

# **Journey to becoming the first Accountable Care Organization in Washington**

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October 2, 2013



# Agenda

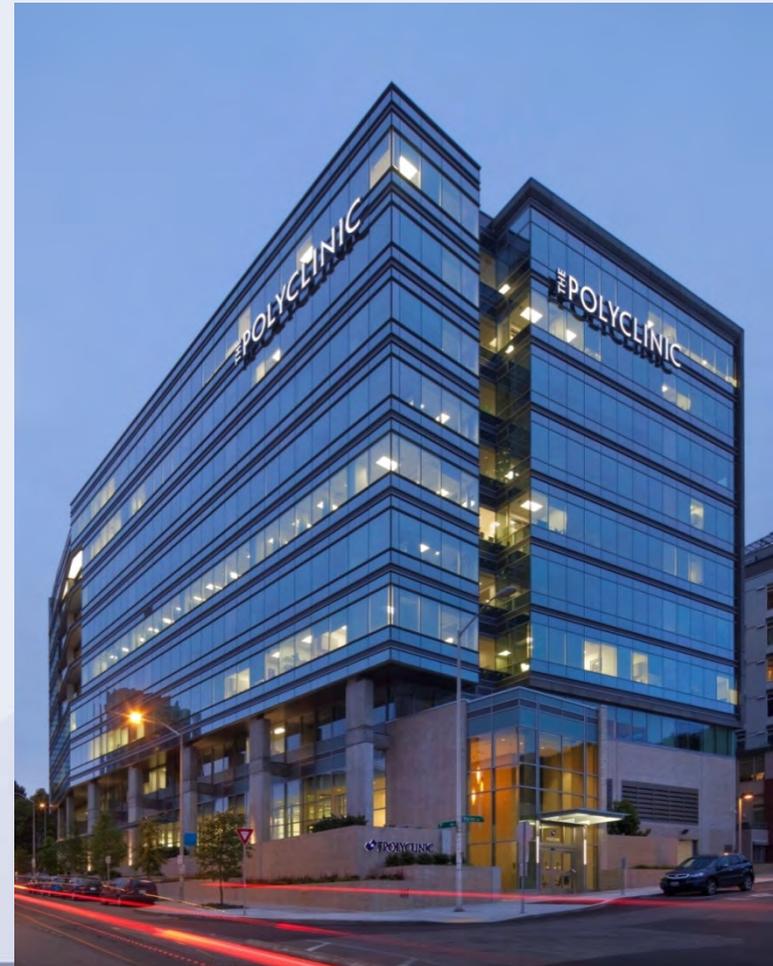


- Background
- Our ACO Strategy
- Commercial ACO
- Medicare ACO
- Population Health Management
- Closing Remarks
- Questions

# Polyclinic Profile



- Independent MD-owned MSGP (1917), Seattle, WA
- 200+ providers, 175 MDs, 30 specialties, ancillaries
- 425,000 visits (2012)
- 180,000 patients
- 25% Medicare
- CMS ACO
- 10 locations

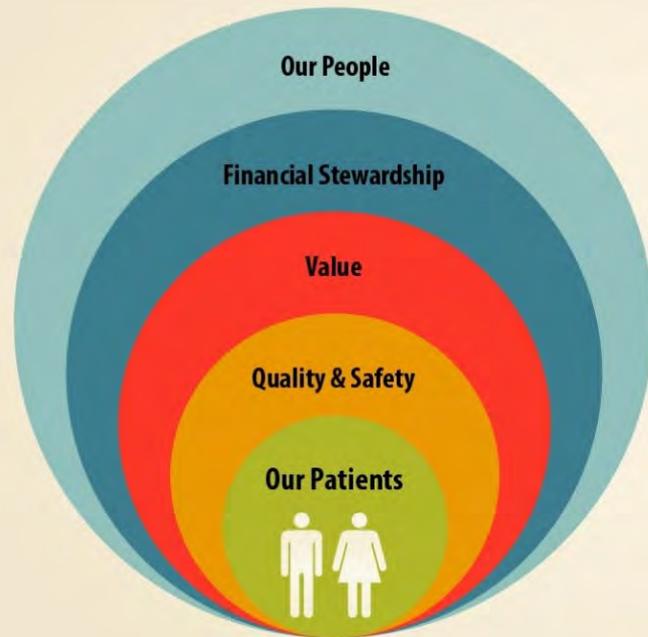


*The Polyclinic Madison Center*

# Mission, Vision, Values

“To promote the health of our patients by providing high quality, comprehensive, personalized health care.”

