prevent Deformity and Contractures
• Prevent Development of Pressure Areas
• To Reduce Pain

Medical Complications of Spasticity/Immobility

• Scoliosis
• Hip Dysplasia
• Contractures
• Cervical spinal disorders
• Pressure areas/Skin Breakdown
• Osteopenia/Osteoporosis/Fractures
• Falls
• Constipation
• Neurogenic Bowel/Bladder
• Swallowing Disorders/Dysphagia
• Difficulty Maintaining Ideal Body Weight/Nutrition

• Difficulties with activities of daily living
  – bathing
  – dressing
  – eating
  – toileting
  – maintaining hygiene
• Poor sleep
  – Sleep Apnea
  – Pain/Discomfort
  – Necessity of being turned by another person every 2 hours is disruptive to sleep
• Depression

Prevent Medical and Orthopedic Complications

Musculoskeletal
Metabolic
Oral Motor
Nutritional
Gastrointestinal
Respiratory

Integumentary
Urologic
Gynecologic
Sleep
Neurologic
Psychosocial

Musculoskeletal - Neuromuscular Scoliosis

• Irregular spinal curvature due to abnormalities of the myoneural (muscle-nerve) pathways.
• Generally most severe in nonambulatory patients.
• Curve progression is much more frequent than idiopathic scoliosis
• Progression continues into adulthood.
• Bracing does not prevent progression of the spinal curvature.

Untreated Scoliosis - Complications

• Cardiopulmonary Complications
  – Respiratory compromise
  – Heart problems - especially with curves over 100 degrees
• Gastrointestinal Complications
  – Reflux
  – Constipation
  – Disrupted anatomy of the internal organs
• Positioning Complications
  – Pressure points
  – Wheelchair
• Functional Implications
  – Use of hands
  – Positioning for safe feeding
• Skin Integrity
• Pain
  – Degenerative disk or arthritic
Untreated Scoliosis

Musculoskeletal-Hip Dysplasia

- Hips are normal at birth
- Progressive hip subluxation occurs in up to 50% of children with spastic quadriparesis.
- Strong tone in hip adductor and flexors leads to scissoring and predisposes to hip subluxation and dislocation
  - dislocation is typically posterior and superior
- In time dysplastic and erosive changes in the cartilage of the femoral head can develop and lead to pain

Hip Dysplasia

Physical Exam - Positive Galeazzi Sign

Osteoporosis Risk Factors

General Population
- Age over 50
- Female
- Menopause
- Family History
- Medications
- Low Body Weight/Being Small and Thin
- Broken Bones or Height Loss
- Not Enough Calcium and Vitamin D
- Too Much Protein, Sodium, Soda and Caffeine.
- Inactive Lifestyle
- Smoking
- Excessive Alcohol

Patients with Cerebral Palsy
- Immobilization
- Non Weight Bearing
- Low weight/Underweight
- Hormonal Issues
  - Menopause
  - Depo Provera
- Nutrition/Feeding Issues
- Low Serum Vitamin D levels
  - Seizure Medications
  - Lack of sun exposure

Nutritional/Oral Motor

Aspiration Risk
- Poor Oral Motor Skills
- Oral Dysphagia
- Pharyngeal Dysphagia
- Esophageal Dysphagia
- Positioning Difficulties
- Needing to be fed by others
- Tube Feeding

Chronic Aspiration can lead to:
- Recurrent Respiratory Infections
- Asthma/Wheezing
- Chronic Lung disease
- Pulmonary Fibrosis
- Cor Pulmonale
- Difficulty Maintaining Weight
Gastrointestinal

Gastroesophageal Reflux
- Frequent regurgitation or vomiting, especially after meals
- Coughing or wheezing
- Arching
- Self-injurious or aggressive behavior
- Screaming, Crying or Irritability especially after eating or at night
- Refusal to eat, at all or in limited amounts
- Failure to maintain weight

Gastrointestinal

Constipation
- Neurogenic Bowel
- Decreased mobility
- Slow gastrointestinal transit
- Inadequate fiber intake
- Stasis of stool, bloating, and impaction
- Worsens GERD

Gastrointestinal

Constipation
- Neurogenic Bowel
- Decreased mobility
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- Worsens GERD

Drooling

Anterior Drooling
- Functional, social, psychological, and clinical implications
- Perioral skin breakdown and infections
  - In severe cases of drooling, dehydration may even become a problem
  - Social embarrassment may limit interaction with peers,
  - May lead to isolation
Posterior drooling
- Problems with breathing, coughing, gagging, vomiting
- Aspiration
- Asthma
- Recurrent respiratory infections/pneumonia

Respiratory

- Scoliosis
- Aspiration
- Poor Chest Wall Motion
- Diaphragmatic Weakness
- Weak Cough
- Chronic Lung Disease
- Lung disease of Prematurity

Integumentary

Prevent Skin Breakdown
- Look at areas of greatest risk on the skin
  - Bony prominences
  - Skin contact: anything that touches the skin
    - Bras, TED hose, Bi-PAP masks, tubes, O2 tubing, NG tubing, heel/elbow foot protectors, Foley catheter, IV tubing and hubs, jewelry etc.
  - If it is covered – uncover and inspect site
  - Turn the person in order to do thorough head to toe skin assessment
## Gynecologic

**Menstrual Management**
- Depo Provera
- Oral Contraceptives
- Analgesics
- Local Pain Relief - Massage, Warm Packs

**Medical Considerations**
- Bone Density
- Risk of Blood Clots
- Menstrual Pain
- PMS
- Seizures

## Personal Hygiene and Perineal Care

## Neurogenic Bladder

- 80% with spastic hyperreflexive type neurogenic bladder on urodynamic testing
- Tendency for urinary retention and hyporeflexia in the adult over 30 years old
- New onset incontinence- consider:
  - Urinary retention (constipation)
  - Cervical spinal stenosis urinary tract infection
  - B12 deficiency
  - Seizures

## Neurologic

- Seizures
  - Antiepileptic medications
  - Ketogenic Diet
  - Vagal Nerve Stimulator
- Shunt management
- Spasticity Management
  - Oral Antispasticity Medications
  - BoTox
  - Baclofen Pump
- Dystonia Management
  - Oral Meds
  - BoTox
- Sensory Deficits
  - Hearing- Sensorineural, conductive
  - Vision- Strabismus, Cortical Visual Impairment

## Sleep

- Interrupted Sleep
- Pain
- Needing to be Repositioned
- Diaper Changes
- Craniofacial deformities
- Sleep Apnea
  - Obstructive
  - Central

## CranioFacial

<table>
<thead>
<tr>
<th>Normal</th>
<th>Mild</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Moderate</th>
<th>Severe</th>
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</tbody>
</table>
Sleep Apnea

**Obstructive**
- Craniofacial Anomalies
- Laryngomalacia
- Reduced Upper Airway muscle tone
- Central Hypotonia
- Medication
- Body position (supine)

**Central**
- Brainstem abnormalities
- Medications
- Normal variability of breathing in REM w/ exaggerated degree of desaturation
- Seizures (overt, subtle)

Depression

**Signs of depression**
- Change in Personality
- Increased anger, irritability, moodiness, aggression, self injury
- Change in appetite
- Change in sleep: difficulty falling asleep, staying asleep, or excessive sleeping
- Loss of energy, lethargy
- Loss of interest in friends, play, activities
- Low self-esteem, self-deprecating and negative talk

Problem Behaviors

- Over 30% of people with ID have a comorbid psychiatric disorder
- Many patients with I/DD are on multiple medications aimed at managing Problem behaviors
- Polypharmacy is Common
- Side Effects and Interactions difficult to sort out-particularly in Non verbal or minimally verbal patient

“Behavior Management” in the I/DD population

- Assessment of target behavior/symptoms
- Rule out medical/environmental/psychosocial
- Initiation of treatment— Start low, go slow, increase over weeks to months
- Change only one thing at a time
- Assessment of out-come and adverse effects,
- Follow-up
- Possibility of discontinuation of treatment— Go slow- taper over weeks
- Change only one medication at a time

Psychotropic Medications-Side Effects

- Weight gain
- Metabolic abnormalities— glucose tolerance — lipid metabolism — prolactin secretion
- Cardiac conduction problems
- Dysphagia/feeding difficulties
- Bowel dysfunction
- Involuntary Movements
- Akathisia
- Acute Dystonia
- Extrapyramidal Symptoms
- Tardive Dyskinesia
- NMS
Antiepileptic Medication - Side Effects

- Hyponatremia (oxcarbazepine, carbamazepine)
- Hepatotoxicity (carbamazepine, phenytoin, valproic acid)
- Blood dyscrasias (phenytoin, carbamazepine, lamotrigine)
- Vitamin D deficiency (phenytoin, phenobarbital)
- Hyperammonemia (valproic acid)
- Gingival hyperplasia (phenytoin)
- Osteoporosis (phenytoin)
- Cerebellar atrophy (phenytoin)
- Vitamin K deficiency (phenytoin)
- Carnitine deficiency (valproic acid)
- Folate Deficiency/Megaloblastic anemia (phenytoin, phenobarbital)

Key Points

- Avoid Polypharmacy
- Try to stabilize the patient on a minimum number of medications prescribed at the lowest possible dose.
- Withdraw one medication at a time.
- Withdraw medication slowly.
- Allow time (sometimes a few weeks) after withdrawing one medication and before starting to withdraw another.

NEW MEXICO PREVENTIVE SCREENING GUIDELINES

- Adapted from US Preventive Services Task Force (USPSTF) "The Guide to Clinical Preventative Services"
- Adapted for Adults with Intellectual/Developmental Disabilities
- Some Syndrome-specific recommendations
- Collaborative project by Continuum of Care (CoC) and Transdisciplinary Evaluation and Support Clinic (TEASC)
- Available electronically on COC website
- http://croc-cmtest.health.unm.edu/resources/guidelines.html

Some New Mexico Resources

- UNM TEASC Project
- Adult Special Needs Clinic
- UNM Continuum of Care Project
- Adult Cerebral Palsy Clinic
- DDMI Clinics
- SAFE Feeding Clinic
- DOH DDSD
- NM DOH Specialty Seating Clinic

Transdisciplinary Evaluation and Support Clinic (TEASC)

- Comprehensive, whole-person evaluations for people with developmental disability provided statewide
- Adult Special Needs Clinic, provided bi-monthly in Albuquerque
- Community-based physician consultations, provider support, technical assistance.
- Contact: Toni Benton, MD through the PALs Line 272-2000 or Liz Donsbach 505-272-5158
- fcm.unm.edu/programs/teasc

Adult Special Needs Clinic (ASNC)

- Team members include family medicine physicians, psychiatrists, neurologists, systems experts, clinical pharmacists, nurses, clinical dental hygienist, neuropsychologists, a variety of medical students/residents/interns.
- Offers whole-person, team evaluations for persons with developmental disabilities
- Meets twice monthly at the Family Practice Clinic on the UNM North Campus in Albuquerque
- Contact: Liz Donsbach 505-272-5158 or Patricia Beery 505-272-2579
- fcm.unm.edu/programs/teasc
**Referral Issues**

TEASC/ASNC sees adults with developmental disabilities for a variety of issues, including:
- Complex behavioral concerns that may result from medical and/or psychiatric conditions
- Assistance in understanding and navigating available adult support systems
- Complex medical pictures that could benefit from transdisciplinary team evaluation

**Continuum Of Care (COC)**

- COC offers a wide range of services to help support individuals with disabilities or chronic illness, their families and those that support them.
- Has established a network of medical professionals at UNM and around the state with expertise in developmental disabilities who are available for consultation.
- To request consultation, call Main: (505) 925-2350; Fax: (505) 925-2389; or toll free 1-877-684-5259
- [coc.unm.edu](http://coc.unm.edu)

**Adult Cerebral Palsy Clinic**

- Comprehensive evaluations include psychosocial assessments, full medical and neurological examinations, and facilitation of specialist referrals as necessary.
  - Family Medicine
  - Neurology
  - Social Work
  - Nursing
- Referrals include spasticity management, functional decline, falls, pain, agitation, unexplained weight loss, behavior changes.
- Contact: Vera Asplund, RN - 505-925-2386

**DDMI Clinics**

- Collaboration with local psychiatrists and primary care
- Clinics for people who have co-occurring developmental disabilities and mental illnesses (DDMI).
- TEASC and Continuum of Care experts work with psychiatrists, families and IDT teams to provide services for individuals with I/DD who present with complex behavioral needs.
- Clinical Sites statewide in Taos, Shiprock, Farmington, Roswell, Las Cruces, Silver City
- Contact Alya Reeve, MD, MPH, at 505-925-2395 or Eula Michaels- administrator at 505-925-2350

**NM SAFE Program (Supports and Assessment for Feeding and Eating)**

- Multidisciplinary team feeding evaluations of children and adults with developmental disabilities, for the purpose of improving health and preventing aspiration.
- The SAFE team includes a registered dietitian, physical therapist, physician and speech pathologist with expertise in swallowing disorders.
- Contact: Deirdre Muldoon, SLP
- [http://cdd.unm.edu/nmsafe](http://cdd.unm.edu/nmsafe)

**NM DDSD Specialty Seating Clinic**

- Based in Albuquerque with a team that travels around the state
- Custom fitted wheelchairs, molded seat formed specifically to the patients needs
- Physical Therapist evaluates and designs the seat for optimal function, safety, skin integrity
- Ideal option for patients who have significant skeletal deformities, contractures and compromised skin integrity
- Contact: 1-800-283-8415
- [http://nmhealth.org/about/ddsd/csbcsw](http://nmhealth.org/about/ddsd/csbcsw)
NM DOH Developmental Disabilities Supports Division (DDSD)
Clinical Services Bureau

- Provides information and referral services to people with disabilities and their families who are seeking help locating the right resources in their communities.
- Oversees various Medicaid home-and community-based waiver programs that are designed to help people with disabilities live as independently as possible.
- Contact: (505) 841-2948 Toll free 1-800-283-8415
- http://nmhealth.org/about/ddsd/csb/
“Contraception Update”

by

Larry Leeman, MD

Larry Leeman, MD is a Professor of Family and Community Medicine and Ob/Gyn at the University of New Mexico. He directs the Family Medicine Maternal and Child Health Service and fellowship, is co-Medical Director of the University Hospital Mother Baby Unit and Medical Director of the UNM Milagro Program for perinatal substance abuse. His research interests include postpartum contraception, childbirth outcomes and rural maternity care. He was a cofounder of the UNM center for Reproductive Health, which offers family planning and contraception training for UNM medical students, residents and fellows.

Email: lleeman@salud.unm.edu

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Review the epidemiology of unintended pregnancy
- Increase understanding of broad range of contraceptive methods
- Understand techniques to improve effective use of contraception including the postpartum period
Contraceptive Update 2014:
Improving use and prevention of unintended pregnancy

Larry Leeman MD MPH
New Mexico Family Medicine Conference
Taos New Mexico
July 31, 2014

Disclosures
• No financial conflicts of interest
• Some slides are from ARHP (Association of Reproductive Health Professional)
• arhp.org and Alan Guttmacher Institute www.guttmacher.org/

Objectives
Participants will understand:
• Epidemiology of contraceptive failure and unintended pregnancy
• Choice study findings that Long Acting Reversible Contraceptives have superior efficacy
• Use of postpartum contraception
• Techniques to increase success of emergency contraception

Half of women at risk are not fully protected from unintended pregnancy

Women report a variety of reasons for contraceptive nonuse

Nearly half of pregnancies in the United States are unintended

Approximately 6.4 million pregnancies per year
Most unintended pregnancies occur when women fail to use contraceptives or use their method inconsistently. Unintended pregnancies occur earlier than desired, 23%. Unintended pregnancies occur after women have reached their desired family size, 30%. Intended pregnancies, 51%.

Half of women at risk are not fully protected from unintended pregnancy. No use, 8%. Gap in use of 1 month or more, 15%. Inconsistent or incorrect use, 27%. 28 million adult women at risk for unintended pregnancy.

Most unintended pregnancies occur when women fail to use contraceptives or use their method inconsistently. Consistent use, method failed, 5%. Inconsistent or incorrect use, 47%. None missed, 55%.

Thirty-eight percent of women use the pill inconsistently. 0% missed, 4% missed 1 time, 11% missed 2 times, 41% missed 3+ times.

Sixty-one percent of couples use condoms inconsistently. Every time, 51%. Most of the time, 28%. About half, 11%. Less than half/none, 19%.

Factors with difficulty in contraceptive use:
- Life changes: Relationship, residence, job/school or personal crisis
- Socioeconomic factors
- Minority populations
- Motivation: Ambivalence about pregnancy
All methods are not equal

- User dependent (OCPs, Condoms) less effective than long acting
- Methods requiring frequent refills or provider visits subject to lack of access or availability

The Choice Project

Large 3 year prospective cohort study of over 9,000 women of reproductive age in the St. Louis area

Study Inclusion Criteria

- Women 14-45 years
- Primary residency in STL City or County
- Sexually active with male partner (or soon to be)
- Does not desire pregnancy during next 12 months
- Desires reversible contraception
- Willing to try a new contraceptive method

Study Design: Prospective Cohort

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNG-IUS</td>
<td>Unintended pregnancy</td>
</tr>
<tr>
<td>Cu-IUD</td>
<td>Teen pregnancy</td>
</tr>
<tr>
<td>Implant</td>
<td>Repeat abortion</td>
</tr>
<tr>
<td>DMPA</td>
<td>Abortion</td>
</tr>
<tr>
<td>Pills</td>
<td>Continuation</td>
</tr>
<tr>
<td>Patch</td>
<td>Satisfaction</td>
</tr>
<tr>
<td>Ring</td>
<td>STI</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

Comparing Typical Effectiveness of Contraceptive Methods

- More effective: ≤ 1 pregnancy/100 women in 1 year
- Less effective: > 17 pregnancies/100 women in 1 year

Chart adapted from WHO 2007.

Rates of Contraceptive Failures (pregnancies) with LARC, Depo Provera, or Pills/Patch/Ring

- LARC
- DMPA
- PR

Baseline Chosen Method

<table>
<thead>
<tr>
<th>Method</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNG-IUS</td>
<td>46.0</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>11.9</td>
</tr>
<tr>
<td>Implant</td>
<td>16.5</td>
</tr>
<tr>
<td>DMPA</td>
<td>6.9</td>
</tr>
<tr>
<td>Pills</td>
<td>9.4</td>
</tr>
<tr>
<td>Ring</td>
<td>7.0</td>
</tr>
<tr>
<td>Patch</td>
<td>1.8</td>
</tr>
<tr>
<td>Other</td>
<td>&lt;1.0</td>
</tr>
</tbody>
</table>

75%

Choice of LARC Methods among Adolescents

Choice of LARC Methods

12-Month Continuation

<table>
<thead>
<tr>
<th>Method</th>
<th>Continuation Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LNG-IUS</td>
<td>87.5</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>84.1</td>
</tr>
<tr>
<td>Implant</td>
<td>83.3</td>
</tr>
<tr>
<td>Any LARC</td>
<td>86.2</td>
</tr>
<tr>
<td>DMPA</td>
<td>56.2</td>
</tr>
<tr>
<td>OCPs</td>
<td>55.0</td>
</tr>
<tr>
<td>Ring</td>
<td>54.2</td>
</tr>
<tr>
<td>Patch</td>
<td>49.5</td>
</tr>
<tr>
<td>Non-LARC</td>
<td>54.7</td>
</tr>
</tbody>
</table>

12-month Continuation: Adolescents Compared to Older Women

Main Findings from CHOICE

- LARC methods associated with higher continuation & satisfaction than shorter-acting methods
  - Regardless of age
- LARC methods associated with lower rates of unintended pregnancy
  - Increasing LARC use can decrease unintended pregnancy in the population

CHOICE Compared to U.S.

- Teen birth rate (age 15-19 years)
  - 6.3 per 1,000 teens
  - Compared to 34.3 per 1,000 nationally
- Abortion rate (women ages 15-44)
  - 6.0 per 1,000 women
  - Compared to 19.6 per 1,000 nationally
- Unintended pregnancy rate
  - 15.0 per 1,000 women
  - Cumulative: 35.0 per 1,000 women
  - Compared to 52.0 per 1,000 nationally
Contraceptive Use in the United States, 2006–2008

<table>
<thead>
<tr>
<th>Method</th>
<th>% of US women who practice contraception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization</td>
<td>37.0</td>
</tr>
<tr>
<td>IUD</td>
<td>5.5</td>
</tr>
<tr>
<td>Ring, Implant, &amp; Patch</td>
<td>3.5</td>
</tr>
<tr>
<td>OC</td>
<td>28.0</td>
</tr>
<tr>
<td>Male condom</td>
<td>16.1</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>1.5</td>
</tr>
<tr>
<td>Other Non-hormonal</td>
<td>5.2</td>
</tr>
</tbody>
</table>


Emphasize Effectiveness in Contraceptive Choice

- “These are the most effective methods but we will support your decision for other methods”
- Permanent sterilization when appropriate—improve access to vasectomy and Essure
- Access to provider after initiating user dependent methods key in ongoing use

IUDs Underutilized in United States

- Lack of awareness
- Residual concerns dating back to Dalkon Shield
- Reluctance to have a device in uterus or anxiety about placement
- High up front costs limiting coverage/access
- Myths about IUDs
- Lawyers trolling for class action cases-negative publicity

Use of IUC by Female Ob/Gyns vs. All Women in the United States

% Using IUC

- Female Ob/Gyn Physicians: 18%
- General Population: 0.7%


Dispelling Myths About IUC

In fact, IUDs:

- Are not abortifacients
- Do not cause ectopic pregnancies
- Do not cause pelvic infection
- Do not decrease the likelihood of future pregnancies
- Are not large in size
- Can be used by nulliparous women
- Can be used by women who have had an ectopic pregnancy
- Do not need to be removed for PID treatment
- Do not have to be removed if inflammatory changes are noted on a Pap test


IUC Available in the United States

- Copper T 380A IUD
- Copper ions
- Approved for 10 years of use

### IUC Mechanism of Action

<table>
<thead>
<tr>
<th>Mechanism of Action</th>
<th>Copper T IUD</th>
<th>LNG 52 IUS</th>
<th>LNG 13.5 IUS</th>
</tr>
</thead>
</table>
| **Primary**         | - Prevents fertilization  
                      - Reduces sperm motility and viability  
                      - Inhibits development of ova | - Inhibits fertilization  
                      - Causes cervical mucus to thicken  
                      - Inhibits sperm motility and function | - Inhibits fertilization  
                      - Causes cervical mucus to thicken  
                      - Inhibits sperm motility and function |
| **Secondary**       | - Inhibits implantation  | - Inhibits implantation | - Inhibits implantation |


### IUC Available in the United States

(continued)

- **LNG 52 IUS**
  - Releases 20 µg of LNG per day
  - Approved for 5 years of use
- **LNG 13.5 IUS**
  - Releases 14 µg of LNG per day
  - Approved for 3 years of use


### Implantoable Method

- **Implanon/Nexplanon**
  - Effective for 3 years
  - 68mg etonogestrel
  - Inhibits ovulation, suppress endometrium, thicken mucous
  - Requires specific training

### Animated Insertion: LNG 52 IUS

https://www.youtube.com/watch?v=zgl3mbW2YdA

### Nexplanon

- Most effective reversible method
- Decreases blood loss with menstruation
- Decreases Dysmenorrhea
- Does not change BMD
- Important to counsel about the likelihood of irregular periods

Nexplanon
• Menstrual pattern at 3 months correlates with pattern for remaining 3 years
• Counsel upfront that bleeding pattern “worse” for most women with Nexplanon compared to Mirena
• 6-23% of users worldwide discontinued the method because of bleeding issues
• Treatment options for irregular periods
  ▫ COC pills taken normally 1-3 months
  ▫ Progesterin-only pills taken for up to three months
  ▫ NSAIDS especially COX-2 inhibitors 5-10d
  ▫ Tranexamic acid 500 mg BID x 5d
  ▫ Doxy 100mg po BID x 14d

The Need for New Developments in Contraception

4.5 million women in the US have an unmet need for contraception

There is a need for...

<table>
<thead>
<tr>
<th>NEW HIGHLY EFFECTIVE AND EASY-TO-USE METHODS</th>
<th>LOWER-COST METHODS</th>
<th>METHODS WITH FEWER SIDE EFFECTS</th>
<th>GREATER VARIETY OF METHODS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LNG 13.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA-Approved April 2013: LNG 13.5 IUS (SkylaTM)</td>
<td>Bayer HealthCare Pharmaceuticals</td>
<td>LNG 13.5 mg</td>
<td>Pregnancy prevention for up to 3 years</td>
</tr>
<tr>
<td></td>
<td>Easy insertion and low pain reported</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LNG 13.5 IUS (SkylaTM) Phase 3 Study Results

<table>
<thead>
<tr>
<th>LNG 13.5</th>
<th>Unadjusted Pearl Index (PI)</th>
<th>0.33</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cumulative failure rates</td>
<td>0.9%</td>
</tr>
<tr>
<td></td>
<td>Serious adverse event (SAE)</td>
<td>2 cases PID</td>
</tr>
<tr>
<td></td>
<td>None observed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 ectopic pregnancies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cumulative risk of expulsion</td>
<td>4.56%</td>
</tr>
</tbody>
</table>

NOTE: LNG 13.5 was previously identified as LCS 12.

LNG 13.5 IUS (SkylaTM) Patient Profile: Anna

• Why might LNG 13.5 IUS (SkylaTM) be a good choice for Anna?
  ▪ 22-year-old, nulliparous
  ▪ 100 lbs./5’ 2”
  ▪ Interested in birth control method not requiring daily action
  ▪ Interested in IUD but scared of insertion procedure

LNG 13.5 IUS (SkylaTM) Patient Profile: Anna (continued)

• Why might LNG 13.5 IUS (SkylaTM) be a good choice for Anna?
  A. Low pain during placement
  B. Lower discomfort/cramping during insertion compared with LNG 52 IUS (Mirena®)
  C. Can last 3 years
  D. All of these
  E. None of these
### Contraceptives Currently in Development for US

<table>
<thead>
<tr>
<th>Available beyond 2014</th>
<th>Available 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hormonal</strong></td>
<td></td>
</tr>
<tr>
<td>MPA 25 mg and estradiol cypionate 5 mg monthly injectable</td>
<td>Nestorone/EE vaginal ring</td>
</tr>
<tr>
<td>LNG/EE low-dose transdermal patch</td>
<td>Gestodene/EE transdermal patch</td>
</tr>
<tr>
<td>LNG 19.5 IUS</td>
<td>LNG 20 IUS</td>
</tr>
<tr>
<td><strong>Non-hormonal</strong></td>
<td></td>
</tr>
<tr>
<td>SILCS diaphragm</td>
<td>PATH female condom</td>
</tr>
</tbody>
</table>

### In Phase 3 Clinical Trial: LNG 19.5 IUS
- Bayer HealthCare Pharmaceuticals
- LNG 19.5 mg
- Similar to LNG 13.5 IUS (Skyla™)
- Well tolerated by patients
- Use for up to 5 years

### Soon-To-Be-Available New Method: Monthly Injectable (Cyclofem®)
- Concept Foundation & Sun Pharmaceutical Industries
- 25 mg MPA + 5 mg estradiol cypionate
- Same formulation as injectable previously marketed in the US (Lunelle®)
- Seeking FDA approval for US

### Soon-To-Be-Available New Method: EE + LNG Transdermal Patch
- Agile Therapeutics
- Low-dose, once-weekly patch
- Minimizes seepage of adhesive around edge of patch ("cold flow")
- ↓ chance of residue on skin
- NDA submitted
- Decision expected 2013

www.conceptfoundation.org/hormonal-contraception.php

### Adverse Event Profile: EE + LNG Transdermal Patch
New low-dose patch showed lower levels of hormone-related side effects

![Graph showing adverse event profile](image)


### Comparison of EE PK Profile
New EE+LNG low-dose patch has ~1/2 the EE exposure of the current norelgestromin/ethinyl estradiol patch (Ortho Evra®)

![Graph comparing EE PK profiles](image)

Future New Method: EE + Gestodene Patch
• Bayer HealthCare Pharmaceuticals
• Contains ethinyl estradiol and gestodene
• Phase 3 trial in progress
  • evaluating effectiveness, general safety, patterns of bleeding, and acceptability

EE + LNG Patch Patient Profile: Jennifer
• 23 yo
• Former patch user
• Stopped patch because exercise caused a sticky ring & breast tenderness
• She liked weekly formulation and birth control she could see and feel

EE + LNG Patch Patient Profile: Jennifer (continued)
Why might this be a good choice for Jennifer?
A. Half the progestin exposure of the currently available patch
B. More reliable than a combined OC pill
C. Less seepage of adhesive around the patch than with the current patch
D. Improved efficacy over the current patch

Future New Method: LNG 20 IUS
• Uteron Pharma Operations (in Belgium)
• Purpose:
  • ↓ cost
  • ↑ use from 5 to 7 years
  • 20 mcg/day LNG
• Study completion ~Dec. 2018

Future New Method: Nestorone/Ethinyl Estradiol 1-Yr Ring
• Population Council
• Releases 150 mcg nestorone + 15 mcg ethinyl estradiol/day
• Used like existing ring (3 weeks in, 1 week out)
• Lasts 13 cycles
• Awaiting FDA approval

Nestorone/EE 1-Year Contraceptive Vaginal Ring: Clinical Trial Results

Future New Method:
Many Pills are in Development

Teva
- OC continuous regimen of LNG 0.15 mg / EE 20 mcg x 42d, 25 mcg x 21d, 30 mcg x 21d, EE mcg x 7d

Bayer
- Combined OC extended regimens w/ drospirenone 3 mg / EE 20 mcg

Merck
- OC containing nomegestrol acetate 2.5 mg, 17ß-estradiol 1.5 mg

BioSante and Pantarhei Bioscience
- OC with estrogen, progestin, and androgen

Future New Method:
SILCS Diaphragm

- PATH and SILCS, Inc.
- Cervical barrier device
- One size fits most
- Developed with input from women and men in multiple countries
- Regulatory applications in Europe and US

Postpartum Contraception
- Opportunity to prevent recurrent unintended pregnancy
- Optimal time for 3rd party coverage
- No concern about luteal phase pregnancy

Postpartum contraception
- Postpartum tubal ligation
- Immediate postplacental IUDs
- Nexplanon or depo prior to discharge
- Initiate OCPs/Patch/Ring at 4 week
- Breastfeeding not concern with above
- Referral for vasectomy and Essure

Immediate postplacental IUD
- Disadvantage is higher expulsion rate than interval – about 10 % compared to 2%
- Copper or Levonorgesterol
- More women will wind up with IUD than if wait till 6 weeks postpartum for variety reasons
- New Mexioc Medicaid now paying outside of Global

Physical Examination before IUD placement
- General well being and postpartum condition
- Normal temperature
- Assessment of involution of uterus and uterine contractions
- No abnormal bleeding/evidence of infection
- Consider cleaning perineal area, particularly if stool present
- Put on a new pair of sterile gloves
Postplacental manual insertion

- Within TEN minutes of placental delivery
- The cervix is open and limp
- Allows for the passage of a hand
- Placement of the IUD high in the fundus
- Chorioamnionitis and ongoing PPH are contraindications

Technique for Postplacental IUD

- Immediate postpartum technique with inserter
- Ring forceps: Grasp the anterior cervix with a ring forceps and place IUD in second ring Forceps
- Manual placement with hand

Permanent Sterilization

- Vasectomy
- Laparoscopic interval tubal ligation
- Essure placement of coils in tubal ostia in clinic or day surgery

Vasectomy

- Outpatient- no scapel no needle techniques
- Lower risk than female sterilization
- Coverage by Title X unlike interval tubal ligation

Essure

- Composition
  - Inner stainless steel core
  - Polyethylene fibers
  - Outer titinol coil
- Mechanism of action
  - Stimulates fibrous ingrowth fixing implant and blocking the tube

Future New Method: PATH Women’s Condom

- PATH
- Polyurethane condom pouch
- Adherence to vaginal walls improved by foam dots
- Soft outer ring
- Dissolving capsule
Emergency Contraception

- Hopes for large effect on unintended pregnancy have not been realized
- Issues of cost and accessibility
- Studies demonstrate less effective in larger women (BMI or weight)
- Unprotected intercourse often a chronic not acute condition
- Still worthwhile but need to look at long acting contraceptive followup

Emergency Contraception Options

Beyond Plan B prescription

- Generic Levonorgesterol available OTC without prescription since March 3 2014 labeled for 17+
- Uro
- Paragard IUD – most effective EC. Levonorgesterol IUD not studied or recommended
- Ulipristal acetate: ella®

Next Choice One Dose™ and My Way™ (generic)

- 1.5mg levonorgestrel (one pill)
- Label: Take within 72 hours after intercourse
- Recommended: up to 120 hours after sex if needed
  - Cost: $35 ($24-$42)
  - 10-20% cheaper than Plan B One-Step

ella®

- 30mg ulipristal acetate (one pill)
- Label: Take within 120 hours after intercourse
- Cost has been coming down
  online prescription + shipping now = $59
  www.ella-kwikmed.com

ParaGard® (Copper-T IUD)

- Off label use
- Placed within 5 days after intercourse
- Effectiveness does not decline with delay
- Placed by a trained clinician
  - Cost may be $500
- Should be free without copay thanks to ACA for most women not working at Hobby Lobby

Experience with IUDs for EC

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>Pregnancies</th>
<th>Rate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>7,034</td>
<td>10</td>
<td>0.14% (0.08%-0.25%)</td>
</tr>
<tr>
<td>China</td>
<td>5,629</td>
<td>6</td>
<td>0.11% (0.05%-0.23%)</td>
</tr>
<tr>
<td>UK</td>
<td>496</td>
<td>0</td>
<td>0.00% (0.00%-0.70%)</td>
</tr>
<tr>
<td>US</td>
<td>401</td>
<td>0</td>
<td>0.00% (0.00%-0.85%)</td>
</tr>
<tr>
<td>Italy</td>
<td>253</td>
<td>0</td>
<td>0.00% (0.00%-1.38%)</td>
</tr>
<tr>
<td>Egypt</td>
<td>200</td>
<td>4</td>
<td>2.00% (0.69%-5.03%)</td>
</tr>
<tr>
<td>Netherlands</td>
<td>55</td>
<td>0</td>
<td>0.00% (0.00%-5.93%)</td>
</tr>
<tr>
<td>Total w/o Egypt</td>
<td>6,834</td>
<td>6</td>
<td>0.09% (0.04%-0.19%)</td>
</tr>
</tbody>
</table>

Cleland et al, 2011
Ulipristal versus Levonorgestrel

- Meta-analysis of two randomized studies found ulipristal superior to levonorgestrel
  - 0-24 h: OR=0.35 (95% CI, 0.11-0.93)
  - 0-72 h: OR=0.58 (95% CI, 0.33-0.99)
  - 0-120 h: OR=0.55 (95% CI, 0.32-0.93)
  - Adjusted for BMI, repeated sex, etc

Glasier AF et al, Lancet 2010

Pregnancy Rates after LNG: Pooled WHO Studies

Glasier, Contraception 2011

Pregnancy rates by time between unprotected sex and use of Ulipristal

ECPs and Obesity

ECP failure among obese vs. non-obese women

- LNG: OR = 4.41, 95%CI 2.05-9.44
- Ulipristal: OR = 2.62, 95%CI 0.89-7.00

Glasier, Contraception 2011.

The limits of efficacy of EC pills

- For LNG: Weight=70 kg (154 lbs)
- For UPA: Weight=88 kg (194 lbs)

On average:
American women weigh 166 lbs

Glasier et al, Contraception 2011

Advance Provision Increases Use of ECPs...BUT

Advance provision of EC pills has not been shown to reduce rates of unintended pregnancy.

Polk, Schaffer, Blanchard Cochrane Database Syst Rev 2010
Raymond EG, Trussell J, Polk, Obstet Gynecol 2007
Why No Reduction in Pregnancies?
Among women who received progestin-only ECPs in advance

45% of women who had UPI did not use ECPs they were provided
San Francisco

33% of women had UPI at least once without using ECPs they were provided
Nevada/NC

Use and Underuse of ECPs

| Woman underestimate their risk of pregnancy |
| ECPs are not used frequently enough |
| Education is needed to encourage women to use ECPs every time they are needed |
| Underuse of ECPs means major public health impact is unlikely |

Polis, Schaffir, Blanchard. Cochrane Database Syst Rev. 2010

Take-Away Points on Effectiveness

- IUD is most effective EC option
  - Especially with repeated unprotected intercourse
  - And especially if she weighs more than 195 lbs

A drop of EC in the ocean of UPS

Summary

- Offer LARCs as most effective methods based on Choice study
- Maintain accessibility for contraception questions
- Unprotected intercourse is chronic condition—consider Paragard IUD and Ulipristal
- Postpartum LARCs now covered by Medicaid outside of global

UNM Center for Reproductive Health

- Referral site for complex contraceptive problems
- Outpatient vasectomy and Essure
- Low cost IUDs and Nexplanons through resident training grants ($125 total)
- Miscarriage management and abortion care
- (505) 925-4455
- 2301 Yale Blvd. SE, Building E, Albuquerque
“Immunizations: Big and Small Changes in Protecting our Patients”

by

Melissa Martinez, MD

Melissa Martinez, MD is a Professor in the Department of Internal Medicine at UNM. She graduated from UNM School of Medicine in 1989 and completed a residency in Family Medicine at UNM. She is Co-Chair of the Immunizations Work Group which is part of the Clinical Prevention Intuitive of the New Mexico Medical Society.

Email: mlmartinez@salud.unm.edu

Learning Objectives

At the end of this presentation, the attendee will be able to:

• Understand the 2014-2015 Advisory Council on Immunizations Practice Guidelines for immunizations
• Compare and contrast influenza vaccines available in 2014
• List indications for 13-valent Pneumococcal Conjugate and 23-valent Pneumococcal Polysaccharide Vaccine in high at risk adults and children
• Describe Health People 2020 population goals for immunizations
• Confidently approach patients and parents who are resistant to vaccination
• Adjust to newly implemented Vaccines for Children requirements
Big and Small Changes in Vaccines
July 31, 2014

Estimated Vaccination Coverage with 4:3:1:3:1 Age 19-35 Months Old, New Mexico and U.S., 2002-2012

Flu Immunization Coverage 2011-2012

Improved immunization rate in children
Better prevention of pneumococcal
More choices of flu shots

Pertussis Outbreaks
Measles Outbreaks
Confusing Schedules
Risks to Universal Purchase
Vaccine Prices

No Conflicts of Interest to Declare


www.cdc.gov/flu/professional/vaccination/report1112/
Objectives:

• List reasons for the increased incidence of pertussis and measles
• Describe ACIP recommendations for Flu Season
• Describe ACIP recommendations for Prevnar (PCV13) use in adults
• Review reasons for vaccine hesitancy
• Explain the business and politics of vaccines

More Pertussis

• Natural Variation
• Better testing/reporting
• Unimmunized/Under-immunized
• Waning Immunity
• Acellular not as protective

Natural Variation

January 1-June 16, 2014
9,964 cases of pertussis
24% increase compared with the same time period in 2013.

Better Testing

• PCR testing easier
• Unofficial reports from TriCore-more tests requested
More Pertussis

• Natural Variation
  ✓ Better testing/reporting
  ▼ Unimmunized/Under-immunized
  • Waning Immunity
  • Acellular not as protective

Unimmunized/Under-immunized

132 Cases Marin County

- Fully Immunized
- Underimmunized
- Unimmunized

Witt et al. Clin Infect Disease 2012 54(12): 1730-3735

More Pertussis

• Natural Variation
  ✓ Better testing/reporting
  ▼ Unimmunized/Under-immunized
  • Waning Immunity
  • Acellular not as protective

Waning Immunity

RR after 5 doses DTaP

Tartof et al. Pediatrics 2013; 131:e1047-e1052

More Pertussis

• Natural Variation
  ✓ Better testing/reporting
  ▼ Unimmunized/Under-immunized
  • Waning Immunity
  • Acellular not as protective

Acellular not as protective

8-20 years olds with Pertussis

8-20 years old Controls

5 DTaP

Vs

≥1 whole cell

8.7 RR

≥1 whole cell

Witt et al. CID 2013: 56 1248-1254
More Pertussis

- Natural Variation
- Better testing/reporting
- Unimmunized/Under-immunized
- Waning Immunity
- Acellular not as protective
  - ?New strains? wrong antigens

Children

DTaP
- 2, 4, 6, Months
- 12-15 Months
- 4-6 Years
- Tdap 11-12 years

Adults

Primary Series
- Dose 1
  - 4 weeks
- Dose 2
  - 6-12 months
- Dose 3
- *One dose Tdap

Boosters
- Tdap once
- Td q 10 year
  - Tdap Every Pregnancy

Conclusion Pertussis

- Tdap Every Pregnancy
- Same childhood and adult schedule
- Stay tuned
  - Change in frequency
  - Change in vaccine --not whole-cellular

What is New with Flu?

- Quadrivalent
- Recombinant
- Cell culture-based
- High dose
- Low dose

Influenza A and B

Influenza A
- Most common cause of flu
  - Example H1N1

Influenza B
- Not as common
  - 2 lineages
  - Yamagata and Victoria

Trivalent (IV3) = 2A + most likely B
Quadrivalent (IV4) = 2A + 2B
TriCore Seasonal Influenza Data

<table>
<thead>
<tr>
<th>Flu Season</th>
<th>Total Flu Isolates</th>
<th>% A</th>
<th>% B</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008 - 2009</td>
<td>559</td>
<td>60.5%</td>
<td>39.5%</td>
</tr>
<tr>
<td>2009 - 2010</td>
<td>2,948</td>
<td>99.9%</td>
<td>0.1%</td>
</tr>
<tr>
<td>2010 - 2011</td>
<td>1,008</td>
<td>70.1%</td>
<td>29.9%</td>
</tr>
<tr>
<td>2011 - 2012</td>
<td>633</td>
<td>96.7%</td>
<td>3.3%</td>
</tr>
<tr>
<td>2012 - 2013</td>
<td>2,365</td>
<td>64.7%</td>
<td>35.3%</td>
</tr>
</tbody>
</table>

Average Flu B over 8 seasons was 10-15% of Overall Flu Cases

Quadrivalent: IV4

- Fluarix® Quadrivalent IM IIV4
- Fluzone® Quadrivalent IM IIV4
- FluMist® IntraNasal (live-attenuated) LAIV4

June 2014 ACIP preference of IntraNasal over injectable for ages 2-8 years

Flumist® IntraNasal (live-attenuated)

- LAIV4
- Metimmue
- Preference over injectable for ages 2-8 years
- Indications ages 2-49
- Contraindications
  - Egg Allergies
  - Asthma/wheezing
  - Immuno-compromised

What is new

- Quadrivalent
- Recombinant
- Cell culture-based
- High dose
- Low dose

Traditional versus Recombinant

- IIV
- Virus grown in eggs
- Virus denatured
- Recombinant
- DNA makes antigens
Recombinant Influenza Vaccine

RIV3
• FluBlok®
• $32.75/dose (whole sale)
• Only vaccine to be used in patients with severe egg allergy

Cell culture-based
• Mammal cells in place of eggs
• Faster and more flexible to manufacture
• Not clear if completely egg-free
• Flucelvax® Novartis
• CCIIV3 (Trivalent)

What is New?
✓ Quadrivalent
✓ Recombinant
✓ Cell culture-based
✓ High dose
✓ Low dose

High Dose
Fluzone HD® Sanofi Pasteur
• Age>65 50-75% lower antibody titer
• High-dose higher post-vaccine antibody
• Will higher antibody levels translate into fewer cases of the flu?
• Study for 2014-2015

What is New?
✓ Quadrivalent
✓ Recombinant
✓ Cellular
✓ High Dose
✓ Low Dose

IntraDermal
Fluzone IntraDermal® Sanofi Pasteur
Trivalent
40% less antigen
Same immune response
Single dose
For needle phobia
So Many Choices

Intranasal preferred 2-8 years
Recombinant -Egg Allergies

The only wrong flu vaccine is the one not given

Streptococcus pneumoniae

• Pneumonia (CAP)
• Invasive Pneumococcal Disease (IPD)
  • Bacteremia/Sepsis
  • Meningitis
  • Other
    • otitis media
    • sinusitis

U.S. Rates of Invasive Pneumococcal Disease (IPD) by Age or Conditions

Pneumococcal Vaccines

• Pneumovax® (PPSV23)
• Polysaccharide vaccine
• Duration 3-5 years
• Repeat vaccination does not improve titers
• May/maynot prevent CAP
• Protection for IPD
• Effectiveness estimates 54-80%

Prevnar® PCV7 in Children

Active Bacterial Core surveillance (ABCs)
Tracked IPD in adults >18 years
• 63% reduction in IPD in adults (1998-1999 vs. 2009)

**Prevnar® (PCV 13)**

- FDA Licensed age > 50
- ACIP
- Cost analysis
- Limited Studies
- Cost effective only in certain conditions

### Conditions

<table>
<thead>
<tr>
<th>Adult (≥65)</th>
<th>Child (0-18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>Cancer</td>
</tr>
<tr>
<td>Chronic heart disease</td>
<td>Chronic heart disease</td>
</tr>
<tr>
<td>Chronic Lung disease (Asthma)</td>
<td>Chronic Lung disease (Asthma)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Alcoholism</td>
<td>Alcoholism</td>
</tr>
<tr>
<td>Chronic liver disease</td>
<td>Chronic liver disease</td>
</tr>
<tr>
<td>Cigarette smoking</td>
<td>Cigarette smoking</td>
</tr>
<tr>
<td>Immunocompromised</td>
<td>Immunocompromised</td>
</tr>
<tr>
<td>Hemoglobinopathies</td>
<td>Hemoglobinopathies</td>
</tr>
<tr>
<td>Asplenia</td>
<td>Asplenia</td>
</tr>
<tr>
<td>Chronic Renal Failure</td>
<td>Chronic Renal Failure</td>
</tr>
<tr>
<td>Nephrotic Syndrome</td>
<td>Nephrotic Syndrome</td>
</tr>
<tr>
<td>Generalized Malignancy</td>
<td>Generalized Malignancy</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>Lymphoma</td>
</tr>
<tr>
<td>Hodgkin's</td>
<td>Hodgkin's</td>
</tr>
<tr>
<td>HIV/Immunocompromised</td>
<td>HIV/Immunocompromised</td>
</tr>
<tr>
<td>Immunosuppression</td>
<td>Immunosuppression</td>
</tr>
<tr>
<td>Solid Organ Transplant</td>
<td>Solid Organ Transplant</td>
</tr>
<tr>
<td>Multiple Myeloma</td>
<td>Multiple Myeloma</td>
</tr>
<tr>
<td>Meningitis risk</td>
<td>Meningitis risk</td>
</tr>
<tr>
<td>Cochlear Implant</td>
<td>Cochlear Implant</td>
</tr>
<tr>
<td>CSF leak</td>
<td>CSF leak</td>
</tr>
</tbody>
</table>

#### PCV13

- One dose if age ≥65
- Repeat dose at age ≥65 (if interval > 5 years)

#### PPSV23

- One dose if age ≥65
- 2 doses after PCV13
- 1 dose after PPSV23
- 8 weeks before or 12 months after PPSV23

### Children 2-59 Months (<5 years)

- PCV13
  - 2, 4, 6 and 12-15 months
  - Parallels schedule for DTaP and other childhood vaccines

### PCV13 for Older Children and Catch-Up Schedule

<table>
<thead>
<tr>
<th>Age at dose</th>
<th>Total doses</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-11 months</td>
<td>3</td>
<td>2 doses ≥ 4 weeks apart, 3rd dose after 12 months</td>
</tr>
<tr>
<td>12-23 months</td>
<td>2</td>
<td>≥ 2 months apart</td>
</tr>
<tr>
<td>24-59 mo. immunocompetent</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>24-59 mo. Immunocompromised received 1 dose</td>
<td>1</td>
<td>Before or ≥ 8 weeks after PPSV23</td>
</tr>
<tr>
<td>24-59 mo. Immunocompromised received &lt;3 doses</td>
<td>2</td>
<td>2 doses given 8 weeks apart Before or ≥ 2 months after PPSV23</td>
</tr>
</tbody>
</table>

---

**Age > 65 without Conditions**

**Indicated Pneumococcal Vaccination(s)**

PPV23 once
6-64 years with Common Conditions*

*Common Conditions
- Chronic heart disease
- Chronic lung disease (Asthma)
- Diabetes mellitus
- Alcoholism
- Chronic liver disease
- Cigarette smoking

Indicated Pneumococcal Vaccination(s)
- PCV13
- PPSV23
- No indication for PCV13

6-64 years – Very Immunocompromised

Hemoglobinopathies
- Asplenia
- Chronic Renal Failure
- Nephrotic Syndrome
- Generalize Malignancy
- Leukemia
- Lymphoma
- Hodgkins
- HIV/Immunocompromised
- Immunosuppression
- Solid Organ Transplant
- Multiple Myloma

Indicated Pneumococcal Vaccination(s)
- PCV13
- PPSV23
- 1 additional dose in 5 years AND Again at age 65 years
- PCV13 8 weeks before or 12 months after PPSV23

6-64 years - Meningitis Risk

Conditions
- Cochlear Implant
- CSF Leak

Indicated Pneumococcal Vaccination(s)
- PCV13
- PPSV23
- No additional dose in 5 years AND Again at age 65 years
- PCV13 8 weeks before or 12 months after PPSV23
**Apps**

http://www.cdc.gov/vaccines/recs/Scheduler/AdultScheduler.htm

http://www.cdc.gov/flu/apps/cdc-influenza-hcp.html

http://immunization.acponline.org/app/

**Vaccine Costs**


Cost excluding administration

- $2,257 per child

Cohort of 4.2 Million

Vaccines saved

$76 Billion

Direct/Indirect Cost


**Prices**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Whole Sale</th>
<th>Retail</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPSV23</td>
<td>$37.99*</td>
<td>$61.94*</td>
</tr>
<tr>
<td>PCV13</td>
<td>$102.03*</td>
<td>$120.90*</td>
</tr>
<tr>
<td>Walgreens</td>
<td>$180.00</td>
<td></td>
</tr>
</tbody>
</table>

*2012 Peds Prices per CDC

**Vaccines at pharmacies**

- PCV13
- HPV
- Certain Flu shots
- Shingles Vaccine

Caution with Medicare and some insurance

Pharmacy vs. medical benefit

**MMR Based on Year of Birth**

**After 1957**

- 2 doses
- Unless
  - Medical Contraindication
  - Previous vaccination or disease
  - Blood tests show immunity

**Before 1957**

- May not need MMR
- Exceptions:
  - Healthcare workers
  - Students in postsecondary educational institutions
  - Exposure
  - Some International Travelers
Vaccine Hesitancy

- Really Want Immunizations
  - Create opportunities
- Unsure
  - Brown et al Fam Prac Mtg March/April 2014
  - http://www.cdc.gov/vaccines/conversations
- No WAY

NO WAY!

- Fire them?
- Report to CPS?
- Opel et al Pediatrics 2014;113;526

The Righteous Mind by Jonathan Haidt

Establish Relationship
Keep trying
Find Allies

CDC Dose Accountability

- Keep Separate Stocks
  - VFC versus Private Insured
  - Borrowing Policy

Universal Purchase

- Age 0-19
  - VFC
  - Private
  - 20-30%

Universal Purchase

- Age 0-19
  - VFC
  - Private
  - $ 8 Million
  - 3.5 Million
  - Uninsured
  - Medicaid
  - Native American

Page 56
Send me your narratives
How would losing Universal Purchase impact your practice and patients?

MLMartinez@salud.unm.edu

Conclusions
Expect Changes in Pertussis Vaccine
Give Flu shots
   Intra Nasal -2-8 (if possible) and recombinant-egg allergies
PCV13 for kids, PPSV23 for adults >65
   References for high risk
Watch for measles
Patience with patients who refuse vaccines
Protect our Children by Protecting Universal Purchase

Resources/Further Reading
Summary Recommendations from ACIP for the 2013-2014 Influenza Season:

CDC FluView (for weekly updates regarding Influenza Activity across U.S.):
http://www.cdc.gov/flu/weekly/

CDC Flu App
http://www.cdc.gov/flu/apps/cdc-influenza-hcp.html

New Mexico Influenza Weekly Surveillance Reports:
http://nmhealth.org/flu/weekly_reports.shtml
# Pneumococcal Vaccines for High Risk Ages 6-64

<table>
<thead>
<tr>
<th>Condition</th>
<th>PVC13</th>
<th>PPSV23</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Common</strong></td>
<td><strong>Not Recommended</strong></td>
<td><strong>One dose</strong></td>
</tr>
<tr>
<td>Chronic heart disease</td>
<td></td>
<td><strong>Repeat once at age 65</strong></td>
</tr>
<tr>
<td>Chronic lung disease (Asthma)</td>
<td></td>
<td><em>(if interval &gt; 5 years)</em></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcoholism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic liver disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cigarette smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Immunocompromised</strong></td>
<td><strong>One dose</strong></td>
<td><strong>Dose 1</strong></td>
</tr>
<tr>
<td>Hemaglobinopathies</td>
<td>8 weeks before or 12 months</td>
<td>8 weeks after PCV13</td>
</tr>
<tr>
<td>Asplenia</td>
<td>after PPSV23</td>
<td>Dose 2 in 5 years</td>
</tr>
<tr>
<td>Chronic Renal Failure</td>
<td></td>
<td>At age 65</td>
</tr>
<tr>
<td>Nephrotic Syndrome</td>
<td></td>
<td><em>(If interval &gt; 5 years)</em></td>
</tr>
<tr>
<td>Generalize Malignancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hodgkins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV/Immunocomprised</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunosuppresion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid Organ Transplant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple Myloma</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Meningitis risk</strong></td>
<td><strong>One dose</strong></td>
<td><strong>One dose</strong></td>
</tr>
<tr>
<td>Cochlear Implant</td>
<td>8 weeks before or 12 months</td>
<td>8 weeks after PCV 13</td>
</tr>
<tr>
<td>CSF Leak</td>
<td>after PPSV23</td>
<td>No repeat until 65</td>
</tr>
</tbody>
</table>
How cost-effective is childhood immunization?

<table>
<thead>
<tr>
<th>Disease</th>
<th>Cases Prevented</th>
<th>Deaths Prevented</th>
<th>Direct Costs Saved, Million $</th>
<th>Societal Costs Saved (Direct + Indirect), Million $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria</td>
<td>275 028</td>
<td>27 503</td>
<td>3654</td>
<td>39 296</td>
</tr>
<tr>
<td>Tetanus</td>
<td>169</td>
<td>25</td>
<td>12</td>
<td>45</td>
</tr>
<tr>
<td>Pertussis</td>
<td>2 950 836</td>
<td>1062</td>
<td>4443</td>
<td>7017</td>
</tr>
<tr>
<td>Hib</td>
<td>19 606</td>
<td>741</td>
<td>1810</td>
<td>3756</td>
</tr>
<tr>
<td>Polio</td>
<td>67 463</td>
<td>800</td>
<td>2898</td>
<td>7259</td>
</tr>
<tr>
<td>Measles</td>
<td>3 835 825</td>
<td>3106</td>
<td>3762</td>
<td>8862</td>
</tr>
<tr>
<td>Mumps</td>
<td>2 312 275</td>
<td>12</td>
<td>1411</td>
<td>2374</td>
</tr>
<tr>
<td>Rubella</td>
<td>1 981 066</td>
<td>15</td>
<td>187</td>
<td>721</td>
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<tr>
<td>Congenital rubella syndrome</td>
<td>632</td>
<td>70</td>
<td>133</td>
<td>257</td>
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<tr>
<td>HepB</td>
<td>239 993</td>
<td>3514</td>
<td>240</td>
<td>1770</td>
</tr>
<tr>
<td>Varicella</td>
<td>3 942 546</td>
<td>73</td>
<td>373</td>
<td>1598</td>
</tr>
<tr>
<td>HepA</td>
<td>153 164</td>
<td>36</td>
<td>52</td>
<td>114</td>
</tr>
<tr>
<td>Pneumococcus-related diseases</td>
<td>2 323 952</td>
<td>5056</td>
<td>965</td>
<td>2696</td>
</tr>
<tr>
<td>Rota</td>
<td>1 582 940</td>
<td>19</td>
<td>327</td>
<td>595</td>
</tr>
<tr>
<td>Total</td>
<td>19 685 495</td>
<td>42 032</td>
<td>20 267</td>
<td>76 360</td>
</tr>
</tbody>
</table>

Benefit to cost ratio

For one birth cohort of 4.2 million

- Direct costs only: 3.0
- Total societal costs: 10.1

That’s $20 BILLION and $76 BILLION!

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age</th>
<th>Dose</th>
<th>Preparations</th>
<th>Mercury</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afluria® CSL Limited</td>
<td>≥9 years</td>
<td>0.5 ml</td>
<td>Single dose syringe and multiuse vial</td>
<td>In MDV</td>
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</tr>
<tr>
<td>Fluarix® GSK</td>
<td>≥3 years</td>
<td>0.5 ml</td>
<td>Single dose</td>
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<td></td>
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<tr>
<td>FlucelVax® Novartis</td>
<td>≥18 years</td>
<td>0.5 ml</td>
<td>Single dose syringe</td>
<td>No</td>
<td>Cellular derived</td>
</tr>
<tr>
<td>FluLaval® GSK</td>
<td>≥18 years</td>
<td>0.5 ml</td>
<td>Multiuse vial</td>
<td>Yes</td>
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</tr>
<tr>
<td>Fluvarin® Novartis</td>
<td>≥4 years</td>
<td>0.5 ml</td>
<td>Single dose syringe and multiuse vial</td>
<td>Yes</td>
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<tr>
<td>Fluzone® Sanofi Pasteur</td>
<td>6-35 months</td>
<td>0.25 ml</td>
<td>Single dose vial</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Fluzone® Sanofi Pasteur</td>
<td>≥36 months</td>
<td>0.5 ml</td>
<td>Single dose vial or prefilled syringe</td>
<td>No</td>
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</tr>
<tr>
<td>Fluzone®</td>
<td>≥6 months</td>
<td>0.5 ml</td>
<td>Multi dose vial</td>
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<td></td>
</tr>
<tr>
<td>FluBlok® Protein Sciences RIV3</td>
<td>18-49 years</td>
<td>0.5 ml</td>
<td>Single dose vial</td>
<td>No</td>
<td>Trivalent Recombinant</td>
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</table>

**Inactivated Influenza Vaccine, Trivalent (IIV3), Standard IM Dose**

**Quadrivalent**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age</th>
<th>Dose</th>
<th>Preparations</th>
<th>Mercury</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>FluMist® MedImmune LAIV4</td>
<td>2-49 years</td>
<td>0.2 mL</td>
<td>prefilled intranasal sprayer</td>
<td>No</td>
<td>Live attenuated Intra Nasal</td>
</tr>
<tr>
<td>Fluarix® Quadrivalent GSK</td>
<td>≥3 years</td>
<td>0.5 ml</td>
<td>single-dose prefilled syringe</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Fluzone® Quadrivalent Sanofi Pasteur</td>
<td>6-35 months</td>
<td>0.25 ml</td>
<td>single-dose prefilled syringe</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Fluzone® Quadrivalent Sanofi Pasteur</td>
<td>≥36 months</td>
<td>0.5 ml</td>
<td>single-dose prefilled syringe or vial</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Fluzone® Quadrivalent Sanofi Pasteur</td>
<td>&gt;65 years</td>
<td>0.5 ml</td>
<td>single-dose prefilled syringe</td>
<td>No</td>
<td>Trivalent</td>
</tr>
<tr>
<td>Fluzone® Intradermal</td>
<td>18-64 years</td>
<td>0.1 ml</td>
<td>prefilled microinjection system</td>
<td>No</td>
<td>Intra Dermal Less pain/vaccine Trivalent</td>
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</table>
Vaccine cost, children’s vaccines; does not include vaccine administration cost

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>#doses</th>
<th>cost/dose</th>
<th>total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>rotavirus</td>
<td>3</td>
<td>$75</td>
<td>$225</td>
</tr>
<tr>
<td>pneumococcal</td>
<td>4</td>
<td>$128</td>
<td>$512</td>
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<tr>
<td>Hib</td>
<td>4</td>
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<td>$104</td>
</tr>
<tr>
<td>DTaP</td>
<td>5</td>
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<td>$120</td>
</tr>
<tr>
<td>Hep B</td>
<td>3</td>
<td>$21</td>
<td>$63</td>
</tr>
<tr>
<td>Polio</td>
<td>4</td>
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<td>Hep A</td>
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<td>$60</td>
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<tr>
<td>MMR</td>
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<td>VZV</td>
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<td>TdaP</td>
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<td>$39</td>
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<tr>
<td>HPV</td>
<td>3</td>
<td>$135</td>
<td>$405</td>
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<tr>
<td>Meningococcal</td>
<td>2</td>
<td>$111</td>
<td>$222</td>
</tr>
<tr>
<td>Flu (LAIV)</td>
<td>19</td>
<td>$23</td>
<td>$437</td>
</tr>
<tr>
<td><strong>GRAND TOTAL</strong></td>
<td></td>
<td></td>
<td><strong>$2,573</strong></td>
</tr>
</tbody>
</table>

as of March 3, 2013: CDC Private Sector prices

Note: Influenza vaccine total cost slightly lower than indicated because LAIV can’t be used for the first three doses.

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Vaccine cost, adult vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Doses</th>
<th>Cost/dose</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>TdaP</td>
<td>1</td>
<td>$39</td>
<td>$39</td>
</tr>
<tr>
<td>Pneumo (PPSV)</td>
<td>1</td>
<td>$68</td>
<td>$68</td>
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<tr>
<td>Shingles</td>
<td>1</td>
<td>$174</td>
<td>$174</td>
</tr>
<tr>
<td>Influenza</td>
<td>1/year</td>
<td>$7.70-17.90</td>
<td>--</td>
</tr>
</tbody>
</table>

As of July 8, 2013. CDC Private Sector Prices
“Integrating Advance Care Planning Discussions into Routine Patient Care”

by

Lorrie Griego
Program Manager of Advanced Care Planning

Lorrie Griego is the Program Manager for Advance Care Planning at Presbyterian Healthcare. In this role she works to strengthen advance care planning within Presbyterian Healthcare and the community. She has over 19 years of experience in healthcare policy. Prior to her work with Presbyterian, Lorrie provided education throughout the United States on Medicare regulatory issues.

Email: lgriego3@phs.org

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Identify the importance of including advance care planning conversations into the routine care for adults in their practice
- Describe appropriate Advance Directives available in New Mexico that can be used to document patient wishes
- Implement strategies that will increase the number of patients who have a current advance directive available in their medical record
Integrating Advance Care Planning Discussions into Routine Patient Care

Nancy Guinn, MD
Lorie Griego

Advance Care Planning

Why Advance Care Planning?

- To know and honor a patient’s informed wishes
- Create an effective plan
- A well-prepared agent
- Specific instructions
- Have the plan available to treating physicians
- Incorporate the plan into decision-making

Advance Care Planning

What is an Advance Directive?

- Two important components
  - Healthcare Decision Maker
  - POA / agent / surrogate
  - Instructions on what type of care a person does or does not want to receive
  - “Living Will” or “Wishes and Values”
  - An individual can delegate individual instructions to their Healthcare Decision Maker

Advance Care Planning

Advance Directives in New Mexico

- No notary required
- No witness required
- No need to consult an attorney

Advance Care Planning

Standard approach?

- Question required by regulation
  - “Do you have an advance directive?”
- Using statutory documents to define the conversation
- Equating advance care planning with code status
  - “If your heart stops, do you want us to use CPR?”

Advance Care Planning

What is the Gold Standard?

- Gundersen Lutheran in La Crosse County, Wisconsin
- Of 400 patients who died in ’07-’08
  - 90% had an advance directive
  - It was in the Medical Record 99.4% of the time
  - It was followed 99.5% of the time

Hammes Et. al JAGS 2010
Advance Care Planning

- The Gundersen Approach

- Five Promises:
  - We will initiate a discussion with every adult
  - We will provide skilled ACP facilitation
  - We will make sure plans are clear
  - We will store and be able to retrieve plans when needed
  - We will follow plans appropriately as needed

Advance Care Planning

- How will New Mexico achieve comparable numbers:
  - Family practice providers
  - Specialists
  - Hospitals
  - Long-term care facilities
  - Community culture shift regarding advance care planning

Developing a Personal Case for Advance Care Planning

- How has advance care planning, or the lack of, had an impact on your personal life?

Developing a Personal Case for Advance Care Planning

- Have you had a significant professional experience surrounding the advance care planning process?

The Integrated Approach to Advance Care Planning

- Keys to success
  - Staff that is invested
  - A clear and dedicated process
  - Location in the medical record
  - Measurable goals
  - Periodic reviews

The Integrated Approach to Advance Care Planning

- Staff that is invested
  - Belief in the benefits
  - Understanding of the basics
  - Commitment to the goals
The Integrated Approach to Advance Care Planning

- What message do you think that you will get from staff when you ask them to add advance care planning to their workload?

A clear and dedicated process
- Ownership at every level
- Touch points that make sense
- Part of routine care
- We make this happen by using the Right Time, Right Staff Member, Right Message model

The Integrated Approach to Advance Care Planning

- The Right Time
  - As part of a routine office visit
  - Especially during a patient’s annual healthcare exams
  - As an individual’s health status changes
  - When an individual expresses an interest / is ready to talk about advance care planning

The Integrated Approach to Advance Care Planning

- The Right Staff Member
  - Level One
    - Healthy Patients
    - Routine Part of Healthcare
    - *Handled by the person who rooms the patient*
  - Level Two
    - Patients with chronic health conditions or multiple diagnoses
    - *Handled by a nurse / care manager
  - Level Three
    - Patients with a life-limiting or very serious illness
    - *Physician / Midlevel Driven

The Integrated Approach to Advance Care Planning

- The Right Message
  - Introduce the conversation in a way that helps the patient feel comfortable with the discussion
  - Ask questions:
    - Understanding of an advance directive
    - Comfort level
    - Goals for care
    - Clarify information
    - Review the conversation

What do your patients think when they are asked to fill out an advance directive?
The Integrated Approach to Advance Care Planning

- Keys to success
  - Staff that is invested
  - A clear and dedicated process
  - Location in the medical record
  - Measurable goals
  - Periodic reviews

The Integrated Approach to Advance Care Planning

- Consistent location in the Medical Record
  - Information is available to any provider who provides care to the patient.
  - Ultimate goal is to assign the same priority to advance directives as to allergies
  - Allows for a process review

The Integrated Approach to Advance Care Planning

- Measurable Goals and Periodic Review
  - Allows you to see if your integrated approach is working – as well as provides valuable feedback that can help reinforce staff efforts.

Resources

- The Conversation Project
  - theconversationproject.org
- Engage with Grace
  - engagewithgrace.org
- New Mexico Medical Orders for Scope of Treatment
  - nmmost.org
- New Mexico Uniform Health Care Decisions Act
  - www.nmcpr.state.nm.us/nmac/parts/title07/07.027.0006.htm

Thanks for attending

Questions / Comments / Feedback?
“Congestive Heart Failure”

by

Bart Cox, MD

Bart Cox, MD is an Associate Professor of Medicine, Division of Cardiology, University of New Mexico School of Medicine. Dr. Cox received his MD from Indiana University School of Medicine. He completed his residency and fellowship at the Medical College of Wisconsin Affiliated Hospitals, Milwaukee, WI. Dr. Cox is ABIM certified in Internal Medicine, Cardiovascular Disease and Advanced Heart Failure/Transplant Cardiology. His area of clinical expertise is heart failure. Dr. Cox is currently Director of the UNM Advanced Heart Failure Program, Medical Director of the UNM In-Patient Cardiology Services, and Medical Director of the UNM Cardiac Rehabilitation.

Email: bartcox@salud.unm.edu

Learning Objectives

At the end of this presentation, the attendee will be able to:

• Understand new Heart Failure definitions
• Know guideline recommendations of ACEI, ARB
• Know guideline recommendations of Aldosterone, Antagonists, Beta Blockers and Diuretics
HEART FAILURE: ANSWERS YOU NEVER GET TO QUESTIONS YOU ALWAYS ASK

BART COX, M.D.FACC
DIRECT OR, ADVANCED HEART FAILURE PROGRAM
ASSOCIATE PROFESSOR OF MEDICINE
UNIVERSITY OF NEW MEXICO SCHOOL OF MEDICINE

DEFINITIONS

- **HEART FAILURE**
  - A complex syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood
  - Irrespective of LVEF, most patients have both systolic and diastolic dysfunction
  - Cardinal manifestations:
    - Exercise intolerance due to dyspnea and fatigue
    - Fluid retention
  - No longer called “congestive” heart failure
  - Not synonymous with cardiomyopathy or LV dysfunction

- **ASYMPTOMATIC LEFT VENTRICULAR DYSFUNCTION**
  - LVEF < 50% and NO history of signs and symptoms of heart failure

HEART FAILURE CLASSIFICATIONS

- **American College of Cardiology / American Heart Association stages of HF**
  - Emphasize the development and progression of disease
  - A: at high risk for HF but without structural heart disease or signs and symptoms of HF
  - B: structural heart disease present but NO past or present HF signs or symptoms present
  - C: structural heart disease present and current or prior HF signs symptoms present
  - D: Refractory HF requiring specialized interventions

- **New York Heart Association functional class**
  - Focuses on exercise capacity and the symptomatic status of the disease
  - NYHA I: no limitation of physical activity. Ordinary physical activity does not cause HF symptoms
  - NYHA II: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in HF symptoms
  - NYHA III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes HF symptoms
  - NYHA IV: Unable to carry on any physical activity without HF symptoms or HF symptoms at rest

DISCLOSURES

NONE
DEFINITIONS OF HF BASED ON EJECTION FRACTION (EF)

- Normal LV ejection fraction (HFrEF): > 55%
- Heart Failure With Reduced EF (HFrEF): HF signs/symptoms + LVEF ≤ 40%
- Heart Failure with Preserved EF (HFpEF): HF signs/symptoms + LVEF ≥ 50%
- Heart Failure with Preserved EF, Borderline: HF signs/symptoms + EF 41-49%
- Heart Failure with Preserved EF, Improved: HF signs/symptoms with prior EF ≤40%, now >40%

EPIDEMIOLOGY

- Prevalence: 5.8 million in US
- Incidence: > 650,000 new cases diagnosed annually in US
- 50% have HFrEF, 50% have HFpEF
  - HFrEF mortality: sudden death or pump failure
  - HFpEF mortality is more noncardiac
- Prognosis: mortality HFpEF = mortality HFrEF
- Expense: approximately $37 billion/year

HFrEF

QUESTIONS & ANSWERS

QUESTION

In a newly diagnosed HFrEF patient, what do I start first- ACEI or beta blocker?

ANSWER

- No evidence supporting superiority of one over the other
- CIBIS 3: ACEI versus bisoprolol as first agent. No difference which was started first.
- Most start with ACEI first, then add beta blocker 2 weeks later.
- Be patient specific: a fib with RVR or history of MI: start beta blocker first.
- Start both within a few weeks of each other and titrate up weekly to every other week.

QUESTION

Does it matter which beta blocker I use for HFrEF patients?
ANSWER

- Not all beta blockers are equal.
- Only 3 are evidence based to improve mortality and are approved for HFrEF (carvedilol, bisoprolol, metoprolol succinate).
- All 3 beta blockers have similar efficacy for preventing mortality and morbidity.
- Achieve the target dose (if possible) used in the trials, even in asymptomatic patients.

ANSWER

- The combination should be used in HFrEF patients unable to tolerate ACEI and ARB due to drug intolerance, hyperkalemia, renal insufficiency, or hypotension.
- Use the combination in African American patients with HFrEF who remain NYHA III-IV despite optimal therapy with beta blocker and ACEI.

ANSWER

- No data on whether it is safe to stop HF meds in a patient who has reversed remodeled.
- Anecdotal reports of some patients with reversible LV dysfunction having meds stopped and not redeveloping HF.
- If the meds are stopped, follow closely for evidence of HF recurrence.
- There are no recommendations in the guidelines.

QUESTION

- Should I use hydralazine and nitrates? If, when? In whom?

QUESTION

- What do I do with medications once the low EF improves?

QUESTION

- When do I add an aldosterone antagonist (eplerenone or spironolactone)?
ANSWER

- LVEF ≤35% + NYHA III-IV + already on ACEI (or ARB) and beta blockers
- LVEF ≤35% + NYHA II + already on ACEI (or ARB) and beta blocker + prior CV hospitalization or elevated BNP
- LVEF ≤40% + Acute MI + either DM or symptoms/signs HF

QUESTION

- When do I add digoxin?

ANSWER

- Digoxin can be beneficial in patients with HFrEF, unless contraindicated, to decrease hospitalizations for HF
  - Keep trough level between 0.5-0.9
- HFrEF + atrial fibrillation + rate not well controlled on optimal dose of beta blocker = addition of digoxin

QUESTION

- When do I anticoagulate a HF patient?

ANSWER

- HF + AF + 1 additional risk factor for cardioembolic stroke (hypertension, age ≥ 75, DM, prior CVA or TIA)
- HF + AF and NO additional risk factors
- Selection of anticoagulation agent (dabigatran, rivaroxaban, apixaban, warfarin) for AF should be individualized
- HF + prior thromboembolic event / cardioembolic source

QUESTION

- How do I treat asymptomatic LV dysfunction stage B (structural heart disease with no prior or current HF signs/symptoms)?
ANSWER

- If history of MI + EF ≤40%, use both ACEI (or ARB) and evidence based beta blocker
- If history of MI, use statins to prevent HF
- BP should be controlled to prevent symptomatic HF
- ACEI + beta blocker should be used in all patients with a reduced EF to prevent HF
- ICD is reasonable in patients with asymptomatic ischemic CM who are > 40 days post MI with LVEF ≤30% + GDMT

QUESTION

- When do I use an ARB rather than an ACEI in HFrEf?

ANSWER

- ARBS may be used in patients with ACEI intolerance (defined as ACEI cough and possibly ACEI induced angioedema)
- ARBS may be used as first line therapy for HFrEF, especially for patients already taking ARBs for other indications
- ARBS may be added to ACEI in persistently symptomatic HFrEF patients in whom aldosterone antagonist is contraindicated

QUESTION

- Which ARBs demonstrated improved survival in Hfref?

ANSWER

- Candesartan (CHARM Alternative) 32 mg/day
- Valsartan (ValHeFT) 160 mg/day
- Losartan (HEAAL) 150 mg / day

QUESTION

- When is Cardiac Resynchronization Therapy (aka biventricular pacemaker) indicated?
HEART FAILURE WITH PRESERVED EJECTION FRACTION (HFpEF)

HFpEF: PATHOPHYSIOLOGY

• HFpEF structural changes are same as those of chronic hypertension
  ◦ Increased vascular stiffening contributing to chronic pressure overload
  ◦ Secondary concentric LV chamber remodeling
  ◦ Left atrial enlargement due to elevated LV diastolic pressures

QUESTION

• When is an ICD indicated for primary prevention of sudden cardiac death (SCD)?

ANSWER

• LVEF ≤ 35% + > 40 days post MI + NYHA II – III on GDMT + reasonable expectation of meaningful survival for > 1 year
• LVEF ≤ 30% + > 40 days post MI + NYHA I on GDMT + reasonable expectation of meaningful survival for > 1 year.
• Nonischemic CM ≤ 35% + NYHA II-III on GDMT

ANSWER

• LVEF ≤ 35% + AF + GDMT + Requires ventricular pacing or otherwise meets CRT criteria + AVN ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT
• LVEF ≤ 35% + GDMT + undergoing a new or replacement device implantation with anticipated requirement for > 40% ventricular pacing

ANSWER

• LVEF ≤ 35% + sinus rhythm + LBBB + QRS > 150 msec + NYHA II, III, or ambulatory IV already on GDMT
• LVEF ≤ 35% + sinus rhythm + non LBBB + QRS ≥ 150 msec + NYHA III/ambulatory IV already on GDMT
• LVEF ≤ 35% + sinus rhythm + LBBB + QRS 120-149 msec + NYHA II, III, ambulatory IV
HFpEF PATHOPHYSIOLOGY: DIASTOLIC DYSFUNCTION

- Pathologic mechanism considered to produce HFpEF symptoms: diastolic dysfunction and nondiastolic mechanism.
- Characterization of diastolic dysfunction
  - Delayed LV relaxation and increased chamber stiffness
- Delayed relaxation and increased chamber stiffness lead to:
  - Impaired diastolic filling or the requirement of pathologically elevated filling pressure to achieve adequate preload
  - Chronic elevation of filling pressure → LA remodelling

HFpEF PATHOPHYSIOLOGY: NONDIASTOLIC DYSFUNCTION

- While EF is normal, other measures of regional, chamber, and myocardial systolic function are impaired.
  - Systolic function is impaired during exercise
  - CO may not increase adequately during exercise
  - Reserve capacity with stress is impaired
- Chronotropic incompetence: unable to increase HR adequately during exercise
- Impaired vasodilation during exercise
- Ventricular-arterial stiffening → labile BP

HEART FAILURE WITH PRESERVED EJECTION FRACTION (HFpEF)

- Symptoms on presentation are exactly like HFrEF
- Exam findings on presentation are exactly like HFrEF (except perhaps for PMI)
  - Physical exam will not reveal the ejection fraction
- May present as acute pulmonary edema or gradually progressive volume overload
- Precipitators for HF decompensation are similar to HFrEF

NONINVASIVE MARKERS OF ELEVATED LV FILLING PRESSURES

- Physical Exam
  - JVD, AJR, S3 gallop, peripheral edema, ascites, hepatomegaly
- Chest radiography
  - Cardiomegaly, pulmonary venous hypertension or edema, pleural effusion, pulmonary artery enlargement
- Echocardiography
  - LA enlargement, elevated PA systolic pressure, IVC dilatation and/or failure to collapse, pulmonary vein Doppler c/w elevated LA pressure, restrictive filling pattern of mitral inflow velocity, high E/E' >15
- Blood Work
  - Elevated BNP or NTproBNP

PRECIPITANTS OF ACUTE DECOMPENSATED HF (HFpEF or HFrEF)

- Myocardial ischemia or infarction
- Hypertension, High Output State, Hypoxia
- Endocrine (e.g., thyroid disease)
- Arrhythmia, Anemia
- Reduction in Therapy, Renal Disease
- Too much Na and fluid intake
- Second Heart Disease (aortic dissection, SBE)
- Drugs, Depressants, Doc
- Infection
- Embolism (PE)
**HFpEF DIAGNOSIS**

- HFpEF is a probabilistic, clinical diagnosis
- Central components of diagnosis:
  - Clinical symptoms compatible with HF
  - Exercise intolerance due to dyspnea, fatigue
  - Salt and water retention (congestion)
  - Objective evidence of cardiac dysfunction
    - Resting or exercise-induced high filling pressures or low cardiac output

- Relative to HFrEF, HFpEF patients have a higher incidence of:
  - Anemia, atrial fibrillation, hypertension, obesity
  - If symptoms are significant with exercise but all resting studies are normal, refer for cardiac catheterization: it's the gold standard of dx
  - Resting hemodynamics may be normal
  - After exercise or saline infusion, filling pressures increase significantly

**HFpEF: A DIAGNOSIS OF EXCLUSION**

- Diseases Commonly Confused With HFpEF can be both cardiovascular and noncardiovascular:
  - HFpEF is not diagnosed until these diseases have been excluded
- Myocardial ischemia causes acute diastolic dysfunction, and evaluation for CAD should be strongly considered
- Pulmonary disease may present with similar symptoms, and pulmonary function testing may help to rule in or exclude this entity

**NONCARDIOVASCULAR DISEASES CONFUSED WITH HFpEF**

- Pulmonary Disease
- Neuromuscular Disease
- Obesity
- Deconditioning
- Thyroid Disease
- Renal Artery Stenosis
- Anemia

**CARDIOVASCULAR DISEASES CONFUSED WITH HFpEF**

- Constrictive Pericarditis
- Coronary Artery Disease
- Hypertrophic Cardiomyopathy
- Infiltrative or Restrictive Cardiomyopathy
- Right Ventricular Myopathies
- Valvular Heart Disease
- Pulmonary Artery Hypertension
- Pulmonary Embolism
- High Output Heart Failure

**HFpEF TREATMENT: 2013 ACCF/AHA GUIDELINES**

- Systolic and diastolic BP should be controlled according to published clinical practice guidelines
- Diuretics should be used for relief of symptoms due to volume overload
- Coronary revascularization for patients with CAD in whom angina or demonstratabale myocardial is present despite GDMT
HFpEF TREATMENT: 2013 ACCF/AHA GUIDELINES

- Management of AF according to published clinical practice guidelines to relieve symptoms
- Use of beta-blocking, ACEI, and ARBS for hypertension in HFpEF
- ARBs might be considered to decrease hospitalization in HFpEF
- Nutritional supplementation is NOT recommended in HFpEF

HFpEF TREATMENT SINCE 2013 ACCF/AHA GUIDELINES

- Aldosterone antagonist: TOPCAT trial results
  - N=3445
  - Average Follow up: 3.3 years
  - Patients Studies: HFpEF: LVEF > 45%
  - Agent: Spironolactone 30-45 mg/day versus placebo
  - Primary Endpoint: CV mortality, aborted cardiac arrest, or HF hospitalization
  - Result: Primary Endpoint NOT met. HF hospitalizations significantly decreased
“Professional Burnout and Resilience: Maintaining Humanity, Compassion and Excellence in an Ever More Challenging Practice Environment”

by

Damian Bello, MD

Damian Bello, MD went to Tufts Medical School and graduated in 1996. He graduated from the Sutter Santa Rosa/UCSF Family Medicine Residency in 1999. He is currently the lead physician at the Presbyterian Medical Group in Los Lunas, New Mexico. He is also a member of the Presbyterian Medical Group Executive Council and on the Subcommittee on Physician Engagement.

Email: bellod@hotmail.com

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Define physician burnout
- Describe the burden of burnout to professionals, patients, and the healthcare system
- Identify the causes of and risk factors for professional burnout
- Discuss the relationship between burnout and engagement
- Discuss ways to treat and prevent burnout and enhance resilience
Professional Burnout and Resilience

57TH ANNUAL FAMILY MEDICINE SEMINAR
JULY 31, 2014
TAOS, NEW MEXICO
DAMIAN BELLO, MD

Professional Burnout and Resilience

MAINTAINING HUMANITY, COMPASSION, AND EXCELLENCE IN AN EVER MORE CHALLENGING PRACTICE ENVIRONMENT.

Rate 6-0

- I feel emotionally drained from my work
- I’ve become more callous towards people since I took this job
- I feel I’m positively influencing other people’s lives through my work

Goals

- Define Burnout
- Describe how it effects providers and patients
- Understand how burnout occurs
- Discuss how burnout is assessed
- Discuss ways to prevent burnout, treat it, and enhance resilience
II. What is Burnout and How Does it Occur?

Definition - Historical Perspective

- Merriam-Webster defines burnout as the condition of someone who has become physically and emotionally tired after doing a difficult job for a long time.
- 1974 – Freudenberger, The extinction of motivation or incentive, especially where one’s devotion to a cause or relationship fails to produce the desired results.
- 1981 – Maslach & Jackson, Maslach Burnout Inventory

Professional Burnout Definition

1. Emotional Exhaustion
2. Depersonalization
3. Decreased Sense of Personal Accomplishment (Ineffectiveness)

How big is the problem?

- Half of all physicians report at least 1 symptom of burnout and 1/3 – 1/2 of physicians meet burnout criteria.
- 1/2 of medical students have symptoms of burnout.
- The rate of burnout is increasing. 63% report more burned out than three years ago.
- 67% of physicians would leave medicine today if they could.
- 2/3 of Family Physicians would choose medicine again, but only 1/3 would choose family medicine.

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3. 2011 Cvejkasurvey
4. Advisory Board
**Symptoms of Burnout**

<table>
<thead>
<tr>
<th>Emotional Exhaustion</th>
<th>Depersonalization</th>
<th>Inefficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of enthusiasm for work</td>
<td>Cynicism/Sarcastism</td>
<td>Low sense of accomplishment</td>
</tr>
<tr>
<td>Dread going to work</td>
<td>Feeling like the patient is the problem</td>
<td>Feeling unproductive</td>
</tr>
<tr>
<td>Hard to get work day started</td>
<td>Getting angry with patients</td>
<td>Loss of job satisfaction</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Irritability and moodiness with co-workers &amp; staff</td>
<td>Worries about getting fired or disciplined</td>
</tr>
<tr>
<td>Desire to retire early or change careers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desire to work less</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Results of burnout/Signs of Burnout**

<table>
<thead>
<tr>
<th>Emotional exhaustion</th>
<th>Depersonalization</th>
<th>Inefficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased hours of work</td>
<td>Decreased patient satisfaction/experience</td>
<td>Decreased job performance</td>
</tr>
<tr>
<td>Early retirement or resignation</td>
<td>Increased patient complaints</td>
<td>Lower quality of work</td>
</tr>
<tr>
<td>Poor physical and mental health</td>
<td></td>
<td>Increased medical errors</td>
</tr>
<tr>
<td>Worry about getting fired or disciplined</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**American Family Physician**

Data Analysis Shows Not Enough Physicians Are Entering Primary Care

- More than 60% of medical school graduates entering primary care specialties report dissatisfaction with their work environment.
- Physicians in primary care specialties report higher levels of emotional exhaustion and depersonalization compared to other specialties.

**CGCAHPS**

- Measures patient experience
- For large medical groups, reimbursement tied to high scores (9-10)
- Examples
  - During your most recent visit, did this provider listen carefully to you?
  - During your most recent visit, did this provider seem to know the important information about your medical history?
  - During your most recent visit, did this provider spend enough time with you?

**Characteristics of Burnout**

- Occurs more frequently than admitted by employers of physicians and by physicians themselves
- Frequently ignored or accepted as part of doing business
- There is an overriding rationalization of and resistance to seeking and accepting help

*Shanafelt, Dyrbye*
More Characteristics

- Occurs on a continuum
- Not related to how hard or how much we are working
- Tends to Occur in phases
- Women and men experience burnout differently
- Women are 60% more likely to be affected by burnout than men

Response to stress – sex differences

**Women**
- Emotional Exhaustion
- Depersonalization
- Lack of efficacy

**Men**
- Depersonalization
- Emotional Exhaustion
- No sense of lack of efficacy

How does Burnout Occur?

Stress is normal, Burnout is not.

Burnout and Engagement

Burnout versus Engagement

- Exhaustion
- Depersonalization
- Inefficacy

- Energy
- Involvement
- Efficacy
“BURNGAGEMENT”

Burnout and Depression - Not the Same

**Burnout**
1. Effects are at work
2. Fatigue
3. Loss of job satisfaction
4. Feeling unproductive
5. Unable to get on top of workload
6. Irritable with co-workers and patients
7. Hard to get work day started

**Depression**
1. Effects all aspects of life
2. Fatigue
3. Anhedonia
4. Low self esteem
5. Poor concentration and memory at work and home
6. Irritable with everyone
7. Hard to get anything started

III. Causes and Risk Factors

Professions with High Stress/Burnout

- Education
- Social Work
- Real Estate
- Health Professions
Job Stressors in High Burnout Professions

<table>
<thead>
<tr>
<th>Physical Stressors</th>
<th>Emotional Stressors</th>
<th>Spiritual/Dissatisfiers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air-traffic controller: X</td>
<td>Hostage negotiator: X</td>
<td>Judge: X</td>
</tr>
<tr>
<td>Hostage negotiator: X</td>
<td>Fudge: X</td>
<td>Motherhood: X</td>
</tr>
<tr>
<td>Fudge: X</td>
<td>Newborn: X</td>
<td>Healthcare professional: X</td>
</tr>
</tbody>
</table>

Forms of stress

- Physical
- Emotional
- Spiritual/Diss satisfiers

Physical Stressors

- Sheer amount of work
- Extremes of activity
- Poor self care (Inadequate sleep - Lack of sleep/poor sleep quality)
- Demands outside work
- Illness or poor health

Emotional Stressors

- High level empathy considered important to do the job well
- Dealing with people in crises is part of the job

Spiritual Stressors

- Things that cause us to question what we are doing and why
- Crisis of meaning
- Inability to reconcile what we are doing with what we want to do.
Self Determination Theory

- Competence
  - The need to feel valued as knowledgeable and skilled
  - To experience mastery
- Relatedness
  - The need to collaborate with colleagues and co-workers
  - The need to interact, be connected to, and experience caring for others
- Autonomy
  - The need to exercise some control/influence to achieve practice goals
  - Sense of contribution to goal.

AMA Study

- 656 physicians, 30 practices, six states
- January 2013 through August 2013
- Key questions:
  - What factors influence physician professional satisfaction
  - What are the implications of these factors for patient care, health systems, and health policy?
- Four Key findings
  - Importance of delivering high-quality healthcare
  - Pros and cons of electronic health records
  - Value of stability and fairness
  - Cumulative burden of regulations

EMR
The Electronic Medical Record

- Positives
  - Legibility
  - Prescribing ease
  - Information Sharing
- Negatives
  - Physical stress: Increased work
  - Emotional stress: Barrier to Empathy
  - Spiritual stress:
    - Often does not improve the clarity of documentation for clinical purposes
    - Sacrifices documentation for patient care for coding and billing and managing population care

Mixed Messages/Competing Demands

- Produce v. Take care of all pts needs today
- See patients v. Participate in meetings
- Produce v. Improve quality
- Document well v. Document fast

Managing Multiple Expectations

- Patients
- Industry
- Ourselves
- The medical profession
- Our practice/employers
- Cultural
- Our families
Risk Factors for Burnout

- Personal Factors
- Cultural Factors
- Level of Social Support
- Religious involvement was protective or not correlated
- Political Leanings
- Work Life
- Psychological health
- Personality

Personality

- Common Characteristics
  - Service
  - Excellence
  - Creative Competence
  - Compassion
  - Learned habits from medical training and reinforced on the job
- Individual Characteristics
  - Work habits, how much we take on
  - Charting habits
  - Demeanor at work
  - Attitude
  - Introversion/extroversion
  - Hardiness with lower risk
  - Compulsiveness correlates with higher BO

Why is burnout so hard to address?

- Providers
  - Pluralistic ignorance: A situation in which a majority of group members privately reject a norm, but incorrectly assume that most others accept it, and therefore go along with it
- Organizations
  - Lack of perceived value
  - Fear

Burnout Pop Quiz

Rate 0-6

1. I feel emotionally drained from my work (Emotional Exhaustion)
2. I've become more callous towards people since I took this job (Depersonalization)
3. I feel I'm positively influencing other people's lives through my work (Personal Accomplishment/Efficacy)

Maslach Burnout Inventory

- 22 total questions
  - 9 on Emotional exhaustion - high is worse,
  - 5 on Depersonalization – high is worse
  - 8 on Personal Accomplishment – high is better
  - Scores are divided into high, moderate, and low
- Abbreviated Maslach Inventory
  - 9 questions – 3 in each area
  - 3 additional questions on "Satisfaction with Medicine"

*Emmanuel

*http://www.mindgarden.com/products/mbl.htm
*McManus 2003, British Medical Journal, 327, 139-142
Compassion Fatigue Assessment

<table>
<thead>
<tr>
<th>Visible Signs</th>
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</thead>
<tbody>
<tr>
<td>1. Marked decline in work efficiency?</td>
</tr>
<tr>
<td>2. Intent on clinical tasks to the detriment of patient interactions?</td>
</tr>
<tr>
<td>3. More callous toward patients than in the past?</td>
</tr>
<tr>
<td>4. Signs of mental or physical breakdown during crisis periods?</td>
</tr>
<tr>
<td>5. Outbursts of anger or irritability with little provocation?</td>
</tr>
<tr>
<td>6. Declining opinion of caregiver role?</td>
</tr>
<tr>
<td>7. Treats patients like impersonal objects?</td>
</tr>
<tr>
<td>8. Developed a pressing desire to explore an entirely different profession?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Invisible Signs</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Reduced sense of accomplishment</td>
</tr>
<tr>
<td>10. Harbored a secret happiness when a procedure is cancelled?</td>
</tr>
<tr>
<td>11. Unhealthy attachment to patients?</td>
</tr>
<tr>
<td>12. Anxiety when interacting with emotional patients?</td>
</tr>
</tbody>
</table>

Informal Surveys

- **Background**
  - The PMG Engagement Subcommittee - with input from Lead Physicians - put together a one page survey, sent out to all providers during the month of December, 2013.

- **Questions** – 5 point scale
  - Does your work schedule allow you to maintain appropriate work/life balance?
  - Are the following staff in your clinic effective and helpful?
  - Do you find yourself working past scheduled hours

- **Results**

Informal Self-Assessment

- Have you become cynical or critical at work?
- Have you become irritable or inpatient with coworkers, customers or clients?
- Do you like the energy to be consistently productive?
- Do you like satisfaction from your achievements?
- Are you using food, drugs or alcohol to feel better or just not feel?
- Have your sleep habits or appetite changed?
- Are you troubled by unexplained headaches, aches, or other physical complaints?

The Burnout Continuum

- Engagement
- At Risk
- Some Burnout
- Full Burnout

V. Treatment/Prevention/Resilience

- "Where there is much information..."
Who’s responsible?

- Individual Providers
- Organizations
- Medical schools
- Medical profession
- Government and policy makers
- Healthcare Industry

Happiness Research Analogy

- 50% predetermined by genetics and family
- 50% changeable
  - 38% determined by recent event
  - 12% under individual control

Lykken, Psychological Science Vol. 7, No. 3, May 1996

Dual Responsibility

Individual Approach

1. Assessment (done)
2. Intervention, Do Something
   1. Take care of your self
   2. Pick something to do

Pick Something To Do

- Decrease Stress/Enhance Resilience
  - Physical
  - Emotional
  - Spiritual
- Address Burnout
  - Emotional Exhaustion
  - Depersonalization
  - Inefficacy

Choose Your Intervention

Ease of Change

Potential Impact

Low hanging fruit

Less likely to happen
Pick Something To Do

- Decrease Stress/Enhance Resilience
  - Physical
  - Emotional
  - Spiritual
- Address Burnout
  - Emotional Exhaustion
  - Depersonalization
  - Inefficacy

Pick Something To Do

- Decrease Stress/Enhance Resilience
  - Physical – *work on sleep or exercise*
  - Emotional - *expectations*
  - Spiritual – *get a handle on finances*
- Address Burnout
  - Emotional Exhaustion
  - Depersonalization
  - Inefficacy

Benefits of Meditation

- Better Focus
- Less Anxiety
- More Creativity
- More Compassion
- Better Memory
- Less Stress
- More Grey Matter
What is this “Mindfulness”?

- A simple form of meditation where you train yourself to notice your thoughts without judging them.
- “Mindfulness means paying attention in a particular way, on purpose, in the present moment, and nonjudgmentally.” Jon Kabat-Zinn
- MBSR (Mindfulness Based Stress Reduction)

Pick Something To Do

- Decrease Stress/Enhance Resilience
  - Physical – **work on sleep or exercise**
  - Emotional - **expectations**
  - Spiritual – **get a handle on finances**
- Address Burnout
  - Emotional Exhaustion – **meditation**
  - Depersonalization
  - Inefficacy

Pick Something To Do

- Decrease Stress/Enhance Resilience
  - Physical – **work on sleep or exercise**
  - Emotional - **expectations**
  - Spiritual – **get a handle on finances**
- Address Burnout
  - Emotional Exhaustion – **meditation**
  - Depersonalization - **acknowledgement**
  - Inefficacy – **creative CME**

Still Stuck? Resource List

Organizational Strategies

- Incorporate provider wellbeing into organizational values and structure
- Prevention strategies should be:
  - Thoughtful
  - Practical
  - Well-supported in the organization
Healthy workplace characteristics

Practice Size

- Large
  - Employed and large group practices
- Small
  - Private practice, self-employed, solo practitioners

Provider Wellness Models

- Passive
  - Open door policy
  - Focusing on positive
- Reactive
  - Critical incident stress debrief
  - Suggesting outside counsel
- Proactive
  - Well-being assessment
  - Thoughtful, practical and supported prevention strategies

Organizational Strategies

- Promote Resiliency
  - Autonomy -
  - Relatedness -
  - Competence -
- Decrease Stress
  - Physical -
  - Emotional -
  - Spiritual -
Organizational Strategies

- Promote Resiliency
  - Autonomy - promote a culture of transparency and fairness
  - Relatedness – promote peer-peer interaction
  - Competence – improve support of CME (time and money)

- Decrease Stress
  - Physical –
  - Emotional -
  - Spiritual –

Support Forums/Schwartz Center Rounds

- Demonstrated best practice
- Combats provider burnout and improves service simultaneously
- Structure and design elements
  - Modeled after M&M rounds
  - Based on case presentations
  - Presentations proud discussions of underlying issues
  - Staff share best practices to address issues
  - Guided by a facilitator

Schwartz Center Rounds

- Demonstrated best practice
- Combats provider burnout and improves service simultaneously
- Structure and design elements
  - Modeled after M&M rounds
  - Based on case presentations
  - Presentations proud discussions of underlying issues
  - Staff share best practices to address issues
  - Guided by a facilitator

Key Attributes
- Structure regular forum for peer-to-peer support
- Opportunity to work together on difficult interactions
- Provision of framework to think too difficult patient situations
- Opportunity to learn from others how to manage stressors
- Open discussion of emotions to help manage stress

Common Pitfalls
- Discussion times fall to the wayside overshadowed by other priorities
- Culture prohibits sharing concerns
- Devolves into a complaining session
- No demonstrated learning change or alleviation of stresses
Schwartz Center Rounds

- Supported by the Schwartz Center founded by Ken Schwartz before he died of lung cancer in 1995
- Nearly 300 hospitals and medical centers hold the rounds
- Open to all professionals with patient care responsibilities
- Help monthly 430 to 150 caregivers at no cost to the hospital
- Rounds first piloted at Mass General Hospital in 1997

Schwartz Center Video

- The Schwartz Center Story
  - http://bcove.me/yjijjtl

VI. Conclude and Closing

Thoughts

Questions and Comments
FRIDAY, AUGUST 1, 2014

7:00 a.m.  Registration, Exhibits Open
Breakfast - Exhibit Hall

8:00 a.m.  “ABFM’s Part IV (PPM;MIMM) - The Best Approach for the Best Results”
Joe Tollison, MD

9:00 a.m.  “Has the Affordable Care Act Made Progress in Reforming Health Care in America?”
Rick Madden, MD

10:00 a.m. Break – Exhibit Hall

10:30 a.m.  “Parasomnias and Sleep-Related Movement Disorders”
Frank Ralls, MD

11:30 a.m.  “Treatment of Major Depressive Disorder in the Patient-Centered Medical Home”
Dion Gallant, MD

12:30 p.m.  Lunch – Exhibit Hall

1:30 p.m.  “Keeping Current with COPD Management”
Fernando Martinez, MD, MS

3:30 p.m.  Break – Exhibit Hall

4:00 p.m.  “Providing Culturally Effective Care to the People of New Mexico”
Felisha Rohan-Minjares, MD & Jessica Goodkind, PhD

5:30 p.m.  Leisure

6:30-10:30 p.m.  Awards Dinner & Dance - Lecture Hall
Special Guest - Lori Heim, MD, Past AAFP Board Chair
Entertainment - Jimmy Stadler
“ABFM’s Part IV (PPM; MIMM)
The Best Approach for the Best Results”

by

Joe Tollison, MD

Joe Tollison, MD is currently Senior Advisor to the President of the American Board of Family Medicine. Previously, he served for ten years as Deputy Executive Director and Senior Vice President of the ABFM with responsibilities involving MC-FP. Prior to this, he was Chair of the Department of Family Medicine at the Medical College of Georgia for fifteen years and also interim Chair of the Department of Psychiatry for a period.

Email: jtollison@theabfm.org

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Understand where to invest your effort (for best results) in an ABFM PPM
- Maximize the aggregate patient data collection method for your ABFM PPM
- Be aware of the approved alternatives (and the individualized programs) for completion of ABFM's PPM
Slides have been enlarged to improve readability on Dr. Tollison’s presentation.

We hope you are able to use this as a future reference guide to navigate the website after this event.
ABFM’s Required Part IV (PPM, MIMM) – The Best Approach for the Best Results

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

DISCLOSURE: Dr. Tollison has nothing to disclose related to his presentation.
ABFM Goal:

LEAVE NO DIPLOMATE BEHIND . . . EVER!
Foundation of Maintenance of Certification for Family Physicians (MC-FP)

- Six Core Competencies are the foundation of MC-FP and are assessed during medical training and throughout a physician’s career.

- They have been endorsed by the Accreditation Council for Graduate Education (ACGME) and the twenty-four members boards of the American Board of Medical Specialties (ABMS).
Core Competencies

1. **Patient Care** that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health.

2. **Medical Knowledge** about established and evolving biomedical, clinical, and cognitive sciences and the application of the knowledge to patient care.

3. **Practice-based Learning and Improvement** that involve investigation and self-evaluation, appraisal and assimilation of scientific evidence, and improvements in patient care.
4. **Interpersonal and Communication Skills** that result in effective information exchange and collaboration with patients, their families, and other health professionals.

5. **Professionalism** as manifested through a commitment to perform professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population.

6. **Systems-based Practice** as manifested by actions that demonstrate an awareness of and responsiveness to the larger context and system of health care and the ability to use system resources to provide optimal care.
Each of the four parts of MC-FP assesses one or more of the Core Competencies.

<table>
<thead>
<tr>
<th>Core Competencies</th>
<th>1 Professional Standing</th>
<th>2 Lifelong Learning</th>
<th>3 Cognitive Expertise</th>
<th>4 Performance In Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Care</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Medical Knowledge</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Practice-based Learning &amp; Improvement</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Interpersonal &amp; Communication Skills</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Professionalism</td>
<td>✓</td>
<td></td>
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<td>✓</td>
</tr>
<tr>
<td>Systems-based Practice</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
Part I: Evidence of professional standing
Part II: Evidence of a commitment to lifelong learning and involvement in a periodic self-assessment process
Part III: Evidence of cognitive expertise
Part IV: Evidence of evaluation of performance in practice

Since Our Inception in 1969
What Exactly are the MC-FP Requirements?

- **7 Year Cycle**
  - 7 Modules Total
  - Certified/Recertified 2003-2010
  - 7 Year Certificate

- **10 Year Cycle**
  - 9 Modules Total
  - Certified/Recertified 2003-2010
  - 10 Year Certificate

- **Continuous**
  - 50 Points Per 3-Year Stage
  - Certified/Recertified 2011 and Beyond
  - Certificate without End Date
Continuous MC-FP

Changes Effective with Continuous MC-FP

• 10-year examination requirement
• 7-year certification plan no longer available
• Point system in place - 50 points required per 3-year Stage
  • SAMs = 15 points
  • PPMs = 20 points
  • MIMMs = 15-20 points
• Certification status contingent on meeting MC-FP requirement WITHIN each 3-year Stage (deadline December 31st of year 3 of Stage)
• Simplified financial plan

• CME requirement per 3-year Stage – 150 credits (Unchanged)
MC-FP Deadline

**Deadline:**
December 31, 2014

- **2011** Diplomates: Complete Continuous Stage MC-FP Components
- **2007** Diplomates: Complete Stage II MC-FP Components
- **2004** Diplomates: Complete Stage III MC-FP Components
Contact the ABFM

• **Support Center**
  - Phone: 877-223-7437
  - Email: help@theabfm.org
  - Live Chat

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

• **ABFM**
  - Phone: 888-995-5700
  - Fax: 859-335-5701
Support Center Assistance

Extended Hours Available!