## Pursuing Perfection



- Our Patients:**  
Every patient is completely satisfied with every interaction
- Quality & Safety:**  
All patients receive complete, appropriate care with no preventable adverse outcomes
- Value:**  
No waste
- Financial Stewardship:**  
Able to finance our mission
- Our People:**  
100% of our people are trained, engaged, empowered and performing

“We are the best place in the Northwest to receive and provide health care.”

# Accountable Care

- Improve health outcomes
- Enhance the patient experience
- Lower overall costs

## ACO:

- Public sector (Medicare)
- Private sector

# Feeling the ACO Elephant



- Patients
- ***Physicians***
- Hospitals
- Private Payers
- Public Payers
- Regulators
- Health Plans
- Policy Makers



# Timeline

- 1997** full risk capitation for both commercial and Medicare populations.
- 2005-2008** various pay for performance programs with a variety of commercial payers around specific goals (i.e. generic prescribing)
- 2010** First commercial shared savings contract based on total cost of care.
- 2012** The clinic is selected by CMS to become an ACO (MSSP).
- 2013** Two additional commercial shared savings agreements.

# Current Status

## Medicare

- 4,000 Medicare Advantage patients (capitation)
- 7,100 MSSP primary care patients attributed by CMS

## Commercial

- 7,000 attributed patients with first payer agreement in 2010
- 7,500 attributed patients added in 2013 (shared savings agreements with 2 additional payers)

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# ACO success?



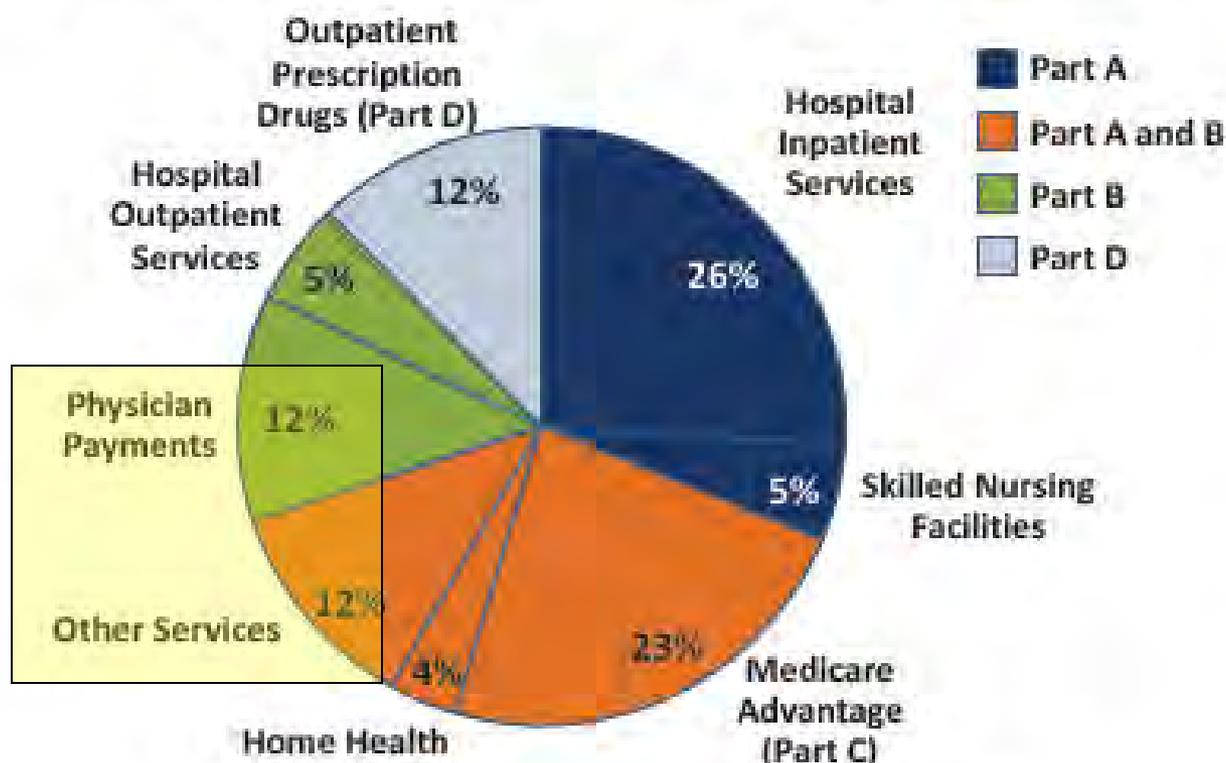
- Strategy
- Infrastructure
- Culture
- Implementation

# Strategy



- Is there a specific “ACO” strategy?
- Is it different from your organization’s overall business strategy?
- Are they aligned?.....Can they be aligned?