8:30 am - 9:00 pm (eastern)
Monday - Friday
&
9:00 am - 5:00 pm (eastern)
Saturday

877-223-7437

• Manned by ABFM Staff located IN the ABFM home office
• Able to answer questions regarding all phases of ABFM business
Live chat available from ABFM Home page

2 Minute Rule
Have a Question after 2 minutes? Contact our Support Center!!
ABFM Maintenance of Certification for Family Physicians (MC-FP)

Part I: Evidence of professional standing
Part II: Evidence of a commitment to lifelong learning and involvement in a periodic self-assessment process
Part III: Evidence of cognitive expertise
Part IV: Evidence of evaluation of performance in practice

Since Our Inception in 1969
Take the Leap
Physician Quality Reporting System

Diabetes Only
PPM
PPM Alternative
MIMM

MC-FP Part IV
Do you have Continuing Patient Care?

YES

ABFM Approved Part IV Activities

NO

MIMM ABFM Approved Part IV

Hand Hygiene with Simulated Patient Data

Self Directed Activity without Patient Data
If you have direct, continuing patient care, click Yes.

If you have NO direct, continuing patient care responsibilities, click NO.
ABFM MC-FP Part IV

Do you have Continuing Patient Care?

- YES
  - ABFM Approved Part IV Activities
    - MIMM ABFM Approved Part IV
    - Hand Hygiene with Simulated Patient Data
    - Self Directed Activity without Patient Data

- NO
ABFM MC-FP Part IV

NO Access to Continuing Patient Care?

Methods in Medicine Modules (MIMMs)

ABFM Products

no additional charge beyond the cost of MC-FP

Current Topics:

Clinical Information Management MIMM
Cultural Competency MIMM
Hand Hygiene PPM (with simulated patient data)
ABFM Self-Directed Activity
Log in to your personal Physician Portfolio from the ABFM Home Page.
Click on "MC-FP Modules" to begin a module.

YOUR Physician Portfolio
The gateway to ABFM processes and products.
To access modules, click on “MC-FP Modules”
Available resources to assist you in completing the MIMM: Introduction Roadmap
To begin a MIMM click on the “START” link next to the MIMM topic of your choice.
Approved Part IV Alternatives

(Examples of Approved Part IV Alternatives)

- American Academy of Family Physicians (METRIC)
- Multi-Specialty Portfolio Approval Program (MSPP) Sponsor organization activities
- National Committee for Quality Assurance (NCQA)
  - Physician Recognition Programs
  - Approved programs: Diabetes, Heart/Stroke, Back Pain, Patient Centered Medical Home
  - Individual-level certificates of recognition in Heart/Stroke, Diabetes, Back Pain, or PCMH (only 2011, Level 3) can be submitted for Part IV credit
  - Organization-level certificates of recognition require additional physician attestation to be considered for Part IV credit

*(Bridges to Excellence programs can be considered through the Self-Directed pathway)*
Visit the ABFM website for the complete current list of Approved Outside Vendor Activities

www.theabfm.org

(listed under the Maintenance of Certification Section–click the Part IV Performance in Practice)
Part IV Alternatives Support

• Nichole Lainhart, Program Manager MC-FP Alternatives Activities
  – Phone: 877-223-7437, ext 1230
  – Email: NLainhart@theabfm.org

• Support Center
  – Phone: 877-223-7437
  – Email: help@theabfm.org
  – Live Chat
Do you have Continuing Patient Care?

NO

ABFM Approved Part IV Activities

Yes

PPM ABFM Approved Part IV with Patient Data

PPM Alternatives Part IV Modules with Patient Data

Self Directed Activity with Patient Data
Access to Continuing Patient Care?

YES

Complete a Performance in Practice Module (PPM)
If you have direct, continuing patient care, click Yes.

If you have NO direct, continuing patient care responsibilities, click NO.
Important Benefits of the PPM

1) Applied to your practice and your patients
2) Provides performance-based overview of your practice
3) Directed and controlled by you
4) Data available only to you (non-discovery)

☆ Physician Quality Reporting System (Diabetes) with potential additional financial benefits available
Log in to your personal Physician Portfolio from the ABFM Home Page.
Click on "MC-FP Modules" to begin a module.

YOUR Physician Portfolio
The gateway to ABFM processes and products.
Available resources to assist you in completing the PPM:
Roadmap
Introduction
PPM Choices currently available online:

- Asthma
- Comprehensive
- Coronary Artery Disease
- Depression
- Diabetes
- Hand Hygiene
- Heart Failure
- Hypertension
- Self-Directed
Steps to complete your first PPM

Choose 1
Clinical Indicator
(Problem Area)

Choose 2
Chronic Care Models
(Change Environment)

Choose 1
Intervention in EACH
Chronic Care Model
(Action Resources Available)
ABFM MC-FP Part IV

Let Your Staff Help

IMPORTANT!!!

Print Forms

Hand Out Forms
(Individual Entry Mode Only)

Input Data
1 Week Minimum
QI Implementation Period Between Pre and Post Data Collection
Step 1
Collect Data for 10 Patients
(Initial Patient Data Collection)

Step 2
Implement Your QI Plan

Step 3
Collect Data for 10 NEW patients
(Final Patient Data Collection)
There are 2 ways to submit patient data in a PPM

**Individual Entry Mode**
- Enter your data prospectively based on individual patients

**Aggregate Entry Mode**
- Enter data retrospectively for multiple patients
- Most commonly used for physicians who have Electronic Health Records (EHR)
What is the Difference Between Individual and Aggregate Data Entry Mode?

**Individual Data Entry Mode**
- Patient Data Collection is Completed on Paper
- Collect Patient Data Prospectively Via Office Visits
- Enter Patient Data into PPM Manually

**Aggregate Data Entry Mode**
- Patient Data Collection is Completed Using EHR
- Collect Patient Data Retrospectively Using EHR
- Enter Data into PPM Using EHR
Individual Entry Mode
Download PPM Indicator Instruments (Questionnaires)

Physician Questionnaire

Patient Questionnaire
Physician Questionnaire

Diabetes Physician Indicators Instrument

1. Have you tested the patient's hemoglobin A1c in the last 6 months? Select Yes or No.
   - Yes
   - No
   If you selected yes, what is the patient's hemoglobin A1c value?
   Hemoglobin A1c __________

2. Have you examined the patient's feet today? Select Yes or No.
   - Yes
   - No
   If you selected yes, select each aspect of the examination that you have performed.
   - Inspection
   - Monofilament Examination
   - Vascular Integrity

3. Have you tested the patient's urine for microalbuminuria this year? Select Yes or No.
   - Yes
   - No
   - Not Applicable
   If you selected yes, was it positive or negative? Select the appropriate response.
   - Positive
Individual Entry Mode:
Diabetes PPM Example Questions:
Patient Questionnaire

1. Have you had your hemoglobin A1c (a test of how much sugar is in your blood) checked in the last 6 months? Select Yes or No.
   - Yes
   - No

2. Has your doctor checked your feet in the last 6 months? Select Yes or No.
   - Yes
   - No

3. Has your doctor tested your urine for signs of diabetic kidney disease this year? Select Yes or No.
   - Yes
   - No

4. Do you smoke? Select Yes or No.
   - Yes
   - No

If you selected yes, has your doctor talked to you about quitting? Select the appropriate answer.
   - Yes
   - No

If you selected yes, was it positive or negative? Select the appropriate response.
   - Positive
Individual Entry Mode

As you and each of your patients complete the Patient Indicator Instrument, you or a member of your staff should enter the data into the online template of your PPM.
### Individual Entry Mode:
**Diabetes PPM Example Questions**

<table>
<thead>
<tr>
<th>Question</th>
<th>Patient 1</th>
<th>Patient 2</th>
<th>Patient 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have you had your hemoglobin A1c (a test of how much sugar is in your blood) checked in the last 6 months? Select Yes or No.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>2. Has your doctor checked your feet in the last 6 months? Select Yes or No.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>3. Has your doctor tested your urine for signs of diabetic kidney disease this year? Select Yes or No.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>4. Do you smoke? Select Yes or No.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Individual Entry Mode
Review the Pre-Quality Improvement Comparison Reports

Individual Entry Mode
Select at least 1 clinical indicator as an area for improvement.
Individual Entry Mode
Select at Least 2 Chronic Care Models (CCM) to guide you in selecting interventions for improvement.
Choose 2 of 6 Chronic Care Model (CCM) Categories

1. Community Resources and Policies
   - Change concepts and interventions that utilize community resources to meet the needs of patients (NCQA Physician Practice Connections category-Patient Education and Support)

2. Health System
   - Change concepts and interventions that create a culture, organization, and mechanisms that promote safe, high-quality healthcare

3. Self-Management Support
   - Change concepts and interventions that empower and prepare patients to manage their health and healthcare (NCQA Physician Practice Connections category-Patient Education and Support)
Choose 2 of 6 Chronic Care Model (CCM) Categories

4. Delivery System Design
   - Change concepts and interventions that assure the delivery of effective, efficient clinical care and self-management support (NCQA Physician Practice Connections category-Care Management)

5. Decision Support
   - Change concepts and interventions that promote clinical care consistent with scientific evidence and patient preferences (NCQA Physician Practice Connections category- Clinical Information Systems/Evidence-Based Medicine)

6. Clinical Information Systems
   - Change concepts and interventions that organize patient and population data to facilitate efficient and effective care (NCQA Physician Practice Connections category- Clinical Information Systems/Evidence-Based Medicine)
Individual Entry Mode

Choose ONE intervention category within each Chronic Care Category previously chosen.

Individual Entry Mode

- Choose 1 Intervention.
- Choose 1 Intervention Item.
Individual Entry Mode

Design your Quality Improvement (QI) Plan

Note: “Add Custom Step” is an optional step.
Implement your QI Program for at least 1 week

Repeat Physician and Patient Questionnaires
Individual Entry Mode
Once the questionnaires are complete and the data is entered in the PPM,

You will be able to review your Post Quality Improvement Comparison charts.
Congratulations!

You have completed your PPM.

Don’t forget to record the number of hours you spent completing the PPM and to print your CME certificate.
Aggregate Entry Mode
Select the type of EHR you use in your practice
Aggregate Entry Mode
Download PPM Indicator Instrument

Physician Indicators Instrument

You will use this form to collect the patient data needed to complete your performance in Practice activities. Please answer all the questions on this form. For each question, please provide the total number of patients from whom you gathered your data (the "denominator") for determining your performance. For each question, also provide either the number of patients who meet the criteria in the question (the "numerator") for determining your performance, or the percentage of patients who meet the criteria.

1. What percentage of your diabetic patients had a hemoglobin A1c test in the last 6 months?
   - Percentage of Patients: __________
   - Number of Patients: __________
   - Total Number of Patients: __________

2. What percentage of your diabetic patients had a foot examination at their last appointment?
   - Percentage of Patients: __________
   - Number of Patients: __________
   - Total Number of Patients: __________

3. What percentage of your diabetic patients were tested for microalbuminuria in the last year?
   - Percentage of Patients: __________
   - Number of Patients: __________
   - Total Number of Patients: __________

4. What percentage of your diabetic patients have been counseled in smoking cessation?
   - Percentage of Patients: __________
   - Number of Patients: __________
   - Total Number of Patients: __________

5. What percentage of your diabetic patients had a documented eye examination performed by an eye care professional in the last 12 months?
   - Percentage of Patients: __________
   - Number of Patients: __________
   - Total Number of Patients: __________
Aggregate Entry Mode:
Diabetes Physician Indicators
Instrument Example Questions

Diabetes PPM Physician Indicators Instrument (Aggregate Data)

1. What percentage of your diabetic patients had a hemoglobin A1c test in the last 6 months?
   Percentage of Patients_________________ | Number of Patients_________________
   or
   Total Number of Patients_________________ | Total Number of Patients_________________

1(a) What percentage of these patients have a hemoglobin A1c value > 9%?
   Percentage of Patients_________________ | Number of Patients_________________
   or
   Total Number of Patients_________________ | Total Number of Patients_________________

2. What percentage of your diabetic patients had a foot examination at their last appointment?
   Percentage of Patients_________________ | Number of Patients_________________
   or
   Total Number of Patients_________________ | Total Number of Patients_________________

2(a) What percentage of these patients received Inspection of the foot examination?
   Percentage of Patients_________________ | Number of Patients_________________
   or
   Total Number of Patients_________________ | Total Number of Patients_________________

2(b) What percentage of these patients received Monofilament examination of the foot examination?
   Percentage of Patients_________________ | Number of Patients_________________
   or
   Total Number of Patients_________________ | Total Number of Patients_________________

2(c) What percentage of these patients received Vascular integrity of the foot examination?
Aggregate Entry Mode

As you complete the Patient Indicator Instrument, you or a member of your staff should enter the data into the online Aggregate Data template of your PPM.
## Aggregate Entry Mode: Diabetes PPM Example Questions

1. What percentage of your diabetic patients had a hemoglobin A1c test in the last 6 months?
   - Percentage of Patients: [ ] [ % ]
   - Number of Patients: [ ]
   - Total Number of Patients: [ ]

1a. What percentage of these patients have a hemoglobin A1c value > 9%?
   - Percentage of Patients: [ ] [ % ]
   - Number of Patients: [ ]
   - Total Number of Patients: [ ]

2. What percentage of your diabetic patients had a foot examination at their last appointment?
   - Percentage of Patients: [ ] [ % ]
   - Number of Patients: [ ]
   - Total Number of Patients: [ ]
Aggregate Entry Mode
Review the Pre-Quality Improvement Comparison Reports

Aggregate Entry Mode
Select at least 1 clinical indicator as an area for improvement.
Aggregate Entry Mode
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   • Change concepts and interventions that organize patient and population data to facilitate efficient and effective care (NCQA Physician Practice Connections category- Clinical Information Systems/Evidence-Based Medicine)
Aggregate Entry Mode

Choose ONE intervention category within each Chronic Care Category previously chosen.

Aggregate Entry Mode

- Choose 1 Intervention.
- Choose 1 Intervention Item.
Aggregate Entry Mode
Design your Quality Improvement (QI) Plan

Note: “Add Custom Step” is an optional step.
Implement your QI Program for at least 1 week

Repeat Physician Indicator Instrument
Aggregate Entry Mode
Once the physician indicator instrument is complete and the data is entered into your PPM,

You will be able to review your Post Quality Improvement Comparison charts.
Congratulations!

You have completed your PPM.

Don’t forget to record the number of hours you spent completing the PPM and to print your CME certificate.
Self-Directed PPM

All activities must:

• Be developed using evidence-based criteria and national standards

• Ensure the physician is meaningfully involved

• Incorporate pre- and post-intervention evaluation of the physician’s performance using evidence-based quality indicators

• Include the development and implementation of an individualized plan for improvement
Self-Directed PPM

- The required attestation form can be accessed through the physician portfolio
- Submission of an attestation form does not guarantee Part IV credit
- Approval occurs on a case-by-case basis
- Allow up to 8 weeks for the review process

Specific Information about the Self-Directed activity can be found in your Physician Portfolio
Part IV Alternatives Support

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  — Phone: 877-223-7437, ext 1230
  — Email: NLainhart@theabfm.org

• Support Center
  — Phone: 877-223-7437
  — Email: help@theabfm.org
  — Live Chat
Opportunities Involving Your Board Certification

• CME – a minimum of 1/4 of your AAFP/ABFM required CME

• Flexibility/Control – increasing number of choices of on-line programs so that you may select and individualize your overall program – among these are many choices of Part IV alternatives, which may save duplication of effort and time

• Exam Locations – greatly increased availability of locations and dates for proximity and travel cost savings

• PQRS – a CMS-sponsored significant financial benefit available through ABFM—may be paired with a PPM quality improvement activity for a “two for”
  • National reporting system for quality of care
  • A one time “snapshot” of current practice
  • A significant financial reward for early adopters
  • Avoid 2015 proposed penalty from CMS
Awarded by the American Academy of Family Physicians

SAM = 12 CME Credits
PPM = 20 CME Credits
MIMM = 20 CME Credits
Cultural Competency MIMM = 9 CME Credits
Track Your Progress
Update Your License
Access MC-FP Modules

Update Your Contact Info
Get a Receipt
Get a Verification Letter
Website Resources

• **General Website**
  – Website Site Map
  – Navigation Tutorial
  – Flash Tutorial

• **Self-Assessment Modules (SAM)**
  – Jing Videos
  – Webinars
  – Flash Tutorial

• **Performance in Practice Modules (PPM)**
  – Flash Tutorial

• **Support Center**
  – Live Chat Opportunity
Continuous MC-FP

Set a Goal of 1 Module Per Year!

- Year 1: Complete 1 Module
- Year 2: Complete 1 Module
- Year 3: Complete 1 Module
# 2014 Fall Exam Deadlines

<table>
<thead>
<tr>
<th>Fall 2014 Exam Deadline</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration Begins</td>
<td>July 25, 2014</td>
</tr>
<tr>
<td>Deadline to submit application without a late fee</td>
<td>August 25, 2014</td>
</tr>
<tr>
<td>Final Deadline to submit application with a $200 late fee</td>
<td>September 15, 2014</td>
</tr>
<tr>
<td>Exam Dates</td>
<td>November 10, 11, 12, 13, 14, 15</td>
</tr>
<tr>
<td>Exam Results</td>
<td>December 19, 2014</td>
</tr>
</tbody>
</table>
BEGIN the formal application prior to the deadline to avoid late filing fees

--- to be able to access the application, all required modules must be paid for/and or started
(completion of the modules is not required to start the application but all modules 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 modules)
ABFM Goal:

LEAVE NO DIPLOMATE BEHIND . . . EVER!
“Has the Affordable Care Act Made Progress in Reforming Health Care in America?”

by

Rick Madden, MD

Rick Madden, MD attended UNM Medical School and UNM Family Medicine Residency, finishing in 1983. He has practiced in Belen, NM since 1985. As a former member of the AAFP Board of Directors, he has been involved with decisions and initiatives related to reforming health care nationally, as well as in New Mexico and in his own practice with Presbyterian Medical Group. He served as Speaker and Vice Speaker of the New Mexico Medical Society until 2013. He is a Clinical Assistant Professor of Family Medicine at the University of New Mexico.

Email: rmadden@phs.org

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Understand what the ACA intended to reform
- Describe the limitations under which the ACA was passed and implemented
- Outline the progress the ACA has made and difficulties the ACA has encountered
- Have the insight into what is to come from full implementation of the ACA
Is the Affordable Care Act Helping?

New Mexico AFP Annual Meeting Taos, NM 8-1-2014

Rick Madden, MD, FAAFP
Family Physician
Presbyterian Medical Group
Belen, New Mexico

Did you hear the story about Obamacare being like...the flea market?

Widely varying perspectives on the ACA

1. Patients vs systems (latter includes, but not limited to: doctors, teams, hospitals, care networks (e.g. solo/independents, IPA, FQHCs, ACOs, public health, long term care))
2. Narrow vs broad: some see only a part of the health care sector (the part that affects them)
3. Insider vs outsider: policy makers, doctors, nurses, administrators are inside; patients and the public are outside
4. Physicians’ quality of life vs quality of care and cost: which focus is at hand during the discussion
5. Specialists vs generalists: differing gains and losses, depending on vested interest, breadth of perspective
6. Age, income, ethnicity/race: each category here has perceived gains and losses, aspirations and needs, affected by change from the status quo
7. Region (of the country), locale (urban, suburban, rural), and practice size: not all equal in measures of health, access, resources, business challenges
8. Levels of awareness of the ACA: varying degrees of news awareness (and willingness to seek balance and depth of information), which of course depends on many of the above.
9. Political persuasion: conservative/liberal

Why did Congress pass the Patient Protection and Affordable Care Act (ACA) of 2010?

- Costs of health care in the U.S. were out of control and increasingly unaffordable.

International comparison of per capita health care spending

Source: OECD Health Data 2011.
Why did Congress pass the Patient Protection and Affordable Care Act (ACA) of 2010?

- Costs of health care in the U.S. were out of control and increasingly unaffordable.
- Costs of health care threatened our economy by consuming state and federal budgets, decreasing worker productivity, and raising costs of business.

Annual U.S. health care spending as percent of GDP

The continuous rise in our national debt has been due not to social security or defense spending, but to:

health care costs

As health care costs consume budgets, other public needs suffer

<table>
<thead>
<tr>
<th>YEAR</th>
<th>TOTAL FEDERAL HEALTH CARE SPENDING (IN BILLIONS)</th>
<th>FEDERAL HEALTH CARE SPENDING AS PERCENT OF FEDERAL BUDGET</th>
<th>MEDICARE (IN BILLIONS)</th>
<th>MEDICATED (IN BILLIONS)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>$2.578</td>
<td>$773.0</td>
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<td>2003</td>
<td>$2.649</td>
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<td>$571.0</td>
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<td>2004</td>
<td>$2.709</td>
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<td>$2.820</td>
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<td>$541.0</td>
<td>$76.0</td>
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<tr>
<td>2007</td>
<td>$2.862</td>
<td>$913.0</td>
<td>$529.0</td>
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<td>$499.0</td>
<td>$53.4</td>
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<tr>
<td>2011</td>
<td>$2.867</td>
<td>$910.0</td>
<td>$514.0</td>
<td>$56.4</td>
</tr>
</tbody>
</table>

Why did Congress pass the Patient Protection and Affordable Care Act (ACA) of 2010?

- Costs of health care in the U.S. were out of control and increasingly unaffordable.
- Costs of health care threatened our economy by consuming state and federal budgets, decreasing worker productivity, and raising costs of business.
- Try as we might, we couldn’t find the way to controlling costs and improving care. And ~50M people (including 31M US citizens) remained uninsured.

New Mexico Demographics

- Total Population = 2,028,100
- Total Uninsured Population = 21%
- Uninsured Individuals = 422,000
- Expanded Medicaid Eligible = 204,000
- Insurance Exchange Eligible = 95,000

Sources: The Kaiser Family Foundation; Center on Budget and Policy Priorities; www.cshp.org; New Mexico Health Insur. Estabilishment Co.

Uninsured Rates Among Nonelderly by State, 2010-2011

- 14% Uninsured (13 states & DC)
- 14 to 18% Uninsured (20 states)
- 18% Uninsured (17 states)

Note the effects of race/ethnicity, education, income, employment on insurance coverage in NM.

Our health care “system”, in part (nice and simple)

© The New Republic, Jonathan Cohn, July 1, 2009.

Figure 3. Demographic Disparities in Healthcare Coverage among Adults, New Mexico, 2012

Disparities in Health-Care Coverage Percentage of Adults Age 18-64 with Coverage, by Demographics, 2012
How did the ACA pass Congress in 2010?

- The White House encouraged Congress to take the lead in developing the bill
- Reform advocates came to believe they would lose if they torpedoed a bill that didn’t contain everything they wanted.
- Many interest groups signed on for different but overlapping reasons: pharma, insurance, hospitals, nurses, AAFP, AMA
- Through consistent efforts by the ACA’s authors to build in cost controls, the CBO estimate of the 10 year cost of the ACA came in under $1Trillion, half paid by savings from the provisions in the bill and half from new revenue from the bill
- The CBO estimated the ACA would reduce the federal deficit over 10 years
- Crucially, in February 2010, Wellpoint announced 39% premium rate hike for California, persuading the US House of Representatives to accept the Senate’s version of the ACA on March 21. President Obama signed March 23
Is Obamacare popular?
No. Most polls show that Americans are sharply divided on Obamacare, with more people viewing the law negatively than favorably.

Source: Vox News 4-14-2014

Opinion of ACA Divided Along Party Lines

More Want Congress To Improve ACA Than Repeal And Replace

Partisan Divide In Reports Of Knowing Someone Who Gained/Lost Coverage

Most Report No Direct Impact From ACA; Democrats More Likely to Feel Helped, Republicans More Likely to Feel Hurt

Source: Kaiser Family Foundation Health Repeal Poll (conducted April 21-25, 2014)
The RAND Health Insurance Experiment of 1974-1981 showed patients do base their choice of how to spend money on health care on their costs.

Patients will restrict their own spending if out of pocket costs are too high, including premium, deductibles and co-pays.

Health reform employs this lesson by holding down costs for patients, proportionate to their ability to pay.

Out of pocket costs do matter to patients in choosing to spend on health care: RAND

- The RAND Health Insurance Experiment of 1974-1981 showed patients do base their choice of how to spend money on health care on their costs.
- Patients will restrict their own spending if out of pocket costs are too high, including premium, deductibles and co-pays.
- Health reform employs this lesson by holding down costs for patients, proportionate to their ability to pay.

Oregon Medicaid expansion reduced financial hardship

Oregon Medicaid expansion increased utilization at one year

Oregon Medicaid expansion improved preventive care
Is the ACA helping?

in the areas of:

- Access
- Cost Control
- Quality Improvement
- Prevention
- Workforce

Access

Is the ACA helping?

Access: Uninsured rate falls to lowest since 2008

Percentage Uninsured in the U.S., by Quarter
Do you have health insurance coverage?
Among adults aged 18 and older

<table>
<thead>
<tr>
<th>Quarter</th>
<th>% Uninsured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 2008</td>
<td>14.4</td>
</tr>
<tr>
<td>Q2 2008</td>
<td>14.4</td>
</tr>
<tr>
<td>Q3 2008</td>
<td>14.4</td>
</tr>
<tr>
<td>Q4 2008</td>
<td>14.4</td>
</tr>
<tr>
<td>Q1 2009</td>
<td>16.4</td>
</tr>
<tr>
<td>Q2 2009</td>
<td>16.4</td>
</tr>
<tr>
<td>Q3 2009</td>
<td>16.4</td>
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<tr>
<td>Q4 2009</td>
<td>16.4</td>
</tr>
<tr>
<td>Q1 2010</td>
<td>16.4</td>
</tr>
<tr>
<td>Q2 2010</td>
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<tr>
<td>Q1 2013</td>
<td>18.9</td>
</tr>
<tr>
<td>Q2 2013</td>
<td>18.9</td>
</tr>
<tr>
<td>Q3 2013</td>
<td>16.8</td>
</tr>
<tr>
<td>Q4 2013</td>
<td>16.8</td>
</tr>
<tr>
<td>Q1 2014</td>
<td>16.8</td>
</tr>
<tr>
<td>Q2 2014</td>
<td>16.8</td>
</tr>
<tr>
<td>Q3 2014</td>
<td>16.8</td>
</tr>
<tr>
<td>Q4 2014</td>
<td>16.8</td>
</tr>
</tbody>
</table>

GALLUP

IS THE ACA HELPING?
ACCESS: OVERALL COVERAGE PROJECTION

CBO estimates that there will be 26 million fewer uninsured in 2024 due to the ACA.

Total Nonelderly Population = 285 million

Without Health Reform
- Uninsured: 20%
- Medicaid/CHIP: 12%
- Exchange: 9%
- Private Non-Group / Other: 40%
- Employer-sponsored Insurance: 20%

With Health Reform
- Uninsured: 11%
- Medicaid/CHIP: 17%
- Exchange: 8%
- Private Non-Group / Other: 32%
- Employer-sponsored Insurance: 48%

NOTE: This assumes that all states choose to expand Medicaid eligibility up to 138% FPL. CBO estimate, Congressional Budget Office, April 2013. Total may not equal 100% due to rounding.

Is the ACA helping?

Access: compare w/ & w/o ACA

Uninsured population, with and without health reform

SOURCE: HEALTH INSURANCE OVERALL COVERAGE PROJECTION

IS THE ACA HELPING?
ACCESS: OVERALL COVERAGE PROJECTION

Effects of the Affordable Care Act on Health Insurance Coverage, 2024

Without the ACA
- Uninsured: 26%
- Employer-sponsored:
  - Employer-based: 6%
  - Non-group: 15%

With the ACA
- Employers and state exchanges
  - Employers: 10%
  - State exchanges: 16%

SOURCE: CBO, 2013

Page 188
Is the ACA helping?
Access: Health Insurance Exchanges

- Health Insurance Exchanges set up, subsidized coverage for income up to 400% FPL ($45,960 individual, $94,200 family of 4)

**FIGURE 8.5 State decisions on exchanges**

Source: The Henry J. Kaiser Family Foundation.

Is the ACA helping?
Access: Health Insurance Exchanges

- Nearly Six In Ten In Exchange Plans Were Previously Uninsured

**Nearly Six In Ten In Exchange Plans Were Previously Uninsured**

- Covered by Medicaid/other public program: 9%
- Covered by employer-sponsored plan: 36%
- Covered by non-employee group plan: 20%
- Different type of plan: 26%
- Uninsured: 14%
- Other/Don’t know/Refused: 4%

Source: Kaiser Family Foundation Survey of Affordability of Health Insurance, conducted April 1- May 12, 2014.

Is the ACA helping?
Access: Health Insurance Exchanges

- Who Says They Benefited Or Were Negatively Affected By ACA?

<table>
<thead>
<tr>
<th>Who Says They Benefited Or Were Negatively Affected By ACA?</th>
<th>Negatively Affected</th>
<th>Benefited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exchange members who report getting financial assistance</td>
<td>42%</td>
<td>58%</td>
</tr>
<tr>
<td>Total exchange members</td>
<td>49%</td>
<td>51%</td>
</tr>
<tr>
<td>Previously uninsured, now in ACA compliant plans</td>
<td>70%</td>
<td>30%</td>
</tr>
<tr>
<td>Total with ACA-compliant plans</td>
<td>72%</td>
<td>28%</td>
</tr>
<tr>
<td>TOTAL BENEFICIARIES</td>
<td>64%</td>
<td>36%</td>
</tr>
<tr>
<td>Non-compliant plans</td>
<td>20%</td>
<td>80%</td>
</tr>
<tr>
<td>Previously EOB/OBRA, now in compliant plans</td>
<td>46%</td>
<td>54%</td>
</tr>
<tr>
<td>Plan selection*</td>
<td>4%</td>
<td>96%</td>
</tr>
<tr>
<td>Non-compliant, ACA-compliant plans</td>
<td>6%</td>
<td>94%</td>
</tr>
<tr>
<td>Non-compliant, ACA-compliant plans, now in compliant plans</td>
<td>30%</td>
<td>70%</td>
</tr>
<tr>
<td>Non-compliant, ACA-compliant plans, &amp; exchange compliant</td>
<td>30%</td>
<td>70%</td>
</tr>
</tbody>
</table>


Is the ACA helping?
Access: Health Insurance Exchanges

- Actuarial Values for Levels of Coverage Provided by Qualified Health Plans

<table>
<thead>
<tr>
<th>Actuarial Values for Levels of Coverage Provided by Qualified Health Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronze</td>
</tr>
<tr>
<td>60%</td>
</tr>
</tbody>
</table>


Is the ACA helping?
Access: Health Insurance Exchanges

Subsidies to ease the patient cost

- Two types of patient subsidies: premium support and cost-sharing
- Small business subsidies (with <25 low wage employees subsidies) for 2014 & 2015 only

Is the ACA helping?
Access: Health Insurance Exchanges

- Insurance coverage must cover these

  - Hospital, ER, doctor office, obstetric care, and pediatric care, including oral and vision
  - Lab and xray
  - Screenings and immunizations
  - Mental health care
  - Drugs, DME, and rehabilitative care
  - Preventive care, chronic disease management
  - Only qualified health plans
  - Guaranteed issue, renewability, no pre-existing condition exclusion, no annual or lifetime limits
Is the ACA helping?
Access: insurance exchanges
Subsidies to ease the patient cost
Average monthly premium after tax credits, among federal marketplace shoppers who qualified for tax credits

Is the ACA helping?
Access: insurance exchanges
Subsidies to ease the patient cost
Average monthly tax credit paid by feds to federal marketplace shoppers who qualified for tax credits

Is the ACA helping?
Access: insurance exchanges
Subsidies to ease the patient cost
Monthly premium after tax credits, among federal marketplace shoppers who qualified for tax credits

Even though there is a penalty, some choose to remain uninsured...

Even though there is a penalty, some choose to remain uninsured...

Penalty for individuals: $95 in 2014, rises to $695 in 2016 (but not > 2.5% household income); in 2017 & after: adjusted with the cost of living (exempt, if cost of lowest price policy > 8% of income)
Is the ACA helping?
Access: Medicaid expansion, June 2014
Current Status of State Medicaid Expansion Decisions, 2014

Is the ACA helping?
Access: Marketplace + Medicaid, June 2014

Is the ACA helping?
Access: Medicaid/CHIP

IS THE ACA HELPING? ACCESS: What happens to poor people in states that do not expand Medicaid?

The south is hardest hit by lack of Medicaid expansion

IS THE ACA HELPING? ACCESS: What happens to poor people in states that do not expand Medicaid?

People who earn less than the poverty line cannot qualify for subsidized private insurance — the legislators who wrote Obamacare anticipated that this population would gain Medicaid coverage and so did not include them in the subsidies. That’s left some of the poorest Americans in a coverage gap, where they are too poor to earn subsidies to help purchase insurance.
Is the ACA helping?
Access: PARENTS, Medicaid, CHIP

- Pre-existing conditions covered; lifetime caps limited; comprehensive coverage for children

- Children’s Health Insurance Program maintained with current benefits, to be covered by feds 100% starting in 2015, if Congress approves its funding

- Medicaid expansion in 24 states cover adults <65 y.o. if income <138% of FPL ($11,490 for individual, $32,550 family of 4 unless covered by workplace or other source). NM covered by 2-2014

<table>
<thead>
<tr>
<th>YEAR</th>
<th>PERCENT OF MEDICAID EXPANSION COST PAID FOR BY THE FEDERAL GOVERNMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014-2016</td>
<td>100%</td>
</tr>
<tr>
<td>2017</td>
<td>95%</td>
</tr>
<tr>
<td>2018</td>
<td>94%</td>
</tr>
<tr>
<td>2019</td>
<td>93%</td>
</tr>
<tr>
<td>2020 and beyond</td>
<td>90%</td>
</tr>
</tbody>
</table>

Source: Congressional Budget Office.

Is the ACA helping?
ACCESS: projected insured by 2020

**FIGURE 8.8 Changes in insurance coverage because of the Affordable Care Act (CBO estimates, in millions)**

<table>
<thead>
<tr>
<th>EFFECTS ON INSURANCE COVERAGE</th>
<th>2020 WITHOUT ACA</th>
<th>2020 WITH ACA</th>
<th>CHANGE BECAUSE OF ACA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total nonelderly population</td>
<td>284</td>
<td>284</td>
<td>0</td>
</tr>
<tr>
<td>Medicaid and CHIP</td>
<td>34</td>
<td>47</td>
<td>+13</td>
</tr>
<tr>
<td>Employer</td>
<td>167</td>
<td>160</td>
<td>-7</td>
</tr>
<tr>
<td>Self-insured and nonelderly Medicaid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exchange</td>
<td>0</td>
<td>24</td>
<td>+24</td>
</tr>
<tr>
<td>Uninsured</td>
<td>56</td>
<td>30</td>
<td>-26</td>
</tr>
<tr>
<td>Insured as a share of the nonelderly population</td>
<td>80%</td>
<td>89%</td>
<td>+9%</td>
</tr>
</tbody>
</table>

Source: Congressional Budget Office.
Is the ACA helping?
Access: rural areas

Uninsured rural residents are more likely than metropolitan residents to fall into the “coverage gap”

Coverage eligibility levels among nonelderly uninsured residents


Is the ACA helping?
Access: insured change by ethnicity

Percentage-point change in insured rate from late 2013 to early 2014 by ethnicity

Source: The Urban Institute

Is the ACA helping?
Access: insured change by income

Percent change in uninsured rate between late 2013 and early 2014 by income

Source: The Urban Institute
Is the ACA helping?
Access: women Pre-ACA

Cost Control

Is the ACA helping?
Cost control: Some only see Health care costs as rising...

Bending The Cost Curve Up
Health care spending will shoot up in 2014, when ObamaCare kicks in, and climb at a faster rate than prior years

9%
Health spending, annual changes

Sources: Centers for Medicare and Medicaid Services, Office of the Actuary

Is the ACA helping?
Cost control: reducing payments
• Reduced and targeted DSH payments to hospitals
• Tighter control on DME costs
• Reduced payment to Medicare Advantage, with increased bonuses for quality
• Medicare Part D drug donut hole phased out by 2020, pharma must cover 50% of costs in donut hole till then for brand drugs
• 40% cadillac tax on premium plans starting 2018, but already putting price pressure on them
• Risk adjustment across insurance companies, $$ transferred to support chronic disease mgmt

Is the ACA helping?
Cost control: reducing volume
• Accountable Care Organizations
• Bundled payments
• Readmissions and hospital acquired condition penalties
• Center for Medicare/Medicaid Innovation (CMMI) to enhance quality and reduce cost, e.g. Comprehensive Primary Care Initiative (4yrs thru 2016, Pvt + govt payers, 7 sites, 2347 physicians, 315,000 patients, pay primary care for results, avg $20 pmpm care mgmt payment)
Is the ACA helping?
Cost control: Pilots of PCMH & ACO

PROVING IT—AGAIN AND AGAIN.
Pilot programs deliver lower costs while improving health across the country.

Is the ACA helping?
Cost control: The IPAB (independent payment advisory board)

- Purpose of IPAB: recommend measures to limit Medicare growth according to a formula; Congress would have to actively override.
- 18 members: none yet appointed due to opposition in Congress to concept of IPAB, seen as “death panel” (though law allows no rationing)
- Was to begin 2013: Medicare expenditures have not grown enough to trigger IPAB; IPAB not yet funded by Congress, future in doubt

**FIGURE 8.4** Budgetary effects of the ACA’s insurance coverage provisions (in billions of dollars)

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual penalty payments</td>
<td>-150</td>
<td>-130</td>
<td>-110</td>
<td>-90</td>
<td>-70</td>
<td>-50</td>
<td>-30</td>
<td>-10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Employer cost sharing</td>
<td>-150</td>
<td>-130</td>
<td>-110</td>
<td>-90</td>
<td>-70</td>
<td>-50</td>
<td>-30</td>
<td>-10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Medicaid expansion costs</td>
<td>-150</td>
<td>-130</td>
<td>-110</td>
<td>-90</td>
<td>-70</td>
<td>-50</td>
<td>-30</td>
<td>-10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other revenues</td>
<td>-150</td>
<td>-130</td>
<td>-110</td>
<td>-90</td>
<td>-70</td>
<td>-50</td>
<td>-30</td>
<td>-10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Net total of coverage provisions</td>
<td>-150</td>
<td>-130</td>
<td>-110</td>
<td>-90</td>
<td>-70</td>
<td>-50</td>
<td>-30</td>
<td>-10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Note: Numbers may not add up to totals because of rounding. Does not include savings from Medicare or Medicaid.

Source: Congressional Budget Office.

Is the ACA helping?
Cost control: insurance competition

- Incentive for insurers, doctors and hospitals to compete on customer service, quality and cost, including in the low cost insurance plans
- Likely to cause insurers to narrow their networks of doctors and hospitals, tighten drug formularies
- Incentive for hospitals to acquire other hospitals regionally to avoid exclusion from insurance contracts; anti-trust issues
- Expensive hospitals, especially brand name and academic, will feel the pressure to prove higher value, i.e. higher quality for lower price

Is the ACA helping?
Cost Control: Medicaid cost to states

- Additional state spending on Medicaid and CHIP under health reform, 2015-2024
- State spending on Medicaid and CHIP without health reform, 2015-2024

$46 billion
(1.6% increase)

$2.3 trillion

*CHIP: Children’s Health Insurance Program
Source: CBO analysis of the Congressional Budget Office's April 2014 Medicaid and CHIP baselines.
Is the ACA helping? Cost control:

Cost Control: Medicaid cost to states

CBO’s latest estimates show a drop in state spending for Medicaid and CHIP from 2015-2024 due to the coverage provisions in the ACA.

<table>
<thead>
<tr>
<th></th>
<th>Federal</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>$862 Billion</td>
<td>$362</td>
<td>$500</td>
</tr>
<tr>
<td>February 2014 Baseline</td>
<td>April 2014 Baseline</td>
<td></td>
</tr>
</tbody>
</table>

Is the ACA helping?

Cost control: What could go wrong?

- If insurers don’t stay in marketplace, competition declines, prices increase. (Already seeing more coming into marketplace).
- If patients don’t shop for the best premiums, competition not fully operational and prices do not decline.
- If focus on price of insurance alone, costs drop but customer service and care quality suffer. (We will know by October 2014).
- If focus on quality without mechanisms to improve efficiency, price of insurance goes up. (Information on quality slower in coming).
- If fee-for-service remains too dominant, incentives to improve quality at lower cost will be hampered.

Quality Improvement

Is the ACA helping? Quality improvement:

Sicker exchange enrollees

Percent of enrollees using health services who had serious conditions:

- 27%
- 21%
- 12%
- 21%
- 16%

Source: Inovalon/WSJ analysis

Is the ACA helping? Quality improvement:

Deaths from diseases that are treatable or preventable with health care

Per 100,000 people

Source: NY Times 5/21/2014
Is the ACA helping?
Quality improvement:
- Hospital-acquired conditions: central line infections down by 50%, urinary catheter and surgical site infections down by 25% between 2010-2014
- Hospital readmissions (for same diagnosis) down from 19.5% in 2009 to 18.4% in 2012
- EMRs (actually part of the ARRA of 2009)
- Quality reporting (carrot becomes stick in 2015)
- Value based purchasing (rewards quality)
- Patient-Centered Outcomes Research Institute (PCORI), non-govt, private + public funding (but not allowed to determine cost effectiveness of interventions!!)

Is the ACA helping?
Quality improvement:
- Variation in colorectal cancer survival: Hawaii vs NY

Is the ACA helping?
Hospital Readmission Rates Initiatives

Is the ACA helping?
Quality improvement:
- Behavioral health: improve access, quality
- End of life care measures
- Infant mortality
- Obesity
- Chronic disease endpoints

Prevention
- Screening tests first dollar coverage (USPSTF list)
- Birth control to prevent unwanted pregnancy (Danger: controversy!)
- Insurance plan incentives for wellness
- Menu nutrition labeling
- Medicare Annual Wellness Visit
- Public Health & Prevention Fund grants (reduced from $15B to $5B)
Workforce

Is the ACA helping?
Workforce: UNITED STATES Primary care 2012

Is the ACA helping?
Workforce: NM primary care physicians 2013

Is the ACA helping?
Workforce: NM Primary Care physician shortage 2013

Is the ACA helping?
Workforce: NEW MEXICO projected primary care need

New Mexico Primary Care shortage if Family Physicians were withdrawn

Source: 2013 NM Health Workforce Committee Annual

Source: 2013 NM Health Workforce Committee Annual

Source: Robt Graham Center, AAFP, Sept 2013

Source: Robt Graham Center, AAFP, Sept 2013
Is the ACA helping?
Workforce: ACA’s Medicare Primary Care incentive payment
• Medicare primary care incentive (10% increase to practices that have >60% of Medicare billings as primary care codes, i.e. office visit codes) to expire end of 2015 (4 year duration)
• But even that is a modest boost, average $3938 per eligible practitioner in 2012
• MedPAC to recommend extension beyond 2015, but modified to “per beneficiary payment”

Is the ACA helping?
Workforce: ACA’s Medicaid parity with Medicare payment
• Medicaid parity with Medicare payment to primary care physicians for primary care services set to expire end of 2014 (2 year duration)
• This is a big boost in some states where Medicaid payment was low (many <75% of Medicare)

Is the ACA helping?
Workforce: POTENTIAL threats to Primary care access as a result of the ACA
MGMA Survey April 2014
• 40,000 practices nationwide (all specialties)
• Not yet overwhelmed by patient demand
• Difficult to verify eligibility, obtain cost sharing info, obtain network info; patients don’t know
• 20% excluded from narrow network; narrow network is a barrier to adequate hospital and specialist care

Is the ACA helping?
Workforce: POTENTIAL threats to Primary care access as a result of the ACA
• Newly insured patients create increased demand for primary care --->
• Primary care practices must have a viable business model --->
• Because most primary care practices have <12 physicians, they may be challenged by new patients who have limited ability to pay out-of-pocket costs
• And because Medicaid parity with Medicare, and Medicare primary care incentive pay are of limited duration, what happens to the business model when they run out?
• More pressure on the business: quality improvement reporting becomes mandatory in 2015, penalties begin

Is the ACA helping?
Workforce: Physician income across specialties

<table>
<thead>
<tr>
<th>Physician Compensation in 2013</th>
<th>$0</th>
<th>$100,000</th>
<th>$200,000</th>
<th>$300,000</th>
<th>$400,000</th>
<th>$500,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopedics</td>
<td></td>
<td>$36,000</td>
<td>$56,000</td>
<td>$76,000</td>
<td>$96,000</td>
<td>$116,000</td>
</tr>
<tr>
<td>Cardiology</td>
<td></td>
<td>$46,000</td>
<td>$66,000</td>
<td>$86,000</td>
<td>$106,000</td>
<td>$126,000</td>
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<tr>
<td>Gastroenterology</td>
<td></td>
<td>$33,000</td>
<td>$53,000</td>
<td>$73,000</td>
<td>$93,000</td>
<td>$113,000</td>
</tr>
<tr>
<td>Neurology</td>
<td></td>
<td>$32,000</td>
<td>$52,000</td>
<td>$72,000</td>
<td>$92,000</td>
<td>$112,000</td>
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<tr>
<td>Ophthalmology</td>
<td></td>
<td>$26,000</td>
<td>$46,000</td>
<td>$66,000</td>
<td>$86,000</td>
<td>$106,000</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td></td>
<td>$22,000</td>
<td>$42,000</td>
<td>$62,000</td>
<td>$82,000</td>
<td>$102,000</td>
</tr>
<tr>
<td>Dermatology</td>
<td></td>
<td>$21,000</td>
<td>$41,000</td>
<td>$61,000</td>
<td>$81,000</td>
<td>$101,000</td>
</tr>
<tr>
<td>Radiation Oncology</td>
<td></td>
<td>$25,000</td>
<td>$45,000</td>
<td>$65,000</td>
<td>$85,000</td>
<td>$105,000</td>
</tr>
<tr>
<td>Gynecology</td>
<td></td>
<td>$37,000</td>
<td>$57,000</td>
<td>$77,000</td>
<td>$97,000</td>
<td>$117,000</td>
</tr>
<tr>
<td>Urology</td>
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<td>$21,000</td>
<td>$41,000</td>
<td>$61,000</td>
<td>$81,000</td>
<td>$101,000</td>
</tr>
<tr>
<td>Neurology</td>
<td></td>
<td>$37,000</td>
<td>$57,000</td>
<td>$77,000</td>
<td>$97,000</td>
<td>$117,000</td>
</tr>
<tr>
<td>Psychiatry &amp; Neurology</td>
<td></td>
<td>$37,000</td>
<td>$57,000</td>
<td>$77,000</td>
<td>$97,000</td>
<td>$117,000</td>
</tr>
<tr>
<td>General Medicine</td>
<td></td>
<td>$37,000</td>
<td>$57,000</td>
<td>$77,000</td>
<td>$97,000</td>
<td>$117,000</td>
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<tr>
<td>Critical Care</td>
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<td>$37,000</td>
<td>$57,000</td>
<td>$77,000</td>
<td>$97,000</td>
<td>$117,000</td>
</tr>
<tr>
<td>Family Medicine</td>
<td></td>
<td>$37,000</td>
<td>$57,000</td>
<td>$77,000</td>
<td>$97,000</td>
<td>$117,000</td>
</tr>
</tbody>
</table>

Source: Medscape Physician Compensation Survey 2015
Is the ACA helping?

Workforce:
PHYSICIAN INCOME GROWTH by specialty 2014

Who's Up, Who's Down?

Source: Medscape Physician Compensation Survey 4-15-2014

Is the ACA helping?

Workforce: PHYSICIAN INCOME BY REGION 2014

Physician Compensation by Geographical Area

Source: Medscape Physician Compensation Survey 4-15-2014

Is the ACA helping?

Workforce: PHYSICIAN SATISFACTION WITH INCOME 2014

Which Physicians Feel Most Fairly Compensated?

Source: Medscape Physician Compensation Survey 4-15-2014

Is the ACA helping?

Workforce: physician income expectations re: insurance exchanges 4/2014

Do You Think Your Income Will Change With Health Insurance Exchanges?

Source: Medscape Physician Compensation Survey 4-15-2014

Is the ACA helping?

Workforce: planning to participate in exchange plans?

Are You Planning to Participate in Health Insurance Exchanges?

Source: Medscape Physician Compensation Survey 4-15-2014

Health care is for everyone
Of course there are Questions!
What are yours?
“Parasomnias and Sleep-Related Movement Disorders”

by

Frank Ralls, MD

Frank Ralls, MD taught elementary education and special education in the public schools prior to medical school. He subsequently attended the University of Wisconsin for medical school and a residency in family medicine. Following more than 10 years of service in a rural community of 5000 residents in north-eastern Wisconsin, he completed fellowships in geriatric and sleep medicine at the University of New Mexico. He is boarded in family medicine, geriatrics, hospice and palliative care, and sleep medicine. He currently serves as an Assistant Professor of Internal Medicine, Program Director for the Fellowship in Sleep Medicine, and the Medical Director for Adult Sleep Services at the UNMH Sleep Disorders Center at the University of New Mexico.

Email: fralls@salud.unm.edu

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Understand the role of sleep deprivation in precipitating parasomnias
- Differentiate sleep related movement disorders that typically occur in the first half of the night versus those that occur in the second half of the night
- Know that some seizure disorders occur almost exclusively in sleep
OBJECTIVES

• To understand the association between sleep deprivation and parasomnias.
• To understand how sleep deprivation may shift sleep time into the day and how wake time may shift into the night.
• To know the features of common parasomnias.
• To know treatments for common parasomnias.
• To be aware of two common sleep related seizure disorders.

PARASOMNIAS AND SLEEP RELATED MOVEMENT DISORDERS

• Sleep Paralysis
• Sleep Related Seizures
• Narcolepsy
• Hypnic JAWS
• RLS
• Rhythmic Movement Disorder
• Confusional Arousals
• Sleepwalking
• Sleeptalking
• Night Terrors
• REM Behavior Disorder (RBD)

NORMAL SLEEP PATTERN

Typical Child

Typical Adult

Normal Sleep Time

Ages 5-12: 10-11 hours/night
Ages 13-19: 9-10 hours/night
Adults: 7.5-9 hours/night

Actual Sleep Time

Ages 5-12: 6-7 hours
Ages 13-19: 6-7 hours
Adults: < 6.5 hours

Parasomnias

"I WANNA BE SEDATED"
Sleep Deprivation

Increased risks of Parasomnias:

Typical Adult

The adult brain is pushed to increase NREM III (slow wave sleep).

Typical Child

40% of teens and college students

10% of adults

- Triggered by sleep deprivation

SLEEP PARALYSIS

- Transient inability to move, despite being fully awake
- Brief persistence of atonia of REM lingering into wakefulness
  - 40% of teens and college students
  - 10% of adults
- Triggered by sleep deprivation

SLEEP PARALYSIS

- Has been reported to occur in families
- SSRIs can be effective when frequent and bothersome
- Key is to avoid sleep deprivation

NARCOLEPSY

SLEEP ENTERING INTO WAKE

- Defect: loss of Hypocretin
- Atonia, an element of REM sleep is expressed into wakefulness
- Symptoms:
  - Excessive daytime sleepiness
  - Sleep paralysis
  - Hypnagogic hallucinations
  - Cataplexy
**Narcolepsy**

**Sleep entering into wake**

- Narcolepsy with cataplexy
- Emotional stimuli stimulates the atonia of REM (laughter, e.g.)
- Retained consciousness
- Reflexes absent
- Treatment
  - Adequate sleep
  - SSRI
  - Modafinil
  - Sodium oxybate

**Sleep starts**

- Otherwise known as hypnic jerks
- One or two abrupt myoclonic flexion jerks, often accompanied by a feeling of falling
- Associated with insufficient sleep
- Benign

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**Restless legs syndrome**

- Clinical diagnosis
  - Urges
    - Urges to move legs
    - Happens at rest
    - Gets up, symptoms improve
    - Evening – when it occurs
    - Symptoms – no other cause

- Tyrosine
- L-Dopa
- Dopamine
- Iron
  - Ferritin > 50

**Treatment of RLS**

1st
- Replace iron if ferritin is < 50
- Ferrous gluconate 325 mg with Vitamin C

2nd
- Dopamine agonists, e.g. pramipexole, ropinirole, rotigotine patch. Monitor for compulsive behavior.
- Opioid-like drugs, e.g. gabapentin, pregabalin. Promotes slow wave sleep and REM sleep.

3rd
- Opioid-like drugs, e.g. tramadol, codeine

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**Periodic limb movements of sleep (PLMS)**

- Involuntary
- Unilateral or bilateral limb movements, occurring periodically during sleep
- Usually involve the legs
- Most frequently found in NREM II
- Occurs in 1-4% of children
- Antidepressants may increase the prevalence by five fold
HYPNIC HALLUCINATIONS

- Occur at sleep onset
- Vivid perceptual experiences
- Sensation of hearing voices
- Feeling someone else is nearby
- Precipitated by
  - Sleep deprivation
  - Narcolepsy
  - Excessive caffeine
  - Emotional stress

RHYTHMIC MOVEMENT DISORDER

- Rhythmic head banging
- Body rocking
- Leg rolling
- 66% of 9 month old babies
- 8% by age 4
- Prevalence in adults is not known
- Typically persists in those with neurodevelopmental and psychiatric disorders
- May follow head trauma

HYPNAGOGIC FOOT TREMOR

- Hypnagogic foot tremor (HFT)
- Occurs during the transition from wakefulness to sleep
- May linger into stages NREM I and NREM II
- 5-8% of adults
- May involve one or both feet
- Rarely disturbs the patient
- Oscillating movements of the toes or whole foot, occurring q 1-2 seconds
- Benign

PARASOMNIAS

UNWANTED BEHAVIORS

FIRST THIRD OF THE NIGHT

- Last less than 30 minutes
  - Confusional arousals
  - Sleepwalking
  - Sleep talking
  - Sleep terrors
  - Sleep related eating behaviors (less common)
  - Sleep related sexual behaviors (less common)

CHILDHOOD NREM PARASOMNIAS

- Occurs in children, ages 30 months to 6 years
  - 84% have sleep talking
  - 46% have sleep bruxism
  - 40% have sleep terrors
  - 25% have nocturnal enuresis
  - 30% sleepwalk
  - 9% exhibit head banging or body rocking

ADULT NREM PARASOMNIAS

- 75% of adults have experienced a parasomnia at least once in their life
- Most common
  - Sleep starts (hypnic jerks)
  - Confusional arousals
  - Nightmares
  - Nocturnal wandering
CONFUSIONAL AROUSALS

- Begin with a sudden arousal from NREM III sleep
- Patient sits up in bed, fumble with bedclothes, mutter unintelligible words
- Typically lay down, but may proceed to sleepwalk or sleep talk

Risk factors
- Sleep deprivation
- Stress
- Sickness (fever)
- Medications
- OSA
- Psychiatric disorders increase risk 13 fold

CONFUSIONAL AROUSALS

- 50-80% of children and 5% of adults
- Half sleep talk only a few times per year
- 10% sleep talk nightly
- Risk increases with
  - Sleep deprivation
  - Stress
  - Illness with fever
  - Medications
  - Runs in families

SLEEP TALKING

- 95% of patients with sleep terrors have a family history of sleep terrors
- Individuals are
  - 3-5 times more likely to have OSA
  - have nightmares more than once a month
  - prone to injury-causing behaviors during sleep

SLEEP TERRORS

- Prevalence
  - In a study of 4972 adults, 4% sleep walked at least twice a year and 0.4% sleepwalked nightly
  - Occurs in 15% of the general population
  - Highest incidence is ages 4-8
  - 40% of children between ages 6 and 16 have had at least one episode
  - 2-3% of children sleepwalk at least once a month
  - Sleepwalking generally stops by age 13
  - 24% of frequent sleepwalkers continue to sleepwalk as adults

Neurology 2012 Ohayon MM

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Neurology 2012 Ohayon MM
SLEEPWALKING (NOCTURNAL WANDERING)

In a study of 19,136 people:
- 30% reported nocturnal wanderings ever
- 30% had a relative who had nocturnal wandering
- 3% reported nocturnal wandering at least once in the previous year
- 1% reported at least two nocturnal wanderings in the previous month
- Children with sleepwalking often had a history of sleep talking

Ohayon, Neurology 2012
Pressman, Neurology 2013

SLEEPWALKING

- Occurs in NREM III
- Patients arise from bed, walk toward a sound or light
- Patients may or may not respond to voices
- Agitated sleepwalkers flee their beds, screaming or crying
- Sleepwalkers may run through the house
- Behavior is often followed by a calm return to bed, or lying down somewhere else in the house

SLEEPWALKING

- Patients appear confused
- Eyes are open, but objects are misidentified
- Patients are slow to respond
- Patients exhibit automatic motor behaviors
- There is little or no responsive to external environment
- Patients are difficult to arouse
- Patients often suffer retrograde amnesia

SLEEPWALKING

- New onset or late recurrence in teenage years warrants consideration of other primary sleep disorders
  - Sleep deprivation
  - Extreme fatigue
  - Obstructive sleep apnea
  - RLS
  - RBD
  - Infections
- Stressful life events often precipitate sleepwalking
  - Changes in sleep environment
  - Family conflicts
  - Personal conflicts
  - Medications
- VIOLENT BEHAVIOR DURING SLEEP (VBS)
  - VBS occurs in 1.5% of adults
  - VBS behaviors range from simple dream enactment to complex behaviors
  - VBS
    - Occurs during the first 2 hours of sleep
    - 70% of people have vivid dreams
    - 31% hurt themselves or someone else
    - Few people consult a physician
    - Risk factors
      - Family member with VBS
      - Age < 35
      - Sleep deprivation
      - Stress
      - Alcohol

Szücs et al, Medical Hypotheses 2014
Ohayon et al, Sleep Medicine 2010
Morrison, Sleep 2014
VIOLENT BEHAVIOR WHILE ASLEEP

• Teeth grinding during sleep
• 33% of children
• 8% of young adults
• Symptoms of tooth-grinding noises, jaw muscle discomfort, abnormal wear of teeth on dental exam
• Risk factors
  ➢ Emotional stress
  ➢ Caffeine
  ➢ Type A personalities

Masuko et al, BMC Research Notes 2014

SLEEP BRUXISM

PARASOMNIAS DURING REM SLEEP

TYPICALLY SECOND HALF OF THE NIGHT

• Long, involved frightening dreams, which cause arousal from REM sleep
• 10-15% of children ages 3-6
• May be caused by a daytime traumatic experience, medications, or disruption in routine
• Precurred by increased heart rate, increased respiration, increased REM
• Produces anxiety or fear
• Results in difficulty returning to sleep

Masabo et al, J of Dev Beh Ped 2014

NIGHTMARE DISORDER

• Reduced movement during sleep
• Heightened anxiety consistent with the suppression of movement exhibited by animals under conditions of perceived threat, i.e. "freezing"
• Treated with reassurance
• Medications that decrease REM sleep are also helpful

Masabo et al, J of Dev Beh Ped 2014

NREM PARASOMNIAS

WHEN TO TREAT?

• Behaviors are dangerous
• Presence of daytime sleepiness
• Psychosocial impairment
• Affecting function
• Injuries

Masabo et al, J of Dev Beh Ped 2014
REM SLEEP BEHAVIOR DISORDER IN CHILDHOOD
(PHYSICALLY ACTING OUT DREAMS)

- Associated with:
  - Neurodevelopmental disabilities
  - Narcolepsy
  - Medication use

- Mean age at diagnosis is 9.5 years
- 75% male prevalence
- Nightmares occur in >75%
- Excessive daytime sleepiness occurs in 30%

Lloyd, J Clin Sleep Med 2012

REM SLEEP BEHAVIOR DISORDER (RBD)
ACTING OUT DREAMS

- Most movements are benign and involve the extremities
- RBD 4% have violent motor behaviors and/or complex vocalizations
- Prevalence in the general population is 0.3-0.5%

REM SLEEP BEHAVIOR DISORDER (RBD)

- Treatment
  - Rule out other sleep disorders
  - Change medications if behavior started after initiation
  - Melatonin
  - Clonazepam

OBSTRUCTIVE SLEEP APNEA
BEHAVIORS MAY BE WORSE IN REM SLEEP

- Isolated sleep epilepsies make up 10% of all cases of epilepsy
- Most common is nocturnal frontal lobe epilepsy (NFLE)
- Mean age of onset is 14 years old
- Diagnosis is often made on clinical grounds
- Patients often have multiple attacks at night

Cheng, J Fam Medicine, 2013
Nobili, Current Neurol Neurosci 2014

SLEEP-RELATED EPILEPTIC SEIZURES

- NREM sleep and sleep deprivation are powerful activators of inter-ictal epileptiform discharges (seizures)
- EEG “rhythmic” and synchronized during NREM sleep with sleep spindles, K complexes, and slow waves
- Sleep deprivation activates seizures from the frontal cerebral cortex
- Nocturnal frontal lobe seizures are often misdiagnosed as sleep terrors, nightmares, or a psychiatric problem
SLEEP-RELATED EPILEPTIC SEIZURES

Typical features include:
• > 90% occur from NREM II sleep
• Explosive onset of motor activity
  ➢ Kicking
  ➢ Running
• Last 20-120 seconds
• Patients often aware of seizure but cannot control movements
• No post-ictal amnesia
• EEG is normal in > 50%

BENIGN CHILDHOOD EPILEPSY WITH CENTRO TEMPORAL SPIKES (BENIGN ROLANDIC EPILEPSY)

• Most common sleep-related partial epilepsy syndrome in children
• 9% of all cases of epilepsy in children
• Mean age of onset is 8.8 years
• Seizures occurred primarily in sleep (88% of the time)

BENIGN CHILDHOOD EPILEPSY WITH CENTRO TEMPORAL SPIKES
AKA: BENIGN ROLANDIC EPILEPSY

• Arousal from NREM II
• Unilateral numbness or tingling of the cheek, tongue, or lips
• Grunting, drooling, unable to speak
• Jerking and pulling of the face to one side
• Consciousness is usually preserved

CONCLUSION

• Common contributors to parasomnias are sleep deprivation, stress, illness (fever) and medications
• When there is a report of abnormal behavior during sleep, consider the presence of a parasomnia
Primary Sleep Disorders and Paroxysmal Nocturnal Nonepileptic Events in Adults With Epilepsy From the Perspective of Sleep Specialists

Madeleine Grigg-Damberger*† and Frank Ralls‡

Abstract: Sleep specialists are frequently referred adults with epilepsy to evaluate their sleep/wake complaints, sometimes to determine whether their paroxysmal nocturnal behaviors are epileptic or not. Many patients with epilepsy have at least one parasomnia (some more than one), and the sleep specialists are often asked to differentiate and treat these. Sleep specialists review which primary sleep disorders are more common in adults with epilepsy and how to evaluate and best treat these. The authors summarize (1) how to evaluate and differentiate parasomnias using video-polySomnography; (2) the value of sleep deprivation and loud auditory stimuli to increase the likelihood of provoking a non-rapid eye movement arousal parasomnia with a single night of video-polySomnography; and (3) how to score excessive muscle activity during rapid eye movement sleep to confirm a diagnosis of rapid eye movement sleep behavior disorder. The clinical semiology and video-polySomnography features of simple and complex sleep-related movement disorders and parasomnias are reviewed.

Key Words: Parasomnia, Polysomnography, Sleepwalking, Sleep terror, Nocturnal frontal lobe epilepsy, REM sleep behavior disorder.

Sleep specialists are frequently referred adults with epilepsy to evaluate their sleep/wake complaints, sometimes to determine whether their paroxysmal nocturnal behaviors are epileptic or not. Many patients with epilepsy have at least one parasomnia (some more than one), and we are often asked to differentiate and treat these. Parasomnias are unusual or undesirable motor, behavioral, and/or experiential events that occur during (or in the transitions from and to) sleep (Kushida et al., 2005). Parasomnias are accompanied by varying combinations of complex motor movements, emotions, perceptions, dreaming, sensory experiences, hallucinations, thought images, and varying degrees of central nervous system sympathetic activation and arousal. If violent or dangerous, parasomnias can injure the patient (or those who attempt to intervene) and, when frequent, can disrupt the sleep/wake schedules and daytime functioning of the patient, bed partner, or family.

Some of these paroxysmal nocturnal behaviors (particularly complex sleep-related movement disorders or parasomnias) represent impaired sleep state synchronization or “state dissociation” disorders. Usually, transitions between wakefulness, non-rapid eye movement (NREM), and REM sleep occur smoothly and completely, but when more gradual or rapidly oscillating, the physiological markers of one sleep state can linger or intrude into another (Mahowald, 2009; Mahowald and Schenck, 2005). Narcolepsy with cataplexy is a prototypical state dissociation disorder in which (1) cataplexy is the sudden onset of REM sleep atonia while awake in response to an emotion-laden event; (2) sleep paralysis is an early or lingering appearance of REM sleep atonia; and (3) hypnic hallucinations fragments of REM sleep dreams persist into wakefulness. Table 1 summarizes the differential diagnosis of paroxysmal nocturnal events we consider in adults referred to sleep specialists.

Epidemiology and Risk Factors for Parasomnias

Parasomnias are particularly common in children and decrease in frequency with increasing age (Klackenberg, 1982). A longitudinal study of child development reported an overall prevalence of 40% for sleep terrors and 14.5% for sleepwalking in children aged 6 years or younger (Petit et al., 2007). An earlier study found that 40% of children (ages 6–16 years) have at least one episode of disorder of arousal (DoA) (mostly between ages 11 and 12 years), but only 2% to 3% of children have more than one DoA per month (Klackenberg, 1982). The majority of children who sleepwalk stop by the age of 13 years, but sleepwalking persists in 24% of frequent sleepwalkers, and 1% to 4% of adults sleepwalk. A telephone survey found that 2% of 4,972 adults in the United Kingdom reported sleepwalking, 2.2% sleep terrors, and 4.2% confusional arousals (Ohayon et al., 1999). However, only 0.4% of adults sleepwalk nightly (Plazzi et al., 2005).

Are parasomnias more common in children and/or adults with epilepsy? A prospective case-control study found a higher incidence of parasomnias among 89 children with idiopathic epilepsy compared with 49 siblings and 321 healthy control children using parental sleep questionnaires (Cortesi et al., 1999). Parasomnias were not more common in a prospective study of adults with a wide variety of different epilepsies and seizure types compared with healthy controls (Khatami et al., 2006). Sixty percent with epilepsy and 58% of the controls complained of at least one parasomnia: most often nocturnal leg cramps (25% vs. 17%), sleep starts (22% vs. 17%), and sleep talking (21% vs. 16%). Reports of sleep hallucinations, sleep paralysis, and violent acts during sleep occurred with equal frequency in patients and controls (16%, 4%, and 2%, respectively), as were shouting out when sleeping (4% vs. 3%). Nightmares and sleep-related bruxism were significantly more common but among control subjects and not the adults with epilepsy (16% vs. 6% and 19% vs. 10%, respectively). None of their study subjects reported sleepwalking or bedwetting.

However, NREM arousal disorders (DoA such as sleepwalking, sleep terrors, and confusional arousals) and sleep-related bruxism are significantly more common in patients and their relatives...
The authors found that (1) OSA symptoms were significantly suggestive of OSA, 25% insomnia, and 17% EDS (Piperidou et al., 2006). Adults with epilepsy were significantly more likely to report sleep complaints compared with 10% of 90 controls in a study by Weerd et al. (2004). Thirty percent of 39 adults with medically intractable epilepsy had undiagnosed OSA [typically defined as a mean of at least five or more apneas and hypopneas per hour of sleep (mean number of apneas and hypopneas per hour of sleep [AHI] ≥5) on overnight polysomnography (PSG)] (Malow et al., 2000). AHI ≥5/hour are found in approximately 24% of men and 9% of women in the general adult population (ages 30–60 years) (Young et al., 1993, 1997). However, note that OSA in these patients was often mild (AHI 5–14/hour), and only 5% had AHI >20/hour (where >15/hour is moderate and >30–40/hour is severe).

Another study screened 283 unselected adults with epilepsy for OSA, identified 40 patients by questionnaire and interview judged to be “at risk for OSA,” and confirmed OSA (AHI ≥5) in 29 by in-laboratory PSG (Manni et al., 2003). OSA was mild in 67% (AHI 5–14/hour), moderate in 22% (15–29/hour), and severe in 11% (>30/hour). Epilepsy patients with OSA were more often male (15.4% men and 5.4% women), older (46 ± 15 years vs. 33 ± 12 years), sleepier (23% vs. 9%), heavier (28.5 ± 3.6 kg/m² vs. 23.3 ± 3.7 kg/m²), and had experienced their first seizure at an older age (32 years vs. 19 years).

Onset of OSA symptoms coincided with a clear increase in seizure frequency or the first appearance of status epilepticus in 29 patients (median age 56 years, 86% men) (Hollinger et al., 2006). Epilepsy patients who had OSA were more likely to complain of EDS (52% with OSA had an Epworth Sleepiness Scale score >10). They recommended considering OSA in epilepsy patients with poor seizure control and/or reappearance of seizures after a seizure-free interval.

A case-control study of 53 older adults (mean age 59 years, 54% male) found OSA in 73% of men and 30% of women who presented to a tertiary epilepsy center with late-onset or worsening epilepsy (Chihorek et al., 2007). Of note, higher AHI (≥10) are common in older adults without sleep/wake complaints [found in 62% of 427 randomly selected community-dwelling elders (65 years or older)] (Anonymous, 1972). The authors also found the Epworth Sleepiness Scale as a useful screening tool in this population (mean score in those with OSA was 12 and those without OSA 6).

**TABLE 1. Differential Diagnosis of Paroxysmal Nocturnal Events in Adults Referred to Sleep Specialists**

- NREM Arousal disorder (confusional arousal, sleep walking, sleep terror)
- Sleep-related epilepsy
- REM sleep behavior disorder (RBD) and pseudo-RBD due to obstructive sleep apnea
- Sleep-related panic attacks
- Nightmare disorder
- Sleep-related dissociative disorder
- Sleep-related choking, laryngospasm, or gastroesophageal reflux
- Sleep-related rhythmic movement disorder with vocalization
- Sleep-related expiratory groaning (catathrenia)
- Post-traumatic stress disorder (PTSD)
- Sudden death when sleeping due to myocardial infarction, Brugada syndrome, untreated OSA, sudden unexpected death in epilepsy, and trauma

with nocturnal frontal lobe epilepsy (NFLE) (Bisulli et al., 2010). An individual with NFLE has a six-fold greater lifetime risk for DoA and five-fold for sleep-related bruxism compared with controls. The lifetime prevalence of a DoA in relatives of patients with NFLE was 4.7 times greater and nightmares 2.6 times greater compared with relatives of control subjects. NFLE predisposes patients and their relatives to the particular parasomnias (DoA and bruxism).

**CERTAIN PRIMARY SLEEP DISORDERS ARE COMMON IN ADULTS WITH EPILEPSY**

Many, but not all studies, report that obstructive sleep apnea (OSA), excessive daytime sleepiness (EDS), and sleep maintenance insomnia (difficulty staying asleep) occur more frequently in adults with epilepsy than the general population (de Weerd et al., 2004; Jennsen et al., 2006; Khattami et al., 2006; Piperidou et al., 2008; Soldatos et al., 2005). Thirty percent of 100 adults with epilepsy reported sleep complaints compared with 10% of 90 controls in a prospective study that used clinical interview and a standardized questionnaire to assess sleep/wake habits and disorders (Khattami et al., 2006). Adults with epilepsy were significantly more likely to have sleep maintenance insomnia (52% vs. 38%, P = 0.06). However, symptoms of sleep-onset insomnia (34% vs. 28%), EDS (19% vs. 14%), sleep apnea (9% vs. 3%), and restless legs (18% vs. 12%) were equally common in both patients and controls. The investigators found that EDS in the adults with epilepsy could be predicted by a history of loud snoring or restless legs symptoms (not by epilepsy type, seizure frequency, or number of antiepileptic medications prescribed). Sleep complaints were two-fold higher (39% vs. 18%) among 486 adults with partial epilepsy who responded to a mailed questionnaire compared with controls (de Weerd et al., 2004). Overall, quality of life (QoL) was reduced in patients with partial epilepsy compared with healthy controls, but those who reported disturbed sleep had the lowest QoL scores.

Several other well-designed studies have found that EDS is more common in adults with epilepsy compared with healthy age-matched controls, often then associated with symptoms suggestive of OSA and/or depression. An international cross-sectional survey of 35,327 individuals found that 17% of epilepsy patients complained of EDS compared with 12% of the general adult population (Soldatos et al., 2005). Twenty-eight percent of 124 consecutive epilepsy patients (mean age 35 ± 13 years, 55% male) who visited a1 outpatient epilepsy clinic over a 10-month period had symptoms suggestive of OSA, 25% insomnia, and 17% EDS (Piperidou et al., 2008). The authors found that (1) OSA symptoms were significantly more common among men and older patients; and (2) insomnia was an independent predictor for reduced QoL. However, Jennsen et al. (2006) found that scores on the Beck Depression Inventory suggestive of moderate to severe depression best predicted a complaint of EDS in patients with epilepsy, whereas sleep apnea scores contributed only minor independent effects.

**Untreated Obstructive Sleep Apnea May Be More Common in Epilepsy Patients With Poorly Controlled Seizures**

The current medical literature suggests that OSA is more likely to be found in those who have medically intractable or late-onset epilepsy, are male, older, or heavier (Hollinger et al., 2006; Malow et al., 2000; Manni et al., 2003). Thirty percent of 39 adults with medically intractable epilepsy had undiagnosed OSA [typically defined as a mean of at least five or more apneas and hypopneas per hour of sleep (mean number of apneas and hypopneas per hour of sleep [AHI] ≥5) on overnight polysomnography (PSG)] (Malow et al., 2000). AHI ≥5/hour are found in approximately 24% of men and 9% of women in the general adult population (ages 30–60 years) (Young et al., 1993, 1997). However, note that OSA in these patients was often mild (AHI 5–14/hour), and only 5% had AHI >20/hour (where >15/hour is moderate and >30–40/hour is severe).

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**Is One Night of Polysomnography Sufficient to Diagnose Obstructive Sleep Apnea in Patients With Epilepsy?**

Is PSG data obtained from sleeping for the first time in the foreign environment of the sleep laboratory reliable? Alterations in normal sleep architecture observed when healthy adults sleep for the first time in a sleep laboratory (called First Night Effects) include longer time to fall asleep (sleep latency), lower sleep efficiency (percent of the time in bed spent sleeping), lower percentage of time spent in REM sleep, and reduced amounts of NREM 3 sleep time compared with the second night (Agnew et al., 1966). Two studies have found that adults with medically refractory epilepsy compared...
with normal age- and gender-matched controls tend to have more NREM 1 and 2 sleep and less REM and NREM 3 sleep not just the first night but also the second (Marzec et al., 2005; Selwa et al., 2008).

However, for most patients with epilepsy, one night of PSG was sufficient to confirm (or exclude) a PSG diagnosis of OSA (Li et al., 2004; Scholle et al., 2003; Verhulst et al., 2006). Selwa et al. (2008) found that 29 patients had OSA (AHI = 5). The results of the first study usually confirmed (or excluded) the diagnosis (Selwa et al., 2008). The median difference between AHI nights between nights 1 and 2 was only 3.25/hour. One patient had an AHI of 3 on the first night and 5.8 on the second. Three patients had an AHI > 5 on the first night but not on the second. Twenty-nine patients had an AHI > 5 on both nights, and 7 had an AHI < 5 on both nights.

Can Treating Obstructive Sleep Apnea in Adults With Epilepsy Improve Seizure Control?

One prospective study examined the effects of treating OSA with continuous positive airway pressure (CPAP) in adults with medically refractory epilepsies (Malow et al., 2008). Investigators found that seizures were reduced ≥50% compared with their baseline in 28% of patients treated with CPAP versus 15% treated with sham CPAP (Malow et al., 2008). Six other small retrospective case series have reported that CPAP improved epilepsy control in some (but not all) when used (Beran et al., 1997; Chihorek et al., 2007; Devinsky et al., 1994; Hollinger et al., 2006; Oliveira et al., 2000; Vaughn et al., 1996). A clear reduction in seizure frequency was observed in four of five adults with epilepsy and OSA treated with CPAP, particularly those who used it faithfully (Devinsky et al., 1994).

CPAP in 12 adults with epilepsy led to a significant reduction in EDS and seizure frequency in 4 (Hollinger et al., 2006). Three of 10 adults with epilepsy became seizure-free after their OSA was treated; one had a >95% reduction in seizure frequency and three others had >50% when their OSA was treated (two with positional therapy to avoid sleep supine and eight with CPAP) (Vaughn et al., 1996). Four patients with medically refractory epilepsy had >50% reduction in their seizure frequency after CPAP use for 6 to 24 months, and antiepileptic medications were discontinued in two of these patients attributing their seizures to the OSA (Beran et al., 1997). Treating eight adults with epilepsy (six with CPAP for OSA, two prescribed supplemental oxygen for chronic obstructive pulmonary disease) led to reduced interictal spiking rates during sleep (Oliveira et al., 2000).

SLEEP-RELATED EPILEPTIC SEIZURES IN ADULTS FROM THE PERSPECTIVE OF SLEEP SPECIALISTS

We regard sleep-related epileptic seizures as an “epileptic” parasomnia. We understand that sleep (particularly NREM) is a powerful activator of interictal epileptiform discharges, certain seizure types, and particular epilepsy syndromes. Frontal lobe seizures are especially activated by sleep (Bazil and Waleczak, 1997; Crespel et al., 2000; Herman et al., 2001). One study found that 57% of partial seizures during sleep arose from the frontal, 44% lateral temporal, 40% medial temporal, and 13% parieto-occipital regions (Herman et al., 2001). Skeletal motor inhibition and desynchronization of EEG during REM sleep are thought to explain why seizures rarely occur during REM sleep (Foldvary-Schaefer and Grigg-Damberger, 2006).

Sleep-related hypermotor seizures are often initially misdiagnosed as NREM disorders of arousal (confusional arousal, sleep-walking, or sleep terrors) (Derry et al., 2006b; Guilleminault et al., 1998; Hughes, 2007; Lugaresi et al., 1991; Meierkord et al., 1992; Montagna, 1992; Nobili, 2007; Oldani et al., 1998; Silvestri and Bromfield, 2004). Most nocturnal hypermotor seizures emanate from the frontal lobe, but one-third are temporal lobe in origin (Mai et al., 2005; Nobili et al., 2004) and some from insula (Ryvlin et al., 2006). Table 2 summarizes the clinical features of nocturnal hypermotor seizures (Combi et al., 2004; Nobili, 2007; Provini et al., 1999, 2000; Terzagli et al., 2007; Timineri et al., 2005).

Patients with NFLE often have attacks of varying severity; the minor ones are hard to distinguish from arousals seen in healthy normal controls. Table 3 summarizes the range of minor, mild, and moderate seizures seen in patients with NFLE (Provini et al., 1999; Zucconi et al., 1997). Zucconi et al. studied the video-PSG features of arousals in patients with NFLE and controls. They found that “normal” nonepileptic arousals from sleep (1) had no dystonic or repetitive features; (2) the motor behaviors were slower, less repetitive, and less stereotyped; and (3) fewer in number (Zucconi et al., 1997).

NFLE usually begins in middle to late childhood or adolescence. The mean age of onset in one series of 100 patients was 14 ± 10 years but the range was 1–64 years (Provini et al., 1999). The mean age of onset was 7.5 years among 22 children with NFLE (Sinclair et al., 2004). The majority (78%) of 100 patients with NFLE deny precipitating factors for their seizures, but 18% reported psychologic stress as a trigger, three said seizures occurred after sleep deprivation and in one near her menses (Provini et al., 1999). A case series of 100 patients with NFLE reported that occasional daytime seizures occurred in 30%, <20% had ever had a generalized convulsion, the neurologic examination was normal in 92%, and the brain MRI normal in 86% (Provini et al., 1999).

Longer lasting nocturnal frontal lobe seizures can lead to “episodic nocturnal wandering” but more often are temporal lobe in origin (Mai et al., 2005; Nobili, 2002, 2004; Plazzi et al., 2005; Tai et al., 2010). Tai et al. (2010) found that postictal wandering was predominantly associated with temporal rather than extratemporal seizures, particularly those arising from the nondominant temporal lobe. Patients prone to “wandering” did so in a minority of their seizures (14%). Most temporal lobe seizures with postictal wandering began during wakefulness. The authors speculated that relatively greater sparing of suprasylvian motor structures after temporal lobe seizures may favor complex automatic wandering behaviors in the postictal state. Fifty to 80% of patients with temporal lobe epilepsy have nocturnal seizures, but nearly all have seizures when awake. Nocturnal temporal lobe seizures tend to be less frequent, do not cluster, and usually do not have the hyperkinetic motor activity of NFLE.

TABLE 2. Clinical Features of Nocturnal Hypermotor Seizures

<table>
<thead>
<tr>
<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>An abrupt, often explosive, onset awakening the patient</td>
</tr>
<tr>
<td>From grossly undisturbed NREM 2 sleep</td>
</tr>
<tr>
<td>Asymmetric dystonic or tonic postures</td>
</tr>
<tr>
<td>Thrashing, pedaling, and kicking of the lower extremities</td>
</tr>
<tr>
<td>Tend to be “fairly” stereotyped in appearance for the</td>
</tr>
<tr>
<td>Individual patient</td>
</tr>
<tr>
<td>Brief (typically lasting 20–30 seconds, less than 1–2</td>
</tr>
<tr>
<td>Minutes)</td>
</tr>
<tr>
<td>Patients are often aware during the seizure but say that</td>
</tr>
<tr>
<td>They cannot control their movements or vocalizations</td>
</tr>
<tr>
<td>No postictal confusion or amnesia</td>
</tr>
<tr>
<td>20% have no scalp-recorded ictal EEG activity accompanying them</td>
</tr>
</tbody>
</table>

Nocturnal Frontal Lobe Epilepsy Often Has a Familial or Genetic Basis

A family history of sleep-related epilepsy is present in 30% of patients with NFLE (Aridon et al., 2006; Marini and Guerrini, 2007;
Oldani et al., 1998; Scheffer et al., 1994). NFLE has an autosomal dominant pattern of inheritance with an estimated 70% penetrance of the trait. More than 100 families with autosomal dominant NFLE (ADNFLE) have been identified, but mutations in the genes coding for various subunits of the neuronal nicotinic acetylcholine receptor (alpha2, alpha4, and beta2 on CHRNA4, CHRNA2, and CHRN2B) on three different chromosomes (8p12.3-8q12.3, 15q4, and 20q13.1-13.3) have been identified in only a few studies (Aridon et al., 2006; De Marco et al., 2007; Diaz-Otero et al., 2008; Hoda et al., 2008; Marini and Guerrini, 2007; Phillips et al., 1995). The gene mutations of NFLE appear to confer a gain of function, leading to an increased sensitivity to acetylcholine (Hoda et al., 2008; Marini and Guerrini, 2007).

NFLE most often begins between ages 5 and 7 years in familial cases, 90% before the age of 21 years (Aridon et al., 2006). Patients with ADNFLE typically have normal neuropsychologic examination, intellect, and brain MRI. Most studies suggest the clinical features and video-EEG findings of ADNFLE do not differ from sporadic NFLE (Marini and Guerrini, 2007). ADNFLE is typically lifelong, although seizures often become less frequent and milder by middle age (Aridon et al., 2006), which is attributed to a loss of nicotinic acetylcholine receptors with aging. NFLE may be associated with subtle deficits in cognitive flexibility compared with controls (Wood et al., 2010).

**Scalp Ictal EEG Often Normal in Patients With Nocturnal Frontal Lobe Epilepsy**

Probably, the greatest challenge when diagnosing NFLE is that 80% of adults with it have no IEDs in their EEGs awake or asleep, 20% have no scalp-recorded ictal EEG activity, and 25% have normal interictal and ictal EEGs (Oldani et al., 1998). In another study, 44% of patients with NFLE had a normal ictal EEG during video-EEG recording (Provini et al., 1999). The lack of scalp ictal EEG activity in NFLE has been attributed to the following: (1) muscle artifact often obscures the tracing; (2) events often last <20 to 30 seconds; (3) little or no postictal slowing; and/or (4) the epileptic focus is “buried” in the mesial frontal or inferior frontal regions “hidden” from scalp EEG recordings.

The diagnosis in these patients is confirmed by recording multiple seizures, noting their relatively stereotyped nature and clinical semiology. It is feasible to confirm the diagnosis with a single night of video-PSG because patients with NFLE tend to have multiple seizures. Provini et al. (1999) found that 100 patients with NFLE averaged 3 ± 3 (range 1–20) seizures per night of video-PSG and a mean of 20 ± 11 seizures per month (61%, >15 seizures per month).

The diagnosis of sleep-related epilepsy in adults is best confirmed by video-EEG, continuous prolonged inpatient recording if needed (Vignatelli et al., 2007). Oldani et al. (1998) compared the diagnostic reliability of routine video-EEG, daytime video-EEG after sleep deprivation, and nocturnal video-PSG to diagnose NFLE in 23 patients. All patients had normal video-EEG when awake. Nocturnal video-PSG confirmed the diagnosis in 87% of patients and daytime video-EEG with sleep deprivation in 52%. Overnight video-PSG is best reserved for NFLE patients in whom OSA or concomitant DoA is suspected.

Eighty percent of adults with NFLE have scalp-recorded ictal EEG activity. When unilateral, it is low-voltage paroxysmal fast activity, rhythmic theta activity, or flattening of the EEG over the frontocentral, fronto-central-temporal, frontotemporal, or parasagittal regions. A unilateral onset may be followed by early or late contralateral propagation. NFLE ictal EEG patterns when bilateral are usually maximal over the frontal, frontocentral, or frontotemporal regions, begin as either rhythmic fast or low-voltage fast activity, and sometimes lateralize to the size of the epileptogenic focus.

Patients with NFLE may complain that their seizures disrupt their sleep (and often they do). A case-control study found that 50% of 33 patients with NFLE complained of nocturnal awakenings compared with 22% of controls; 36% of patients complained of EDS (11% of controls), and those who complained of EDS were more likely to report frequent nocturnal awakenings (Vignatelli et al., 2006).

Vignatelli et al. (2007) evaluated the ability of six physicians (one sleep expert, two epilepsy experts, and three trainees in sleep medicine) to correctly diagnose NFLE (ranging from very brief paroxysmal arousals to nocturnal wandering) in 104 patients. Substantial to almost perfect inter-rater reliability was observed for more prolonged events or those with hypermotor or dystonic features. However, inter-rater reliability was at times only fair when raters were forced to distinguish brief paroxysmal arousals from equally brief nonepileptic arousals, especially when a patient had only one event in a single night of recording. The level of agreement between experts and trainees (with some training) was similar especially for longer lasting seizures. The authors argue that video recording (without the ictal EEG correlate that is often lacking) is probably sufficient to reliably diagnose NFLE when characterized by hypermotor or asymmetric dystonic seizures.

### Treatment Strategies for Nocturnal Frontal Lobe Epilepsy

Carbamazepine is an appropriate first drug for NFLE, often effective at low doses (Oldani et al., 1998; Provini et al., 1999). Carbamazepine rendered 20% of 100 consecutive NFLE patients seizure-free and reduced seizure frequency by ≥50% in another 48% of patients (Provini et al., 1999). The effectiveness of carbamazepine in controlling seizures in ADNFLE may be related to its particular ability to inhibit mutated nicotinic acetylcholine receptors (Picard et al., 1999). Oxcarbazepine may also be effective for...

### TABLE 3. Nocturnal Frontal Lobe Epilepsy Characterized by Paroxysmal Attacks of Increasing Complexity

<table>
<thead>
<tr>
<th>Attack Type</th>
<th>Duration</th>
<th>Clinical Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor attacks</td>
<td>2–4 seconds</td>
<td>Stereotyped head, axial, or limb movements</td>
</tr>
<tr>
<td>Paroxysmal arousals</td>
<td>5–10 seconds</td>
<td>Abrupt arousal accompanied by trunk and head elevation often with vocalization and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>a frightened expression</td>
</tr>
<tr>
<td>Major attacks (formerly called</td>
<td>20–30 seconds</td>
<td>Begin as an abrupt arousal rapidly progress to bipedal automatism, rhythmic</td>
</tr>
<tr>
<td>paroxysmal dystonia)</td>
<td></td>
<td>twisting movements of trunk, bizarre repetitive hypermotor behaviors, and/or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>asymmetric dystonic or tonic postures</td>
</tr>
<tr>
<td>Episodic nocturnal wanderings</td>
<td>&gt;1–3 minutes</td>
<td>Begins as a paroxysmal arousal process followed by leaping from bed, walking,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>running, screaming, or loud vocalization; often accompanied by fear and bizarre</td>
</tr>
<tr>
<td></td>
<td></td>
<td>behaviors</td>
</tr>
</tbody>
</table>

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children with NFLE (Di Resta et al., 2010; Raju et al., 2007). Topiramate given as a single 50 to 300 mg dose at bedtime completely controlled NFLE in 25% of 24 adults with NFLE, while another 68% experienced ≥50% reduction (Oldani et al., 2006).

Particularly interesting are reports of tobacco use or nicotine patches improving AD/E in 22 adults with NFLE (Brodtkorb and Picard, 2006). Although NFLE seizures persisted in the seven adults with NFLE who did not use tobacco, seizure fluctuations (including long remissions) corresponded to changes in tobacco habits in several patients. One patient who recently had begun treatment with transdermal nicotine experienced improvement. Nicotine normalized the intracellular subunit stoichiometry of nicotinic receptors in cultured cell lines carrying mutations linked to ADNFLE (Son et al., 2009). Although evidence is limited, consider a trial of transdermal nicotine patches for medically refractory NFLE.

Approximately 30% of cases of sporadic NFLE are medically refractory. Patients with medically refractory NFLE may be candidates for tailored frontal lobe resections (Nobili et al., 2007; Sinclair et al., 2004). Nearly three-fourths (73%) of 21 cases of medically refractory NFLE became seizure-free after tailored frontal lobe epilepsy focus resections, and seizure control improved in another 23% (Nobili et al., 2007).

HOW DO SLEEP SPECIALISTS EVALUATE PARASOMNIAS IN ADULTS?

When asked to diagnose paroxysmal events or abnormal movements during sleep, we begin by asking whether these only occur around or during sleep (Walters, 2007). If these also occur while awake, consider whether the patient has a movement disorder when awake. Contrary to older teachings, most diurnal movement disorders (including tremor, dystonia, chorea, hemiballismus, and myoclonus) persist or intermittently recur in sleep (albeit more intermittent and reduced in frequency and duration than when awake).

Then, obtain a detailed description of the events regarding (1) stereotyped or variable; (2) consciousness is preserved before, during, and/or after them; (3) number and time(s) of occurrence related to sleep onset; (4) precipitating factors; (5) recall of the events; (6) potential to cause injury; (7) daytime consequences of them including cognitive slowing or daytime sleepiness; and (8) sleep/wake habits of the individual searching for irregular sleep/wake schedules and partial sleep deprivation. Next, obtain a thorough medical, sleep, social, and family histories, specifically asking whether they have a prior personal and/or family history of parasomnias or sleep/wake problems. A physical examination should follow searching for a movement disorder when awake, dementia, confusion, depression, anxiety, upper airway or body habits at risk for OSA, and underlying cardiac, pulmonary, neurodegenerative, or peripheral nerve disorders.

Based on the clinical descriptions provided by observers (often unreliable because they are aroused after the onset of an event), determine whether the nighttime movements are simple or complex. Table 4 summarizes simple sleep-related movement disorders which may be misconstrued as epileptic because of their rhythmic or forceful nature. Figure 1 provides a flow chart for assessing sleep-related movement disorders and parasomnias.

Indications for Video-Polysomnography When Evaluating Parasomnias in Adults

The American Academy of Sleep Medicine (AASM) clinical practice parameters recommend in-laboratory video-PSG (V-PSG) be used to evaluate parasomnias that are unusual or atypical because of patient’s age at onset; the time, duration, or frequency of occurrence of the behavior; or the specifics of the particular motor patterns in question (e.g., stereotypical, repetitive, or focal) (Kushida et al., 2005). Comprehensive in-laboratory video-PSG is not routinely indicated for “typical” sleep terrors or sleepwalking in young children (Kushida et al., 2005). However, video-PSG is usually warranted to evaluate parasomnias in adults which (1) begin or recur in adulthood; (2) occur more than 2 to 3 times per week; (3) are potentially injurious or have caused injury to the patient or others; and (4) could be seizure-related but the initial clinical evaluation and a standard EEG inconclusive (Kushida et al., 2005).

Clinical features that warrant concern for sleep-related epileptic seizures are as follows: (1) events occur any time of the night, occur just after falling asleep, or shortly before awakening in the morning; (2) multiple events a night; and/or (3) occasional occurrence of these events when awake or during a brief nap. If we suspect that the nocturnal events are sleep-related epilepsy and the patient has not had an EEG with sleep, we request one first. If the first (or second with 24-hour of sleep deprivation) routine EEG with sleep is normal and our clinical suspicion for a sleep-related epilepsy remains, we request continuous inpatient video-EEG monitoring (long-term monitoring) for 2 to 5 days.

Unfortunately, the habitual nocturnal event may not be captured by one night of in-laboratory video-PSG. One to two consecutive nights of v-PSG provided valuable diagnostic information in 69% of 41 patients whose paroxysmal motor behaviors were “prominent,” 41% of 11 patients referred for minor motor activity in sleep, and 78% of 36 patients with known epilepsy (Aldrich and Jahnke, 1991). Another study found that video-PSG was diagnostic in 65% and “helpful” in another 26% of 100 consecutive adults referred for frequent sleep-related injuries; video-PSG identified DoA in 54, REM sleep behavior disorder (RBD) in 36, sleep-related dissociative disorders in 7, nocturnal seizures in 2, and OSA in 1 (Schenck et al., 1989). Unfortunately, only one-third of patients with paroxysmal nocturnal events will have a typical spell a single night of video-PSG (Aldrich and Jahnke, 1991; Blatt et al., 1991).

The AASM recommends that video-PSGs be done to diagnose parasomnias need (1) “additional EEG derivations in an expanded bilateral montage” to diagnose paroxysmal arousals or other sleep disruptions thought to be seizure-related when the initial clinical evaluation and results of a standard EEG are inconclusive; (2) recording surface electromyographic (EMG) activity from the left and right anterior tibialis and extensor digitorum muscles; (3) good audiovisual recording; and (4) a sleep technologist present throughout the study to observe and document events (Kushida et al., 2005).

We typically use bandpass of 0.3 to 35 Hz when reviewing in-laboratory PSG, but in patients with suspected or known epilepsy, we set the high-frequency filters to 70 Hz. We also review portions of the recording using vertical screen times (epochs) of 10 or 15 seconds, whereas we typically score sleep stages using 30-second epochs. The AASM encourages that polysomnographers and electroencephalographers who are not experienced or trained in recognizing and interpreting both PSG and EEG abnormalities should seek appropriate consultation or should refer patients to a center where this expertise is available (Kushida et al., 2005).

If the goal is to differentiate epileptic seizures from nonepileptic events, especially frontal lobe seizures, 18 channels of EEG are needed when recording video-PSG (Foldvary-Schaefer et al., 2006). That said, recording 18 channels of EEG during v-PSG did not improve the ability to recognize frontal lobe seizures. Adding 7 or 18 channels of EEG improved the accuracy of temporal lobe seizure detection (sensitivity 67% for 4 channels, 82% for 7, and 86% for 18) (Foldvary et al., 2000).
<table>
<thead>
<tr>
<th>Simple Sleep-Related Movement Disorder</th>
<th>Clinical Features</th>
<th>Video-EEG or PSG Features</th>
<th>Neurophysiological Basis</th>
<th>Epidemiology and Sleep/Wake Timing</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sleep starts (hypnic jerks)</strong></td>
<td>In sleep/wake transition, 1–2 abrupt myoclonic flexion jerks (generalized or partial, often asymmetric), often accompanied by a feeling of falling, a sensory flash, and/or a bit of dream-like imagery</td>
<td>A single brief EMG burst lasts &lt;250 milliseconds, often occurs asymmetrically and simultaneously, or sequentially in various muscles, and often causes a brief EEG arousal</td>
<td>Sudden descending brainstem reticular formation volleys activated by the instability of the system in the wake/sleep transition</td>
<td>Occur occasionally in 70% of general adult population</td>
<td>Reassurance Avoid sleep deprivation or insufficient sleep which may provoke them</td>
</tr>
<tr>
<td><strong>Sleep paralysis</strong></td>
<td>Upon awakening or going to sleep, transient inability to move despite being fully awake</td>
<td>REM sleep patterns, eye movements, and respiration spared</td>
<td>A brief persistence or intrusion of the skeletal muscle motor suppression of REM sleep into wakefulness</td>
<td>Occurs most often and frequently in narcolepsy with cataplexy Can occur in healthy adults often with 2 hours of sleep onset especially when sleep deprived</td>
<td>Reassurance Avoid sleep deprivation</td>
</tr>
<tr>
<td><strong>Hypnagogic foot tremor</strong></td>
<td>Single short trains of rhythmic 1–2/second oscillating movements of the toes or whole foot of one or both feet most often wake/sleep, but often linger into stages REM 1 or NREM 2 sleep, and may recur after sleep-related arousals</td>
<td>A series of single-phasic EMG bursts lasting 300 to 700 milliseconds recurring at 1 to 2/second for 10 to 20 seconds (Wichniak et al., 2001) May alternate from leg to leg</td>
<td>May be another manifestation of sleep-related periodic limb movements</td>
<td>8% of 375 consecutive patients complaining of disturbed sleep and 5% of 20 healthy young controls (Wichniak et al., 2001) 70% in one series were taking selective serotonin reuptake inhibitors (Chervin et al., 2003)</td>
<td>Usually do not disturb sleep or need treatment</td>
</tr>
<tr>
<td><strong>Propiospinal myoclonus</strong></td>
<td>Series of involuntary myoclonic jerks that begin in the upper rectus abdominus or lower intercostal muscles and propagate rostrally to the upper intercostals and caudally to the lower abdominus muscles when trying to fall asleep or relax, usually disappear NREM 2 sleep onset</td>
<td>EMG of PSM shows spontaneous intermittent rhythmic or arrhythmic brief myoclonic bursts, which usually arise in the upper rectus abdominus or lower intercostal axial muscles followed by propagation rostrally to upper intercostal and caudally to the abdominal muscles at slow conduction velocities of 2 to 16 milliseconds (Montagna et al., 2006)</td>
<td>Myoclonic jerk time-locked to brain averaging have shown that PSM does not originate in the cerebral cortex. PSG can develop within days or weeks of cervical trauma, suggesting that it may represent a partial release of a spinal central pattern generator (Brown et al., 1994), propagated up and down the spinal cord by slow conducting pathways, such as propiospinal fibers (Chokroverty et al., 1992)</td>
<td>Rare can cause severe sleep-onset insomnia May occur after trauma. Can coexist with restless legs syndrome or periodic limb movements</td>
<td>Clonazepam (0.5–2 mg) before bed usually provides partial relief for patients with PSM who complain of inability to fall asleep because of the PSM (Montagna et al., 2006)</td>
</tr>
</tbody>
</table>

(Continued)
<table>
<thead>
<tr>
<th>Simple Sleep-Related Movement Disorder</th>
<th>Clinical Features</th>
<th>Video-EEG or PSG Features</th>
<th>Neurophysiological Basis</th>
<th>Epidemiology and Sleep/Wake Timing</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleep-related bruxism</td>
<td>Grinding or clenching of teeth during sleep, which often occurs with or after arousals</td>
<td>Recurring episodes of bruxing movements of masseter and temporalis muscles accompanied by the noise of grinding teeth, which usually follow an arousal, and sometimes concludes with a swallow, and can occur in any stage of sleep but most often NREM 1 or NREM 2</td>
<td>Sleep-related release of brainstem central pattern generators</td>
<td>8% of young to middle-aged adults and 3% of older persons (Lavigne et al., 2008) Major risk factors for SB include tobacco, caffeine, heavy alcohol, type A personality, and other sleep disorders, especially sleep apnea or PLMS (Walters et al., 2007)</td>
<td>Mouth guard or mandibular advance appliance worn when sleeping or clonazepam taken before bed are the most successful treatments for SB (Landry et al., 2006; Huynh et al., 2007; Landry-Schonbecker et al., 2009)</td>
</tr>
<tr>
<td>Sleep-related faciomandibular myoclonus</td>
<td>Spontaneous myoclonic jerks of the facial, masticatory, and sometimes sternocleidomastoid muscles during NREM sleep without the tonic EMG masticatory activity typical of sleep bruxism (Loi et al., 2007)</td>
<td>Spontaneous myoclonic jerks in facial, masseter, and neck muscles during NREM sleep</td>
<td>Sleep-related release of brainstem central pattern generators</td>
<td>May cause tongue-biting; Sometimes mistaken for sleep-related epilepsy (Dylgjeri et al., 2009)</td>
<td></td>
</tr>
<tr>
<td>Excessive fragmentary myoclonus</td>
<td>Small muscle twitches about the mouth, fingers, or toes or small muscle twitches that resemble muscle fasciculations because they cause no movement across a joint space (Broughton et al., 1985)</td>
<td>Very brief (75–150 milliseconds) EMG bursts in various muscles which occur asynchronously and asymmetically in a sustained manner without clustering for at least 20 minutes of sleep (Medicine 2005). EEG-EMG back averaging has shown that these are not generated by the cerebral cortex (Vetrugno et al., 2002)</td>
<td>Arousal from sleep can lead to a temporary loss of control of the neomammalian cortex provoking emergence of different types of motor behaviors, which are genetically determined and species-specific central pattern generators.</td>
<td>Incidental finding in PSG; patients are usually unaware of the movements nor do they affect sleep onset or sleep quality, or need treatment. Occasionally, a bed partner asks for an explanation for them</td>
<td></td>
</tr>
</tbody>
</table>
Finally, when should we retreat to the epilepsy monitoring unit to confirm sleep-related events are epileptic? Prolonged inpatient video-EEG monitoring is often a better choice in adults with undiagnosed paroxysmal nocturnal events when (1) the nocturnal behaviors do not occur nightly or every other night; (2) a primary sleep disorder (e.g., OSA) is unlikely; (3) a history of postictal agitation or wandering exists; and/or (4) cooperation of the patient is questionable.

Alternative Methods for Diagnosing Parasomnias

Derry et al. (2006a) designed a frontal lobe epilepsy and parasomnias (FLEP) scale to assess the likelihood a paroxysmal nocturnal event was likely to be NFLE based on the clinical history alone. The FLEP consists of a series of questions based on an initial series of cases and clinical expertise. Responses to the questions asked in the FLEP scale that favored nocturnal seizures were events lasting <2 minutes, occur ≥3 to 5 times per night, and behaviors during them are highly stereotyped. PNE (paroxysmal nocturnal events), which begin after age 55 and/or have highly variable clinical semiology, are unlikely to be NFLE. A patient with a score of 0 or less on the FLEP scale is very unlikely to have epilepsy, and any patient with a score of +3 is very likely to have epilepsy, whereas video-EEG or PSG monitoring is needed for those with a FLEP score of +1 to +3. For NFLE, the FLEP scale had a sensitivity of 71%, a specificity of 100%, a positive predictive value of 100%, and a negative predictive value of 91% (Derry et al., 2006a).