## Medicare Benefit Payments By Type of Service, 2011



**Total Benefit Payments = \$551 billion**

NOTE: Numbers do not sum to 100% due to rounding. Total does not include administrative expenses and is net of recoveries.  
 SOURCE: CBO Medicare Baseline, March 2011.

# Strategies to reduce the overall cost of care

- **Reduce unnecessary ER visits**
  - Standardized message and triage by on call MDs
  - After-hours care centers as ER alternative \* \*
  - Follow-up of ER visits to prevent bounce back
  - Patient education
- **Reduce hospitalizations**
  - Re-admissions
  - Follow-up of discharges
  - 1 day stays
  - Avoidable admissions
  - Alternative sites of service
- **Reduce pharmacy expense**
  - Generic prescribing
  - Standardized approach to biologic modifiers
  - Standardized approach to HIV treatment

# Strategies to reduce the overall cost of care (cont'd.)



- **Reduce unnecessary advanced imaging**
  - Prior authorization
  - Radiologist consultation
  - Best practices for cardiac imaging
  - Best practices for interval surveillance imaging in oncology
- **Risk assessment**
  - Care management of high utilizers
- **Reduce futile care**
  - Advanced directives
  - Acceptable alternatives (Palliative care, Hospice)
- **Alternative care delivery**
  - E-consults
  - Primary Care / Specialty service agreements

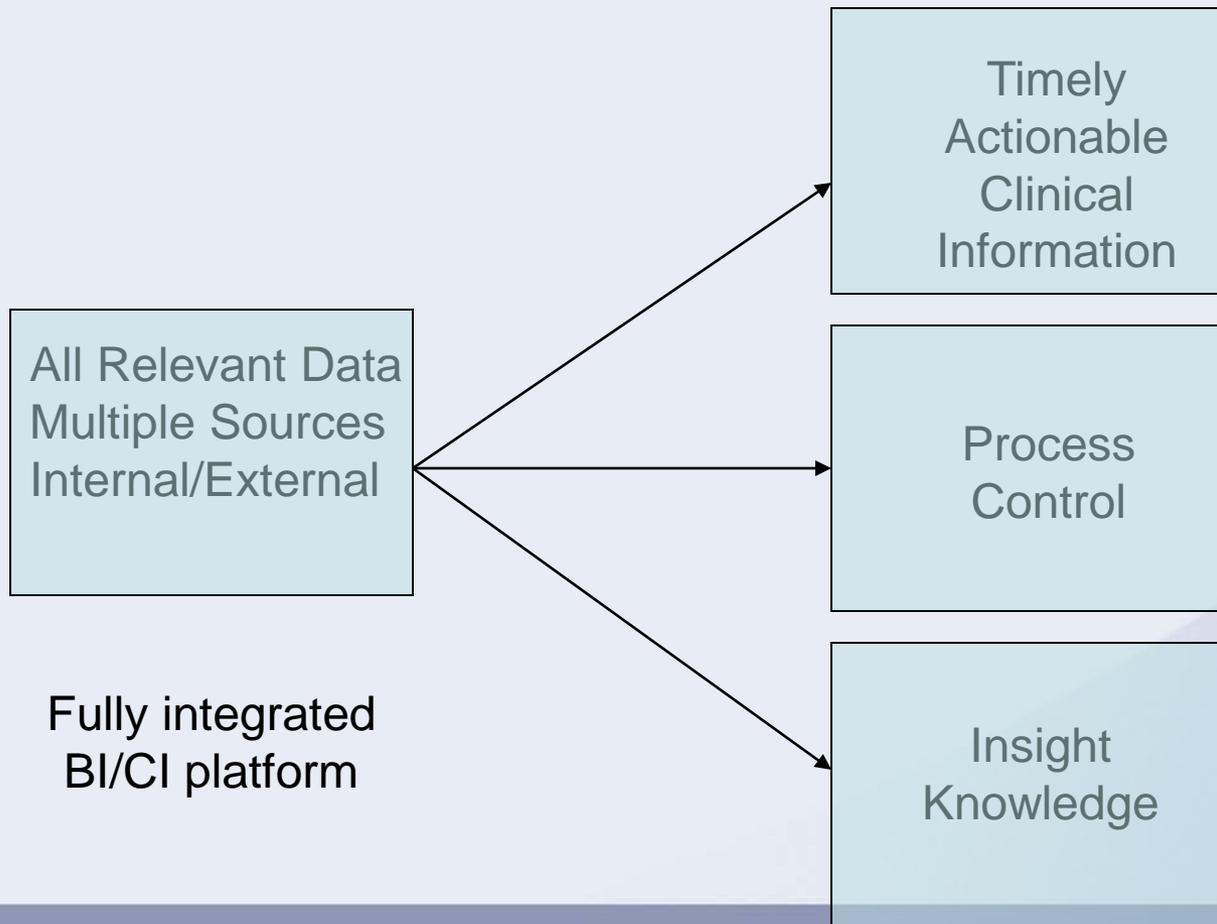
# Culture



Accountable Care  
is a Team Sport

# Infrastructure

It is really about information and the ability to use information to create market value and internal value



# Implementation



- Have clear objectives
- Communicate the objectives and build support with all stakeholders
- Use data wisely
- Be timely and directionally correct
- Use continuous process improvement
- Stay true to your values

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You can't start until you start.....

# 2009 Issues List (Commercial ACO Agreement)



- Methodology (metrics, measurement period, savings calculations, risk adjustment, comparison group)
- Costs included/excluded (outliers, other adjustments)
- Member Attribution
- Hospital costs
- Data sharing
- Other Considerations (quality benchmarks)

# Results

- 2010, both parties shared \$600,000 in savings on approximately \$35M in total costs
- 2011, both parties shared about \$2.1M on about \$60M in total costs
- 2012, there were no shared savings

# What Changed in 2012?

## **2010-2011 Success**

- Pharmacy savings