Manni et al. (2008) also found that the FLEP scale usually identifies NFLE, but it is less reliable for differentiating sleepwalking from epileptic nocturnal wandering and distinguishing RBD from epilepsy. Manni et al. evaluated the reliability of the FLEP scale in 71 subjects (mean age 54 ± 21 years, 85% men) of whom 11 had DoA, 14 NFLE, and 46 idiopathic RBD; the FLEP scale incorrectly diagnosed 4 (6%) of the patients (specifically NFLE patients who had epileptic nocturnal wandering). FLEP scores were in the equivocal range (+1 to +3) in 31% of the patients requiring video-PSG or video-EEG.

The diagnostic yield of home video recordings in capturing “spells” in children has been reported and studied (Beun et al., 1994; Sartori et al., 2008; Sheth and Bodensteiner, 1994; Stephenson et al., 2004; Woody, 1985). These are simple to request and obtain if events are frequent enough, and families have readily available camcorders, digital cameras, or cell phones to record the events. However, too often, the crucial beginning of an event is lost.

SLEEPWALKING AND SLEEP TERRORS IN ADULTS

Most adults referred to sleep specialists for parasomnias have NREM disorders of arousal (DoA), which include confusional arousals, sleepwalking, sleep terrors, sleep-related eating, or sexual behaviors (Hughes, 2007; Plazzi et al., 2005; Schenck et al., 2007; Vetrugno et al., 2006). As discussed earlier in the Introduction section, 40% of children have at least one episode of sleepwalking, but only 2% to 3% have more than one a month; most stop walking by age 13, 24% continue to sleepwalk, and 2% to 4% of adults sleepwalk but only 0.4% nightly.

Risk factors for confusional arousals in adults were age younger than 35 years, OSA, a bipolar or anxiety disorder, or shift or night work (Ohayon et al., 2000). In an earlier study, Ohayon et al. (1999) found that bipolar disorder increased the odds ratio for confusional arousals in an adult 13 times, an adjustment disorder...
three-fold, shift work or daytime sleepiness two-fold. However, adults who reported sleep terrors were three to five times more likely to be reported by those who also had symptoms suggestive of OSA, nightmares more than once a month, consumed alcohol at bedtime, or were prone to violent or injury-causing behaviors during sleep. Table 5 lists factors that predispose, prime, or perpetuate DoA.

Clinical Semiology of NREM Arousal Disorders

DoA most often occur 90 to 180 minutes after sleep onset in a transition from NREM 3 (occasionally NREM 2) sleep to wakefulness or REM sleep. DoA typically last for a few minutes, are nonstereotyped, and can be provoked by sensory stimuli (OSA, a loud noise, or bright light half-awakening the patient). Patients during DoA appear confused, disoriented, and are slow to respond. Their eyes are open (as opposed to closed during RBD or NFLE); visual inspection functions but objects are often misidentified (e.g., trying to use the bedside water glass as a telephone receiver, the closet as a bathroom). They have little or no responsiveness to their external environment and exhibit automatic behaviors. They are difficult to arouse from an event, and if aroused, they recall only fragmentary dream-like images (often of being trapped or attacked). Varying degrees of central nervous sympathetic activation accompany DoA: mild for “passive” sleepwalking, moderate in confusional arousals, markedly for sleep terrors or “agitated” sleepwalking. Episodes end with a return to sleep and retrograde amnesia for the events (although some adults can recall fragments of some events).

During a confusional arousal, the patient often suddenly sits up in bed, may then fumble with bedclothes, trash, flail or kick, moan, whimper, and/or utter often unintelligible words. Sleep sex is abnormal sexual behavior occurring when sleeping and classified as a variant of confusional arousal in the second edition of the International Classification of Sleep Disorders. First described by Guilleminault et al. in 2002, 11 patients (7 men) exhibited atypical sexual behaviors while asleep. These included loud sexual vocalizations, fondling their bedpartner, sexual intercourse with or without orgasm, sexual assault, and atypical for the particular individual’s awake deviant sexual behaviors. “Passive” sleepwalking often begins as a confusional arousal but the patient leaves the bed, walking toward a sound, light, or a particular room. While sleepwalking, the person may eat, urinate in a closet or next to the toilet, or walk outside.

Sleep terrors and agitated sleepwalking often begin with a bloodcurdling scream or cry, the patient exhibiting severe agitation, greater fear, more vocalization, and marked sympathetic arousal with mydriasis, tachycardia, tachypnea, and sweating. They flee their bed screaming or crying, run through the house, down the stairs, or out the front door. They may recoil and have increased agitation when touched or held; innocent attempts by bystanders to touch or direct them may then lead to injury to (themselves or others). Violent DoA in adults can cause injury to patient or bedpartner, and self-injury during a DoA is misdiagnosed as suicide (suicidality) (Mahowald et al., 2003). Agitated sleepwalkers are more often an adolescent or adult. Even violent DoA usually last a few to rarely as long as 30 minutes, often followed by a calm return to bed or sleep somewhere else in the house or outside.

Video-Polysomnographic Features of NREM Arousal Disorders

DoA usually emerge from NREM 3, occasionally from NREM 2 sleep (Schenck et al., 1998; Zadra et al., 2004). The onset of DoA event is best identified by the appearance of tachycardia from NREM 3 sleep: the acceleration of the heart rate is typically greatest for a sleep terror or agitated sleepwalking, moderate for confusional arousal, and least for passive sleepwalking.

EEG during a DoA event in 38 adult sleepwalkers (mean age 29 years, 55% men) was characterized by either regular rhythmic hypersynchronous delta or theta activity or high-amplitude delta intermixed with alpha or beta activity (Schenck et al., 1998). A case-control study compared PSG in 24 adult sleepwalkers (18–25 years old) and 12 age-matched controls (Blatt et al., 1991). Sleepwalkers had more 30-second epochs of sleep containing hypersynchronous delta waves (60 ± 60 vs. 2 ± 3), a greater percentage of NREM 3 sleep time with hypersynchronous delta waves (25% ± 21% vs. 1% ± 2%), more NREM 3 sleep interruptions (8 ± 5 vs. 4 ± 2), and a greater percent of their total sleep time spent in NREM 3 (31% ± 12% vs. 23% ± 7%).

Studies comparing sleep microarchitecture and EEG power in adults with sleepwalking or sleep terrors to controls report that patients with sleepwalking/sleep terrors have (1) increased number of brief arousals from NREM 3 sleep especially during the first NREM cycle of a night; (2) reduced delta power of the slow-wave activity especially during first NREM cycle; (3) slower decay of EEG delta power of NREM 3 sleep across recurring cycles of NREM sleep; and (4) alterations in cyclic alternating pattern during NREM sleep consistent with increased NREM 3 sleep instability. More work is needed to see whether individuals with DoA can be identified by abnormalities in their sleep microarchitecture.

Techniques for Activating NREM Arousal Disorders in the Sleep Laboratory

Montplaisir et al. developed “activation” techniques that increased the likelihood of capturing a patient’s sleepwalking or sleep terror event in a single night of in-laboratory recording. Patients would arrive at their customary bedtime, remained awake the entire night, and then permitted to fall asleep 1 hour later than their usual wake time (i.e., 25 hours of prior wakefulness). To further provoke DoA events, investigators subjected patients (and controls) to six auditory stimuli [AS, 3 seconds of a pure sound at 1,000 Hz presenting in ascending intensities of 10 dB (from 40 to 90 dB)] with a minimal interval of 1 minute between two stimuli. The AS was delivered to the patient or control subject by earphones inserted into both ears. Whenever possible, the first and second groups of AS were presented during NREM 3 sleep during the first and second NREM-REM sleep cycles.

Using this technique, the investigators found that they could trigger 1 to 3 sleepwalking events in 30% of 10 patients with DoA by sounding a 40 to 70 dB buzzer during NREM 3 sleep. After 25 hours of total sleep deprivation, the AS provoked DoA behaviors in 100% of their subjects (and none of their controls). A few sleepwalking events were induced from NREM 2 sleep. No episodes were induced from REM sleep. Sleep deprivation nearly tripled the percentage of auditory stimulus trials that induced a behavioral
event (57% vs. 20%). We have begun to employ these methods to provoke DoA events in adults in the sleep laboratory. We advise patients of the entire process before the recording begins.

Genetic Predisposition to Disorders of Arousal and Other Parasomnias

Genetic predisposition for DoA is the most significant predisposing factor for DoA in children (Hublin and Kaprio, 2003; Kales et al., 1980; Petit et al., 2007). Psychopathology is usually not a factor in young children with arousal disorders (Petit et al., 2007). Psychopathology is often a significant factor when sleepwalking first appears in older teens and adults, but partial sleep deprivation, situational stress, and genetics often contribute.

Genetic predisposition is also significant factor for DoA in adults. Hublin et al. (1997) found in a study population of 11,220 Finnish adults (33–60 years) that 3.9% of men and 3.1% of women reported sleepwalking (weekly in only 0.4%). Twenty percent of the men and 18% of the women who were sleepwalkers as children continued to sleepwalk as adults. Only 0.6% of the adult sleepwalkers reported never sleepwalking as a child. The authors found that they could attribute 66% of the phenotypic variance to genetic influences in men and 57% in women with a history of sleepwalking as children; 80% in men and 36% in women in the adult sleepwalkers. In a later study, they found that other parasomnias (bruxism, nightmares, and sleepwalking) are also much more common in families of individuals affected by sleepwalking (Hublin et al., 2001).

NREM Arousal Disorders Expression of a Sleep-Related Loss of Inhibition of Central Pattern Generators

DoA are thought to represent the release or expression of central pattern generators (CPGs): standing, walking, vocalization, eating, aggression, and sexual behaviors (Tassinari et al., 2005, 2009). CPGs (listed in Table 6) are genetically determined neuronal aggregates in the mesencephalon, pons, and spinal cord, which code for species-specific motor behaviors and emotions essential for survival (e.g., feeding, locomotion, defense, and copulation) (Tassinari et al., 2005). After infancy, CPGs are usually suppressed by the cerebral neocortex when awake. However, CPGs released from neocortical inhibition during DOA often lead sleepwalkers to the kitchen to eat (often foods they would not eat when awake), to urinate (next to the toilet or in a closet), or outside (through a window or door).

Tassinari et al. (2005) argue that the clinical semiology of NFLE and many parasomnias [DoA, bruxism, periodic limb movements during sleep (PLMS), faciomandibular myoclonus, and catathrenia] are similar because they reflect release of neocortical inhibition of the same CPGs during sleep. The higher prevalence of sleepwalking in families with NFLE may reflect that both occur when CPGs are disinhibited (Bisulli et al., 2010; Tassinari et al., 2009; Tinuper et al., 2010).

Treatment Strategies for NREM Arousal Disorders in Adults

DoA in adults are often triggered by conditions and/or substances that increase NREM 3 sleep or make arousal from sleep more difficult (Table 5). Identifying, avoiding, or treating these are sufficient treatment for DoA. Further treatment strategies for DoA in adults are provided in Table 7. We consider pharmacotherapy for DoA in adults when they (1) are frequent; (2) are danger to the patient or others; (3) are chronic; (4) cause undesirable secondary consequences (EDS and weight gain from nocturnal eating); (5) are sufficiently distressing to the patient or family; and/or (6) cause legal issues regarding sexual or violent behavior. When medication is needed in adults with DoA, sleep specialists often first prescribe clonazepam (0.5–2 mg QHS). The value of clonazepam to suppress frequent DoA in adults is based on five small case series, which together show that 83% of 61 sleepwalkers responded to it (Harris and Grunstein, 2009). The effectiveness of clonazepam for suppressing DoA is thought to be related to inhibition of arousals or locomotor activity rather than pharmacological suppression of NREM 3 sleep.

REM Sleep Behavior Disorder

RBD is a parasomnia characterized by abnormal and often violent motor behaviors and complex vocalizations in which patients appear to enact their dreams while in REM sleep (Trotti, 2010). Skeletal muscles (except those innervating eye muscles and the diaphragm) are normally paralyzed during REM sleep (preventing dream enactment behavior). Skeletal atonia is normally present throughout a REM sleep period interrupted by intermittent phasic bursts of rapid eye movements and facial and limb phasic muscle twitches (Fig. 2). We differentiate but do not score phasic and tonic REM sleep in a PSG: so-called “tonic” REM sleep is characterized by an EEG background of low-voltage mixed frequencies (and sometimes diffuse alpha activity at frequency 1–2 Hz slower than the waking dominant posterior rhythm) and chin muscle atonia with superimposed periods of “phasic” REM sleep with runs or bursts of rapid eye movements, saw tooth waves, phasic muscle twitches, and irregular respiration (Fig. 3). The tonic and phasic components of REM sleep are markedly altered in patients with RBD, with partial or complete loss of tonic chin EMG atonia normally seen throughout a period of REM sleep and excessive amounts of phasic EMG activity in the chin and limb channels (Fig. 3).

TABLE 6. Emergence of Different Central Pattern Generators in Parasomnias and Nocturnal Frontal Lobe Epilepsy

<table>
<thead>
<tr>
<th>Central Pattern Generator Type</th>
<th>Range of Motor Behaviors</th>
</tr>
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<tbody>
<tr>
<td>Alimentary</td>
<td>Bruxism, chewing, swallowing, lip smacking</td>
</tr>
<tr>
<td>Defensive/predatory</td>
<td>Biting, teeth chattering, faciomandibular myoclonus</td>
</tr>
<tr>
<td>Emotional</td>
<td>Universal facial expression (fear) and encoded vocalizations</td>
</tr>
<tr>
<td>Locomotor</td>
<td>Pedaling (supine), tetrapod progression (prone), fugue (wandering), cyclic (periodic) leg movements, bimanual pedal activity</td>
</tr>
<tr>
<td>Copulatory</td>
<td>Repetitive pelvic thrusting</td>
</tr>
</tbody>
</table>

TABLE 7. Treatment Strategies for NREM Sleep Disorders of Arousal (DOA) in Adults

- Regular bed- and wake-times with adequate amounts of sleep
- Avoid sleep restriction, sleep deprivation, jet lag, and night or shift work
- Avoid visual, auditory, or tactile stimuli especially during the first third of the night which may trigger an event
- Decrease noise, light, pain, nocturia, or dyspnea, which may contribute to partial arousal
- Avoid extreme exercise, fatigue, and emotional or situational stress
- Search for and treat sleep apnea, restless legs, narcolepsy, and gastroesophageal reflux
- Avoid alcohol, antipsychotics, antidepressants, antihistamines, sedative-hypnotics, and benzodiazepines
- Clonazepam may cause excessive daytime sleepiness or disinhibition
REM sleep without atonia (RSWA) was first induced experimentally by making bilateral lesions in the dorsolateral pontine tegmentum of cats (Jouvet, 1965; Mahowald and Schenck, 2004). Depending on the size and extent of the brainstem lesions, the cats could stand, walk, attack, and “act out their dreams” during REM sleep, culminating in attack behaviors when they extended the lesions into midbrain interrupting amygdalar pathways. First described in humans by Schenck and Mahowald (Schenck et al., 1986), RBD is an uncommon condition diagnosed in 34 (4.8%) of 703 consecutive patients referred to a tertiary sleep center (Frauscher et al., 2010). Only 17% were referred specifically for suspected RBD, 60% only reported RBD symptoms when specifically questioned, and clinical RBD behaviors were incidentally found on video-PSG in 24% (Frauscher et al., 2010). Sleep-related injuries (bruises, abrasions, lacerations, fractures, choking episodes, running into walls or glass doors, and rarely subdural hematomas) to the patient or bed partner were the presenting complaint in 33% to 85% of patients with RBD (Olson et al., 2000; Schenck et al., 1989, 1993).

RBD usually presents after age 50, although any age group can be affected (Chiu et al., 1997). Chronic RBD most often affects older men: 87% of 93 consecutive patients with RBD seen at the Mayo Clinic over a 4-year period were men (Olson et al., 2000). A male predominance is observed in most other large case series (Iranzo et al., 2006; Postuma et al., 2009a; Schenck et al., 1996, 2003). Estimates of the prevalence of RBD in the general population range from 0.38% (Chiu et al., 2000) to 0.5% (Ohayon et al., 1997).

RBD can be idiopathic or secondary. Secondary RBD can be related to neurodegenerative disorders, other neurologic disorders, sleep disorders, or medications, including withdrawal states (Aurora et al., 2010). Symptomatic RBD in older adults is most often associated with an α-synucleinopathy, which manifests as dementia with Lewy Bodies (DLB), Parkinson’s disease (PD), or multiple system atrophy (MSA) (Boeve and Saper, 2006; Boeve et al., 2001, 2003, 2004, 2007; Gagnon et al., 2006a; Iranzo et al., 2006; Mahowald et al., 2007; Postuma et al., 2006b; Stiasny-Kolster et al., 2005; Weyer et al., 2006). Between 38% and 65% of patients with “idiopathic” RBD followed longitudinally subsequently developed an α-synucleinopathy 10 to 29 years after the onset of RBD (Iranzo et al., 2006; Postuma et al., 2009a; Schenck et al., 1996, 2003). Based on a prospective longitudinal study of 93 iRBD patients, Postuma et al. (2009) recently estimated that the 5-year risk of neurodegenerative disease was 18%, increasing to 41% and 52% at 10 and 12 years, respectively.

RBD is often the first clinical sign of an α-synucleinopathy, preceding other early nonmotor signs (olfactory dysfunction and depression) of Parkinsonism and/or dementia by years or decades (Boeve et al., 1998; Claassen et al., 2010; Iranzo et al., 2006; Postuma et al., 2009; Schenck et al., 1996). A recent retrospective study showed that RBD preceded other signs or symptoms of synucleinopathy by as long as 50 years (median interval 25 years) (Claassen et al., 2010). However, RBD behaviors that typically

FIGURE 2. A 30-second epoch of normal REM sleep characterized by intermittent phasic bursts of rapid eye movements, chin EMG atonia, an EEG background of low-voltage mixed frequencies and rare phasic muscle twitches.
appear early in the course of synucleinopathies may lessen or disappear later (Boeve et al., 1998; Bugalho et al., 2011). RBD can be misdiagnosed as sleep-related epilepsy, agitated sleepwalking, nocturnal panic attacks, nocturnal hallucinations, agitated delirium in intensive care units, sundowning, and/or intentional spouse abuse. Some patients with RBD also have OSA, nocturnal epilepsy, confusional arousals, and/or sleepwalking.

For example, dream enactment behavior during REM sleep can be observed in patients with severe OSA. Iranzo et al. reported 16 adults with severe OSA (mean AHI of 68 ± 19/hour) who were thought likely to have RBD because they complained of dream-enacting behaviors and unpleasant dreams (Iranzo and Santamaria, 2005). However, skeletal atonia was preserved during REM sleep in these patients with “pseudoRBD,” and CPAP therapy eliminated the abnormal behaviors, unpleasant dreams, daytime sleepiness, and snoring.

Epilepsy coexisting with RBD was found by Manni et al. (2007) in 10 (12.5%) of 80 older adults (mean age 71 ± 7 years, 47 men) with epilepsy. RBD episodes preceded seizure onset by 4.5 years in six subjects and followed it by 9.7 years in four. RBD has also been observed in 10% to 15% of patients with narcolepsy with cataplexy (Billiard, 2009; Dauvilliers et al., 2007; Schenck and Mahowald, 1992), and others have RSWA without clinical RBD (Dauvilliers et al., 2007). RBD in patients with narcolepsy needs to be distinguished from sleepwalking, PLMS, and abnormal dreaming, all more common in these patients. Medications prescribed to treat their cataplexy can induce or aggravate RBD.

**FIGURE 3.** These two 30-second epochs of PSG recorded during REM sleep illustrate characteristics of the two different substates of REM sleep. Phasic REM sleep is characterized by runs or bursts of rapid eye movements, saw tooth waves, phasic muscle twitches, and irregular respiration. Brief periods of phasic REM sleep are superimposed on tonic REM sleep with chin muscle atonia, and an EEG background of low-voltage mixed frequencies (and sometimes diffuse alpha activity at a frequency of 1–2 Hz slower than the waking dominant posterior rhythm). We recognize phasic and tonic sleep during a PSG but score all as REM sleep.
(Abril et al., 2007; Ahmed, 2008; Schenck and Mahowald, 1992). Suffice it to say, separating these out can be challenging.

**Clinical Semiology of REM Sleep Behavior Disorder**

RBD episodes usually appear in the first 90 minutes after sleep onset, typically last 1 to 5 minutes, and recur three to five times at 90- to 120-minute intervals across an entire night of sleep during recurring periods of REM sleep. As opposed to DoA, patients with RBD are easily aroused from an event. Once aroused, they are able to recount dreams (if not too demented), which correspond to the observed behaviors (Schenck et al., 1986, 1987). Their eyes are typically closed during events. Their heart rates do not increase during RBD events (perhaps reflecting loss of sympathetic autonomic regulation).

Motor behaviors during RBD dream enactment events are much more frequent than vocalizations (Iranzo et al., 2009). RBD motor behaviors can be simple (talking, shouting, and excessive jerking of limbs or body) or complex (arm flailing, slapping, kicking, sitting up, leaping from bed, running, crawling, gesturing, and swearing) (AASM, 2005). A case-control video-PSG study found that 75% of RBD motor events lasted <2 seconds, 83% were simple, 14% complex, 11% associated with vocalizations, and 4% violent in the patient with RBD. RBD averaged 54 ± 23 limb movements per 10 minutes of REM sleep compared with 4 ± 2 per hour in healthy age- and gender-matched controls. Motor behaviors during REM sleep in the control subjects were usually simple (91%). Some of the RBD events are enactment of nonviolent dreams with the patients singing, dancing, saluting, marching, clapping, or snapping their fingers (Oudiette et al., 2009).

RBD behaviors are often more plentiful and severe at the end of the night when REM sleep is most plentiful (Iranzo et al., 2009). Paroxysmal motor RBD behaviors were more likely to occur in phasic portions of REM sleep (when rapid eye movements and saw tooth waves are seen) rather than in tonic REM sleep (Manni et al., 2009). A case-control study of five PD patients with RBD found that limb jerking was the most common behavioral expression of RBD (Frauscher et al., 2007).

Speech in RBD events can vary from mumbling to logical sentences. A particularly interesting study by De Cock et al. (2007b) found that 38% of 53 PD patients moved much better and had louder more intelligible speech during their RBD episodes when awake. The authors speculated that improved motor and vocal abilities during RBD events may mean that the extrapyramidal system is bypassed in these patients during REM sleep. RBD is also a dream disorder: patients report that the content of their dreams become increasingly violent and disturbed. Their dreams often involve frighteningly unfamiliar people or animals, confrontation, attacking or chasing themes, and the behaviors often depict the sleeper depending himself. The personality, temperament, and behavior of RBD patients awake are discordant with their nocturnal aggressive behaviors.

**Video-Polysomnographic Features of REM Sleep Behavior Disorder**

Video-PSG confirmation of RSWA is required to diagnose RBD (Kushida et al., 2005). RBD is diagnosed by (1) excessive amounts of phasic and/or tonic submental and/or excessive phasic limb EMG activity during REM sleep on video-PSG; (2) the presence of abnormal REM sleep clinical dream enactment behaviors during video-PSG and/or a clinical history of sleep-related injurious, potentially injurious, or disruptive behaviors; and (3) exclusion of substance abuse; other medical, neurologic, psychiatric, or sleep disorder; or medication(s) that better explain the sleep disturbance (Aurora et al., 2010; Iber et al., 2007; Medicine, 2005; Walters et al., 2007).

To score excessive tonic and/or phasic EMG activity during REM sleep, we use scoring criteria published by the AASM in 2007 (Iber et al., 2007). A 30-second epoch of REM sleep is regarded as containing excessive tonic activity when the amplitude of the chin EMG is of higher amplitude than its lowest amplitude during NREM sleep for 50% or more the epoch (Fig. 3). Excessive phasic EMG activity in REM sleep is scored by subdividing the 30-second PSG epoch into 10 consecutive 3-second mini-epochs, identifying and tallying the number of 3-second mini-epochs that contain phasic EMG activity lasting 0.1 to 5.0 seconds, which is at least four times as high as the baseline EMG activity. If five or more 3-second mini-epochs of a 30-second epoch of REM sleep contain excessive phasic EMG activity, the REM sleep epoch is regarded as containing excessive phasic EMG activity (Fig. 4).

If a video-PSG contains excessive EMG activity during REM sleep but the patient has no clinical history suggestive of dream enactment behaviors and none seen on the PSG, we say that the PSG shows RSWA. Because many of the RBD motor and/or vocal behaviors usually last only a few seconds, we have found it particularly useful to review carefully epochs of REM sleep in the video-PSG when the excessive phasic motor activity is observed, confirming clinical manifestations of RBD that are easily missed. However, clinical confirmation of RSWA and/or RBD may be missed by a single night of video-PSG. Zhang et al. (2008) retrospectively analyzed video-PSG of 55 patients with RBD who have at least two consecutive video-PSGs. They found (1) weak first night effects with increased REM sleep latency, increased NREM 1 sleep, and increased mean number of arousals per hour of sleep (arousal index); (2) they could diagnose RBD in 95% of patients by recording and carefully analyzing the amounts of REM-related EMG activity, RSWA, and motor events observed on video-PSG; (3) no significant difference in the amounts of phasic and tonic EMG activity during REM sleep between nights 1 and 2 but dream enactment motor events varied between nights; (4) interstudy agreement were lowest for video analysis (kappa coefficients of 0.64, 0.51, and 0.31 between nights 1 and 2 for REM sleep-related EMG activity, RSWA, and video analysis); and (5) they were able to diagnose RBD even in patients with concomitant OSA, use of CPAP, or clonazepam treatment. Note that dream enactment behaviors are most susceptible to night-to-night variability, so a single night of video-PSG in a patient with no clinical history of RBD might be labeled only RSWA.

Patients with RBD characteristically exhibit excessive tonic activity in their chin EMG and/or excessive phasic activity in their chin and/or limb EMG. In routine PSG, we only record EMG from the chin and anterior tibialis leg muscles. We add surface EMG electrodes to the wrist extensors when recording patients with suspected RBD (Aldrich and Jahnke, 1991; Chesson et al., 1997; Frauscher et al., 2007; Kushida et al., 2005).

**Scoring REM Sleep in Patients With REM Sleep Without Atonia**

Epochs of REM sleep in a PSG is scored first and foremost by the presence of low or absent chin muscle activity, soon followed by rapid eye movements, saw tooth waves, and an EEG background of continuous low-amplitude mixed frequencies (Fig. 2). Burns et al. (2007) developed a computerized metric to assess chin EMG variance to confirm RSWA in patients with RBD. They thought that a normal chin EMG during REM sleep should be below the lowest 5% of its amplitude during NREM sleep.

We must score REM sleep in patients with RSWA and RBD “ignoring” the chin EMG: (1) the onset of a REM sleep period is identified by the first rapid eye movement in the presence of EEG activity typical of REM sleep (low-amplitude mixed frequencies and
absence of sleep spindles or K-complexes); (2) offset of REM sleep by a specific marker of another sleep stage (sleep spindle, K-complex, EEG arousal, or wakefulness) or the absence of rapid eye movements for 3 minutes; (3) if an epoch of REM sleep is disrupted by movement arousals or artifact, continue to score REM sleep as long as rapid eye movements, increased motor activity with erratic behavior, or incongruous vocalizations were used to identify reappearance of REM sleep if the EEG signals were consistent with REM sleep (low-voltage mixed frequencies) and alpha frequencies absent; and (4) if a patient has OSA fragmenting REM sleep by excluding EMG increases from respiratory-induced arousals and snoring artifacts (Dauvilliers et al., 2007; Iranzo and Santamaria, 2005; Lapierre and Montplaisir, 1992).

Which Muscles Should We Record to Identify REM Sleep Without Atonia in a Polysomnogram?

Unfortunately, the AASM rules for scoring RSWA and clinical RBD in a PSG do not specify which (and how many) skeletal muscles should be recorded during a video-PSG to confirm RBD or RSWA. Recent studies show that excessive phasic EMG activity and RSWA during REM sleep is (1) more frequent in distal than proximal limb muscles; (2) more frequent in upper limbs than lower limbs; and (3) RSWA cannot be scored based on chin EMG alone but requires recording and scoring of excessive phasic EMG activity in the upper and lower distal limb muscles.

Frauscher et al. (2008) recorded 13 different muscles in 17 RBD patients (9 with PD) to determine which combination of muscles provides the highest rates of phasic EMG activity during REM sleep in patients with RBD. They found that the greatest amounts of excessive phasic EMG activity during REM sleep was observed in the mentalis, flexor digitorum superficialis, and extensor digitorum brevis muscles. This combination of muscles detected 82% of all mini-epochs containing phasic EMG activity while only 55% of excessive phasic activity would be scored if only the chin EMG was recorded.

Bliwise and Rye (2008) recorded EMG activity from five muscle groups (mentalis, left/right anterior tibialis, and left/right brachioradialis) in 11 patients with RBD compared with 31 elderly controls (without RBD or PLMS). They found that the greatest amounts of excessive phasic EMG activity during REM sleep in patients with RBD compared with healthy older controls were recorded from the mentalis and brachioradialis muscles.

When Is the Lowest Percentage of Excessive Muscle Activity in a Polysomnogram Considered REM Sleep Without Atonia?

The AASM rules for scoring RBD and RSWA in a PSG only specify what constitutes excessive tonic or phasic EMG activity in a 30-second epoch of REM sleep (Burns et al., 2007; Fantini et al., 2005; Ferri et al., 2008; Frauscher et al., 2007; Mayer et al., 2008; Sforza et al., 1997). In defense of this omission, there was simply no enough evidence (or even expert consensus) available to write a rule for this. However, recently published studies are providing evidence to guide us.

Montplaisir et al. (2010) retrospectively reanalyzed video-PSG data in 80 patients with idiopathic RBD and 80 age- and gender-matched controls. Clinical RBD by history was confirmed in the video-PSG in 82%. Based on the case-control data, they were able to draw receiver operating characteristic curves for each of the REM sleep EMG parameters to determine cut-off values showing the highest sensitivity and specificity in discriminating RBD patients from controls. They found a tonic chin EMG density (percentage of 2-second mini-epochs of REM sleep) ≥30%, phasic chin EMG.
density $\geq 15\%$, and $\geq 24$ leg movements per hour of REM sleep would correctly identify RBD in $82\%$ of their 80 patients but misidentified it in one control. Five patients with RBD by history and on video-PSG did not fulfill any of these PSG criteria. Unfortunately, this study collected from earlier studies could not provide crucial cut-off values for the upper limits, which in other studies show the most plentiful excessive phasic activity during RSWA and RBD. They also found no between-group differences in sleep architecture with comparable values for total sleep time, sleep efficiency, REM sleep percent, efficiency, and mean number of rapid eye movements per epoch of REM sleep (REM density).

Montplaisir et al. emphasized that their data showed an absence of a bimodal distribution, which suggests the loss of skeletal muscle atonia and/or the increase of excessive phasic activity during REM sleep in RBD represents a continuous process reflecting underlying disease progression. Supporting this contention, Iranzo et al. (2009) found that the percentages of excessive muscle activity in mentalis, biceps brachii, and anterior tibialis muscles during REM sleep was significantly greater in all five muscles recorded in 11 patients with idiopathic RBD when a second PSG was recorded a mean of 5 years later. Chin tonic EMG activity alone increased from 30% to 54% (Iranzo et al., 2009).

Consens et al. (2005) used computerized quantitative analysis techniques to identify and compare EMG activity from submentalis, forearm extensors, and anterior tibialis muscles in 9 patients with possible or probable RBD and 14 controls. They tallied the percentage of 30-second REM epochs with at least 15 seconds of tonic EMG activity and the percentage of 3-second REM mini-epochs that contained phasic EMG bursts from chin and bilateral surface EMG from the electrodes placed over the forearm extensors and anterior tibialis from two or more consecutive PSGs for each subject. They further devised an “RBD PSG score,” which was a combined measure of the proportion of 30-second epochs of REM sleep containing elevated muscle tone and the measure for the proportion of 3-second mini-epochs containing burst activity. Of note, the abnormalities found on the first night of PSG confirming RBD correlated well with those found on the second night ($p > 0.70$, $P < 0.0001$), confirming again that the RSWA seen in one night of PSG is more often comparable to that seen the next night.

They found the mean percentage ($\pm$SD) of REM sleep epochs containing excessive tonic chin EMG activity were $29\% \pm 19\%$ in those with RBD compared with $22\% \pm 18\%$ in the controls. The mean percentage of 3-second mini-epochs of REM sleep containing phasic EMG activity was $50\% \pm 41\%$ in the patients versus $30\% \pm 38\%$ in controls. The mean PSG RBD scores were $40\% \pm 22\%$ in those with RBD compared with $26\% \pm 24\%$ in controls ($P = 0.02$). Consens et al. suggested that $\geq 10\%$ of REM sleep spent with elevated EMG tone or phasic burst activity would confirm a diagnosis of clinical RBD (based on the receiver-operator curves), providing a sensitivity of $89\%$ but a specificity of only $57\%$.

Ferri et al. have developed a “REM sleep atonia index (RAI)” to identify abnormally elevated submental muscle amplitude during REM sleep in patients with idiopathic RBD, narcolepsy with cataplexy (with and without RBD), and normal age-matched controls using computerized quantitative analysis (De Carli et al., 2004; Ferri et al., 2008, 2010). They define RAI as the ratio between the percentage of EMG 1-second mini-epochs with average amplitude $\leq 1$ $\mu$V and the total mini-epochs (excluding those with $1 < \text{amplitude} \leq 2$ $\mu$V). Mathematically, the RAI can vary from 0 (absence of mini-epochs with amplitude $\leq 1$ $\mu$V and consistent with complete RSWA), to 1 (stable EMG atonia).

After correcting for signal noise, they report that RAI values $<0.8$ were strongly indicative of RSWA, values 0.8 to 0.9 less evident (and often seen in older but not young controls), and $>0.9$ present in majority of controls. Three-fourths of their subjects with idiopathic RBD had RAI $<0.9$, and all with RBD and MSA had RAI $<0.8$. In another study, Ferri et al. (2008) found that RAI was lower (greater percentage of REM sleep with excessive tonic chin EMG) in 34 patients with narcolepsy with cataplexy compared with age-matched normal controls. Seventeen of the patients with narcolepsy had PSG-confirmed RBD. Those with RBD had more phasic chin EMG activity than those without RBD, but the elevated tonic chin EMG values did not differ between those with and without RBD.

**Symptomatic Forms of REM Sleep Behavior Disorder**

Frauscher et al. (2010) found RBD in 34 (4.8%) of 703 consecutive patients referred to a tertiary sleep center. RBD was idiopathic in 11 patients and symptomatic in 23; causes of symptomatic RBD were parkinsonian syndromes in 11, antidepressants in 7, narcolepsy with cataplexy in 4, and pontine infarction in 1. Using logistic regression analysis, the investigators found that the presence of a parkinsonian syndrome increased the odds ratio a patient would have RBD by 16.8 times, narcolepsy with cataplexy (odds ratio 10.7). The odds ratio of RBD increased 1.5 years for every 10-year increase. However, secondary RBD can also develop in patients with neurologic disorders that are not synucleinopathies and have been observed in patients with brain lesions that most often involve the pontine tegmentum. Table 8 summarizes other neurologic and neurodegenerative disorders and medications associated with chronic RBD. Because the frequency of RBD is so much greater among patients with DLB, MSA, and PD with dementia, we cite the medical literature regarding this in these patient populations.

**Dementia With Lewy Bodies**

DLB is the second most common late-life dementia and probably accounts for approximately 20% of all late-onset dementias, 10% to 15% at autopsy (McKeith et al., 2005). RBD occurs in 50% to 80% of patients with DLB (Boeve et al., 2004). The percentage of patients with DLB who have RBD is likely to be greater than reported because many patients deny having it. One study found 59% of 17 patients with video-PSG-confirmed RBD were unaware of their RBD behaviors and 18% could not recall

<table>
<thead>
<tr>
<th>TABLE 8. Other Neurological Disorders Associated With REM Sleep Behavior Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narcolepsy with cataplexy (10%–15%, others have RSWA without clinical RBD) (Billiard 2009; Dauvilliers et al., 2007; Schenck and Mahowald 1992)</td>
</tr>
<tr>
<td>Parkinson’s disease due to Parkin mutations (10%–15%) (Iranzo et al., 2005; Plazzi et al., 1998; Tachibana and Oka, 2004)</td>
</tr>
<tr>
<td>Paraneoplastic limbic encephalitis with voltage-gated potassium channel antibodies (five cases) (Iranzo et al., 2003)</td>
</tr>
<tr>
<td>Guadalpean Parkinsonism (78%) (De Cock et al., 2007a; Iranzo et al., 2009)</td>
</tr>
<tr>
<td>Progressive supranuclear palsy (&lt;5%) (Arnulf et al., 2005; Cooper and Josephs, 2009; Montplaisir et al., 1997; Pareja et al., 1996)</td>
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<tr>
<td>Huntington’s disease (12%) (Arnulf et al., 2008)</td>
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<tr>
<td>Spinocerebellar ataxia type 3 (Friedman et al., 2005; Iranzo et al., 2003; Syed et al., 2003)</td>
</tr>
<tr>
<td>Pure autonomic failure (Weyer et al., 2006)</td>
</tr>
<tr>
<td>Chiari malformations (20%) (Henriques-Filho and Pratesi, 2008)</td>
</tr>
<tr>
<td>Structural lesions most often involving the pontine tegmentum (Kimura et al., 2000; Plazzi and Montagna, 2002; Tippmann-Peikert et al., 2006) Ischemic infarction, multiple sclerosis, brain stem tumor, trauma, or surgery</td>
</tr>
</tbody>
</table>

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unpleasant dreams (Iranzo et al., 2009). A diagnosis of RBD in a patient with Parkinsonism or dementia warrants consideration of DLB. Diagnostic criteria for probable DLB is suggested by the presence of dementia and RBD with at least one of the three core features of visual hallucinations, fluctuating cognition, or Parkinsonism (McKeith, 2006).

Recognizing DLB is clinically important because patients with it often have (1) an extreme sensitivity to the side effects of neuroleptics; (2) a good response to cholinesterase inhibitors; and (3) their episodes of disturbed consciousness or “delirium” misdiagnosed. DLB tends to have a more rapid progression than Alzheimer’s disease (mean survival 8 ± 3 years) and two-thirds are men (in contrast to the predominance of Alzheimer’s disease in women (McKeith et al., 2005). Consider DLB in patients who have unexplained recurrent delirium, episodic disturbances of consciousness, syncope, and sleep disorders.

**Parkinson’s Disease**

RBD occurs in approximately 15% to 50% of patients with PD (Comella et al., 1998; De Cocks et al., 2008; Gagnon et al., 2002; Lee et al., 2009). Another third of PD patients have RSWA on their PSG without any clinical history of RBD behaviors or symptoms (Gagnon et al., 2002). RBD may be even more common in PD because 65% were unaware of their RBD symptoms and 24% did not recall violent dreams (Iranzo et al., 2005).

Recent studies suggest that PD patients with RBD may have a different neurodegenerative profile than those without RBD (Bliwise et al., 2010; Bugallo et al., 2011; Kumru et al., 2007; Postuma et al., 2008). PD patients with RBD were (1) more likely to have rigid-akinetic PD and less likely to have tremor-predominant PD (Bliwise et al., 2010; Bugallo et al., 2011; Kumru et al., 2007; Postuma et al., 2008); (2) more often were older, had a longer duration of PD, and were more disabled (Lee et al., 2010); and (3) have orthostatic hypotension (71% compared with 27%, without RBD) (Postuma et al., 2008).

A few studies have examined whether sleep architecture and phasic EMG activity is different in PD patients with rigid-akinetic and tremor-predominant forms, especially because RBD is much more likely to develop or be present in those with rigid-akinetic PD. Higher percentages of excessive phasic EMG activity during REM and NREM sleep were found in patients with rigid-akinetic PD compared with tremor-predominant PD (Bliwise et al., 2010). PD patients with RBD are more likely to have slowed EEG backgrounds when awake compared with PD patients without RBD (Gagnon et al., 2004) and poorer performance in executive function, verbal memory, and visuospatial dysfunction on neuropsychological testing than PD without RBD (Vendette et al., 2007).

**Multiple System Atrophy**

RBD is often the initial symptom of MSA (Tison et al., 1995). Clinical RBD was reported in 69% of 39 consecutive cases of MSA, and 90% had RSWSA on their video-PSG (Plazzi et al., 1997). As MSA patients with RBD are often unaware of their RBD behaviors or disturbing dreams, the percentage of MSA with clinical RBD may be underestimated without video-PSG (Tachibana and Oka., 2004). RBD is a red flag for the diagnosis of MSA (Köllensperger et al., 2008).

Consider MSA in a RBD patient who has axial rigidity (less often a jerky postural tremor) and a history of (1) symptomatic orthostatic hypotension or urinary incontinence beginning <1 year after the onset of the Parkinsonism; (2) early postural instability and falls <3 years after onset; and (3) rapid progression to wheelchair within <5 years despite dopaminergic therapy (Iranzo et al., 2005; Köllensperger et al., 2008; Plazzi et al., 1997). Consider MSA in any older woman who has or develops RBD because no gender predominance is observed in MSA. MSA patients with RBD on video-PSG had higher percentages of RSWA, greater periodic limb movement indexes, and less total sleep time when compared with PD patients with RBD (Iranzo et al., 2005). Some of the highest percentages of RSWA are observed in patients with MSA.

**Treatment Strategies for REM Sleep Behavior Disorder**

The first step in the treatment of RBD is to remove drugs that can precipitate or worsen it. Drugs used to treat depression or anxiety which have been reported to cause or worsen RBD include paroxetine, fluoxetine, imipramine, venlafaxine, and mirtazapine (Onofri et al., 2003; Parish, 2007; Schenck et al., 1992; Schutte and Doghramji, 1996; Teman et al., 2009). Fluoxetine or sodium oxybutyrate is used to treat cataplexy in patients with narcolepsy with cataplexy and can induce or aggravate their RBD (Ablil et al., 2007; Ahmed, 2008; Schenck and Mahowald, 1992). Other drugs that have been reported to cause RBD include bisoprolol (a beta-blocker), rivastigmine, and withdrawal from alcohol or barbiturates, but all of these are based solely on case reports (Aurora et al., 2010b; Iranzo and Santamaria, 1999; Yeh et al., 2010).

Many drugs do seem to increase EMG activity in PSG, worsen symptoms of restless legs syndrome and PLMS, and cause or exacerbate RBD and/or RSWSA. Hoque and Chesson (2010) recently analyzed evidence for drugs causing excessive EMG activity in patients with restless legs, periodic limb movements, RBD, and RSWSA. They found that the strongest evidence for drug-induced restless legs syndrome were for escitalopram, fluoxetine, t-dopa/carbidopa, pergolide, t-thyroxine, mianserin, mirtazapine, olanzapine, tramadol, bupropion, clomipramine, fluoxetine, paroxetine, sertraline, and venlafaxine for periodic limb movements and clomipramine, selegiline, and phenelzine for drug-induced RBD/RSWA.

If a drug that is aggravating RBD cannot be discontinued (too often the case in patients with concomitant depression treated with venlafaxine or a selective serotonin reuptake inhibitor), try reducing the daily dose. Consider prescribing bupropion to treat depression in patients with RBD because it does not worsen RBD, restless legs syndrome, or PLMS (Kim et al., 2005; Lee et al., 2009; Nozinger et al., 2000; Yang et al., 2005).

The next step in treating RBD is to secure the bedroom and protect the patient and bed partner from injury. Safety measures to protect the patient and bed partner from RBD behaviors include padding bedrails, pillow or plastic screen barricades, pad sharp corners and move furniture away from the bed, remove dangerous objects from bedroom, locks on doors and windows, motion-detected alarms, and consider having the patient sleep on a mattress on the floor or in another bedroom (Abad and Guillemainault, 2004; Olson et al., 2000; Schenck and Mahowald, 1991). Of note, maternal restraints should not be used because sudden twisting movements during RBD events may lead to greater injury (Aurora et al., 2010).

RBD warrants pharmacotherapy to (1) prevent injuries in patients with violent dream enactment; (2) reduce the intensity of the unpleasant dreams; and (3) permit the bed partner to sleep safely and comfortably near the patient (Aurora et al., 2010). Unfortunately, there are no randomized, double-blind controlled or head-to-head clinical trials of pharmacologic therapy for RBD. Most often clonazepam or melatonin (and sometimes in combination) are prescribed to treat RBD.

Small case series and case reports have found clonazepam effective in treating RBD in the majority (90%) of patients (Comella et al., 1998; Fantini et al., 2005; Gagnon et al., 2006b; Iranzo et al., 2005, 2009; Massironi et al., 2003; Nomura et al., 2003; Olson et al.,
2000; Schenck and Mahowald, 1996; Schenck et al., 1987). Clonazepam (0.25–4 mg before bed, mean dose 1 mg) usually decreases the frequency and severity of both dream enactment behaviors and unpleasant dream recall within the first week of treatment without loss of effectiveness or the development of tolerance over time. Clonazepam has an elimination half-life of 30 to 40 hours, and maximum plasma concentrations occur within 1 to 4 hours after oral ingestion (Anderson and Shneerson, 2009). Even if the RBD behaviors are suppressed, RSWA usually remains on the video-PSG. Clonazepam suppresses the clinical RBD behaviors but does not improve RSWA or alter sleep architecture (Lapierre and Montplaisir, 1992; Schenck and Mahowald, 1990). Holding clonazepam for a single night in hospitalized RBD patients or periodic attempts to taper clonazepam have been shown to result in an almost immediate recurrence of dream enactment behaviors (Schenck and Mahowald, 1991, 1996). However, dream enactment and sleep-related injuries often decrease or disappear late in the course of the disease progression, permitting us to discontinue pharmacotherapy altogether. Clonazepam to treat RBD is often limited by side effects: sedation especially upon awakening, early morning clumsiness, impotence, and confusion (Olson et al., 2000; Schenck and Mahowald, 1990, 1996). Clonazepam taken only at night can cause memory or word-finding difficulties, depression, disinhibition, and if the dose is too low may trigger sleepwalking/sleep terrors or confusional arousals, especially in older adults with or without dementia. Clonazepam is relatively contraindicated in patients with a history of substance or alcohol abuse, untreated sleep disordered breathing, cognitive or motor dysfunction, or a nocturnal dissociative disorder; and it should be used with caution in patients with dementia, gait disorders, or concomitant OSA, all of which develop in varying degrees over the clinical course of RBD (Ferman et al., 1999).

We have begun to prescribe melatonin first in patients with RBD because it is often just as effective and has far fewer side effects than clonazepam. Oral exogenous melatonin (3–12 mg before bed) has been shown to suppress RBD behaviors (Boeve et al., 2003; Kunz and Mahlberg, 2010; Kunz et al., 2004; Takeuchi et al., 2001) and even decrease (but not eliminate) the number of 30-second REM sleep epochs of RSWA and movement time during REM sleep (Kunz and Bes, 1999; Kunz et al., 2004; Takeuchi et al., 2001). Side effects reported when melatonin is prescribed for RBD include morning headache, morning sleepiness, delusions, or hallucinations (Boeve et al., 2003). The AASM best practice guideline argues that melatonin may be a better first choice of a medication to treat RBD than clonazepam because it has far fewer effects (Aurora et al., 2010).

The first double-blind, placebo-controlled trial of exogenous melatonin to treat RBD was recently published (Kunz and Mahlberg, 2010), but the study population consisted of only eight consecutively recruited males with RBD (mean age 54 years). Subjects received 3 mg of melatonin or placebo between 2200 and 2300 hours over a 4-week period. Compared with baseline, melatonin significantly decreased the number of 30-second REM sleep epochs of RSWA (39% vs. 27%, P = 0.012). Of interest, the number of REM sleep epochs of RSWA remained lower in patients who then were crossed over to placebo (–16% compared with baseline, P = 0.043). RBD in some patients with PD or DLB may respond to treatment with pramipexole (a dopamine receptor agonist) or rivastigmine (a reversible acetylcholinesterase inhibitor) (Fantini et al., 2003; Kumru et al., 2008; Schmidt et al., 2006), although these medications can paradoxically activate RBD in others (Comella et al., 1993; Fantini et al., 2003; Kumru et al., 2008; Schmidt et al., 2006; Tan et al., 1996; Yeh et al., 2010).

**FUTURE DIRECTIONS**

Much more research and knowledge is needed to better understand (1) the mechanisms that underlie cortical excitation during or from sleep in patients with sleep-related episodes; (2) the role of sleep in sudden unexpected death in patients with epilepsy; (3) the influence of circadian rhythms and chronotypes on different epilepsy syndromes; (4) whether IEDs and seizures when sufficiently frequent impair long-term development and cognitive functioning in neonates and children; (5) whether treating OSA in patients with epilepsy improves seizure control; (6) why is sleep macro- and microarchitecture altered in patients with epilepsy; and (7) the link between particular epilepsies, nonepileptic parasomnias, sleep fragmentation, and arousal to understand how to best improve overall function and that a multidisciplinary model will best serve patients with these disorders.

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“Treatment of Major Depressive Disorder in the Patient-Centered Medical Home”

by

Dion Gallant, MD

Dion Gallant, MD was raised in Albuquerque where he graduated from Eldorado High School in 1988. He then attended Georgetown University, graduating in 1992 with a degree in history. Pre-med work was done at University of Colorado at Boulder and medical school and residency were done at UNM. As a medical student, Dr. Gallant received the Khatali Alumni Association Outstanding Medical Research Award and in residency he received the Society of Teachers of Family Medicine Resident Teaching Award. Dr. Gallant enjoys patient-centered collaborative primary care. He joined Presbyterian Kaseman Family Healthcare in 2002 and currently works for the Presbyterian Medical Group as the Medical Director for Primary Care. He is Past President of the NMAFP and of the Greater Albuquerque Medical Association. He continues to represent NM at the national Academy of Family Physicians Congress of Delegates. He serves on the PMG Executive Council, The GAMA Board of Directors, the NM Medical Society Board of Directors and the PHS Board of Directors Quality subcommittee. His hobbies include travel, hiking, skiing, woodworking, playing guitar, listening to university courses on CD, and spending time with his family. He has traveled extensively in Mexico and Latin America and speaks Spanish.

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Learning Objectives

At the end of this presentation, the attendee will be able to:

- Describe the DSM-5 Diagnostic criteria for Major Depressive Disorder (MDD)
- Describe the current understanding of MDD as a bio/psycho/social illness
- Describe the serotonergic system and its role in MDD
- Describe the overall efficacy rates for current MDD treatments and the continuing unmet needs for new treatment options
- Select appropriate pharmacologic and non-pharmacologic therapies for patients with MDD
- Be able to assess and, if necessary, treat residual symptoms of MDD
- Recognize the significant potential differences in presentation, treatment responsiveness, and presence of comorbidities and/or Polypharmacy that may exist in older adults with MDD compared with younger adults
- Describe the principles of patient-centered, collaborative care in the treatment of patients with MDD to improve adherence to therapy, and overall quality of care
Disclosures

Dr. Gallant has indicated he has nothing to disclose relevant to this presentation.

Learning Objectives

At the conclusion of this program you should be able to:

1. Describe the current understanding of MDD as a bio-psychosocial illness
2. Describe the serotonergic system and its role in MDD
3. Describe the DSM-5 diagnostic criteria for MDD

Learning Objectives (Con’t)

At the conclusion of this program you should be able to:

4. Select appropriate pharmacologic/non-pharmacologic therapies for patients with MDD and monitor treatment efficacy
5. Assess for, and, if necessary, treat residual symptoms of MDD
6. Recognize significant potential differences in presentation and treatment response that may exist in older adults with MDD compared with younger adults

Unique Opportunity
To Register:

- See course representative at the back of the room
- Register yourself – The URL is listed on the session poster

Overview

- A minority of those with MDD are adequately treated
- PCPs manage roughly \( \frac{1}{3} \) to \( \frac{1}{2} \) of depressed younger adults and nearly \( \frac{2}{3} \) of depressed older adults
- As a bio-psychosocial disorder, MDD is most effectively treated with a multi-modal approach that includes non-pharmacological strategies
- The PCMH model can be more effective than usual care for the management of MDD

The Reality of Depression

“That the word ‘indescribable’ should present itself is not surprising, since it has to be emphasized that if the pain were readily describable most of the countless sufferers from this ancient affliction would have been able to confidently depict for their friends and loved ones (even their physicians) some of the actual dimensions of their torment.”

MDD: Under-recognized & Under-treated

14 million U.S. adults

- 7.2M treated
- 6.8M untreated

3.2M inadequately treated

4M poorly served

Inadequate response

Intolerant to side effects

Etiology

- Depression recognized since ancient times
- Early 20th century: Adolf Meyer coins “psychobiology”
- Freud’s psychotherapeutic perspective
- 1950s: rise of biogenic amine theory
- Late 20th century: serotonin hypothesis
- Stress cortisol hypothesis

Etiology—Current Understanding

- Many non-monoaminergic molecular mechanisms are being explored
- NMDA antagonists show rapid alleviation of depressive symptoms
- Depression is a highly heterogeneous condition with multiple and complexly-interacting etiologies
MDD in Context of DSM-5

- Disruptive mood dysregulation disorder
- Major Depressive Disorder
- Persistent Depressive Disorder (formerly dysthymia)
- Premenstrual dysphoric disorder
- Substance/medication-induced depressive disorder
- Depressive disorder due to another medical condition
- Unspecified depressive disorder

Bipolar disorders are not included with depressive disorders in DSM-5

DSM-5 and Bereavement

- The “Bereavement Exclusion” was eliminated in DSM-5 because:
  - Normal grief often lasts longer than 2 mo.
  - Bereavement may precipitate a major depressive episode in vulnerable individuals
  - Bereavement-related depression responds to the same psychosocial and medication Tx as non-bereavement-related depression

Screening & Assessment of MDD

- PHQ-2: two simple questions about mood and anhedonia
  - 38% positive predictive value
  - 93% negative predictive value
- PHQ-9 commonly used for confirmation
  - 2-5 minutes to complete
  - 61% sensitivity
  - 94% specificity

DSM-5 Diagnostic Criteria for MDD

Depressed mood or anhedonia + 4 or more symptoms most of the day, nearly every day, during a 2 week period:

- Significant weight loss (when not dieting), or weight gain, or a marked increase or decrease in appetite nearly every day
- Excessive sleepiness or insomnia
- Agitation and restlessness
- Fatigue
- Feelings of worthlessness or excessive and inappropriate guilt nearly every day
- Diminished ability to think, concentrate, or make decisions
- Recurrent thoughts of death or suicide

Differential Diagnosis

Symptoms of depression can be caused by:

- Unrecognized thyroid disease
- Structural brain diseases such as stroke or tumor
- Parkinson’s disease
- Metabolic conditions (e.g., vitamin B12 deficiency)
- Infections (e.g., HIV)
- Certain cancers (e.g., pancreatic cancer)

Differential Diagnosis

- Alcohol
- Amphetamines
- Antihypertensive drugs
- Barbiturates
- Benzodiazepines
- Beta-adrenergic blockers
- Chemotherapy agents
- Cimetidine
- Corticosteroids
- Metronidazole
- Fluoroquinolone antibiotics
- H2-receptor antagonists
- Opioid pain medications
- Oral contraceptives
- Transplant anti-rejection agents
Depression & Dementia

- Patients in early phase of dementia may present with signs of depression
- Patients who are depressed may be misdiagnosed as having dementia
- Clinical features can help distinguish MDD from dementia:
  - On cognitive tasks, depressed patients generally exert less effort and report greater incapacity than patients with dementia
  - Depressed patients are more likely to report being unable to think or remember
- If in doubt, consult a specialist in geriatric psychology

Evaluating Suicide Risk

- Suicide risk factors:
  - Male gender, especially age ≥ 60
  - Being single or living alone
  - Prominent feelings of hopelessness
  - Psychotic features
  - Other significant psychiatric disorders
  - Access to means of suicide and the lethality of those means
  - Alcohol or other substance use

Phases of Treatment

![Phases of Treatment Diagram](Image)

MDD Treatment Overview

Treatment goal: full remission of symptoms and restoration of psychosocial functioning

- Choice of initial approach depends on the severity and nature of the symptoms
- Options include:
  - Psychotherapy
  - Pharmacotherapy
  - Somatic therapies (e.g., exercise, light therapy, electroconvulsive therapy, other devices)

The Value of Psychotherapy

- Mild-to-moderate MDD - psychotherapy may be as effective as pharmacotherapy
- Psychotherapy can play a vital supporting role for more serious forms of MDD
- Different forms of psychotherapy may help address complications such as addiction or difficulty with interpersonal relationships
- Rebuilding lives often requires treating complex emotional and lifestyle issues
- Greater psychological resilience cannot be obtained by a medication

“Prescribing” Psychotherapy

- Solid evidence supports the following types of therapy for MDD:
  - Cognitive-behavioral therapy (CBT)
  - Interpersonal psychotherapy (IPT)
  - Behavioral activation (BA)
- However, one meta-analysis found no large differences in long-term efficacy between 7 common types of psychotherapy
- Psychotherapies generally have longer-lasting effects than antidepressants

Pharmacotherapy for MDD

- Antidepressants are:
  - An option for mild-to-moderate MDD
  - Recommended for moderate-to-severe MDD (unless patient is expected to undergo ECT)

- Decision must be weighed carefully because:
  - Side effects may occur
  - Average efficacy is relatively modest
  - Discontinuation is seldom as easy as initiation

Lessons From STAR*D


Lessons From STAR*D

Choosing an Antidepressant

Factors to consider
- Side effect profile
- Patient preference
- Nature of prior response to medication
- Safety and tolerability
- Co-occurring psychiatric/general medical conditions
- Potential drug interactions
- Half-life
- Cost

Selective Serotonin Reuptake Inhibitors

Currently-available SSRIs:
- Fluoxetine (Prozac)
- Sertraline (Zoloft)
- Paroxetine (Paxil)
- Fluvoxamine (Luvox)
- Citalopram (Celexa)
- Escitalopram (Lexapro)
- Vilazodone (Viibryd)
- Vortioxetine (Brintellix)
Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)
Currently-available SNRIs:
• Venlafaxine (Effexor, Efexor)
• Desvenlafaxine (Pristiq)
• Duloxetine (Cymbalta)

Dopamine-Norepinephrine Reuptake Inhibitors (DNRI)
Currently-available DNRI:
• Bupropion (Wellbutrin)

Other Antidepressants
Currently-available:
• Mirtazapine (Remeron, others)
• Nefazodone (available as generic)
• Trazodone (Desyrel, others)

Combination Treatment
• Adding a second antidepressant of a different class can be beneficial
• Most commonly-studied combination is an SSRI with a TCA
• Some studies have found benefit with combination of an SSRI with venlafaxine, bupropion, or mirtazapine

Adjunctive Agents
• Lithium
• Thyroid hormone supplementation (even in euthyroid patients)
• Atypical antipsychotics
• Psychostimulants

Treatment-Resistance/Residual Symptoms
Contributing Factors
• Patient—non adherence
• Inadequate treatment
• Undesirable/intolerable side effects
• Genetic variations in drug responses
• Incorrect diagnosis
• Comorbid substance abuse; comorbid personality disorder; history of physical, sexual, or emotional abuse
• Cognitive impairment; neurological disease
• Biological treatments do not address all symptoms or all types of depression

Strategies To Address Treatment-Resistance/Residual Symptoms

- Look for environmental/social stresses that might be exacerbating/contributing to symptoms
- Consider optimizing (typically raising) medication dose or intensity of psychotherapy
- Re-screen for substance use, bipolar, and anxiety disorders
- Switch to a different antidepressant
- Augment with another medication
- Change to/augment with psychotherapy
- Consider psychiatric consultation

Biomedical Devices for MDD

- Electroconvulsive Therapy
- Transcranial Magnetic Stimulation
- Vagus Nerve Stimulation

Patient-Centered Management of MDD

Supportive data from:
- PRISMe study
- Nurse Telehealth study
- IMPACT study

Mental health professionals can be integrated into practice by:
- Hiring a psychiatric nurse practitioner, either full or part-time
- Using “physician extenders” such as mental health social workers, psychologists, or counselors

Case Study #1: Marquesa

Age: 42
BMI: borderline underweight
PHQ-9 score: 11
Non-smoker, moderate alcohol (~1-2 drinks/day)
Complaint: weight loss, “ataque de nervios”
Notes: takes “herbs” for symptoms

Question 1: Which of the following would not be recommended as a next step?

A. Administer the PHQ-2 or PHQ-9 in either English or Spanish, depending on patient preference
B. Take a detailed psychosocial history
C. Prescribe an SSRI antidepressant with a relatively long half-life
D. Provide a patient-education handout about depression in either English or Spanish, depending on patient preference

Answer: C

Case Study #1: Marquesa

Question 1: Which of the following would not be recommended as a next step?

A. Administer the PHQ-2 or PHQ-9 in either English or Spanish, depending on patient preference
B. Take a detailed psychosocial history
C. Prescribe an SSRI antidepressant with a relatively long half-life
D. Provide a patient-education handout about depression in either English or Spanish, depending on patient preference

Answer: C
Case Study #1: Marquesa

- You provide advice about nutrition, exercise, sleep, and avoiding alcohol. Ask her to return in 4 weeks
- Marquesa is subdued. Reports marital problems
- Supplement she takes contains ephedra
- You recommend:
  - Consult with psychiatric nurse
  - Stopping supplement
  - Generic citalopram, 20 mg/day

Discussion Questions
1. What cultural barriers might exist that could affect Marquesa’s ability to adhere to the medication regimen?
2. What kinds of follow-up attention could you or a “physician extender” provide to support Marquesa?
3. What behavioral counseling recommendations could you make?

Case Study #1: Marquesa

- Rx refill because husband flushed her medications down the toilet
- At 5 weeks, Marquesa appears more energetic, but struggling
- Asks for a sleeping pill

Question 2: Which of the following would be an appropriate way to respond to Marquesa’s request?
A. Switch from citalopram to trazodone
B. Suggest she try over-the-counter melatonin and advise about sleep hygiene
C. Prescribe zolpidem 5 mg/prn
D. Lower the dose of citalopram

Answer: B

Case Study #2: Flora

Age: 71
BMI: normal
PHQ-9 score: 16
O₂ saturation: normal
Complaint: Diffuse aches and pains; fatigue
Co-morbid conditions: COPD
Medications:
- ✔️ Long-acting inhaled anticholinergic
- ✔️ Short-acting beta-agonist
Case Study #2: Flora

Question 1: Which of the following might be a reasonable first choice of antidepressant for this patient?

A. Phenelzine
B. Imipramine
C. Nefazodone
D. Fluoxetine

Answer: D

Case Study #2: Flora

Case Study #2: Flora

Case Study #2: Flora

Case Study #2: Flora

Case Study #2: Flora

Conclusions

1. MDD is a challenge and an opportunity for family physicians, who manage more than half of adults treated for MDD

2. Management of MDD in the context of a PCMH can be implemented without adding burden

3. A wide range of psychotherapeutic, pharmacologic, and medical device options exist to treat MDD
Discussion

Don’t forget to sign up for the virtual classroom to earn additional CME credit, engage with renowned faculty, and gain much more practical insights into managing MDD!

MDD Virtual Course
“Keeping Current with COPD Management”

by

Fernando Martinez, MD, MS

Fernando Martinez, MD, MS is an Associate Professor of Medicine, Division of Pulmonary, Allergy and Critical Care Medicine at the University of Michigan Health Systems, Ann Arbor, Michigan. He has a long standing interest in advanced lung disease having participated in international guideline panels for COPD, IPF, lung transplantation, and exercise testing. He has particular expertise in general pulmonary medicine, the evaluation and management of COPD, interstitial lung diseases (including idiopathic pulmonary fibrosis), breathlessness and cough. He is an active participant or co-director of the UM lung transplantation, lung volume reduction surgery, and fibrosing lung disease Destination Programs. Dr. Martinez coordinates a broad research program which focuses on the evaluation and management of interstitial lung diseases, particularly idiopathic pulmonary fibrosis. This includes a series of clinical trials of novel therapeutic approaches. A related research program includes a broad NIH and industry funded portfolio focused on the evaluation and management of COPD. These two arenas include extensive collaborative work to define the biological underpinnings of progressive disease and how to target novel therapeutic approaches.

Email: fmartine@umich.edu

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Differentiate between asthma and COPD
- Screen Patients at risk for COPD
- Establish a diagnosis based on current guidelines
- Formulate treatment plans for patients with COPD, based in updated, published guidelines
Keeping Current with COPD Management in Family Practice

Friday 4:45 pm visit
- Nancy—56 yo with cc of bronchitis
- Coughing >2 weeks, productive-yellow
- ?Fever, some breathlessness climbing stairs
- Does not want to go to the ED again
- Does not want chest x-ray
- Wants antibiotics before the weekend
  - The last kind she received worked

What Will You Do?
A. Give her the prescription and have her return in 2 weeks for evaluation
B. Take more history
C. Explain that she has no fever, no purulent sputum and does not need antibiotics
D. Begin smoking cessation discussion—she smells like tobacco smoke

What Should We Do?
- Take more history
  - Smoker 35 pack years
  - Third episode of “bronchitis” in past 2 years
    - Colds last for weeks
    - Always worse than others
  - Decrease in activities due to trouble breathing with walking. Now SOB with 6 stairs.
  - Has “smoker’s cough” for past 3 years
  - Mother developed “asthma” at age 60 and died of CHF at age 68
- Think chronic lung disease!

Definition of COPD
- Chronic Obstructive Pulmonary Disease (COPD), a common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases
- Exacerbations and comorbidities contribute to the overall burden of disease in individual patients

Mechanisms Underlying Airflow Limitation in COPD
- Small Airways Disease
  - Airway inflammation
  - Airway fibrosis, luminal plugs
  - Increased airway resistance
- Parenchymal Destruction
  - Loss of alveolar attachments
  - Decrease of elastic recoil

AIRFLOW LIMITATION
Burden of COPD

- COPD is a leading cause of morbidity and mortality worldwide and third leading cause of death in the US
- The burden of COPD is projected to increase in coming decades due to continued exposure to COPD risk factors and the aging of the world’s population
- COPD is associated with significant economic burden

COPD Deaths by Sex

COPD Prevalence by Sex and Age

COPD Prevalence by Income & Sex

Why Is COPD Underdiagnosed?
Clinicians Tell All

PATHOLOGY OF COPD

Why Is COPD Underdiagnosed?
Clinicians Tell All

Survey of 278 Clinicians

- Patient has multiple chronic conditions
- Patient lacks information/recognizes dyspnea
- Inadequate knowledge and training
- Patient lacks specific symptoms
- Lack access to spirometry
- Lack of effective treatment

Survey of 278 Clinicians

Survey of 278 Clinicians

- Patient has multiple chronic conditions
- Patient lacks information/recognizes dyspnea
- Inadequate knowledge and training
- Patient lacks specific symptoms
- Lack access to spirometry
- Lack of effective treatment
Key Barriers to COPD Diagnosis

• COPD not in differential diagnosis
• Failure of patients to notice and report symptoms
  — Early symptoms often do not interfere with activities of daily living
  — Symptom severity increases very slowly
• Failure of health professionals to inquire about respiratory issues
  — Tools to help
  — Be specific
• Misdiagnosis of COPD as asthma or bronchitis
• Underuse of spirometry

More about Nancy

• Need to treat acute episode but with what? Antibiotics, SABA, steroids?
• Diagnosis what she has—asthma, COPD or something else?
• Chest x-ray—little help?
• Spirometry—can she do it now with cough?
• Stress test—maybe breathlessness is CV in origin?
• Smoking cessation—Never wrong, time to try!

PMH
Hypertension—diuritic
Osteopenia—Ca and Vit D
Hysterectomy—age 51
35 pack-year history
Multiple ED visits—bronchitis
No asthma
Family history—CVD, late asthma

COPD Population Screener (COPD-PS)

1. During the past 4 weeks, how much of the time did you feel short of breath?

2. Do you ever cough up any “stuff,” such as mucus or phlegm?

3. Please select the answer that best describes you in the past 12 months,
   I do less than I used to because of my breathing problems.

5. How old are you?

Characteristics That Help Distinguish COPD From Asthma

<table>
<thead>
<tr>
<th>Feature</th>
<th>COPD</th>
<th>Asthma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset</td>
<td>Often in midlife</td>
<td>Often in childhood</td>
</tr>
<tr>
<td>Family history</td>
<td>Variable</td>
<td>Often</td>
</tr>
<tr>
<td>Medical or social history</td>
<td>Smoking (often ≥20 pack-years)</td>
<td>Atopy (ie, allergy and/or eczema)</td>
</tr>
<tr>
<td>Patients report symptoms as...</td>
<td>Most notable during exercise</td>
<td>Most notable at night or early morning</td>
</tr>
<tr>
<td>Airflow obstruction</td>
<td>May be some reversibility with bronchodilation</td>
<td>Largely reversible with bronchodilation</td>
</tr>
</tbody>
</table>

Key Indicators of COPD

• Chronic cough
  — Present intermittently or every day
  — Often present throughout the day; seldom only nocturnal
• Chronic sputum production
  — Any pattern chronic sputum production may indicate COPD
• Dyspnea that is
  — Progressive (worsens over month/years)
  — Persistent (present every day)
  — Worse with exercise
  — Worse during respiratory infections

Key Indicators of COPD

• Presence of risk factors
  — Host factors
    • Genetics (alpha-antitrypsin)
    • Hyperresponsiveness
    • Lung growth
  — Exposure to
    • Tobacco smoke
    • Smoke from home cooking and heating fuels
    • Occupational dusts and chemicals
COPD Missed Diagnoses

Hypothetical female patient with COPD symptoms
32% diagnosed as COPD by physicians

Hypothetical male patient with COPD symptoms
42% diagnosed as COPD by physicians

COPD symptoms in women were most commonly misdiagnosed as asthma

42% diagnosed as COPD by physicians
32% diagnosed as COPD by physicians

Nancy Needs Spirometry!

- Often have to wait 4 to 6 weeks to return to baseline after acute event (exacerbation)
- See her before you obtain test or at least evaluate over the phone
- Needs pre and post bronchodilator to see about reversibility and if she meets obstruction definition
- Need FEV1 and FVC to determine severity and how to begin maintenance therapy

Spirometry: Normal Trace Showing FEV1 and FVC

- FEV1 = 4L
- FVC = 5L
- FEV1/FVC = 0.8

Spirometry: Obstructive Disease

- FEV1 = 1.8L
- FVC = 3.2L
- FEV1/FVC = 0.56

Prebronchodilator and Postbronchodilator Testing

- Bronchodilator reversibility testing can help rule out asthma diagnosis and guide initial treatment decisions
  - Complete or very nearly complete reversibility (return to normal lung function metrics) suggests asthma, whereas partial reversibility (not returning to normal or near normal) suggests COPD
  - Some reversibility is possible in people with COPD
- Basic Protocol
  - Give 1 puff, wait 1 minute, then administer the second dose
  - Wait 20 minutes for the inhaler to take effect
  - Repeat the pulmonary function study
  - Compare post results to pre results

Algorithm for Interpreting Spirometry Results

- Acceptable Spirogram
- Obstructive defect
- Mixed obstructive/restrictive defect or hyperinflation
- Restrictive defect
- Normal
- Mixed obstruction/restrictive defect or hyperinflation
- Near-total reversal with use of bron agonist?
- Asthma
- COPD

Nancy’s Numbers

- You do spirometry on Nancy and get the following results
  - Good quality tracing—rated B

<table>
<thead>
<tr>
<th>Pre-bronchodilator</th>
<th>Post-bronchodilator</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV₁ 2.2 L 65% pred</td>
<td>FEV₁ 2.7 L 68% pred</td>
</tr>
<tr>
<td>FVC 4.0 L</td>
<td>FVC 4.1 L</td>
</tr>
<tr>
<td>FEV₁/FVC 0.55</td>
<td>FEV₁/FVC 0.66</td>
</tr>
</tbody>
</table>

What is Your Spirometry-Confirmed Diagnosis?

1. Normal spirometry
2. Poor quality can’t interpret
3. Asthma
4. Obstructive lung disease consistent with COPD
5. Restrictive lung disease

Avoid Interpretation Pitfalls

- Common Interpretation Errors Among Family Physicians (N = 12) New to Interpreting Spirometry
  - Interpreting a normal result as an obstructive pattern
  - Interpreting a poor effort as a restrictive pattern
  - Diagnosing COPD in the absence of an FEV₁/FVC ratio <70%


Spirometry Reimbursement

- Billing codes and reimbursement for simple spirometry vary by state

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CPT Code</th>
<th>2006 National Average Medicare Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple spirometry</td>
<td>94010</td>
<td>$55.32</td>
</tr>
<tr>
<td>Prebronchodilator and postbronchodilator</td>
<td>94060</td>
<td>$56.61</td>
</tr>
<tr>
<td>Smoking cessation counseling*</td>
<td>99406*</td>
<td>$12.13</td>
</tr>
<tr>
<td>Inhaler training*</td>
<td>94064</td>
<td>$14.02</td>
</tr>
</tbody>
</table>
* Append Modifier -25 code to CPT code in order to be reimbursed for these procedures.
* 4 to 10 minutes.
* >10 minutes.


Spirometry Is Useful for Monitoring Disease Progression

Changes Can Be Seen Earlier in Spirometry than in Many Other Respiratory Parameters

<table>
<thead>
<tr>
<th>Spirometry</th>
<th>Normal</th>
<th>Borderline</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>Normal</td>
<td>Exertional</td>
<td>Resting</td>
<td>Dyspnea</td>
<td>Hypoxemia</td>
</tr>
<tr>
<td>Arterial blood gas</td>
<td>Normal</td>
<td>Exertional</td>
<td>Resting</td>
<td>Dyspnea</td>
<td>Hypoxemia</td>
</tr>
<tr>
<td>Chest X-ray</td>
<td>Normal</td>
<td>Hyperinflated</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

COPD Management

- Suspect COPD
- Spirometry
- Select Rx based on: Symptoms, FEV₁, Exacerbations
- Why inadequate?
  - Adherence
  - Triggers
  - Comorbidities
  - Co-medications
  - Social
  - Inhaler technique
  - Dose changes
  - Disease progression
- Inadequate response
- Adequate response
Using the Global Initiative for Chronic Obstructive Lung Disease™ (GOLD) Guidelines

A Discussion

See full 2014 GOLD guidelines at www.goldcopd.org

Assessment of COPD: Goals

See full 2014 GOLD guidelines at www.goldcopd.org

Symptoms of COPD

See full 2014 GOLD guidelines at www.goldcopd.org

Modified MRC (mMRC) Questionnaire

PLEASE TICK IN THE BOX THAT APPLIES TO YOU

(ONE BOX ONLY)

mMRC Grade 0. I only get breathless with strenuous exercise.

mMRC Grade 1. I get short of breath when hurrying on the level or walking up a slight hill.

mMRC Grade 2. I walk slower than people of the same age on the level because of breathlessness, or I have to stop for breath when walking on my own pace on the level.

mMRC Grade 3. I stop for breath after walking about 100 meters or after a few minutes on the level.

mMRC Grade 4. I am too breathless to leave the house or I am breathless when dressing or undressing.

Assessment of COPD

See full 2014 GOLD guidelines at www.goldcopd.org
Classification of Severity of Airflow Limitation in COPD*: 2013

Assessment of COPD

See full 2014 GOLD guidelines at www.goldcopd.org

Assess Risk of Exacerbations

Nancy Again

• MMRC is 2
• Exacerbations? Probably 2 per year
• FEV₁—68% of predicted
• On no therapy until you treated “bronchitis” and began SABA.

Combined Assessment of COPD

See full 2014 GOLD guidelines at www.goldcopd.org
Additional Investigations

See full 2014 GOLD guidelines at www.goldcopd.org

Manage Stable COPD: Goals of Therapy

See full 2014 GOLD guidelines at www.goldcopd.org

Therapeutic Options: Key Points

See full 2014 GOLD guidelines at www.goldcopd.org

Cigarette Smoking in the US: The Epidemic Continues (2002 Data)*

*The percentage of all adults in each state/area who reported having smoked ≥100 cigarettes during their lifetime and who currently smoke every day or some days.


Addressing Smoking Cessation

• Best thing parents can do for themselves and their children
• Clinician intervention is effective and cost effective
• Nicotine is addictive, relapse is prevalent

Smoking Cessation Interventions

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Studies evaluated [n]</th>
<th>Absolute Increase in Cessation Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief physician contact</td>
<td>16 (Cochrane) 7 (US DHHS)</td>
<td>2% 2.3%</td>
</tr>
<tr>
<td>Group counseling</td>
<td>6 (Cochrane) 58 (US DHHS)</td>
<td>10% 3.1%</td>
</tr>
<tr>
<td>Nicotine gum</td>
<td>51 (Cochrane) 13 (US DHHS)</td>
<td>8% 6.6%</td>
</tr>
<tr>
<td>Nicotine nasal spray</td>
<td>4 (Cochrane) 3 (US DHHS)</td>
<td>12% 16.6%</td>
</tr>
<tr>
<td>Bupropion (300 mg/day SR)</td>
<td>7 (Cochrane) 2 (US DHHS)</td>
<td>10% 13.2%</td>
</tr>
</tbody>
</table>

### Therapeutic Options for COPD: Formulations and Duration of Action

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Inhaler</th>
<th>Oral</th>
<th>Duration of Action, Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>β-agonists</td>
<td>Short-acting</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Long-acting</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticholinergics</td>
<td>Short-acting</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Combination short-acting β-agonists and anticholinergic</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Combination long-acting β-agonists plus an inhaled corticosteroid</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combination long-acting β-agonists plus an inhaled corticosteroid</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pharmacotherapy Overview

**A**
- Minimal Symptoms
- Mild-Moderate Exacerbations (≤2/yr)
- Short-acting bronchodilator (prn)
- Consider adding other agents

**B**
- Severe symptoms
- Severe-Very Severe Exacerbations (≥2/yr)
- Scheduled: Long-acting bronchodilator
- Scheduled: Inhaled corticosteroid + long-acting beta agonist or Long-acting muscarinic antagonist

**C**
- Minimal Symptoms
- Mild-Moderate Exacerbations (≤2/yr)
- Short-acting bronchodilator

**D**
- Severe symptoms
- Severe-Very Severe Exacerbations (≥2/yr)
- Scheduled: Long-acting bronchodilator
- Scheduled: Inhaled corticosteroid + long-acting beta agonist or Long-acting muscarinic antagonist

Therapeutic Options: COPD Medications

<table>
<thead>
<tr>
<th>Hierarchy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-acting β-agonists or Short acting anticholinergics or Combination</td>
</tr>
<tr>
<td>Long-acting β-agonists or Long-acting anticholinergics or Combination</td>
</tr>
<tr>
<td>Inhaled corticosteroids usually in combination with LABA or LAMA or both</td>
</tr>
</tbody>
</table>

Phosphodiesterase-4 inhibitors
- Methylxanthines
- Systemic corticosteroids

**Patients often do NOT progress through the Grades of COPD Sequentially**

- **A**
  - Minimal Symptoms
  - Mild-Moderate Exacerbations (≤2/yr)
  - Short-acting bronchodilator (prn)
- **B**
  - Severe symptoms
  - Severe-Very Severe Exacerbations (≥2/yr)
  - Scheduled: Long-acting bronchodilator
  - Scheduled: Inhaled corticosteroid + long-acting beta agonist or Long-acting muscarinic antagonist
  - Consider adding other agents

- **C**
  - Minimal Symptoms
  - Mild-Moderate Exacerbations (≤2/yr)
  - Short-acting bronchodilator
- **D**
  - Severe symptoms
  - Severe-Very Severe Exacerbations (≥2/yr)
  - Scheduled: Long-acting bronchodilator
  - Scheduled: Inhaled corticosteroid + long-acting beta agonist or Long-acting muscarinic antagonist
  - Consider adding other agents
Recommended Pharmacotherapy

**A**
- Minimal Symptoms
- SABA (pm) (short-acting bronchodilator)

**B**
- Severe Symptoms
- LABA or LAMA (long-acting bronchodilators)

**C**
- Severe Symptoms
- ICS/LABA (scheduled)

**D**
- Severe Symptoms
- LABA + LAMA (scheduled)


**Therapeutic Options:** Phosphodiesterase-4 Inhibitors

See full 2014 GOLD guidelines at www.goldcopd.org
What Will Be Nancy’s Initial Therapy?

She is a “C”
1. SABA or SAMA
2. LABA or LAMA
3. LABA + LAMA
4. LABA or LAMA + ICS

Therapeutic Options: Other Pharmacologic Treatment

See full 2014 GOLD guidelines at www.goldcopd.org

Manage Stable COPD: Non-pharmacologic

See full 2014 GOLD guidelines at www.goldcopd.org

Activity in People with COPD

• COPD patients are very inactive
• This inactivity is present in all GOLD-stages

COPD: The Vicious Circle

Chronic Pulmonary Disease

Increased \( \dot{V}e \) Requirements

Physical Deconditioning

Increased Breathlessness

Decreased Exercise Capacity

Immobility

Pulmonary Rehabilitation

Increased Exercise Capacity

Decreased Breathlessness

Physical Reconditioning

Decreased \( \dot{V}e \) Requirements

See full 2014 GOLD guidelines at www.goldcopd.org

Pitta A et al., AJRCCM 2005; 171: 972-977


Chronic Pulmonary Disease
Pulmonary Rehabilitation Improves CRQ Dyspnea

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behnke 2000a</td>
<td>2.26 (1.34, 3.18)</td>
</tr>
<tr>
<td>Cambach 1997</td>
<td>1.00 (0.86, 1.14)</td>
</tr>
<tr>
<td>Goldstein 1994</td>
<td>0.66 (0.12, 1.20)</td>
</tr>
<tr>
<td>Gosselin 2000</td>
<td>0.82 (0.17, 1.47)</td>
</tr>
<tr>
<td>Griffiths 2000</td>
<td>1.48 (0.85, 1.51)</td>
</tr>
<tr>
<td>Gell 1995</td>
<td>1.00 (0.66, 1.36)</td>
</tr>
<tr>
<td>Gell 1998</td>
<td>1.00 (0.20, 1.80)</td>
</tr>
<tr>
<td>Hernandez 2000</td>
<td>0.78 (0.02, 1.54)</td>
</tr>
<tr>
<td>Simpson 1992</td>
<td>1.20 (0.37, 2.03)</td>
</tr>
<tr>
<td>Singh 2003</td>
<td>0.88 (0.35, 1.41)</td>
</tr>
<tr>
<td>Wijkstra 1994</td>
<td>0.90 (0.13, 1.67)</td>
</tr>
<tr>
<td>Total</td>
<td>1.06 (0.85, 1.26)</td>
</tr>
</tbody>
</table>

Lacasse et al, Cochrane Database of Systematic Reviews 2006; Issue 4; Art. No.: CD003793

Address Comorbidities of COPD

- Lung Cancer
- Pulmonary Hypertension
- Anemia
- Cardiac Failure
- Diabetes
- Metabolic Syndrome
- Peptic Ulcers
- GI complications

Risk of Lung Cancer in COPD: Meta-analysis

- 4 large population-based prospective studies that used standardized methods & did not select population on basis of disease.
- Highest quintile of FEV1 had lowest risk of lung cancer; lowest quintile had highest risk. For same marginal decrease in FEV1, adj. for smoking, women are ~2X more likely to develop lung cancer than men.

Anxiety in COPD

- Anxiety is independently associated with:
  - poorer exercise performance
  - greater disability
  - greater hospitalizations for acute exacerbations
  - decreased quality of life
- Independent of lung function, dyspnea ratings, other chronic diseases

Osteoporosis

- Severity of COPD: GOLD I, GOLD II, GOLD III-IV
- Normal, Osteopenia, Osteoporosis

From What Do COPD Patients Die?

- COPD
- ASCVD
- Lung cancer
- Pneum/Inf
- Other
Kurt

• Kurt is 58-year-old retired man with COPD diagnosed 3 years ago during hospitalization for "pneumonia"
• Today he comes in for follow up of visit to the ED for "bronchitis"
• He has a 40-year pack history of smoking cigarettes, stopped smoking 3 years ago, 2 years ago and last year
• Spirometry FEV1/FVC = 0.55, FEV1 is 61, 1 "exacerbation" past 3 years
• MMRC=2—walks slower than others his age
• He has moderate COPD and has been prescribed tiotropium once daily
• Additional medications include a diuretic for his hypertension, calcium and vitamin D for his osteopenia (had non-traumatic FX) and escitalopram oxalate (Lexapro) for his "mood"

Kurt’s Comorbidities?

• Depression: very common in COPD
  — Decreases adherence
  — Antidepressant stopped in 1 to 2 months
  — Not followed like the chronic disease it is
  — Considered PHQ-9 to reassess
• Osteopenia
  — Unusual for a relatively young man
  — Good workup after FX
• What about CVD?
  — Stress test?
• What about his recurrent attempts at smoking cessation?

Kurt’s Management Program

1. Smoking cessation
2. Pulmonary rehabilitation/activity
3. May need CV evaluation
4. Tiotropium and SABA
5. Plan and education for exacerbation recognition
6. Monitoring and managing comorbidities
7. Regular visits

Manage Exacerbations

An exacerbation of COPD is: "an acute event characterized by a worsening of the patient’s respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication."

Manage Exacerbations: Key Points

See full 2014 GOLD guidelines at www.goldcopd.org
Consequences of COPD Exacerbations

EXACERBATIONS
- Negative impact on quality of life
- Impact on symptoms and lung function
- Accelerated lung function decline
- Increased economic costs
- Increased Mortality

Manage Exacerbations: Treatment Options

See full 2014 GOLD guidelines at www.goldcopd.org

Manage Exacerbations: Treatment Options

Must Haves for COPD
- Spirometry
- Smoking cessation
- Pulmonary rehabilitation
- Pharmacotherapy
- Assessment and therapy of co-morbidities
- Good across group communications
- Team approach

Question
Joel's COPD was diagnosed 5 years ago. His latest FEV₁ was 62% last year and his MRC today is 2. He is taking Tiotropium once a day. He has had 1 exacerbation (outpatient RX) last year.

Which COPD control square is Joel in?
- A
- B
- C
- D

Question
- Why is Joel not a candidate for ICS?
  - Only 1 exacerbation past 2 years
  - His FEV₁ is too high
  - His insurance company won't pay
  - His is afraid of ICS
- Evaluate the risk and benefits!
"Unfortunately, there's no one - thank's not even a tax for a tax."
“Providing Culturally Effective Care to the People of New Mexico”

by

Felisha Rohan-Minjares, MD

&

Jessica Goodkind, PhD

Felisha Rohan-Minjares, MD was born and raised in Gallup, New Mexico. She attended Stanford Medical School and completed her Family Medicine residency at the University of New Mexico. She is currently an assistant professor at UNM, and she practices family medicine at the Southeast Heights Clinic in Albuquerque. She is Co-Director of the Cultural Competency Curriculum at the School of Medicine and she is the Director of the Research Education and Training Core in the NM CARES Health Disparities Center

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Jessica Goodkind, PhD is a community psychologist and faculty member of the University of New Mexico Departments of Sociology and Psychiatry (Center for Rural and Community Behavioral Health), and Co-Director of the Cultural Competency Curriculum for the School of Medicine. Her primary interests are in working collaboratively with communities to address the social determinants of mental health and to promote healing and well-being.

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Learning Objectives

At the end of this presentation, the attendee will be able to:

- Describe demographics specific to New Mexico that underline the importance of delivery culturally competent care
- Discuss current trends of cultural competency education in medical school, residency education and continuing medical education
- Describe skills that improve culturally effective health care delivery and consider incorporation into your own practice
- Define unconscious bias and articulate how bias might impact patient care
PROVIDING CULTURALLY EFFECTIVE CARE TO THE PEOPLE OF NEW MEXICO

NMAFP SUMMER MEETING
AUGUST 1, 2014

Felisha Rohan-Mejias, MD
Associate Professor
Family and Community Medicine
University of New Mexico

Jessica Goodkind, PhD
Assistant Professor
Sociology & Psychiatry
University of New Mexico

OBJECTIVES

- Describe demographics specific to New Mexico that underline the importance of delivering culturally competent care
- Discuss current trends of cultural competency education in medical school, residency education and continuing medical education
- Define unconscious bias and articulate how bias might impact patient care
- Describe skills that improve culturally effective health care delivery and consider incorporation into your own practice

SURVEY QUESTION

Was teaching about cultural competency a part of your professional educational program?

a) Yes
b) No

cultural “Competence” training offers a tool to improve healthcare professionals’ ability to provide quality care to diverse populations and thereby reduce healthcare disparities

SURVEY QUESTION

How relevant are your attitudes, beliefs, and stereotypes to patient care?

- Not at all relevant
- Marginally relevant
- Moderately relevant
- Quite relevant
- Very relevant

CULTURAL MEDICINE SURVEY

How often do you ask patients what their beliefs are about their illness and what they think might help?

- Never
- Rarely
- Monthly
- Weekly
- Daily

PLEASE DISCUSS WITH SOMEONE NEXT TO YOU
A DEFINITION OF CULTURE
A set of learned and shared beliefs, values, traditions, languages, and norms applied to social interactions and to the interpretation of experiences.

- Cultures are dynamic.
- Cultures are created across many dimensions of identity - not only race and ethnicity but also class, age, gender, sexual orientation, and other social categories.

Mutha S, Allen C, Welch M. Toward Culturally Competent Care: Center for the Health Professions, Univ. of San Francisco, 2002

CULTURALLY RESPONSIVE CARE
- Communication with patients and their families - goal is that patients' health beliefs are understood and incorporated into care
- Be aware of a patient's:
  - Background
  - Affect
  - Main concerns
  - How patient is currently coping with health concerns
- Important skills: empathy and values clarification

CULTURAL MEDICINE SURVEY
- I can describe the health practices and beliefs that are common in the community my program serves.
  
  a) True
  b) False

CULTURAL HUMILITY
"Cultural humility incorporates a lifelong commitment to self-evaluation and self-critique to redressing the power imbalances in the patient-physician dynamic, and to developing mutual beneficial and nonpaternalistic clinical and advocacy partnerships with communities on behalf of individuals and defined populations."


CULTURAL COMPETENCY IN CONTINUING MEDICAL EDUCATION
Some states are requiring Cultural Competency courses to be completed for medical licensure.

- New Jersey - Since 2005, physicians required to complete CME on cultural competency to maintain licensure
- California - Since 2006 mandates cultural competency to be incorporated into CME
- Maryland - "Strongly recommends" cultural competency education in CME
- New Mexico - No mandate for practicing clinicians
- Debate continues in other states

Accreditation Council for Graduate Medical Education

Medical residents are required by the to be able to "communicate effectively with patients, families and the public, as appropriate, across a broad range of socioeconomic and cultural backgrounds."

Liaison Committee on Medical Education

The faculty and students must demonstrate an understanding of the manner in which people of diverse cultures and belief systems perceive health and illness and respond to various symptoms, diseases, and treatments.

New Mexico State Legislature - State Bill 600, 2007 Cultural competency requirement in all health professional schools

Philosophy of lifetime learning

Safe learning environment with experienced facilitators

Emphasis on self-reflection

"Culturally Effective Care" leading toward health equity

Directors: Felisha Rohan-Minjares, MD
Jessica Goodkind, PhD

Diversity of the Human Experience - required course in the 1st, 2nd, and 3rd year of medical school; total of 20 contact hours; combination of lecture, small group activities, standardized patient exercises, and reflective writing

Interpreter Use Curriculum in first year, 2nd year transitions block, and 3rd year pediatrics rotation

Goal: 4 year integrated curriculum

Cultural Competence is one tool that can be employed to ensure equitable care among diverse populations

Multiple social determinants must be considered when engaging the care of individuals and when making efforts to improve the health of entire communities

Health disparities are differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups in the United States
**POTENTIAL SOURCES OF DISPARITIES IN CARE**

- Health systems-level factors
  - Financing, structure of care; cultural and linguistic barriers
- Patient-level factors
  - Patient preferences, refusal of treatment, poor adherence, biological differences
- Disparities arising from the clinical encounter

Source: Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare, Institute of Medicine

**Fig. 1: Differences, Disparities, and Discrimination: Populations with Equal Access to Health Care**

**PROVIDING CARE FOR NM**

- Total population of 1,942,847
- Only 8 NM cities have populations over 30,000
- 16 of 33 NM’s counties are classified as “frontier”
- 5th largest state in the US


**GEOGRAPHIC CHALLENGES**

**HEALTH PROFESSIONAL HERITAGE AREAS**

2010

**NATIVE AMERICAN TRIBES**
Racial and Ethnic Diversity
A Minority-Majority State

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>African American</td>
<td>2.5%</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>1.4%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>44%</td>
</tr>
<tr>
<td>Native American</td>
<td>9.8%</td>
</tr>
<tr>
<td>White</td>
<td>42.8%</td>
</tr>
</tbody>
</table>

25% of the US Population is minority

<table>
<thead>
<tr>
<th>Health Professions</th>
<th>% Minorities In Profession</th>
<th>% Minority Faculty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing</td>
<td>7.4%</td>
<td>10%</td>
</tr>
<tr>
<td>Dentistry</td>
<td>6.8%</td>
<td>8.6%</td>
</tr>
<tr>
<td>Medicine</td>
<td>6.1%</td>
<td>4.2%</td>
</tr>
</tbody>
</table>

Cultural Medicine Survey

How often do you work with a professional interpreter in your practice setting?

- a) Never
- b) Rarely
- c) Monthly
- d) Weekly
- e) Daily

State Profile
Challenges - Language Barrier

Language Spoken At Home in 2000
Percent of Persons 5 Years and Over
By Language and Ability to Speak English
New Mexico and U.S.

Communication in the Healthcare Setting

- Language barriers pose a significant problem to accessing healthcare
- Affect the delivery of adequate care through:
  - Poor exchange of information
  - Loss of important cultural information
  - Misunderstanding of instruction
  - Poor shared decision making
  - Ethical compromises such as difficulty obtaining informed consent (Woloshin et al., 1995)

Educational Challenges

- New Mexico 12% high school dropouts
  (US average = 8%)
- New Mexico 35% of 4th graders are below basic proficiency level in math
  (US average = 21%)
- New Mexico 49% of 4th graders are reading below proficiency
  (US average = 38%)

"The ability to distinguish friend from foe helped early humans survive, and the ability to quickly and automatically categorize people is a fundamental quality of the human mind. Categories give order to life, and every day, we group other people into categories based on social and other characteristics. This is the foundation of stereotypes, prejudice and, ultimately, discrimination."

Tolerance.org, Hidden Bias: A Primer.

**CONSIDERING DIFFERENCE**

Quickly list the ways that your patients may differ from you - don’t judge each other’s ideas, just record them.

Select two of the above differences that at least one person in the group finds challenging for him/her in providing excellent care. Provide your ideas about why each difference provides a challenge and how it might affect care.

Difference 1
What makes this difference challenging in a clinical encounter?
List ways this could affect the care provided.

Difference 2
What makes this difference challenging in a clinical encounter?
List ways this could affect the care provided.

**UNCONSCIOUS BIAS**

* Also known as implicit bias or hidden bias

* Conceptually arose as a way to explain why discrimination persists even though research clearly shows that people oppose it

* Per Greenwald and Banaji (developers of the IAT), much of our social behavior is driven by learned stereotypes that operate automatically - and therefore unconsciously – when we interact with other people.

* Growing evidence demonstrates that these implicit biases impact behavior.

* EVERYONE HAS THEM
Implicit Association Tests

- Collaborative research effort between researches at Harvard, University of Virginia and University of Washington
- Use reaction time measurement to examine unconscious bias

First step in decreasing discrimination and thereby decreasing health disparities is to recognize our individual biases. The IAT can be a starting point.

What Can We Do About It?

- Awareness of the concept of unconscious bias is the first step.
- Begin to “feel” the bias and take steps to modify behavior
- Create an environment that allows for behaviors and decisions to be well-thought out and not time pressured.

Exploring Unconscious Bias in Disparities Research and Medical Education

- On the IAT, medical students had implicit biases similar to those found in other populations favoring whites over blacks and upper-class over lower-class individuals, BUT students provided “equal treatment” on case vignettes about white and black patients.
- Deliberate, thought-out decisions with cognitive resources, motivation, and opportunity to consider pros and cons of different actions.

Tools: Respect Model

- Tool developed a diverse group of clinicians/educators at an inner-city safety-net hospital to teach relational skills to reduce disparities at the point of care
- Adds attention to the relational dimension, addressing documented disparities in respect, empathy, power-sharing, and trust while incorporating prior cross-cultural models
- Concrete, practical, integrated model for teaching patient care

Respect Model

- Respect
- Explanatory model
- Social context, including Stressors, Supports, Strengths and Spirituality
- Power
- Empathy
- Concerns
- Trust/Therapeutic alliance/Team

Tools: Kleinman Questions

- What do you think caused the problem?
- Why do you think it started when it did?
- What do you think your sickness does to you? How does it work?
- How severe is your sickness? Do you think it will last a long time or will it be better soon, in your opinion?
- What kind of treatment do you think you should receive?
- What are the most important results you hope to receive from this treatment?
- What are the main problems your sickness has caused for you?
- What do you fear most about your sickness?
CASE STUDY: MR. KOCHI
Afghani immigrant with gastric cancer

CASE DISCUSSION
- In a small group, discuss the case. What was challenging about it?
- How could the clinician have used the RESPECT model to improve the care provided?
- Brainstorm how YOU would have used the Kleinman questions with this patient.

TOOLS: INTERPRETER USE TIPS
- Find the best interpreter available.
- Never use a child to interpret.
- If it all possible, avoid family members interpreting.

INTERPRETER USE TIPS
- Introduce yourself to the interpreter.
- You may briefly tell the interpreter about the patient and the case if you are familiar with the patient.
- Speak in the 1st person and make eye contact with the patient while speaking, not the interpreter.
- Speak clearly and in your normal tone of voice. Speak at a normal to slow-normal pace.
- Use short sentences.
- Be aware that many concepts you express may have no linguistic or conceptual equivalent in other languages. *Don't use idioms.* (i.e. “It's a long shot”, “kill two birds with one stone”, etc.)

INTERPRETER USE TIPS
- Most untrained interpreters know little medical terminology. Use plain English.
- Encourage the interpreter to ask questions and to alert you about cultural misunderstandings.
- Never Assume Confidentiality with non-hospital interpreters! Ask the patient if there are issues that they don’t want to discuss if family member is interpreting.

CULTURALLY EFFECTIVE CARE
- Requires lifelong learning and cultural humility
- Allows for the provider to reflect critically upon challenging clinical scenarios
- Emphasizes the importance of empathy and values clarification
- Incorporates an understanding of implicit bias and encourages providers to recognize when bias may impact care
- Recognizes that the social determinants of health contribute immensely to the health of each individual patient and must be considered
SATURDAY, AUGUST 2, 2014

7:00 a.m.   Registration, Exhibits Open
            Breakfast - Exhibit Hall

8:00 a.m.   “Adverse Childhood Events”
            Andy Hsi, MD

9:00 a.m.   “ACO Implications on Wellness”
            Lori Heim, MD, Past AAFP Board Chair

10:00 a.m.  Break – Exhibit Hall

            George Bakris, MD

11:30 a.m.  “Tools for Helping Control Obesity from a Pharmacist, Psychologist, Bariatric Surgeon and Nutritionist Point of View”
            Larry Georgopoulos, PharmD, PhC
            Sara Perovich, MPH, RD, LD, CDE
            Duc Vuong, MD
            Marlin Hoover, PhD, MS

1:00 p.m.   Afternoon at Leisure

1:00 p.m.   NMAFP Board Meeting – Sagebrush Conference Center, Zuni Meeting Room
            (Lunch Served)
“Adverse Childhood Events”

by

Andy Hsi, MD

Andy Hsi, MD is a general pediatrician who has focused on developing systems of care, specifically the FOCUS and Milagro Programs, for children and families affected by prenatal alcohol and drug exposure, family violence, parental mental illnesses including maternal depression and postpartum depression, and unsupported teen parenting. Through his work and that of the teams he’s led, the programs have had 22 years of delivering services in the Greater Albuquerque area. In 1999 he received the first national Humanism in Medicine Award from the American Association of Medical Colleges and Pfizer Pharmaceuticals. As an advocate for children in Albuquerque, he was awarded the Children's Champion Award in 2001 from All Faith's Receiving Home. In 2007, he received an award from New Mexico Voices for Children as the health professional who has made significant contributions to child health over 20 years. He received the Humanity in Medicine Award from the Pediatric Residency Program of UNM in 2008, 2009, and 2011. As part of an interdisciplinary effort, he assists research into the effects of Adverse Childhood and Adult Events with a focus on aiding primary care providers in organizing treatment protocols for adults with histories of adverse events.

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Learning Objectives

At the end of this presentation, the attendee will be able to:

- Identify Adverse Childhood Events
- Understand the increased health risk from Adverse Childhood Events
- Gain an understanding of the association of the role of toxic stress from Adverse Childhood Events and chronic health problems across the lifespan
The Effects of Adverse Childhood Experiences on Health Risk Behaviors and Health Across the Lifespan

Andrew Hsi, MD, MPH
UNM Departments of Family and Community Medicine and Pediatrics

Objectives for Presentation

- Definition of ACEs
- Toxic stress and Adverse Childhood Events (ACEs)
- Risk behaviors leading to early chronic illnesses
- The significance of ACEs in health over lifespan
- Mechanisms related to toxic stress and ACEs
- Chronic illnesses and impact on lifespan
- How to "embrace" a family seen in FOCUS Program

An Analogy

Three friends approach a wide, beautiful river. The idyllic scene is shattered by the cries of a small child in the water, flailing his arms while struggling to stay afloat. He's fast approaching the waterfall...

Description of A Family at Start of Services

- 34 year old Eva on methadone
- 17 year history of heroin injection
- Previous 3 children taken away
- Delivered baby LaMarcus
  - He stayed in hospital 20+ days
  - Went through methadone withdrawal
- CYFD did investigation
- Discharged LaMarcus home to mom

Issues for Family After Leaving the Hospital

- Eva was alone in Albuquerque
- Hard to attend drug treatment
  - Needed help with childcare
  - Needed help with housing
- Mother had depression
- LaMarcus started with adversity
- Would Eva accept her new role?