- ER/Inpatient stayed flat even though risk scores went up due to interventions
- Majority of trend reduction was related to risk adjusting
  - Unrelated Medicare HCC coding program spillover

## **2012 – In the Red**

- Victim of our own success – higher unit costs not offset by higher risk patients or reduced utilization
  - Shared savings applied directly to 2012 fee schedule and became new base rate
  - Coding efforts not applied to Specialty Providers

# short term

- We need way to get the value of saving other than through future fee increases
- While our comfort and ability to share data has increased dramatically, there are still a few crucial areas where lag time is impeding performance improvement.
- Continuous process improvement activities

# longer term

- First mover advantage eventually disappears
- This is a transitional state for reimbursement
- Fundamental misalignments of a fee-for-service reimbursement remain
- Fundamental pricing problem in health care remains
- Sustaining Innovation vs. Disruptive Innovation

# Agenda



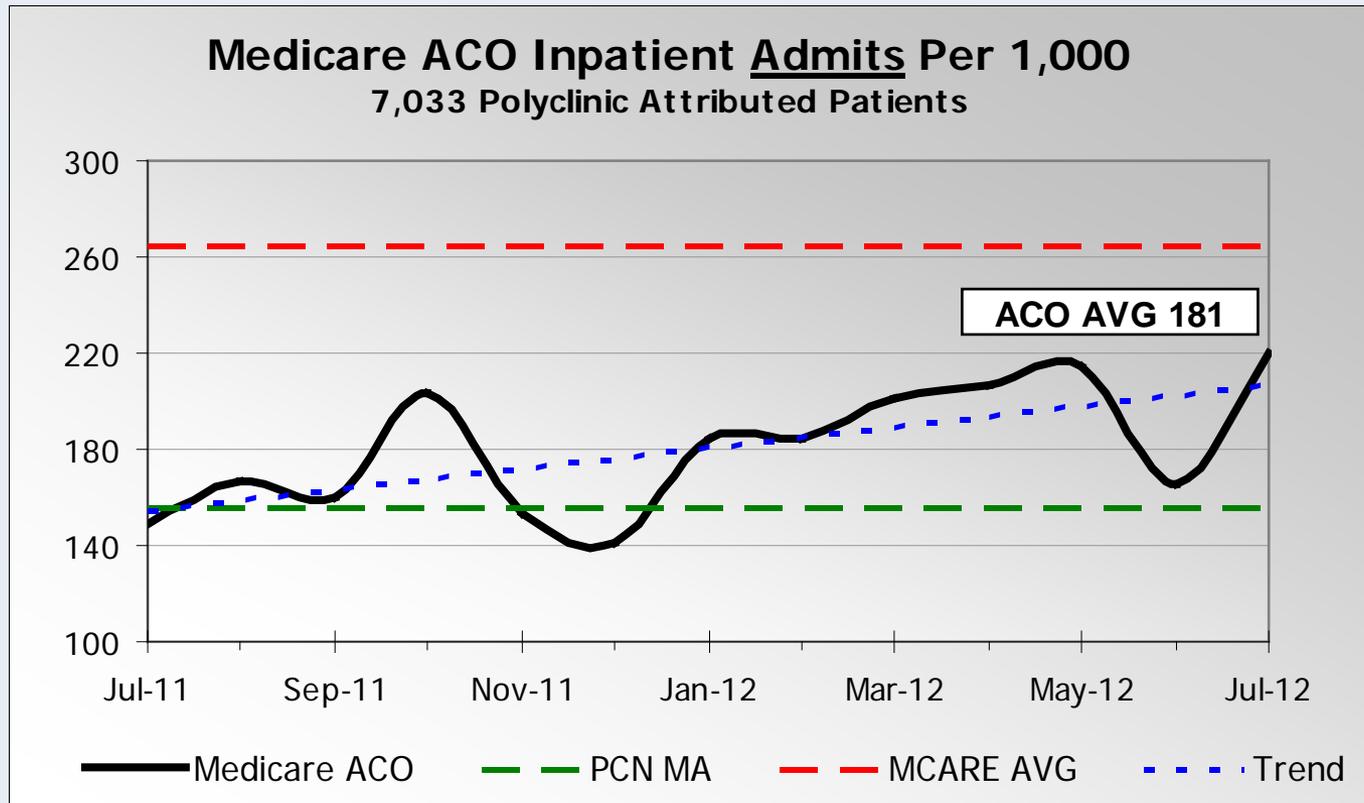
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# Medicare ACO