Adverse Childhood Experiences (ACEs) Defined

Existence of Past ACEs in Adult Patient Population
Study of ACEs Data by Kaiser Permanente and CDC

- Evaluation at Kaiser Health Appraisal Clinic
- 50,000 patients evaluated annually
- Over every 4 years, 81% HMO members seen
- Medical, psychosocial, preventive evaluations
- Sent survey of general health risk factors
- 68% response rate of all patients evaluated
- Survey questions included ACEs questions
- 17,337 of 18,175 completed mailed survey
- Average age of those completing surveys was 56 years


Abusive Adverse Childhood Experiences

- Child psychological abuse 11%
- Child physical abuse 28%
- Child sexual abuse 22%

Child Raised in A Home Environment With:

- Family member as alcoholic or drug abuser: 27%
- Family member mentally ill or suicidal: 19%
- Violence directed against the child's mother: 13%
- Family member imprisoned: 5%
- Loss of biological parent: 22%

Summary of ACEs in Study

1. Childhood psychological abuse 11%
2. Childhood physical abuse 11%
3. Childhood sexual abuse 22%
4. Family member abused alcohol or drugs 26%
5. Loss of biological parent 22%
6. Family member mentally ill or suicidal 19%
7. Violence directed against the child's mother 13%
8. Family member imprisoned 4%
9. Parents ever separated or divorced 23%

64% Had At Least 1 Adverse Childhood Experience

- Adults with 0 36.1%
- Adults with 1 26.0%
- Adults with 2 15.9%
- Adults with 3 9.5%
- Adults with 4 or more 12.5%

No data on numbers of events or intensity within a single type of adverse experience

Stress and Toxic Stress Defined

- Positive stress: causes minor physiological changes
- Tolerable stress: Death of a loved one, a natural disaster, family disruptions With support of loved one, tolerable stress can be overcome Without support, can become toxic to child

CDC publication:
Effects of Childhood Stress on Health Across the Lifespan 2008
Father Brings Son to Clinic

- Richard brings Curtis, age 12
- Curtis coming back to father's home
- Had lived in foster care 6 months
- EPSDT for transition to Richard
- 2 Siblings placed out of home
  - Carl, 14 year old in treatment center
  - Cheryl, 10 year sister in foster home

Background for Clinic Visit
Richard and Curtis

- 2 years ago Carl set the family porch on fire
- CYFD investigated
  - Richard not able to control Curtis, age 10
  - Chronic truancy for all 3 kids
- Carl at 12 placed in residential treatment
- Curtis and Cheryl placed in treatment foster care

History of Violence Between Parents, Richard and Michelle

- Richard experienced abuse as child
- Michelle used heroin during all 3 pregnancies
- Richard had past history of mental illness
- Michelle reported many times for child abuse
- Children lived with Richard most of their lives

Findings of CYFD Investigation 2005

- Richard and Michelle bonded to children
- Michelle inconsistent attending drug treatment
- Richard had gone to counseling
- Violence between parents with children present
- Children had learning and medical problems
  - Curtis had speech delays, no therapy services
  - Cheryl had asthma, may have developmental delays

Toxic Stress Causes Distress that Children Find Difficult to Manage

- Toxic Stress lasts for weeks, months or years
  - Child maltreatment, includes neglect and abuse
  - Curtis and Cheryl lived through parents' violence
  - Lived through Michelle's drug use episodes
- Exceeds children's coping mechanisms
- Stress system activated for prolonged time
  - Leads to permanent changes in developing brain
  - Negative effects can be lessened with support

ACEs Are Stressors That Produce Risk Behaviors

- Risk behaviors leading to decreased "health outcomes" and early chronic illnesses in adult life
Self-Reported Early Smoking and Chronic Lung Disease

5 Times Greater Risk Initiation of Alcohol Use By Age 14, 1962-78

Adverse Experiences and Adult Alcoholism

Relative Risks of Health Behaviors Associated with Risks for Early Death

Possible Mechanisms for the Effects of Adverse Childhood Experiences (ACEs) Beyond Poverty
Under Chronic ACEs Stimulation the Brain Changes
- Smaller size of brain areas in toxic stress
- Higher level of secreted brain hormones
  - Norepinephrine, fight or flight response
  - Cortisol, effects on adrenal hormones
  - Cortico Releasing Factor (CRF), affects pituitary
- Less regulated responses to environment
- Occur in sensitive time periods in child life

Impact of Chronic Stress on Child Development
- Hippocampus smaller, less learning acquired
  - In utero environment; drug exposure causes delays
  - Genetic variability in reaction to stresses
- Home environment stresses have negative impact
  - Stimulation of negative emotional adaptation;
  - Chronic neglect of development, intellect, health
- Impact puts child at risk of emotional delays
- Resilience factors have unknown role
- Not every child permanently affected

Children Exposed to ACEs Seem Delayed; Curtis as Young Child
- Witness to violence in home
- Possibly suffered neglect by Michelle
- Loss of his biological mother when Michelle ODs
- Curtis had at least 3 ACEs as young child
- Experiences significant stressors
- Had temper tantrums frequently at daycare
- Demonstrates low frustration level

Curtis Experienced High Stress
- His brain perceived high conflict in home
- Activated stress hormones, chronic activation
- Stress hormones change brain structure
  - Affect development of memory
  - Change emotional responses
  - Alter emotional regulation
  - Difficult relationships with siblings

Chronic Stress Affects Brain
- Brain changes; structural, neurochemical
  - Decreased size of hippocampus; memories affected
  - Disturbed regulation of amygdala
    - Center of learning for emotional response to stimuli
    - Responds to fear inducing stimuli
  - Glucocorticoid and HPA axis signaling changed
    - Sympathetic system reacts seconds to minutes
    - Cortisol action hours to weeks
  - Hippocampus and amygdala rich in glucocorticoid receptors

Under Chronic ACEs Stresses the Brain Changes
- Smaller size of brain areas from toxic stress
- Higher level of secreted brain hormones
  - Norepinephrine, fight or flight response
  - Serotonin system responsiveness
  - Cortisol, effects on adrenal hormones
  - Cortico Releasing Factor (CRF), affects pituitary
- Less regulated responses to environment
- Occur in sensitive time periods in child life
Association of Stress and Altered Glucocorticoid Receptors
- Adults with and without history of ACEs
- DNA examined for WBC glucocorticoid receptor
- Associated with abnormalities in hippocampus
- Altered stress hormone secretion levels
- Individuals with greater adversity had:
  - Higher epigenetic alteration associated with ACEs
  - Lower response to cortisol challenge
- Risk behaviors may be self treating for altered capacity to respond to stress

The Significance of ACEs in Health Over Lifespan
Effects of risk behaviors and chronic health problems

Premature Death and Excess Morbidity in US Adults
- Result from small number of common diseases
- Associated with behavioral components
- Examples (top 4) and related chronic behaviors:
  - Heart disease with obesity, smoking
  - Cancer; contributions of smoking, alcohol use
  - Stroke with high blood pressure, low exercise
  - Emphysema and asthma (COPD) with smoking

Long Incubation Period Occurs for Brain Changes from ACEs
- Children under 3 years demonstrate
  - Fearfulness in strange situations
  - Overly affectionate, lack of boundaries
  - Delays in speech production
  - Delays in problem solving tasks
- Preschool kids with regulation problems
- Elementary kids with attention problems
- Teens with anger, social skills problems

Connection of ACEs and Poorer Mental Health Measures
- ≥4 ACEs compared to 0 events
- Risks 2 to 2.7 times greater
- Disorders of mood and affect
  - Panic reactions,
  - Depressed affect,
  - Anxiety, and hallucinations
- Physical symptoms
  - Sleep disturbance,
  - Severe obesity, and
  - Multiple somatic symptoms

ACEs and Emotional Disorders
- With ≥ 4 ACEs risks 2.2 to 5.5 times for
  - High perceived stress,
  - Difficulty controlling anger, and
  - Risk of perpetrating intimate partner violence
- ≥ 4 ACEs combining difficulty controlling anger and risk of perpetrating IPV
  - 6.3 times greater risk for men and
  - 7.6 times greater risk for women
Teens Display Negative Coping Mechanisms for Mood, Emotion, Anger, Stress
- Socialize with others with social problems
- Aggressive activities, risk of injuries, fighting
- Tobacco use for calming effect, social group
- Alcohol use
- Difficult relationships, sexual acting out
- Attention attracting behaviors

Eva and LaMarcus Come to Clinic
- 42 year old Eva, 9 year old LaMarcus
- LaMarcus was healthy for past year
- Child at same school for entire year
- Went to 3 different school past year
- What’s happened?
  - Attending charter school
  - Attending science and math camp
  - Mom continually evaluating school and educational activities

Positive Attributes that Reduce Effects of ACEs
- Study of resiliency factors reassuring
- Childhood support systems related to better outcomes
- Attitudes and personal strengths helped resilience
- Adult support systems supported individual
- However, more ACEs reduced resilience factors
- Kauai longitudinal study, 10% had ACEs
  - 1/3 did well over 50+ years
  - Ability to attract positive attention, great talent
  - One adult who loved child unconditionally
  - Adult gatekeeper in child’s life

How Did This Eva Make Changes in Her Life?
- Completed treatment
- Completed education
- Has stable housing
- Employed at UNM
- Active in church
- Active with child’s school

Role of Primary Care
- Identify ACE occurrence in childhood
- Eliminate further abuse and neglect
- Reduce frequency of environmental events
- Identify ACE history before parenthood
  - Support during prenatal care
  - Parenting support and counseling
  - Facilitate access to behavioral health
  - Organize medical, mental health for parent

History of FOCUS Program Efforts to Assist Resilience in Eva, mother of LaMarcus
- Helped Eva get benefits
  - Medicaid for baby
  - Welfare support
  - Vouchers to continue methadone
- Assisted with housing application
  - Eva and LaMarcus had apartment
  - Neighborhood challenging
  - Eva found church group
  - Came to well child visits
**Family Progress with Program**

- Eva kept all visits
- Accepted home visits
- Baby had good development
- Eva completed treatment
- Found part time work
- LaMarcus in daycare
  - Daycare hard on child
  - Not enough stimulation
- Eva saw LaMarcus faced discrimination
- Program aided enrollment in strong licensed preschool

**What Accepting the Role as Mother Required From Eva**

- Develop support system
- Changed social context, find housing
- Eva became more isolated at first
- Attend drug treatment
- Needed help with childcare
- Arrange transportation to ASAP
- Address depression by counseling
- Worked to reduce child’s adversity
- Worked to increase her capacity

**Progress of LaMarcus Since Starting School**

- LaMarcus is a physical big boy
- Physically active
- Attracts negative attention
  - Teachers targeted child
  - No fights, no bullying behaviors
- Eva had many meetings with principals
- Eva went to CNM for counseling degree

**How the Future Looks**

- LaMarcus attends charter school
- Grades above average
- Has friends, likes school
- Eva first employed in data entry
- Her welfare benefits decreased
- Rent up $100/mo, food stamps down $200/mo
- Finished education as counselor
- New job as counselor, research
- Child part of science competition

**Revised ACEs-IQ for Use Internationally**

- Questions related to marital status
  - Freedom to select and decide to marry
  - Legal versus informal marriage status
- Added for bullying or receiving bullying
- Experience with fighting
- Neighborhood safety
- Exposure to war or collective violence

**Thank you**

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FOCUS Programs at the Center for Development and Disability, UNM
“ACO Implications on Wellness”

by

Lori Heim, MD, FAAFP – Past AAFP Board Chair

Lori Heim, MD, FAAFP is a family physician who serves as a hospitalist at Scotland Memorial Hospital in Laurinburg, N.C., and Prior Board Chair and Past President of the American Academy of Family Physicians with over 115,900 members. Heim earned her medical degree at the Uniformed Services University of the Health Sciences, then a residency in family medicine, and later a fellowship in faculty development and research from the University of North Carolina at Chapel Hill. Heim’s appointments with the Air Force included staff physician, clinic chief, residency director, assistant professor, university health center director, chief of the medical staff and commander. She retired as a Colonel from the Air Force after 25 years of service and joined a 2-physician private practice in Pinehurst, NC which included outpatient and inpatient responsibilities. She has lectured internationally and published in peer review journals on a variety of clinical and policy issues.

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Learning Objectives

At the end of this presentation, the attendee will be able to:

- Describe impact of ACO on Family Medicine
- Elaborate on the role of AAFP members in the payment & delivery models pertinent to Family Medicine
- Evaluate the ACO in the context of health care reform, Patient Centered Medical Home and impact on Family Medicine
Affordable Care Organizations: Implications on Wellness

Aug 2, 2014

Lori Heim, M.D. FAAFP
Past President & Board Chair
American Academy of Family Physicians

Objectives

1) Describe impact of ACO on Family Medicine
2) Elaborate on the role of AAFP members in the payment & delivery models pertinent to Family Medicine
3) Evaluate the ACO in the context of health care reform, Patient Centered Medical Home and impact on Family Medicine.

Abbreviations

• Accountable Care Organizations (ACO)
• Feds
  – Center for Medicare & Medicaid Services (CMS)
  – Health & Human Services (HHS)
• Patient Centered Medical Home (PCMH)
• Per-member-per-month payment (PMPM) or per-patient-per-month
• Fee-for-Service (FFS)

Incentives from ACA

• Community-based care funds grants
• Programs to keep patients at home
• Initiates payment reforms and pilots for PCMH,
• ACO’s and bundled payment models

Push for ACA

• Control health care costs
  – This was #1 priority for many
  – Question has been how best to do this
• Expand health insurance coverage
• Improve health

President Obama signs Affordable Care Act
(ACA) 3/2010

• Control health care costs
  – This was #1 priority for many
  – Question has been how best to do this
• Expand health insurance coverage
• Improve health
Budget-Based Payment
- Attempts to shift delivery from volume to value
  - Away from FFS
- Capitation
- Shared savings
- Bundled

Capitation
- Prospective global payment
- Risk falls to provider
  - FFS risk is with payer
- Payment for patient includes:
  - Complications
  - Utilization extremes
- Managed Care is example

Episode-Based
- Bundled payment synonym (sometimes)
- Payment is bundled = single payment
- Specific condition
- All setting
- Provider has all the risk but less exposure due to limited time

What is an ACO?
- Takes concept of PCMH "neighborhood"
- PCMH are foundational to success
- Assume responsibility for defined population
- Financial risk and savings issues
  - Must understand risk adjustment

Why the push for ACO?
- Attempt to move to new model
- Away from traditional fee-for-service
- Control costs
- Achieve quality markers

PCMH Neighborhood
- PCMH primary care based
- Expanded with:
  - Subspecialists
  - Mental Health
  - Support services
  - +/- hospital
ACO Payment Structures

- Medicare contracts
- Medicaid (dual eligible)
- Private insurance contracts
- Degree of provider integration predictor of ACO formation
  - Integrated hospital systems and larger PC groups increased ACOs.

Types of Payment Structures

- Shared savings
  - FFS is basis
- Capitation
- Bundled/ DRG
- Pay for Performance
  - Bonus or increased differential on top of FFS

Shared Savings Options

- Upside or both upside & downside
  - Retrospective adjustments to payments based on cost and quality
  - 2 sided= provider repays if cost overruns but gets share of savings if costs are less than predicted
  - 1 sided= shares in savings if any, but less $$ than 2 sided formulas since there is less risk

Payment Issues

- Risk of penalties if miss savings targets
- Acuity of patients
- 3 year baseline formula for spending target
- Have to calculate the start-up cost
  - Staff support, IT

Quality measures- CMS

- 33 NQF measures in 4 areas:
  1. Care coordination and patient safety
  2. Preventive care
  3. Patient experience
  4. Care for at risk populations

Quality Markers

- HEDIS measures
- Inpatient hospitalization & readmissions
  - Usually ambulatory care-sensitive (CV, DM)
- Patient satisfaction
  - May not be indicative of either quality of care or predictive of cost expenditures or savings

Medicare Program

• 366 ACOs after 4 rounds of Medicare Shared Saving Programs (MSSP) contracts
• 606 including public & private ACOs
• Minimum of 5,000 beneficiaries
• 3 year commitment
• Adhere to same basic coverage as set in ACA rules

ACO Penetration

ACO in NM

• Accountable Care Coalition of New Mexico, LLC
• GPIPA ACO
• Presbyterian Healthcare Services

ACO Structure Options

• Physician led/owned- predominant
• Hospital system
• Non-profit community organization
• Practice management companies

Physician Leadership in ACOs

• 51% physician led, 33% physician + hospital
• 78% majority on governing boards
• 40% physician owned
Physician Led ACO Examples

- Wilmington Health, NC
  - Medicare Shared Savings
  - BCBS

ACO impact for FM

- Opportunity for income but also for financial risk depending on structure
- Need to determine how savings are shared: Who gets what cut of the pie
- Very difficult (impossible) for solo without other integration but doesn’t require hospital centric platform, just more common

ACO Implications for Patients

- Attempts to balance cost savings with quality & patient outcomes
  - Reaction to prior managed care & incentive to withhold care to control costs
- Emphasis on integration of care, communication, prevention
  - Most realize cornerstone is adequate network of primary care

Vulnerable Populations

- High-risk clinical populations
  - CHF, DM, mental health issues, etc
- High-risk social populations
  - Poverty, illiteracy, etc
- Opportunity to target interventions with greatest reward either in cost savings (decreased ER/hospital $) or increased quality

Cautions & Challenges

- Defined patient population—“attribution”
- Management of “drift” outside network
  - Penalties to pts for this?
- Data is mandatory
  - “big data” but also actionable patient level
- Support to act on this data

Data

- Attribution of patients
  - Prospective vs performance year methods
- Track by population and by individual and their provider group
- Requires current claims data-Medicare, Medicaid, private insurance
Patient Engagement

• Critical component for ACO and any intervention
• Yet this is elusive

Summary

• ACO likely to propagate further
• Resources available to evaluate plan to determine if wise move:
  – cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html
  – AMA, AAFP, Most state medical societies
  – Health Affairs, Commonwealth Fund, Kaiser Permanente Foundation

Resources

by

George Bakris, MD

George Bakris, MD received his medical degree from the Rosalind Franklin Medical School. He completed his residency in Internal Medicine at the Mayo Graduate School of Medicine where he also completed a research fellowship in Physiology and Biophysics. He then completed fellowships in Nephrology and Clinical Pharmacology at the University of Chicago. From 1988 to 1991, he served as Director of Renal Research at the Ochsner Clinic and had faculty appointments in the Departments of Medicine and Physiology at Tulane University School of Medicine. He later was Professor and Vice Chairman of Preventive Medicine and Director of the Rush University Hypertension Center in Chicago from 1993 until 2006. Currently, he is a Professor of Medicine and Director of the ASH Comprehensive Hypertension Center in the Department of Medicine at the University of Chicago Medicine.

Dr. Bakris has published over 600 peer-reviewed articles and book chapters in the areas of diabetic kidney disease, hypertension and progression of nephropathy. He is the Editor or Co-Editor of 17 books, in the areas of Kidney Disease Progression and Diabetes. Additionally, he is an Associate Editor of the International Textbook of Cardiology. He was a member of the NIH National High Blood Pressure Education Program Working Group on Hypertension and Renal Disease. He also serves as an expert-consultant to the Cardio-renal Advisory Board of the FDA and to CMS. He was a co-principal investigator on the NIH Clinical Research training grant for clinical research (K30). He chaired the first National Kidney Foundation Consensus report on blood pressure and impact on renal disease progression. He has also served on many national guideline committees including: the Joint National Committee Writing Groups VI & 7, the JNC 7 executive committee, the American Diabetes Association Clinical Practice Guideline Committee, the National Kidney Foundation (K-DOQI) Blood Pressure Guideline committee and (K-DOQI) Diabetes Guideline committee. Dr. Bakris is the past-president of the American College of Clinical Pharmacology and the American Society of Hypertension (ASH).

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Learning Objectives

At the end of this presentation, the attendee will be able to:

- Define individual T2DM and cardiovascular disease goals
- Formulate a patient management strategy that targets the “ABC’s”: A1C, Blood Pressure and Cholesterol
- Explain the rationale for targeting renal glucose transport, and interpret related clinical data and the potential role of SGLT2 inhibition in individualized T2DM therapies
- Distinguish the unique differences between new SGLT2 inhibitors and discuss the clinical implications of these differences on appropriate patient selection
Program Title: The Emerging Role of SGLT Inhibitors in Individualized Treatment of T2DM

Activity Faculty
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Chicago, Illinois

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University of California, San Diego
Veterans Affairs Healthcare System

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45 Minutes: The Emerging Role of SGLT Inhibitors in Individualized Treatment of T2DM
15 minutes: Questions and Answers

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University of Rochester School of Medicine

George L. Bakris, MD
The University of Chicago

Vivian A. Fonseca, MD, FRCP
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Sponsored by
The France Foundation

Target Audience
This activity is intended for primary care physicians and other health care professionals who manage patients with type 2 diabetes.

Educational Activity Learning Objectives
Upon completion of this course, the participants should be able to:

• Define individual T2DM and cardiovascular disease goals
• Formulate a patient management strategy that targets the “ABCs”: A1C, Blood Pressure, and Cholesterol
• Explain the rationale for targeting renal glucose transport, and interpret related clinical data and the potential role
• Distinguish the unique differences between new SGLT2 inhibitors and discuss the clinical implications of these differences on appropriate patient selection
Statement of Need
This activity is designed to improve knowledge, competency, and practice improvements in the diagnosis, management, and treatment of patients with type 2 diabetes mellitus (T2DM).

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The Emerging Role of SGLT Inhibitors in Individualized Treatment of T2DM

George L. Bakris, MD
Professor of Medicine
Director, ASH Comprehensive Hypertension Center
The University of Chicago
Chicago, Illinois

Learning Objectives

• Define individual T2DM and cardiovascular disease targets
• Establish patient targets for the “ABCs”: A1C, Blood pressure, and Cholesterol
• Explain the rationale for targeting renal glucose transport, and interpret related clinical data and the potential role of SGLT2 inhibition in personalized T2DM therapies
• Distinguish the potential differences among new SGLT2 inhibitors and discuss the clinical implications of these differences on appropriate patient selection

Glucose Homeostasis

Contribution of Tissues to Glucose Uptake

Hypoglycemia
- Cognitive impairment
- Seizure
- Coma
- Brain death
- Arrhythmia
- Heart attack
- Palpitations

Hyperglycemia
- CV disease
- Retinopathy
- Neuropathy
- Nephropathy
- Glucotoxicity


Multiple Therapies for Type 2 Diabetes

- Metformin
- Insulin
- Thiazolidinediones
- GLP-1 analogues
- DPP-4 inhibitors
- SGLT2 Inhibitors
- α-glucosidase inhibitors
- Sulfonurias

Diabetes Drugs Impact Multiple Endpoints

<table>
<thead>
<tr>
<th>Drug</th>
<th>BW</th>
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<th>DL</th>
<th>Hypoglycemia Risk</th>
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<tr>
<td>α-glucosidase inhibitors</td>
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<td>Improved</td>
<td>Neut</td>
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<td>DPP-4 inhibitors</td>
<td>Loss/Neutral</td>
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<td>Improved</td>
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<td>GLP-1 agonists</td>
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<td>Insulin</td>
<td>Gain</td>
<td>Neutral*</td>
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<td>Improved</td>
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<td>Improved</td>
<td>Low</td>
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<td>SGLT2 inhibitors</td>
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<td>7</td>
<td>Low</td>
</tr>
<tr>
<td>Sulfonurias</td>
<td>Gain</td>
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<td>Variable</td>
<td>Moderate</td>
</tr>
<tr>
<td>TZD</td>
<td>Gain</td>
<td>Improved</td>
<td>Improved</td>
<td>Low</td>
</tr>
</tbody>
</table>

*Hyperinsulinemia is associated with hypertension

Learning Objectives

- Define individual T2DM and cardiovascular disease goals
- Formulate a patient management strategy that targets the “ABCs”: A1C, Blood pressure, and Cholesterol
- Explain the rationale for targeting renal glucose transport, and interpret related clinical data and the potential role of SGLT2 inhibition in individualized T2DM therapies
- Distinguish the unique differences between new SGLT2 inhibitors and discuss the clinical implications of these differences on appropriate patient selection

Treatment Goals: ABCs of Diabetes

- **HbA1C**
  - < 7 % for many people
  - Preprandial capillary plasma glucose 70–130 mg/dl
  - Peak postprandial (1-2 hours) capillary plasma glucose < 180 mg/dl
- **Blood pressure (mmHg)**
  - Systolic < 140 for most people
  - Diastolic < 80 (< 90 per Joint National Committee-8 2014 guideline)
- **Cholesterol – Lipid Profile (mg/dl)**
  - LDL Cholesterol < 100
    - LDL < 70 with overt CVD
  - HDL Cholesterol Men > 40, Women > 50
  - Triglycerides < 150

Impact of ABC Control Overview

- **Glucose Control**
  - Benefits both type 1 or type 2 diabetes
  - Every point drop in HbA1C reduces risk of complications
    - Microvascular 40% lower
    - Macrovascular 16% lower
- **Blood Pressure Control**
  - Reduces the risk of CV disease by 33 to 50%
  - Reduces the risk of microvascular complications by about 33%
  - A 10 mmHg reduction in systolic BP reduces the risk for any complication related to diabetes by 12 percent
  - Systolic BP goal < 140 mmHg based on expert opinion

Impact of ABC Control Overview (cont.)

• Control of Blood Lipids
  – Improved control of LDL can reduce CV complications by 20 to 50%

BP Intervention Trials in T2DM UKPDS

• Tight SBP (target < 150 mmHg) vs standard (< 180)
• Adults with new diagnosis of T2DM (mean age 46 at 10 y follow-up)
• No reductions in
  – Stroke
  – MI
  – All-cause mortality
• Reduced peripheral vascular disease during trial
• Improvements not sustained after relaxation of BP control

Impact of LDL Control

• Meta-analysis of statin trials
  – 14 randomized trials
  – 17,220 patients with T2DM
  – 71,370 patients without diabetes
• All-cause mortality reduced with statin treatment (per mmol/L)
  – Diabetes: 9% (P = 0.02)
  – No diabetes: 13% (P < 0.0001)

Diabetes Patients at Goal


Learning Objectives

• Define individual T2DM and cardiovascular disease goals
• Formulate a patient management strategy that targets the “ABCs”: A1C, Blood pressure, and Cholesterol
• Explain the rationale for targeting renal glucose transport, and interpret related clinical data and the potential role of SGLT2 inhibition in individualized T2DM therapies
• Distinguish the unique differences between new SGLT2 inhibitors and discuss the clinical implications of these differences on appropriate patient selection

Considerations for Patient Management

• Where is the patient now?
• What are the goals for this patient?
• What are the specific approaches to A, B, and C?
• Monitoring and office visit frequency
Considerations for Patient Management (cont.)

- How is this patient special?
  - Multiple medications/interactions
  - Efficacy of current medications
  - Side effects experienced
  - Adherence
    - Willingness to take medications
    - Cognitive state
    - Support
    - Cost
    - Pill burden/needle aversion
    - Side effect tolerance

Diabetes Management Schedule

<table>
<thead>
<tr>
<th>Item</th>
<th>Weekly</th>
<th>Bi-Weekly</th>
<th>Monthly</th>
<th>Quarterly</th>
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<tr>
<td>Weight and BP</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot exam</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking cessation and alcohol use</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Review medications</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Self management: glucose monitoring, diet, physical activity</td>
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</tr>
<tr>
<td>Assess for depression/mood disorder</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>LDL, serum creatinine, urine albumin/creatinine ratio</td>
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<td></td>
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<td></td>
<td>X</td>
</tr>
<tr>
<td>Eye, foot, dental exams</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Influenza vaccination</td>
<td>X</td>
<td></td>
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</tr>
</tbody>
</table>

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Role of the Kidney in Glucose Metabolism

Production

Utilization

Reabsorption

Glucose: From Blood to Urine


Upregulation of SGLT2 Transporter and Enhanced Cellular Glucose Uptake in Type 2 Diabetes

The Renal Glucose Threshold (RTG) Concept in Healthy Subjects

Healthy RTG ~10 mmol/L

Below RTG Minimal Glucosuria Occurs

Above RTG Glucosuria Occurs

Plasma Glucose (mmol/L)

Renal Glucose Re-Absorption

Glucose Flux (mmol/min)

Reabsorbed glucose

Excreted glucose

Plasma Glucose (mmol/l)

Renal Reuptake Summary

- In type 2 diabetes, enhanced renal glucose reabsorption contributes to hyperglycemia
- The glucose transporter SGLT2 is responsible for 90% of this glucose reabsorption
- Inhibition of SGLT2 will
  - Decrease glucose reabsorption
  - Increase urinary glucose excretion
- Predict weight loss and reduction in blood pressure

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Weighing SGLT2 Inhibition

Potential Benefits
- HbA1c lowering
- Mechanism complementary to other therapies
- Improved beta cell function
- Weight loss
- Reduced blood pressure
- Renal protection?

Potential Risks
- Vaginitis, balanitis
- Hypovolemia symptoms
- Increased LDL
- Polyuria
- Hyperkalemia
## Regulatory Status of SGLT2 Inhibitors

- **Canagliflozin**: Approved in United States 2013
  Approved in Europe 2013
- **Dapagliflozin**: Approved in United States 2014
  Approved in Europe 2012
- **Empagliflozin**: Application submitted to EMA and FDA 2013
  Approval likely in 2014

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## SGLT2 Inhibitors Reduce HbA1c

### Monotherapy

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Baseline</th>
<th>Treatment Effect vs Baseline</th>
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<tbody>
<tr>
<td>Canagliflozin¹</td>
<td>-2.0 kg vs placebo</td>
<td>9.6 kg</td>
</tr>
<tr>
<td>Dapagliflozin²</td>
<td>-1.73 kg vs placebo</td>
<td>8.4 kg</td>
</tr>
<tr>
<td>Empagliflozin³</td>
<td>-8.3 vs placebo</td>
<td>-8.3 vs placebo</td>
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<tr>
<td>Ipragliflozin⁴</td>
<td>-8.3 vs placebo</td>
<td>-8.3 vs placebo</td>
</tr>
</tbody>
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## SGLT2 Inhibitors Reduce Body Weight

### Monotherapy

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Baseline</th>
<th>Treatment Effect vs Baseline</th>
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<tr>
<td>Canagliflozin¹</td>
<td>-3.14% vs placebo</td>
<td>8.0%</td>
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<tr>
<td>Dapagliflozin²</td>
<td>-0.6% vs placebo</td>
<td>7.8%</td>
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<tr>
<td>Empagliflozin³</td>
<td>-0.47% vs baseline</td>
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</tr>
<tr>
<td>Ipragliflozin⁴</td>
<td>-0.81% vs placebo</td>
<td>7.9%</td>
</tr>
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## SGLT2 Inhibitors Reduce SBP

### Monotherapy

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Baseline</th>
<th>Treatment Effect vs Baseline</th>
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</tr>
<tr>
<td>Ipragliflozin⁴</td>
<td>-0.81% vs placebo</td>
<td>7.9%</td>
</tr>
</tbody>
</table>

SGLT2 Inhibitors Reduce SBP Added to Metformin

- Canagliflozin\(^1\) – 26 weeks, 300 mg
- Dapagliflozin\(^2\) – 24 weeks, 10 mg
- Empagliflozin\(^3\) – 12 weeks, 25 mg
- Ipragliflozin\(^4\) – 12 weeks, 300 mg

Treatment Group

Baseline

All in mmHg:

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Baseline</th>
<th>12-week SBP Reduction</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canagliflozin(^1)</td>
<td>135.9</td>
<td>-4.6 vs placebo</td>
<td>128.7</td>
</tr>
<tr>
<td>Dapagliflozin(^2)</td>
<td>135.3</td>
<td>-2.8 vs placebo</td>
<td>133.5</td>
</tr>
<tr>
<td>Empagliflozin(^3)</td>
<td>135.3</td>
<td>-4.3 vs placebo</td>
<td>130.5</td>
</tr>
<tr>
<td>Ipragliflozin(^4)</td>
<td>NA</td>
<td>-4.3 vs placebo</td>
<td>NA</td>
</tr>
</tbody>
</table>


SGLT2 Inhibitors Increase LDL Monotherapy

- Canagliflozin\(^1\) – 26 weeks, 300 mg
- Dapagliflozin\(^2\) – 24 weeks, 10 mg
- Empagliflozin\(^3\) – 12 weeks, 25 mg

Treatment Group

Baseline

All in mg/dL:

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Baseline</th>
<th>12-week LDL Increase</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canagliflozin(^1)</td>
<td>112</td>
<td>+8.2 vs placebo</td>
<td>103.8</td>
</tr>
<tr>
<td>Dapagliflozin(^2)</td>
<td>66</td>
<td>+3.7 vs placebo</td>
<td>62.3</td>
</tr>
<tr>
<td>Empagliflozin(^3)</td>
<td>66</td>
<td>+2.7 vs placebo</td>
<td>63.6</td>
</tr>
</tbody>
</table>


Dapagliflozin: Infections Monotherapy, 24 weeks

- Genital Infections
- Urinary Tract Infections

Patients (%)

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Genital Infections</th>
<th>Urinary Tract Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBO</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>5 mg</td>
<td>5.7</td>
<td>7.4</td>
</tr>
<tr>
<td>10 mg</td>
<td>12.5</td>
<td>12.9</td>
</tr>
<tr>
<td>N</td>
<td>75</td>
<td>75</td>
</tr>
</tbody>
</table>

Men vs Women

Canagliflozin: Infections Monotherapy, 26 weeks

- Genital Infections
- Urinary Tract Infections

Patients (%)

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Genital Infections</th>
<th>Urinary Tract Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBO</td>
<td>2.1</td>
<td>2.1</td>
</tr>
<tr>
<td>100 mg</td>
<td>6.2</td>
<td>6.8</td>
</tr>
<tr>
<td>300 mg</td>
<td>6.6</td>
<td>7.2</td>
</tr>
<tr>
<td>N</td>
<td>192</td>
<td>195</td>
</tr>
</tbody>
</table>

Men vs Women

Empagliflozin: Infections 78 Week Open Label Extension Study

- Genital Infections
- Urinary Tract Infections

Patients (%)

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Genital Infections</th>
<th>Urinary Tract Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Met</td>
<td>3.6</td>
<td>7.1</td>
</tr>
<tr>
<td>10 mg</td>
<td>4.3</td>
<td>7.1</td>
</tr>
<tr>
<td>25 mg</td>
<td>5.8</td>
<td>7.1</td>
</tr>
<tr>
<td>Empa</td>
<td>3.6</td>
<td>7.1</td>
</tr>
<tr>
<td>10 mg</td>
<td>4.3</td>
<td>7.1</td>
</tr>
<tr>
<td>25 mg</td>
<td>5.8</td>
<td>7.1</td>
</tr>
<tr>
<td>N</td>
<td>56</td>
<td>106</td>
</tr>
</tbody>
</table>

SGLT2 Inhibitors: Adverse Events

- Increased genital mycotic infection – 2% to 8% excess over placebo
- Bacterial urinary tract infections – 1% to 12% excess over placebo
- No observed episodes of pyelonephritis or urosepsis
- Infections were manageable and rarely led to discontinuation of treatment – Managed with standard antifungal creams and hygienic measures

SGLT2 Inhibition as a Treatment for Diabetes

- **Efficacy**
  - Reduction in HbA1c of 0.5% to 1.0%
  - Weight reduction of ~3 kg
  - Reduction in systolic BP of 3 to 5 mmHg
  - Effective as monotherapy and in combination

- **Safety**
  - Little or no risk of hypoglycemia
  - Increased risk of mycotic genital infections
  - Uncommon hyperkalemia in select populations
    - Elderly
    - ACE inhibitors
    - ARB
    - Diuretic

- **Side Effects**
  - Polyuria
  - Transient mild hypotension

Clinical Outcome: MACE
CV Death, MI, Stroke

- Canagliflozin\(^1\)  HR = 0.91
- Dapagliflozin\(^2\)  HR = 0.77

---

Summary

- Glucose, lipid, and blood pressure control are all important in managing patients with diabetes
  - Less than 20% of patients are at goal for all 3
- Glucose reuptake in the kidney is a new mechanism for managing hyperglycemia
- Drugs that inhibit SGLT2 have positive effects on
  - A: HbA1c
  - B: blood pressure
  - And body weight!
- Lipid effects vary with inhibitor, class effect not clear
- SGLT2 inhibitors may impact CV events
- Major adverse effect is increased genital infection

\(^1\) Canagliflozin FDA Advisory Committee Meeting. January 10, 2013.
“Tools for Helping Control Obesity from a Pharmacist, Psychologist, Bariatric Surgeon and Nutritionist Point of View”

by

Larry Georgopoulos, PharmD, PhC; Sara Perovich, MPH, RD, LD, CDE; Duc Vuong, MD; & Marlin Hoover, PhD, MS

Larry Georgopoulos, PharmD, PhC joined the UNM College of Pharmacy as an Associate Dean of Clinical Affairs and Professor of Pharmacy Practice in 2010, and brings over 40 years of experience, most of it in leadership roles with large integrated healthcare systems. His teaching and research interests are in managed care pharmacy practice, health care delivery, pharacoconomics and health outcomes. His health care delivery operations and managed health care experience includes FHP International/Pacificare Inc. where he was Regional Vice President of Medical and Pharmacy Operations for AZ/NM, Sierra Health Services Inc. where he was Corporate Vice President Pharmacy Programs/Operations, and Presbyterian where he was Executive Director of Pharmacy Services.

Dr. Georgopoulos is also the Steering Committee Chair for the New Mexico Prescription Improvement Coalition (NMPIC) which has launched CMS Innovation Center funded medication safety related projects in the areas of e-Prescribing, Medication Therapy Management, Inappropriate Prescription Drug Abuse, and Inappropriate Medication Use in Seniors. NMPIC is sponsored by HealthInsight New Mexico. Dr. Georgopoulos received his PharmBS, degree from the University of Utah, College of Pharmacy and his PharmD degree from the University of New Mexico. He also completed a Fellowship Certificate Program in Medical Management from the University of California, Irvine Health Sciences Center.

Email: LGeorgopoulos@salud.unm.edu

Sara J. Perovich, MPH, RD, LD, CDE is a Clinical Dietitian at Presbyterian Healthcare Services in Albuquerque, New Mexico. Over decades of dietetic practice in a variety of settings, Sara has promoted healthful eating to prevent, treat, and manage obesity among people of all ages. She completed her MPH at the University of Hawaii with an emphasis in public health nutrition. She completed her BS degree and dietetic training in Home Economics/Dietetics at the University of New Mexico with an emphasis in community dietetics. In addition, Sara is a part-time nutrition instructor at the Central New Mexico Community College in Albuquerque and a regular contributor to the Eating Well column in the Albuquerque Journal.

Email: sperovich@phs.org

(Bios and Learning Objectives continued on the next page)
Duc Vuong, MD is an internationally renowned bariatric surgeon and director of Lovelace Bariatrics in Albuquerque. He founded and is the President of the New Mexico Bariatric Society and is on the board of the International Bariatric Club, which is a unique consortium of bariatric surgeons across the globe. Dr. Vuong is from Houston, TX, and moved to Albuquerque last August.

Known as the Support Surgeon, Dr. Vuong is recognized for his unique patient education program and has written multiple popular patient books, which prepares patients for success after weight loss surgery. He is a popular speaker and costars in the TLC reality show “900 Pound Man: Race Against Time.”

Email: duc.vuong@lovelace.com

Marlin Hoover, PhD, MS is a Prescribing Psychologist who is a Behavioral Science Faculty person at the Southern New Mexico Family Medicine Residency Program (SNMFMRP). Dr. Hoover has a Masters in Divinity from Bethany Theological Seminary, a Masters in Social Science and a Masters in Behavioral Science from the University of Chicago, a Doctorate in Behavioral Science from the University of Chicago and a Postdoctoral Masters in Clinical Psychopharmacology from Farleigh Dickenson University. In addition to his position at the SNMFMRP, Dr. Hoover is an Adjunct Professor at Fairleigh Dickenson University's Department of Psychology and at New Mexico State University's Department of Counseling Psychology’s program teaching postdoctoral psychologists clinical psychopharmacology. Dr. Hoover maintains supervision of his clinical practice based in Tinley Park, Illinois and is past president of the Illinois Psychological Association. Dr. Hoover is actively working to promote collaboration between Family Physicians and psychologists.

Email: marlin.hoover@lpnt.net

**Learning Objectives**

At the end of this presentation, the attendee will be:

- Able to list several medicines that can be used in assisting patients with obesity
- Aware of nutritional principles to help guide patients to lose weight
- Aware of at least one surgical procedure that will be helpful to weight loss
- Aware of behavioral interventions that would assist patients to lose weight
New and Emerging Pharmacotherapy Options as Adjuncts to New Obesity Treatment Approaches

- Obesity is associated with increased morbidity and mortality, as well as increased healthcare costs. The burden of obesity quantified including the impact of cardiometabolic risks.
- Evaluate the safety, efficacy and cost-effectiveness models in assessing newer and emerging obesity treatment options.
- Transitioning away from a ‘BMI-centric model’ to a ‘cardiometabolic-centric or complication-centric’ models when making treatment decisions.
Discussion Points

- Facts about obesity
- A few nutrition points of interest
- Food logs

Facts about Obesity

Facts that help establish a framework for intervention and prevention:

- Heritability is not destiny; moderate environmental changes can promote as much weight loss as the most efficacious pharmaceutical agents available

- Reduced energy intake very effectively reduces weight, but trying to go on a diet or recommending that someone go on a diet generally does not work well in the long-term


Facts about Obesity

Facts that are prescriptive, offering tools for the public:

- Increased exercise has health benefits regardless of weight
- Physical activity in a sufficient dose aids in long-term weight maintenance
- Continuation of conditions that promote weight loss promotes maintenance of lower weight
- For OW children, programs that involve parents and the home environment promote greater weight loss


Facts about Obesity

Facts that are suited to clinical settings:

- Provision of meals and use of meal-replacement products promote greater weight loss

- Some drugs can help patients maintain weight loss as long as the agents continue to be used

- In appropriate patients, bariatric surgery results in long-term weight loss


Barbara Rolls, PhD

- Volumetrics
- Energy Density
- Satiety

Energy Density

- Over the course of a day or two a person will eat about the same weight of food.
- To lose weight, eat the usual amount of food but lower the amount of calories in each portion.
- Calories/Weight (g)=Energy density (E.D.)
- The lower the number, the better.

<table>
<thead>
<tr>
<th>Energy Density of Some Combination Foods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food</strong></td>
</tr>
<tr>
<td>Beef stew with vegetables</td>
</tr>
<tr>
<td>Chicken chow mein</td>
</tr>
<tr>
<td>Chili con carne with beans, canned</td>
</tr>
<tr>
<td>Spaghetti with meat sauce</td>
</tr>
<tr>
<td>Bean and cheese burrito</td>
</tr>
<tr>
<td>Hot dog with bun, plain</td>
</tr>
<tr>
<td>Cheese pizza, thick crust</td>
</tr>
</tbody>
</table>

Energy Density of Some Protein Foods

<table>
<thead>
<tr>
<th>Food</th>
<th>Serving Size</th>
<th>Energy Density</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skim Milk</td>
<td>1 cup</td>
<td>0.35</td>
</tr>
<tr>
<td>Black beans</td>
<td>½ cup</td>
<td>0.9</td>
</tr>
<tr>
<td>Low-fat yogurt, fruit</td>
<td>1 cup</td>
<td>1.0</td>
</tr>
<tr>
<td>Chicken breast, no skin</td>
<td>3 ounces</td>
<td>1.3</td>
</tr>
<tr>
<td>Boiled egg</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td>Lean ground beef</td>
<td>3 ounces</td>
<td>2.7</td>
</tr>
<tr>
<td>Cheddar cheese</td>
<td>1 ounce</td>
<td>4.0</td>
</tr>
</tbody>
</table>

Consider MyPlate

Satiety

- The feeling of fullness at the end of the meal
- The more satiety you feel at the end of a meal, the less you’ll eat at the next.

Sensory Specific Satiety

- As we eat, the pleasure we get from a specific food slowly declines
- The changes in pleasantness of tastes and smells occur quite rapidly as we eat a meal
- Variety encourages us to eat
Managing Variety

• Fully enjoy food- savor its flavor, texture and aroma
• Look for ways to add flavor with fewer calories
• Start with a low E.D. food, such as salad or broth-based soup
• Balance high-calorie with low-calorie foods

Lower E.D. foods are more satisfying to your body

• Mind
• Eyes
• Nose, Mouth
• Stomach

Food Logs: tools for self-monitoring

• Provide useful information for weight management planning
  • Increase awareness
  • Reinforce behaviors that assist in meeting goals
  • Illustrate circumstances to manage stimulus control
  • Develop analytical and problem-solving skills
  • Provide evidence that setbacks are controllable
• Can be used to track
  • Specific food or beverage
  • Quantity
  • Preparation method
  • Time of day
  • Place of eating
  • Mood, hunger level

Options for tracking food

• Hand written- notebook, diary, notecards
• Computer, tablet- spreadsheet, software
• Phone- apps for dietary software, pictures of meals
  • Software ideas
    • Choosemyplate.gov
    • Myfitnesspal
    • Gomeals

Conclusions

• Diet is a very important aspect of weight management
• Eating a variety of foods is important for nutrition and meal satisfaction
• Choosing a combination of foods that, overall, lower the energy density of a meal can be successful in reducing calories for weight management
• Self-monitoring with food logs helps in weight management planning

Sara Perovich
sperovich@phs.org
THANK YOU!
Dr Duc. Vuong

1) An update on Weight Loss and Metabolic Surgery—Gastric banding has drastically declined. Sleeve gastrectomy is expected to be the number one bariatric procedure worldwide this year. Sleeve gastrectomy is now considered a metabolic surgery and is an effective treatment for diabetes. Rise in revisional bariatric surgery—a cloudy picture. New technologies—what’s on the horizon?

2) What Family Practitioners Need to Know to Care for Bariatric Patients—longterm results, common postop complications, common nutritional deficiencies, when to request additional studies and when to refer back to bariatric surgeon.
SUNDAY, AUGUST 3, 2014

7:00 a.m. Exhibits Open
Breakfast - Exhibit Hall

8:00 a.m. “Keeping the Population of New Mexico Healthy Using the ECHO Model”
Arthur Bankhurst, MD

9:00 a.m. “Enlightened Well Woman Care”
Jennifer Phillips, MD

10:00 a.m. Break – Exhibit Hall

10:30 a.m. “Enlightened Well Man Care”
Alfredo Vigil, MD

11:30 a.m. “Primary Care and Prevention for the Addicted Patient”
Valerie Carrejo, MD

12:30 p.m. Drawing for Door Prizes
Must be registered for the conference & present to win
“Keeping the Population of New Mexico Healthy Using the ECHO Model”

by

Arthur Bankhurst, MD

Arthur Bankhurst, MD is the Chair of the Department of Rheumatology, a division of the Department of Internal Medicine at the University of New Mexico, Albuquerque, NM. In addition, Dr. Bankhurst directs the Project ECHO weekly Rheumatology Tele-clinic. He has numerous publications and years of research under his belt. He remains passionate about improving the lives of New Mexicans struggling with rheumatologic conditions and is equally passionate about increasing clinical knowledge related to rheumatology. Dr. Bankhurst received his post-graduate education from Case Western Reserve University in Cleveland, OH.

Email: ABankhurst@salud.unm.edu

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Understand and utilize a new model that enhances access to treatment for patients in rural areas and management of patients’ chronic and complex diseases
- Detail the platforms by which Project ECHO clinicians gain competency and expertise in the delivery of specialized complex care to patients with chronic health conditions
The mission of Project ECHO® is to expand the capacity to provide best practice care for common and complex diseases in rural and underserved areas and to monitor outcomes.

A Global Health Problem
Over 170 Million Carriers Worldwide, 3-4 Million new cases/year

New Mexico
- Estimated number is greater than 28,000
- In 2004 less than 5% had been treated
  - 2,300 prisoners were HCV positive (~40% of those entering the corrections system), none were treated

Treatment
Good news ...
- Curable in 70% of cases

Bad news ...
- Severe side effects:
  - anemia (100%)
  - neutropenia >35%
  - depression >25%
  - No Primary Care Physicians treating HCV

Rural New Mexico
Underserved Area for Healthcare Services
- 121,356 square miles
- 2.08 million people
- 47% Hispanic
- 10.2% Native American
- 19% poverty rate compared to 14.3% nationally
- 21% lack health insurance compared to 10% nationally

- 32 of 33 New Mexico counties are listed as Medically Underserved Areas (MUsAs)
- 14 counties designated as Health Professional Shortage Areas (HPSAs)
Goals of Project ECHO®

Develop capacity to safely and effectively treat HCV in all areas of New Mexico and to monitor outcomes.

Develop a model to treat complex diseases in rural locations and developing countries.

Partners

- University of New Mexico School of Medicine Department of Medicine, Telemedicine and CME
- NM Department of Corrections
- NM Department of Health
- Indian Health Service
- FQHCs and Community Clinics
- Primary Care Association

Methods

- Use Technology
- Sharing “best practices”
- Case based learning
- Web-based database to monitor outcomes

What is Best Practice in Medicine

- Algorithm
- Check Lists
- Process
- Wisdom Based on Experience

Steps

- Train physicians, mid-level providers, nurses, pharmacists, educators in HCV
- Train to use web based software — “iHealth”
- Conduct telemedicine clinics — “Knowledge Network”
- Initiate co-management — “Learning Loops”
- Collect data and monitor outcomes centrally
- Assess cost and effectiveness of programs

Benefits to Rural Clinicians

- No cost CMEs and Nursing CEUs
- Professional interaction with colleagues with similar interest
  - Less isolation with improved recruitment and retention
- A mix of work and learning
- Access to specialty consultation with GI, hepatology, psychiatry, infectious diseases, addiction specialist, pharmacist, patient educator
Technology

- Videoconferencing Hardware
- Videoconferencing Software
- Video Recording System
- You Tube-like Website/Archive
- iHealth – Electronic Clinical Management Tool
- iECHO – Electronic TeleECHOClinic Management Solution

How well has model worked?

- 500 HCV TeleECHO™ Clinics have been conducted
- >5,000 patients entered HCV disease management program
- CME’s/CE’s issued:
  - Total CME hours 57,000 hours at no cost for HCV and 12 other disease areas

Project ECHO® Clinicians
HCV Knowledge Skills and Abilities (Self-Efficacy)

<table>
<thead>
<tr>
<th>Community Clinicians N=25</th>
<th>BEFORE Participation MEAN (SD)</th>
<th>TODAY MEAN (SD)</th>
<th>Paired Difference (p-value) MEAN (SD)</th>
<th>Effect Size for the change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ability to identify suitable candidates for treatment for HCV</td>
<td>2.8 (1.2)</td>
<td>5.6 (0.8)</td>
<td>2.8 (1.2) (0.0001)</td>
<td>2.4</td>
</tr>
<tr>
<td>2. Ability to assess severity of liver disease in patients with HCV</td>
<td>3.2 (1.2)</td>
<td>5.5 (0.9)</td>
<td>2.3 (1.1) (0.0001)</td>
<td>2.1</td>
</tr>
<tr>
<td>3. Ability to treat HCV patients and manage side effects</td>
<td>2.0 (1.1)</td>
<td>5.2 (0.8)</td>
<td>3.2 (1.3) (0.0001)</td>
<td>2.6</td>
</tr>
</tbody>
</table>

(continued)
### Project ECHO® Clinicians

**HCV Knowledge Skills and Abilities (Self-efficacy)**

<table>
<thead>
<tr>
<th>Community Clinicians</th>
<th>BEFORE Participation</th>
<th>TODAY Participation</th>
<th>Paired Difference (p-value)</th>
<th>Effect Size for the change</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=25</td>
<td>MEAN (SD)</td>
<td>MEAN (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Competence</td>
<td>2.8* (0.9)</td>
<td>5.5* (0.6)</td>
<td>2.7 (0.9) (&lt;0.0001)</td>
<td>2.9</td>
</tr>
</tbody>
</table>

Cronbach’s alpha for the BEFORE ratings = 0.92 and Cronbach’s alpha for the TODAY ratings = 0.86 indicating a high degree of consistency in the ratings on the 9 items.


### Clinician Benefits

(Data Source; 6 month Q-5/2008)

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Not/Minor Benefits</th>
<th>Moderate/Major Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enhanced knowledge about management and treatment of HCV patients.</td>
<td>3% (1)</td>
<td>97% (34)</td>
</tr>
<tr>
<td>Being well-informed about symptoms of HCV patients in treatment.</td>
<td>6% (2)</td>
<td>94% (33)</td>
</tr>
<tr>
<td>Achieving competence in caring for HCV patients.</td>
<td>3% (1)</td>
<td>98% (34)</td>
</tr>
</tbody>
</table>

### Project ECHO® Annual Meeting Survey

<table>
<thead>
<tr>
<th>N=17</th>
<th>Mean Score (Range 1-5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project ECHO® has diminished my professional isolation.</td>
<td>4.3</td>
</tr>
<tr>
<td>My participation in Project ECHO® has enhanced my professional satisfaction.</td>
<td>4.8</td>
</tr>
<tr>
<td>Collaboration among agencies in Project ECHO® is a benefit to my clinic.</td>
<td>4.9</td>
</tr>
<tr>
<td>Project ECHO® has expanded access to HCV treatment for patients in our community.</td>
<td>4.9</td>
</tr>
<tr>
<td>Access, in general, to specialist expertise and consultation is a major area of need for you and your clinic.</td>
<td>4.9</td>
</tr>
<tr>
<td>Access to HCV specialist expertise and consultation is a major area of need for you and your clinic.</td>
<td>4.9</td>
</tr>
</tbody>
</table>

### Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers

Results of the HCV Outcomes Study


### Objectives

- To train primary care clinicians in rural areas and prisons to deliver Hepatitis C treatment to rural populations of New Mexico
- To show that such care is as safe and effective as that given in a university clinic
- To show that Project ECHO® improves access to Hepatitis C care for minorities

### Participants

- Study sites
  - Intervention (ECHO)
    - Community-based clinics: 16
    - New Mexico Department of Corrections: 5
  - Control: University of New Mexico (UNM) Liver Clinic
Principle Endpoint
Sustained Viral Response (SVR): no detectable virus 6 months after completion of treatment

Treatment Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>ECHO</th>
<th>UNMH</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minority</td>
<td>68%</td>
<td>49%</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>SVR* (Cure) Genotype 1</td>
<td>50%</td>
<td>46%</td>
<td>NS</td>
</tr>
<tr>
<td>SVR* (Cure) Genotype 2/3</td>
<td>70%</td>
<td>71%</td>
<td>NS</td>
</tr>
</tbody>
</table>

*SVR=sustained viral response

Conclusions
- Rural primary care Clinicians deliver Hepatitis C care under the ages of Project ECHO that is as safe and effective as that given in a University clinic.
- Project ECHO improves access to hepatitis C care for New Mexico minorities.

ECHO Model is Cost Effective
- In 60 Percent of Patients treated for HCV the model was cost savings
- Overall Cost per Discounted Quality of Life Year Gained was less than 3500 dollars

AASLD Presentation Washington DC
November 2013

Disease Selection
- Common diseases
- Management is complex
- Evolving treatments and medicines
- High societal impact (health and economic)
- Serious outcomes of untreated disease
- Improved outcomes with disease management

Bridge Building
Pareto’s Principle
- Chronic Pain
- Rheumatoid Arthritis + Rheumatology Consultation
- Substance Use and Mental Health Disorders
Force Multiplier
Use Existing Community Clinicians

Specialists  Primary Care  Physician Assistants  Nurse Practitioners

Chronic Pain

Rheumatoid Arthritis + Rheumatology Consultation

Substance Use and Mental Health Disorders

Successful Expansion into Multiple Diseases

<table>
<thead>
<tr>
<th></th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thurs</th>
<th>Fri</th>
</tr>
</thead>
<tbody>
<tr>
<td>8-10 a.m.</td>
<td>Hepatitis</td>
<td>Diabetes</td>
<td>Dementia</td>
<td>Palliative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Arora</td>
<td>&amp; Endocrinology</td>
<td>Herman</td>
<td>Care</td>
<td>Neale</td>
</tr>
<tr>
<td>10-12 a.m.</td>
<td>Rheumatology</td>
<td>Chronic Pain</td>
<td>Integrated</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bankhurst</td>
<td>Katzman</td>
<td>Addictions &amp; Psychiatry</td>
<td>Komaromy</td>
<td></td>
</tr>
<tr>
<td>2-4 p.m.</td>
<td>HIV</td>
<td>Roulette</td>
<td>HIV Peer Educator Training</td>
<td>Komaromy</td>
<td></td>
</tr>
</tbody>
</table>

Transforming Primary Care with Knowledge Networks

"Expanding the Definition of Underserved Population"
Chronic Disease Management is a Team Sport

Primary Care Nurse Medical Assistant Community Health Worker

- Diabetes and Cardiac Risk Reduction
- Asthma and COPD
- Substance Use and Mental Health Disorders

Community Based Care for Cardiac Risk Factor Reduction was more Effective than Enhanced Primary Care

![](chart.png)

Why is a CHW Intervention Effective?

- Live in Community
- Understand culture
- Appreciate economic limitations of patient and know community resources available to patient
- Often know family and can engage other social resources for patient
- Spend more time with patient

ECHO CHW Training

Multiple Tracks

- CHW Specialist Training
  - CREW: Diabetes, Obesity, Hypertension, Cholesterol, Smoking Cessation, Exercise Physiology
  - CARS: Substance Use Disorders
  - ECHO Care™: Complex Multiple Diagnoses
- Prison Peer Educator Training

Specialty CHW Program

- Narrow Focus — Deep Knowledge
- Standardized Curriculum
- 3 Day Onsite
- Webcam/Weekly Video Based Clinics
  - Diet
  - Exercise
  - Smoking Cessation
  - Motivational Interviewing
  - Gentle Nudges
  - Finger Stick
  - Foot Exam
- Ongoing support via knowledge networks
- Part of Disease Management Team

Community Health Workers in Prison

The New Mexico Peer Education Program

Graduation Ceremony of First Cohort
The New Mexico Peer Education Program

Potential Benefits of ECHO Model™ to Health System

- Quality and Safety
- Rapid Learning and best-practice dissemination
- Reduce variations in care
- Access for Rural and Underserved Patients, reduced disparities
- Workforce Training and Force Multiplier
- Demonopolize Knowledge
- Improving Professional Satisfaction/Retention
- Supporting the Medical Home Model
- Cost Effective Care - Avoid Excessive Testing and Travel
- Prevent Cost of Untreated Disease (e.g.: liver transplant or dialysis)
- Integration of Public Health into treatment paradigm
ECHO Replication in US:

- University of Washington (HCV, Chronic Pain, HIV, Addiction)
- University of Chicago (Hypertension, Breast Cancer, ADHD, Childhood Obesity)
- Department of Defense – Worldwide Initiative (Chronic Pain)
- Veterans Administration Health System – 11 Regions (Chronic Pain, Diabetes, Heart Failure, HCV)
- University of Nebraska (Diabetes/Cardiovascular Risk Reduction, Sports Medicine, Thyroid & Diabetes, Antibiotic Stewardship, Mental Health, Rheumatology)
- University of Miami (HIV, Stroke and Liver Care)
- University of South Florida, ETA and Florida/Caribbean, AETC (General HIV, Adolescents/Pediatrics MCH/AIDS Infection, Psychiatry & HIV, Spanish Language HIV)
- Harvard, Beth Israel Deaconess Medical Center (HCV, Gerontology – ECHO AGE)
- St Joseph Hospital and Medical Center – Arizona (HCV)
- Community Health Center, Inc. – Connecticut (HIV, HCV, Chronic Pain, Opioid Addiction – Buprenorphine)
- LA Net, Project ECHO LA (AAPA Preventive Care, Nephrology, Adult Psychiatry)
- UNM: Envision NM (Childhood Overweight Medical Management, Pediatric Nutrition, Psychiatry, Asthma/Pulmonology)

ECHO Replication Sites Worldwide:

- Maulana Azad Medical College – New Delhi, India (HIV)
- Institute of Liver and Biliary Sciences – New Delhi, India (HCV)
- ECHO India – Mumbai, Chandigargh, & Lucknow (Autism)
- Uruguay (Liver Disease)

Use of multipoint videoconferencing, best practice protocols, co-management of patients with case based learning (the ECHO model) is a robust method to safely and effectively treat common and complex diseases in rural and underserved areas and to monitor outcomes.
“Enlightened Well Woman Care”

by

Jennifer Phillips, MD

Jennifer Phillips, MD is an associate professor at the University of New Mexico Department of Family and Community Medicine. She graduated from UNM in 1997 and UNM Medical School in 2001. She completed three years of her residency training at UNM Program in Family and Community Medicine and graduated in November 2005. Her special interests are women’s health and reproduction, obstetrics, pediatrics, and preventative care. She comes from a long line of educators and is excited about the opportunity to empower those who would like to learn about medicine. Jennifer practices patient-centered medicine, and seeks to inspire her patients to be attentive to living healthy lives, involving the body, mind and spirit. She is a native New Mexican, and enjoys being in the mountains and the city with her daughter; they like to hike, paint, and dance together.

Email: jkphillips@salud.unm.edu

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Understand the hazards of over-screening for disease
- Understand the USPSTF guidelines for evidence-based care of women
Case 1
• 17 yr old young woman
• Never been pregnant
• Sexually active and interested in birth control
• Non-smoker
• What screening tests are important?
• What exam is important?

Case 2
• 28 yr old woman
• Monogamous relationship
• Non-smoker
• Has Mirena IUD 😊
• What screening tests are important?
• What exam is important?

Case 3
• 55 yr old woman
• No family history of breast or ovarian cancer
• Smoker
• Not sexually active
• What screening tests are important?
• What exam is important?

Some basic principles
• There are consequences to over-screening and over-treatment
• Sometimes less is more
• Avoid hazards of false positive tests
• Avoid unneeded work-ups
• First, do no harm

Screening Tests
• Screening tests are good when the prevalence of disease is high in the targeted population
• Screening tests are good when there is effective treatment for the disease being screened
• Screening tests are good when they are easy to administer, cause little discomfort, and are inexpensive and accurate
Why do less?

- Avoid a wasted visit - Improve access
- Avoid lost time for visits of little or no benefit
- Save health care dollars
- Remember screening tests are only a small part of preventive health care

Don’t hold birth control hostage!

http://www.self.com/images/health/2006/05/issues-accessing-birth-control-

Health screening visit vs Family Planning visit

- Never hold birth control hostage for pap smears
- Tailor visit to your patient’s needs

2004 WHO Practice Recommendations for Contraception

- BP should be measured before OCPs, DMPA (depo) and Nexplanon
- No need for: Breast exam, pap, genital exam, STD screen, physical exam or lab tests
- They deemed these as not “contributing substantially to safe and effective use of hormonal contraceptive methods.”
- They can actually be a barrier to contraception

Family Planning Visit

- Supports correct and consistent use of chosen contraception
- Checks for contraceptive satisfaction 😊
- Helps clarify reproductive life plan
- Encourages a healthy reproductive life
- STD screening
### Well Woman Care = Health Screening Visit
- Improves health through anticipatory guidance and screening
- Improves woman’s sense of well being through attention to “health visit” instead of “sick visit”
- Promotes therapeutic relationship between woman and provider
- Encourages positive action towards maintenance of health

### If you aren’t their Primary Care Provider
- Find out if they have one
- Don’t duplicate services
- Having a primary care provider improves health outcomes!

### Well Woman Visit
- Family Planning / STD screening PLUS
- Appropriate cancer screening
- Address alcohol use, drug use, smoking
- Intimate partner violence screening
- Depression screening
- Vaccinations

### General Health Issues
- Diet and exercise
- Lab work: screening for high cholesterol and diabetes
- Osteoporosis screening
- Overweight and Obesity
- Blood pressure screening

### Well Woman Care Differs Throughout a Woman’s Lifecycle
- Early Womanhood— HPV vaccine, other Vaccinations, STD screening, sexual education
- Womanhood— Contraception, Options, Preconception Counselling, Pregnancy and Prenatal care, Mental Health, Cancer Screening, Vaccinations
- Late Womanhood and Grandmotherhood— Menopause and Postmenopause, Cancer Screening, Vaccinations

### Who do you listen to?
- There are many organizations with guidelines for well woman care
- AAFP, ACOG, ACS, AMA, USPSTF
Who Defines Well Woman Services?

US Preventive Services Taskforce

- Agency for Healthcare Research & Quality
- Rigorous evidence-based review process
- Multidisciplinary, non-industry expert panel
- Screening recommendations by disease and by four age groups + pregnancy
- Supports “opportunistic prevention” model

USPSTF 2007: Strength of Recommendation

<table>
<thead>
<tr>
<th>Grade</th>
<th>Comment</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Recommend</td>
<td>Net benefit is substantial</td>
</tr>
<tr>
<td>B</td>
<td>Recommend</td>
<td>Net benefit is moderate</td>
</tr>
<tr>
<td>C</td>
<td>Recommend against providing routinely</td>
<td>May be considerations that support the service in an individual patient</td>
</tr>
<tr>
<td>D</td>
<td>Recommend against</td>
<td>No net benefit (or) harms outweigh benefits</td>
</tr>
<tr>
<td>I</td>
<td>Evidence is insufficient</td>
<td>Evidence is lacking, poor quality, or conflicting</td>
</tr>
</tbody>
</table>

www.uspreventiveservicestaskforce.org

Case 1
17 yr old young woman

- What’s recommended according to USPSTF app?
  - non-smoker
  - sexually active
  - not pregnant

Grade A Recommendations

- Chlamydia screening
- Folic acid supplementation for all woman planning or capable of pregnancy
- HIV screening if at increased risk
- Syphilis screening if at increased risk

Case 2
28 yr old woman

- What’s recommended according to USPSTF app?
  - non-smoker
  - sexually active
  - not pregnant

Grade A Recommendations

- Pap
- Chlamydia screen only if at increased risk
- Folic acid supplement
- HIV screen only if at increased risk
- BP check
- Syphilis screen only if at increased risk
**Grade B Recommendations**

- Screen for alcohol misuse
- BRCA mutation testing for woman at increased risk
- Depression screening
- Gonorrhea screening only for women at increased risk
- Healthy diet counseling
- Lipid screening for those at increased risk for CAD
- Obesity screening and counseling
- Screen for Type 2 Diabetes if BP > 135/80

**Case 3**

55 yr old woman

- What’s recommended according to the USPSTF app?
  - Smoker
  - Not sexually active
  - Postmenopausal

**Grade A Recommendations**

- Aspirin to prevent CVD
- Pap
- Colon cancer screening
- BP check
- Lipid screening
- Counsel on tobacco use

**Immunizations**

- Women should be immunized at recommended intervals unless there are individual contraindications
- HPV vaccine in early adolescence
- Tdap booster
- Rubella if not immune
- Influenza every year
- Go to [http://www.cdc.gov/vaccines/schedules/easy-to-read/adult.html](http://www.cdc.gov/vaccines/schedules/easy-to-read/adult.html)

**Is a Well Woman Visit Advised Annually?**

- USPSTF says visits can be every 1-3 yrs depending on health status, risk factors and patient preference
- ACOG says annually
Is a physical exam always necessary?

- “Laying of hands” is therapeutic
- Parts of exam should be as needed
- Some visits may be mostly counseling, education and vital signs

Breast Cancer Screening Guidelines

<table>
<thead>
<tr>
<th>Test</th>
<th>Previous Guideline</th>
<th>ACS 2003</th>
<th>USPSTF 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast Self Exam (BSE)</td>
<td>Monthly</td>
<td>Optional</td>
<td>[D]</td>
</tr>
<tr>
<td>Mammogram</td>
<td>Baseline @ 35 + 40-49: Q2 yrs ≥ 50: yearly</td>
<td>≥ 40: annually</td>
<td>40-49: [C] 50-74: [B], every 2 yrs ≥75: [I]</td>
</tr>
</tbody>
</table>

Breast Self-Examination (BSE)

- Two very large RCTs (Shanghai, Russia)
- Mortality, survival equal in treatment and controls
- BSE no better than coincidental discovery of mass
- USPSTF 2009 [D] recommends against teaching BSE saying BSE is ineffective and potentially harmful
- American Cancer Society 2003
  - At ≥ 20 years old, inform of benefits, limitations
  - If BSE chosen, provide instruction in use
  - Acceptable not to do BSE or to do irregularly
  - Goal of BSE is “increased breast awareness”

Breast Self-Awareness (BSA)

- BSA is defined as women’s awareness of the normal appearance and feel of her breasts
- Endorsed by ACOG and ACS
- The effect of BSA education has not been studied
- Rationale
  - ½ of breast cancer cases ≥50 y.o. and 70% of cases in younger women detected incidentally
  - New cases can arise during screening intervals, and BSA may prompt women not to delay in reporting breast changes based on a recent negative screening result

Clinical Breast Exam (CBE)

- Sensitivity: 54%, specificity: 93-94%
- 10% of breast cancers detected on CBE alone, especially in younger women
- Rationale
  - USPSTF 2009: [I] recommendation
  - Most recommendations: start CBE at 40; perform annually (concurrent with mammogram) except
  - ACS 2012: 20-39 every 1-3 years, then annually
  - ACOG 2011: 20-39 every 1-3 years, then annually

Screening tests available to prevent 26% of cancer deaths

<table>
<thead>
<tr>
<th>Female cancer deaths</th>
<th>% Deaths</th>
<th>Screening Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>27%</td>
<td>None</td>
</tr>
<tr>
<td>Breast</td>
<td>15%</td>
<td>Yes</td>
</tr>
<tr>
<td>Bowel, Rectum</td>
<td>10%</td>
<td>Yes</td>
</tr>
<tr>
<td>Lymphoma/Leukemia</td>
<td>7%</td>
<td>None</td>
</tr>
<tr>
<td>Pancreas</td>
<td>6%</td>
<td>None</td>
</tr>
<tr>
<td>Ovary</td>
<td>6%</td>
<td>None (low risk)</td>
</tr>
<tr>
<td>Uterus</td>
<td>3%</td>
<td>None</td>
</tr>
<tr>
<td>Cervix</td>
<td>1%</td>
<td>Yes</td>
</tr>
</tbody>
</table>

ACOG Practice Bulletin No. 122, 2011
The USPSTF recommends:

- Biennial mammography 50-74 years [B]
- Against routine mammography 40-49 years [C]
- Evidence is insufficient to assess benefits, harms of mammography in women >75 years old [I]
- Digital mammography or MRI (vs film) [I]

The USPSTF recommends against routine screening mammography in women aged 40 to 49 years [C]

"The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient’s values regarding specific benefits and harms”

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-39</td>
<td>Screen if specified high risk factors</td>
</tr>
<tr>
<td>40-49</td>
<td>Discuss pros and cons of screening*</td>
</tr>
<tr>
<td>50-59</td>
<td>Encourage screening*</td>
</tr>
<tr>
<td>60-69</td>
<td>Strongly encourage screening*</td>
</tr>
<tr>
<td>70-74</td>
<td>Discuss pros and cons of screening*</td>
</tr>
<tr>
<td>&gt;75</td>
<td>Little data</td>
</tr>
</tbody>
</table>

*When done, perform routine mammography biennially

Screening Mammography Guidelines

USPSTF 2009

Screening Mammography: Benefits

- Sensitivity (positive when cancer present): 80-95%
- Specificity: (negative when cancer absent): 93-97%
- False positive (pos in absence of cancer): 3-7%
- Breast cancer deaths after ≥ 10 yrs screening
  - ACS meta-analysis 24% reduction
  - Women 50-69 years old 20-35% reduction

Screening Mammography: Harms

- Harms more likely in younger women
- Physical and psychological harms of over-diagnosis
- Unnecessary diagnostic imaging tests
- Biopsies in women without cancer
- Inconvenience due to false-positive screening results
- Harms of over-treatment of a breast cancer that would not become apparent during a woman’s lifetime
- Have become apparent, but wouldn’t shorten life

Exceptions

- Annual mammogram starting 10 years before the age of diagnosis of 1st degree relative with breast CA but not before age 30
- Annual mammogram after diagnosis of breast CA
- Annual mammogram starting at age 25-30 if BRCA2 carrier
- Annual mammogram starting at age 20-25 if BRCA1 carrier
Cervical Cancer Screening

- Most successful cancer screening program in the US
- 70% reduction in cervical cancer deaths in past 60 years
- 2010: 12,000 new cervical cancers; 4,200 deaths per year
- Advances in cervical cancer prevention since 1940s
  - Liquid-based cytology
  - hrHPV-DNA testing...co-testing and triage of test results
  - HPV vaccination...primary prevention of cervical cancer
  - Evidence-based cytology screening guidelines

Cervical Cytology Guidelines

**ACOG 2009**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women under 21 yrs old</td>
<td>Avoid screening</td>
</tr>
<tr>
<td>21-29 years old</td>
<td>Screen every 2 years</td>
</tr>
<tr>
<td>30 to 65 or 70 years old</td>
<td>May screen every 3 years</td>
</tr>
<tr>
<td>65 or 70 years old and older</td>
<td>May discontinue screening</td>
</tr>
<tr>
<td>HIV-positive</td>
<td>Screen annually</td>
</tr>
<tr>
<td>Immunosuppressed</td>
<td></td>
</tr>
<tr>
<td>Exposed in utero to DES</td>
<td></td>
</tr>
</tbody>
</table>

USPSTF Cervical Cytology Guidelines

**March 2012**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 to 65 years old</td>
<td>Every 3 years  A</td>
</tr>
<tr>
<td>Cytology + HPV combination, 30-65 years old</td>
<td>Every 5 years  A</td>
</tr>
<tr>
<td>Women under 21 yrs old</td>
<td>Avoid screening D</td>
</tr>
<tr>
<td>Age &gt;65 with adequate prior screening and not high risk</td>
<td>Avoid screening D</td>
</tr>
<tr>
<td>Total hysterectomy</td>
<td>Avoid screening D</td>
</tr>
<tr>
<td>HPV testing, alone or in combination, &lt; 30 years old</td>
<td>Avoid screening D</td>
</tr>
</tbody>
</table>

**Triple A Guideline: ACS, ASCCP, Am Society for Clinical Pathology**

CA CANCER J CLIN March 2012

<table>
<thead>
<tr>
<th>Years of Age</th>
<th>Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;21</td>
<td>No screening</td>
</tr>
<tr>
<td>21-29</td>
<td>Cytology alone every 3 years</td>
</tr>
<tr>
<td>30-65</td>
<td>Preferred: HPV + cytology every 5 years* OR Acceptable: Cytology alone every 3 years*</td>
</tr>
<tr>
<td>&gt;65</td>
<td>No screening, following adequate neg prior screens</td>
</tr>
<tr>
<td>After total hysterectomy</td>
<td>No screening, if no history of CIN2+ in the past 20 years or cervical cancer ever</td>
</tr>
</tbody>
</table>

*If cytology result is negative or ASCUS + HPV negative

**Triple A: HPV Positive, Cytology Negative**

- Occurs in 2.6% (age 60-65) to 11% (age 30 to 34)
- Option 1: repeat co-testing in 12-months
  - If co-test positive or LSIL+: colposcopy
  - If co-test negative or HPV-negative ASC-US: rescreen with co-testing in 5 years
- Option 2: reflex test for HPV16 or HPV16/18 genotypes
  - If HPV16 or HPV16/18 positive: colposcopy
  - If HPV16 or HPV16/18 negative: co-test in 12-months
  - Then manage as in option 1
- Do not immediately colposcope HPV positive/cytology negatives

**Other Important Messages**

- For women 65 and older
  - “Adequate screening” is defined as...
    - 3 consecutively negative results in prior 10 years, or
    - 2 negative co-tests, most recently within 5 years
- Women treated for CIN 2+ or AIS must be regularly screened for 20 years, even if 65 or older
  - With cytology alone Q 3 years or HPV+ cytology Q 5 years
Summary of Cervical Cancer Guidelines

<table>
<thead>
<tr>
<th>Age Group</th>
<th>USPSTF 2012</th>
<th>Triple A 2012</th>
<th>ACOG 2012</th>
<th>hrHPV test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 21 years old</td>
<td>[D]</td>
<td>None</td>
<td>“Avoid”</td>
<td>Reflex</td>
</tr>
<tr>
<td>21-29 years old</td>
<td>Every 3 y</td>
<td>Co-test: QS</td>
<td>Co-test: QS</td>
<td>Reflex</td>
</tr>
<tr>
<td>30-65 years old</td>
<td>Co-test: Q3</td>
<td>Cytology: Q3</td>
<td>Cytology: Q3</td>
<td>Reflex</td>
</tr>
<tr>
<td>&gt;65 years old</td>
<td>None*</td>
<td>None</td>
<td>None</td>
<td>Reflex</td>
</tr>
<tr>
<td>Hyst, benign</td>
<td>[D]</td>
<td>None</td>
<td>None</td>
<td>Reflex</td>
</tr>
</tbody>
</table>

* If adequate prior screening with negative results
Co-test: cervical cytology plus hrHPV test
Cytology: cervical cytology (Pap smear) alone

Why these guidelines make sense

- HPV infections are transient and common in young women
- CIN3 peaks in the late 20s
- Spontaneous regression of CIN1 and CIN2 is common
- In teens screening does not reduce mortality
- There are consequences to over screening (emotional harm) and overtreatment (preterm birth with LEEP)

Ovarian Cancer Screening

- Options for screening
  - (Bimanual) Pelvic examination
  - Transvaginal pelvic ultrasound (TVS)
  - Serum Tumor Marker: CA-125
- Not recommended for low risk asymptomatic women
  - Low sensitivity, specificity for early disease
  - Low prevalence of disease
  - High cost of evaluation

Ovarian Cancer Screening

USPSTF (2012)

- Screening asymptomatic women with ultrasound, tumor markers, or exam is not recommended [D]
- Insufficient evidence to recommend for or against in asymptomatic women at increased risk [I]

Pelvic Exam at the Well-Woman Visit

ACOG Committee Opinion 524; August 2012

- Women younger than 21 years
  - Pelvic exam only when indicated by medical history
  - Screen for GC, chlamydia with vaginal swab or urine
- Women aged 21 years or older
  - “ACOG recommends an annual pelvic examination”
    - No evidence supports or refutes routine exam if low risk
  - If asymptomatic, pelvic exam should be a “shared decision”
    - Individual risk factors, patient expectations, and medico-legal concerns may influence these decisions
  - If TAH-BSO, decision “left to the patient” if asymptomatic

Routine Cancer Screening in Women

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Cervix CA</th>
<th>CBE</th>
<th>Mammogram</th>
<th>Colorectal cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-20</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>21-25</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Hi Risk</td>
</tr>
<tr>
<td>26-29</td>
<td>Co-test: Q3</td>
<td>Q3 y</td>
<td>Annual</td>
<td>Annual</td>
</tr>
<tr>
<td>30-39</td>
<td>Q3 yrs</td>
<td></td>
<td>MG</td>
<td>MG</td>
</tr>
<tr>
<td>40-49</td>
<td></td>
<td></td>
<td></td>
<td>[I]</td>
</tr>
<tr>
<td>50-59</td>
<td></td>
<td></td>
<td></td>
<td>[A]</td>
</tr>
</tbody>
</table>

ACOG: Am College of Ob-Gyn
ACS: American Cancer Society
CBE: Clinical breast exam
CDC: Centers for Disease Control
USPSTF: US Preventive Services Task Force
Routine STI Screening

Age | 18-20 | 21-25 | 26-29 | 30-39 | 40-49 | 50-59
---|---|---|---|---|---|---
CT (Both) | Annually | Targeted
GC (Both) | Targeted
HIV | 
CDU | Once, then HI risk only
USPSTF | HI Risk
Syphilis | Both

ACOG: Am College of Ob-Gyn
CDC: Centers for Disease Control
ACOG: American Cancer Society
USPSTF: US Prev Services Task Force
Both: CDC-USPSTF

Routine Metabolic Screening

Age | 18-19 | 20-25 | 26-29 | 30-39 | 40-49 | 50-59
---|---|---|---|---|---|---
BP | ≤Q2 yrs
BMI | ≤Q2 yrs
T2DM | ADA
| USPSTF
| Hi Risk
HTN | Q3 yrs
| HTN[A]
Lipids | ATP
| USPSTF
| Q3 yrs
| Hi Risk

ATP: Adult Treatment Panel
CHD: coronary heart disease
T2DM: Type 2 diabetes mellitus
USPSTF: US Prev Services Task Force

What May Be the Real Value of Health Screening Visits?

- “Carves out a time and a place for prevention”
- Opportunity for behavioral anticipatory guidance
- Establishment of the clinician-patient relationship
- Increased sense of patient well-being; positive action toward self-maintenance of health
- More likely to seek care when a problem occurs
- Desirable tests more likely to be done at Health Screening visits than during problem-oriented care

Promoting Prevention through the Affordable Care Act
Howard K. Esh, M.D., M.P.H., and Kathleen G. Selberan, M.F.A.

- Specified preventive services must be covered with no cost-sharing for deductibles and co-payments
- Preventive services include
  - USPSTF grade [A] or [B] recommendations
  - AAP Bright Futures recommendations for adolescents
  - CDC ACIP vaccination recommendations
- 2011: additional women’s preventive services not addressed by USPSTF… to “close the gaps”

Reproductive Health
Cancer
Healthy Behaviors
Pregnancy related
Immunizations
Chronic conditions
STI and HIV counseling (all sexually active F)
Breast Cancer
Mammography
Alcohol S&C
Alcohol S&C
Tobacco C&I
Tobacco C&I
Chl, HTN, lipids
Chl, HTN, lipids
C, G, Syphilis screening
Genetic S&C
Tobacco C&I
Tobacco C&I
Influenza
T2DM screen
HIV screening (all sexually active F)
Preventive counseling
Diet counseling
Chl, HTN, lipids
Hepatitis A, B
Meningococcal
Depression screen
Contraception (women w/repro capacity)
Cytology
HPV and Hymen screen
GDM screen
S&C
Folic acid supplement
Pneumococcal
Zoster
Rheumatoid arthritis
Obesity screen; C&I if obese
Lactation support

Stroke Prevention

- The USPSTF recommends that women 55 to 79 years of age take around 75 mg of aspirin per day when the benefit of ischemic stroke reduction outweighs the increased risk of gastrointestinal hemorrhage
- A tool to help determine an individual’s risk of stroke is available at http://www.westernstroke.org/PersonalStrokeRisk.xls.
Osteoporosis Screening and Prevention

- Screening with DEXA (dual energy x-ray absorptiometry) is recommended for women 65 years and older
- USPSTF recommends using WHO’s Fracture Risk Assessment Tool to help risk-stratify women younger than 65
- A 2011 meta-analysis found that Calcium and Vitamin D may reduce fractures in adults

Calcium/Vitamin D and weight bearing exercise

- USPSTF 2012 stated current evidence is insufficient to assess benefits and risks of Calcium and Vitamin D supplementation for prevention of fracture in premenopausal and non-institutionalized postmenopausal women
- NIH recommends a total daily intake of 1,000 mg of calcium for women 19-50 years old and 1200 mg for women >50 in addition to 600-800 IU of Vitamin D
- ACOG recommends counseling women about weight bearing exercise, muscle strengthening, smoking cessation, moderation of alcohol and fall-prevention

Summary

- Well woman care is an opportunity to focus on disease prevention, screening and health promotion
- Don’t confuse family planning visit with health screening visit
- The recommendations are constantly evolving; find an up to date source like USPSTF and stay tuned!

Thanks

- To Michael Policar MD, MPH, professor of OBGYN at UCSF School of Medicine for inspiring this talk and letting me reference his old talks and most recent slides

References

- The Evolving Well Woman Visit, Michael Policar, 12/2012
- Health Maintenance in Women; Riley et al, American Family Physician, Volume 87, number 1, January 1, 2013, pages 30-37
- U.S. Preventive Services Task Force Recommendation Statements
“Enlightened Well Man Care”

by

Alfredo Vigil, MD

Alfredo Vigil, MD has been a family physician for 35 years working throughout New Mexico in community health centers as well as private practice. Besides clinical practice, he has served on many boards and commissions including the New Mexico Medical Board, the EMS Licensing Commission, and the New Mexico Academy of Family Physicians. He also served as the Cabinet Secretary for the New Mexico Department of Health. Dr. Vigil lives and practices in Taos for El Centro Family Health.

Email: doctorvigil@hotmail.com

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Define “well care” for men
- List the high priority interventions that improve health in men
- Describe possible changes in daily practice that will facilitate the routine implementation of appropriate interventions
ENLIGHTENED WELL MAN CARE
Alfredo Vigil, MD
August 3, 2014

The REAL Problem
- It is impossible, in a typical primary care practice to do a good job of acute and chronic care and still cover all the reasonable goals of prevention, screening, and education.
- The American model of “make an appointment” health care is grossly inadequate.
- Other countries make much more use of health extenders and community-based models of health maintenance.

Case 1
- 17 yr old young man
- Sexually active and interested in birth control
- Non-smoker
- What screening tests are important?
- What exam is important?

Case 2
- 28 yr old man
- Monogamous relationship
- Non-smoker
- What screening tests are important?
- What exam is important?

Case 3
- 55 yr old man
- Smoker
- Sexually active
- What screening tests are important?
- What exam is important?
Some basic principles

- There are consequences to over-screening and over-treatment
- Sometimes less is more
- Avoid hazards of false positive tests
- Avoid unneeded work-ups
- First, do no harm

Nihilist v. Blind Believer

- “I don’t believe in tests.”
- “I want my serum porcelain level checked.”
- What are the limits between reasonable cooperation and bad medical practice?

Screening Tests

- Screening tests are good when the prevalence of disease is high in the targeted population
- Screening tests are good when there is effective treatment for the disease being screened
- Screening tests are good when they are easy to administer, cause little discomfort, and are inexpensive and accurate

Why do less?

- Avoid a wasted visit - Improve access
- Avoid lost time for visits of little or no benefit
- Save health care dollars
- Remember screening tests are only a small part of preventive health care

Well Man Care = Health Screening Visit

- Improves health through anticipatory guidance and screening
- Improves man’s sense of well being through attention to “health visit” instead of “sick visit”
- Promotes therapeutic relationship between woman and provider
- Encourages positive action towards maintenance of health

If you aren’t their Primary Care Provider

- Find out if they have one
- Don’t duplicate services
- Having a primary care provider improves health outcomes!
Well Man Visit

- Family Planning / STD screening PLUS
- Appropriate cancer screening
- Address alcohol use, drug use, smoking
- Depression screening
- Vaccinations

General Health Issues

- Diet and exercise
- Lab work- screening for high cholesterol and diabetes
- Overweight and Obesity
- Blood pressure screening

Well Man Care Differs Throughout a Man’s Lifecycle

- Early Manhood--- HPV vaccine, other Vaccinations, STD screening, sexual education
- Manhood--- Cardiovascular Risks, Mental Health, Cancer Screening, Vaccinations
- Late Manhood and Grandfatherhood--- Male Menopause, Cancer Screening, Vaccinations

What About the Leading Causes of Death

- Accidents, injuries, homicide, and suicide are at the top of the list for men from birth to age 44.
- Number 3 on the list from age 45 to 65.
- If we REALLY wanted to save men’s lives, we would address violence in its many forms.
  - Social Determinants of Health
  - Testosterone Poisoning
- Public Health Strategies versus “In the office” care.

Who do you listen to?

- There are many organizations with guidelines for well man care
- AAFP, ACS, AMA, USPSTF
- Men’s Health, Maxim, Esquire (kidding…)

Who Do Men Listen To?

- Not as much to their same gender as women.
- In general, they don’t read, discuss, think about health as much as women.
- As a result, men have more “sketchy” understanding about health.
- Truth is, women often play a major role in men’s health.
- God save us all from the anti-science mongers that have infiltrated policy, education, and the media.
Who Defines Well Man Services?

US Preventive Services Taskforce
- Agency for Healthcare Research & Quality
- Rigorous evidence-based review process
- Multidisciplinary, non-industry expert panel
- Screening recommendations by disease and by four age groups + pregnancy
- Supports “opportunistic prevention” model

USPSTF 2007: Strength of Recommendation

<table>
<thead>
<tr>
<th>Comment</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Recommend</td>
<td>Net benefit is substantial</td>
</tr>
<tr>
<td>B Recommend</td>
<td>Net benefit is moderate</td>
</tr>
<tr>
<td>C Recommend against</td>
<td>May be considerations that support the service in an individual patient</td>
</tr>
<tr>
<td>against providing</td>
<td></td>
</tr>
<tr>
<td>routinely</td>
<td></td>
</tr>
<tr>
<td>D Recommend against</td>
<td>No net benefit (or) harms outweigh benefits</td>
</tr>
<tr>
<td>I Evidence is insufficient</td>
<td>Evidence is lacking, poor quality, or conflicting</td>
</tr>
</tbody>
</table>

Case 1
17 yr old young man
- What’s recommended according to USPSTF app?
- non-smoker
- sexually active

Grade A Recommendations
- HIV screening if at increased risk
- Syphilis screening if at increased risk

Case 2
28 yr old man
- What’s recommended according to USPSTF app?
- non-smoker
- sexually active

Grade A Recommendations
- HIV screen only if at increased risk
- BP check
- Syphilis screen only if at increased risk
Case 3
55 yr old man
- What’s recommended according to the USPSTF app?
- Smoker
- Not sexually active

Grade A Recommendations
- Aspirin to prevent CVD
- Colon cancer screening
- HIV screening
- BP check
- Lipid screening
- Syphilis screening if high risk
- Counsel on tobacco use

Screening in Over 76 yo
- Aspirin up to 79
- BP monitoring
- Lipids
- Syphilis at high risk
- Falls
- Nutrition – Over and Under

Immunizations
- Men should be immunized at recommended intervals unless there are individual contraindications
- HPV vaccine in early adolescence
- Tdap booster
- Rubella if not immune
- Influenza every year
- Go to http://www.cdc.gov/vaccines/schedules/easy-to-read/adult.html

Is a Well Man Visit Advised Annually?
- USPSTF says visits can be every 1-3 yrs depending on health status, risk factors and patient preference.
- Given that it is difficult to get men to go to a primary care provider for ANY reason, ANY encounter should be guided toward prevention services.
- The key to improving the behavior of all patients, including men, is the relationship between patient and provider!

Is a physical exam always necessary?
- There has been a shameful loss of physical examination as the foundation of diagnosis.
- “Laying of hands” is therapeutic
- Parts of exam should be as needed
- Some visits may be mostly counseling, education and vital signs
What May Be the Real Value of Health Screening Visits?

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- Opportunity for behavioral anticipatory guidance
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Howard K. Koh, M.D., M.P.H., and Kathleen G. Sebelius, M.P.A.

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Summary

- Well man care is an opportunity to focus on disease prevention, screening and health promotion
- The recommendations are constantly evolving—find an up to date source like USPSTF and stay tuned!
“Primary Care and Prevention for the Addicted Patient”

by

Valerie Carrejo, MD

Valerie Carrejo, MD received her medical degree from the University of New Mexico, School of Medicine, and completed her residency with the Department of Family and Community Medicine at UNM in 2007. She then practiced in community-based healthcare for several years. In 2010, she became board certified in Addiction Medicine, due to an expanding interest in treating patients with substance abuse issues. She joined the UNM Department of Family Medicine in the fall of 2012 to become more involved in education and further development in treating addictions in primary care, an ever-growing need in New Mexico. She still practices full-spectrum family medicine, including obstetrics, and is Assistant Professor at the UNM Family Medicine Clinic.

Email: vcarrejo@salud.unm.edu

Learning Objectives

At the end of this presentation, the attendee will be able to:

- Review appropriated screening and preventive care for this high risk population
- Review options for office based treatment for common addiction disorders in New Mexico – opioid dependence, alcohol, methamphetamine
OBJECTIVES
- Identify the importance of addressing substance abuse in the primary care setting
- Identify useful screening tools for substance abuse
- Review common medical issues unique to patients with substance abuse and how we can address these issues in primary care
- List options for medical management of alcohol, opioid and nicotine dependence
- Review and discuss the treatment of chronic pain in the addicted patient

BACKGROUND
- In recent years, a number of changes to the healthcare system have made the integration of primary care and substance use disorder treatment a more viable option
- More treatment options for substance use disorders in primary care
  - Buprenorphine
  - Naltrexone
  - Acamprosate
  - Disulfuram
  - Zyban
  - Chantix

AFFORDABLE CARE ACT 10 ESSENTIAL BENEFITS
- Ambulatory patient services
- Emergency services
- Hospitalization
- Maternity and newborn care
- Mental health and substance use disorder services, including behavioral health treatment
- Prescription drugs
- Rehabilitative services and devices
- Laboratory services
- Preventive and wellness services and chronic disease management
- Pediatric services, including oral and vision care.

SUBSTANCE ABUSE IMPACTS PRIMARY CARE
- Infectious disease
  - A leading route of infection for HIV and Hepatitis
- Cardiovascular disease
  - 9 times greater risk of developing congestive heart failure
- Pulmonary disease
  - 12 times greater risk of developing pneumonia
- Liver disease
  - 12 times greater risk of developing cirrhosis
“SBIRT” MODEL
- Screening quickly assesses the severity of substance use and identifies the appropriate level of treatment.
- Brief intervention focuses on increasing insight and awareness regarding substance use and motivation toward behavioral change.
- Referral to treatment provides those identified as needing more extensive treatment with access to specialty care.

ASK ABOUT SUBSTANCE USE
- Many validated screening tools
  - Tobacco use- now asked at every visit
  - AUDIT-C
  - AUDIT
  - CAGE
  - DAST-10
  - “In the past year, how often have you used...?”

NIDA QUICK SCREEN

<table>
<thead>
<tr>
<th>In the past year how often have you used the following?</th>
<th>Never</th>
<th>1-2 times</th>
<th>Monthly</th>
<th>Weekly</th>
<th>Daily or almost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
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<tr>
<td>Men- 5 drinks per day</td>
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<tr>
<td>Women-4 drinks per day</td>
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<tr>
<td>Tobacco</td>
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<tr>
<td>Prescription drugs for non-medical reason</td>
<td></td>
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<tr>
<td>Illegal drugs</td>
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</table>

SO WHAT DO WE DO NEXT?
- Positive screen for abuse or misuse
  - Assess readiness for change
  - Offer treatment if interested
  - Not ready to quit?
    - DON'T JUDGE
    - TREAT THE PATIENT FOR GENERAL HEALTH

ROUTE OF DRUG USE
- Ask about the route of use

SMOKED DRUGS
**INTRANASAL**
- Tobacco
- Heroin
- Cocaine
- Methamphetamines
- Opioid pills

**INTRA静脉**
- Heroin
- Cocaine
- Methamphetamines

**ORAL INGESTION**
- Alcohol
- Tobacco – chewing
- Marijuana
- MDMA/Ecstacy/GHB
- Cocaine
- Methamphetamines

**INHALANTS**
- Similar to smoking
- Toxins can affect all organ systems
- Intranasal use
- Infections
- Chronic sinusitis
- Nasal septal defects
- Can transmit HIV or Hepatitis C

**MEDICAL COMPLICATIONS BY ROUTE**
- Smoking
  - Infection
    - Bronchitis
    - Pneumonia
  - Pulmonary emboli
  - Pulmonary hypertension
  - COPD
  - Asthma
  - Respiratory suppression with opioids

**MEDICAL COMPLICATIONS BY ROUTE**
- Inhalants
  - Similar to smoking
  - Toxins can affect all organ systems

MEDICAL COMPLICATIONS BY ROUTE
- Oral
  - Gastrointestinal symptoms
  - GERD
  - Variation in intoxication
    - May have longer onset, but longer duration
- Intravenous
  - Skin infections
  - Pulmonary infections
  - Septic emboli
  - Endocarditis
  - HIV
  - Hepatitis C

HEPATITIS C
- Yearly monitoring of liver function
  - CBC, LFTs, vitamin D
- Immunizations
  - Hepatitis A and B
  - Pneumovax
  - Annual flu vaccin
- Control comorbidities
  - Diabetes
  - Obesity
- Referral for treatment
  - New treatments are making treatment options more promising
- Hepatocellular carcinoma screening
  - Only if cirrhosis

IMMUNIZATIONS
- Tdap, Td
- Annual Flu
- Consider Pneumovax prior to age 65
  - Especially with smoking and inhaling
- Consider Hepatitis A and Hepatitis B vaccines
  - Especially in IV and intranasal drug use

MONITORING THE DRINKER
- Standard Drink- 14gm alcohol
  - Beer 12 oz
  - Wine 5 oz
  - Liquor 1.5 oz
  - Microbrew 8-10 oz
  - Malt liquor 6-8oz
- At risk- at any time
  - Men > 4 drinks in a day
  - Women > 3 drinks in a day

HAZARDOUS DRINKING
- All-cause mortality
- Hypertension
- Cardiomyopathy
- Diabetes
- Trauma
- Stroke
- More serious alcohol disorders
- Cancers
- Particularly upper GI and breast cancers

MONITORING THE DRINKER
- Screen for hypertension regularly
  - Coronary Artery Disease
  - Cardiomyopathy
  - Arrhythmias
- Gastrointestinal Disorders
  - GERD
  - Gastric and Peptic Ulcers
  - Pancreatitis
- Renal
  - Electrolyte disturbances
  - Hepatorenal syndrome
  - Rhabdomyolysis
### Monitoring the Drinker

- Psychiatric disorders
  - Anxiety
  - Depression
  - PTSD
- Sleep disorders
  - Insomnia
  - Sleep cycle disturbance
- Nutritional deficiency
  - Vitamin deficiencies
- Liver disease
  - Alcoholic hepatitis
  - Fatty liver
  - Cirrhosis

### Medical Management - Alcohol

- **Naltrexone**
  - 50mg daily
  - Monitor liver function
  - Cannot use with opioid medications
- **Acamprosate**
  - 666mg three times daily
  - Monitor renal function
- **Disulfuram**
  - 250mg – 500mg daily
  - Monitor liver function
  - Avoid all alcohol containing items

### Cirrhosis

- High risk complication in patients with substance abuse
- Progression of disease
  - 20% with alcohol alone
  - 20% with hepatitis C alone
  - 90% with hepatitis C and concurrent alcohol use
  - Marijuana may also worsen risk of fibrosis in hepatitis C

### Complications of Cirrhosis

- Variceal hemorrhage
- Ascites
- Spontaneous bacterial peritonitis
- Hepatic encephalopathy
- Hepatocellular carcinoma
- Hepatorenal syndrome
- Hepatopulmonary syndrome

### Monitoring Cirrhosis

- Monitor liver function every six months
  - CBC, LFTs, vit D, PT/INR, Chem 10
- Hepatocellular carcinoma screening every six months
  - AFP
  - RUQ ultrasound
- Esophageal variceal screening
  - EGD annually

### Management of Cirrhosis

The major goals of managing patients with cirrhosis include:

- Slowing or reversing the progression of liver disease
- Preventing superimposed insults to the liver
- Identifying medications that require dose adjustments or should be avoided entirely
- Managing symptoms and laboratory abnormalities
- Preventing, identifying, and treating the complications of cirrhosis
- Determining the appropriateness and optimal timing for liver transplantation
MONITORING THE OPIATE USER

- Harm reduction
  - Education
  - Needle exchanges
  - Narcan programs
- Medical complications
  - Gastrointestinal
    - Constipation
    - Laxative misuse
  - Pulmonary
    - Respiratory suppression
    - Pulmonary hypertension

MONITORING THE NICOTINE USER

- Tobacco use is the leading cause
  - Coronary Artery Disease
  - Cancer
  - Chronic bronchitis
  - Chronic Obstructive Pulmonary Disease
  - AAA screening in all men age 65-75 who have ever smoked
- Tobacco and Nicotine also causes
  - Gastroesophageal reflux disease
  - Peptic ulcer
  - Sleep disturbance
  - Mouth cancers

MONITORING THE STIMULANT USER

- Monitor for hypertension
- Acute coronary syndrome
- Increased progression of atherosclerosis
- Rhabdomyolysis
- No specific guidelines on these patients
- Suggest echocardiogram to monitor
  - Cardiomyopathy
  - Pulmonary hypertension
  - Interval unknown

MEDICAL MANAGEMENT - OPIOIDS

- Methadone
  - Must be treated in a site specifically qualified to treat with methadone
- Buprenorphine (Suboxone)
  - Office based treatment
  - Primary care can make the biggest impact
  - Requires special training and DEA waiver
- Naltrexone
  - Opioid antagonist
  - Blocks opioid from receptor
  - Compliance is an issue

MEDICAL MANAGEMENT - NICOTINE

- Nicotine replacement
  - E-Cig is not nicotine replacement
- Buproprion
  - Initial dose 15mg daily
  - Maintenance dose 150mg BID
  - Continue for at least 7 weeks after quit date
- Varenicline
  - Taper dose 0.5mg daily x 3 days, then 0.5mg BID x 4 days
  - Maintenance dose 1mg BID
  - Continue 12 weeks
  - Monitor for suicidality

CHRONIC PAIN AND ADDICTION

- Chronic pain is common in substance abuse patients
- Many patients self medicate with other substances or purchase opioid medications off the streets
- Tolerance may be complicating the picture
MANAGING PAIN IN THE ADDICTED PATIENT
- Complicated
- Generalized fear of prescribing opioid medications to an addict
- Scrutiny by governing entities and uncertainty about laws and regulations
- Moral vs. social views on addiction
- Clinical concerns about causing or contributing to addiction

PRESCRIBING OPIOIDS TO THE ADDICTED PATIENT

<table>
<thead>
<tr>
<th>Potential risks of prescribing</th>
<th>Potential risk of NOT prescribing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribed opioid may serve as a trigger for relapse</td>
<td></td>
</tr>
<tr>
<td>Difficulty controlling use</td>
<td></td>
</tr>
<tr>
<td>Patient may feel pressure to &quot;supply&quot; friends</td>
<td></td>
</tr>
<tr>
<td>Patient may be tempted to sell meds to supplement income</td>
<td></td>
</tr>
<tr>
<td>Continued addiction and self-medication of pain</td>
<td></td>
</tr>
<tr>
<td>Unsuccessful detox due to pain with withdrawal</td>
<td></td>
</tr>
<tr>
<td>Increased distress leads may trigger relapse to use alcohol or drugs</td>
<td></td>
</tr>
</tbody>
</table>

ADDITION ALTERS THE PAIN EXPERIENCE
- Both stimulant and opioid abuses have less pain tolerance than peers in remission or matched controls
- Former opioid abusers have decreased pain tolerance to pain compared to non-addict siblings
- HIV infected patients with h/o substance abuse required higher doses of opioid analgesics than patients without a h/o of substance abuse
- Therefore, patients with a history of addiction may be more pain sensitive and require higher doses

CAN OPIOID MEDICATIONS BE USED?
- Opioids can be effective and safe in an addicted patient
- Patients on chronic opioid medications should be assessed for risk of misuse
- Predicting and diagnosing addiction in patients with chronic pain can be challenging
- Patients with a history of opioid dependence, including those on maintenance therapy (methadone, buprenorphine), have a lower pain tolerance
- Acute management of pain requires continuation of maintenance opioid, with addition of higher doses of opioid

HOW DO I DO THIS IN MY PRACTICE?
- Take a thorough pain history
- Take a thorough social history
- Take a thorough substance use history
- Used opioid risk screening tools
- Use nonopioid medications and adjunctive therapies
- Don’t judge the patient based on their substance use, treat them as a person with pain

MONITORING FOR MISUSE
- Universal Precautions
  - Agreements/Contracts
  - Monitor for aberrant behavior
  - Monitor for adherence, addiction, and diversion
    - Urine drug screens
    - Pill counts
  - Establish a refill and cross coverage system
  - Prescription monitoring program
ABERRANT BEHAVIORS
LESS PREDICTIVE OF ADDICTION
- Complaints about need for more medication
- Drug hoarding
- Requesting specific medications
- Openly acquiring similar medication from other providers
- Occasional unsanctioned dose escalation
- Non-adherence to other recommendations for pain therapy

ABERRANT BEHAVIORS
MORE PREDICTIVE OF ADDICTION
- Deterioration in functioning at work or socially
- Illegal activities– selling, buying, forging
- Injecting or snorting medications
- Multiple episodes of “lost” or “stolen” medication
- Resistance to change therapy despite adverse effects
- Refusal to comply with random drug screens
- Concurrent use of alcohol or illicit drugs
- Use of multiple physicians and pharmacies

WHEN ENOUGH IS ENOUGH!
- It is okay to discontinue the opioid medications and offer other medical therapies
- Refer to treatment for addiction if indicated
- Express concern, not what you may really feel inside...

IF WE ALL HELP TREAT THIS POPULATION, THERE IS HOPE
- Questions?
- Comments?
33rd Annual NMAFP
Winter Refresher in Albuquerque
February 21, 2015
Hotel Albuquerque
Old Town
Albuquerque, New Mexico

58th Annual NMAFP Family Medicine Seminar
July 16-19, 2015
Ruidoso Convention Center & Lodge at Sierra Blanca
Ruidoso, New Mexico