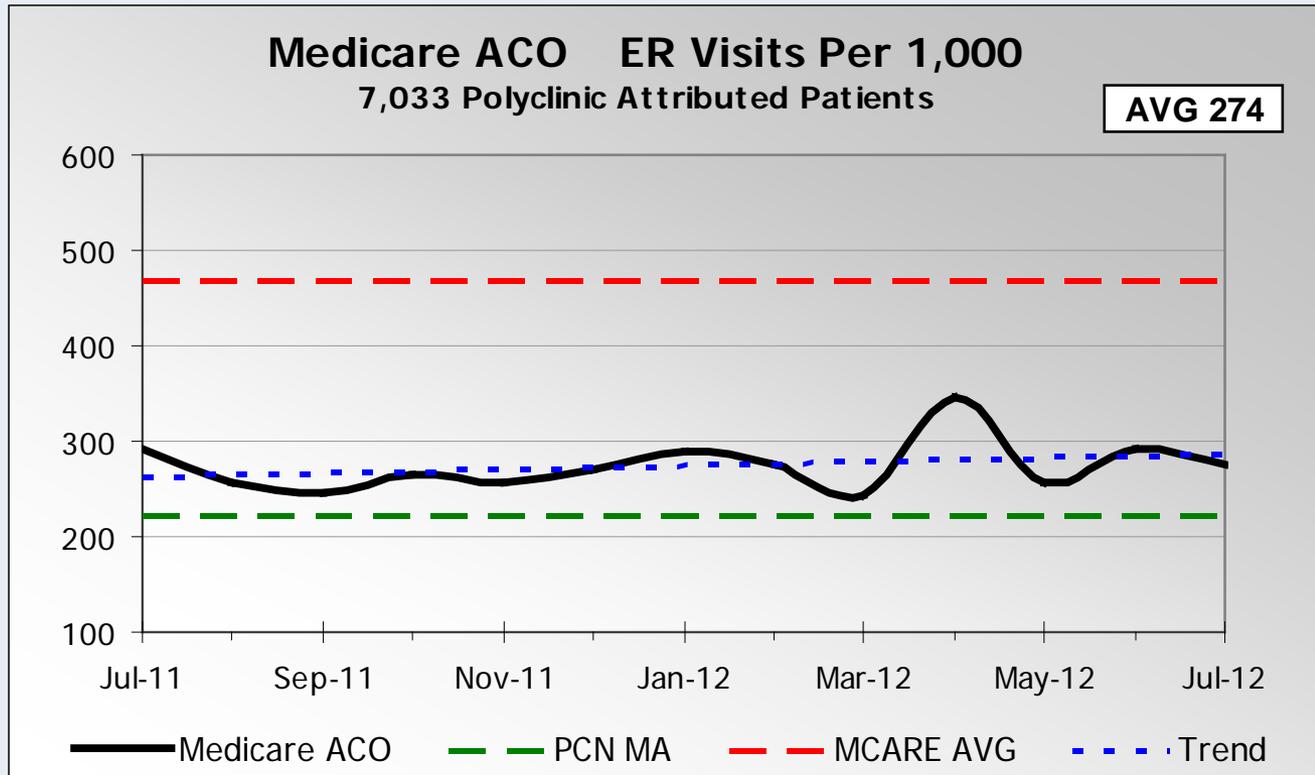
- On July 1, 2012 the polyclinic was approved for participation in the Medicare shared savings program as an accountable care organization.
- Agreed to participate for three years
- established separate legal entity with a new taxpayer ID
- 7100 primary care patients attributed by CMS
- accepted one-sided risk and agreed to a minimum 3% savings before sharing begins
- Agreed to publicly report
  - Organizational information
  - Shared savings payments received
  - Proportion of shared savings invested in infrastructure
  - Proportion of shared savings distributed to ACO participants
  - Results of 33 quality measures related to patient experience  
preventative health care coordination patient safety and at-risk populations

# Medicare ACO - Inpatient



ACO patient admissions are lower than Medicare average for our region, and are similar to our Medicare Advantage results

# Medicare ACO – Emergency Dept



Our Medicare Advantage and ACO patients have a low ER utilization rate compared to regional benchmark.

# Medicare ACO savings potential



- Savings determinations are based upon the difference between part a and part B fee-for-service payments for the year attributable to the defined population and risk-adjusted benchmark that is an estimate of the Medicare expenditures that would have occurred.
- **The expenditure benchmark is based on the previous three-year expenditure history.**
- With a total historical annual spend of \$7300 per patient it will be challenging for The Polyclinic to be able to reduce cost to a significant level to cover the cost we have incurred to develop the infrastructure and be able to participate in the Medicare shared savings program.

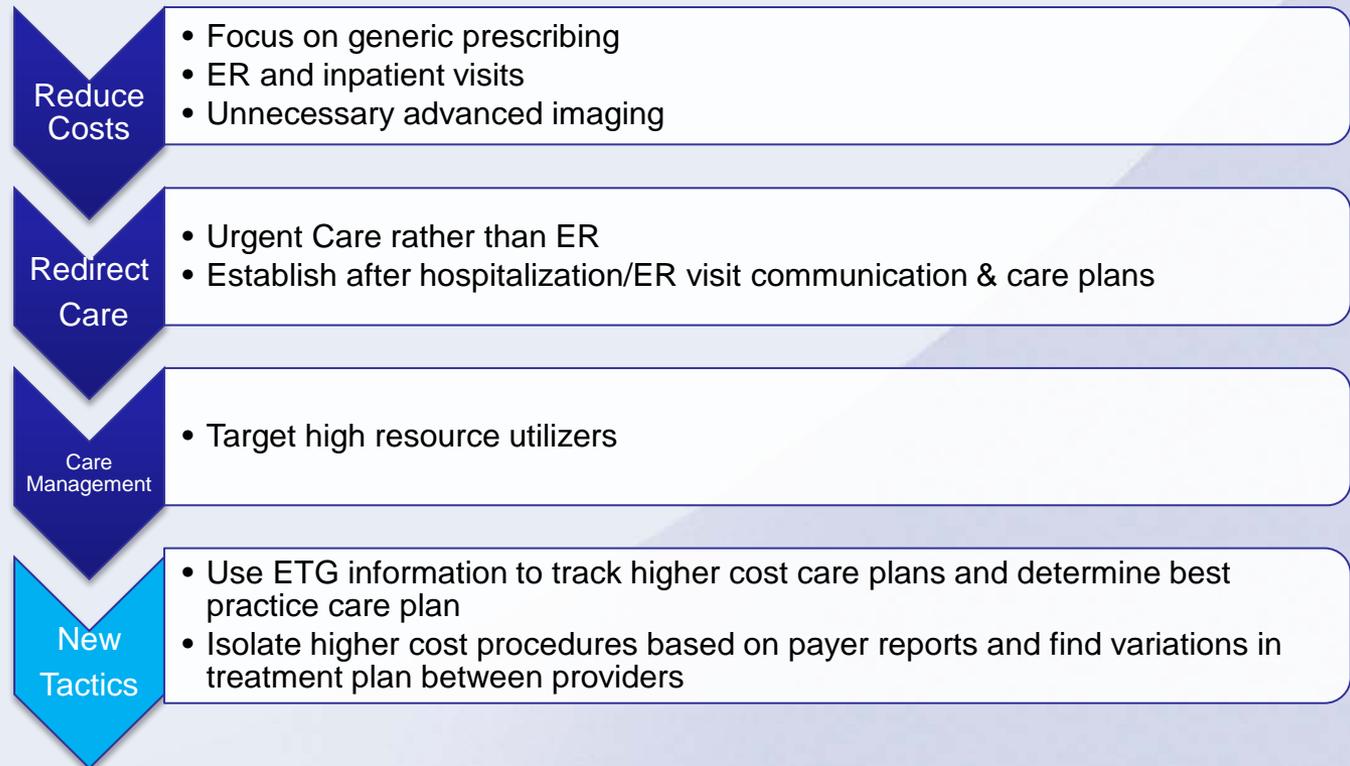
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# Our Starting Point for Population Health Management

- Focus on reducing total cost of care
  - Reduce unnecessary care
  - Use most cost effective sites of service
  - Manage Care



# Care Management Program



- **Program Oversight:**
  - Medical Director and Care Management Committee
- **Major Components**
  - Utilization Management
  - Complex Case Management
  - Enhanced Care
  - TeamCare
- **Future**
  - Wellness

In 2013 the program will include a total of 25,000 patients.

# The Care Management Program



- Enhanced Care Program
  - Embedded care managers with Primary Care Providers
  - Focus is on potential high cost/high utilizers with at least one chronic condition
  - Close care gaps and strengthen engagement with PCP
- TEAMCare
  - Subset of Enhanced Care Program
  - One chronic condition with depression
  - Wellness Coaching – Future Expansion
    - Focus is early engagement
    - Slow migration towards a chronic condition

# ECP Successes



- Hired 6 ECP RNs
- Enrolled 440 patients
- Engaged additional 97 patients with TEAMCare
- Utilized basic tools built internally to manage program
  - Database
  - Reporting metrics

Decrease in hospitalizations and ER encounters



What's  
next?

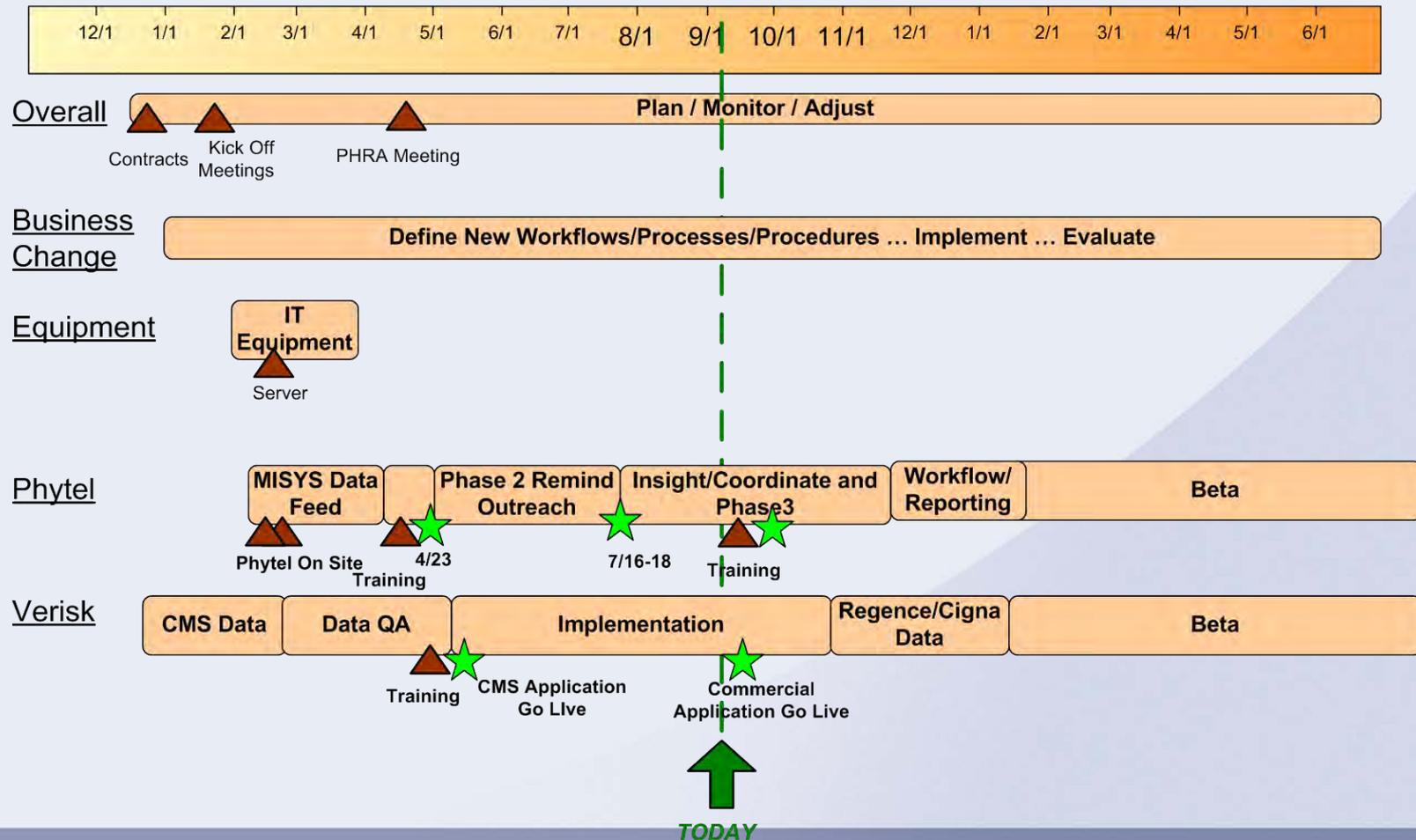


# Care Innovations Project Timeline



## Care Innovations – Overall Project Plan April 24, 2013 First Go-live

Updated: Aug 29, 2013



# Phytel-Outreach



- Set up protocols (preventative and chronic care follow up)
- Protocols may require tweaking but are customizable
- Identify patients due for care
- Enhanced outreach will use data from Epic
- Preliminary data suggests patients will engage system after Outreach calls

Population Management System

Search Patients Go

Patients Appointments Outreach Population Insight Care Management PQRS Hospital Readmission Reports

Confirmation Summary Settings

Sort By: Protocol Name

Group: Medical Center, Westside Provider: Casey, Ben G MD Date: April 13, 2011

### Outreach Settings

Export Print

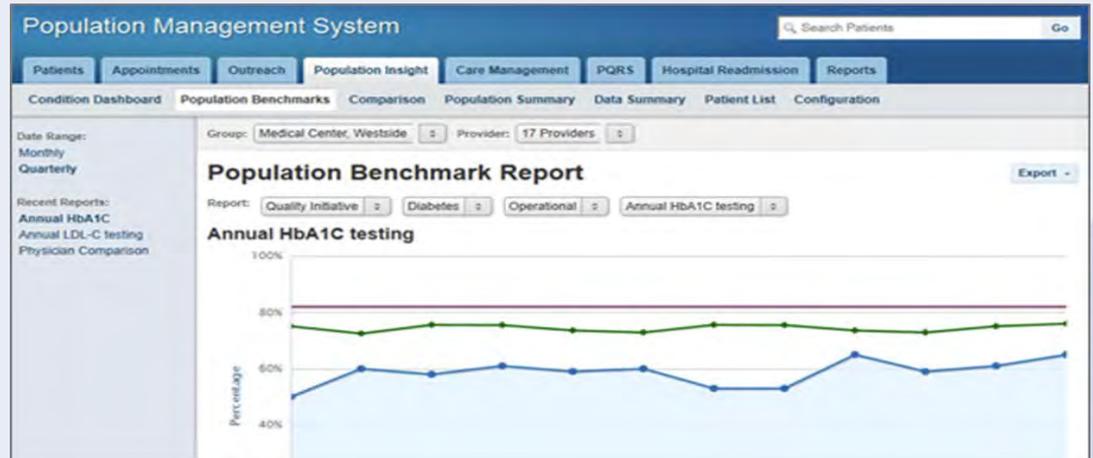
Name	# Drs. Using	Call Interval	Gender	Age Range
Asthma	50	12 mo.	M,F	10-99
Bone Mineral Density Scan (DXA)	50	24 mo.	M,F	65-99
Diabetes	10	6 mo.	M,F	10-99
Hypertension	50	6 mo.	M,F	10-99
Mammography Screening	25	12 mo.	M,F	40-64

1 2 3 4 5 6 7 8 Next

# Phytel-Insight & Coordinate



- Identify patients whose care falls outside of standard guidelines
- Assess performance of providers across the program
- Assist with pre-visit planning
- Planned implementation in Fall



# Project to Date



- Phytel
  - Implemented Remind for 147 schedules
    - 90 day ~25,000 appointments reminded
  - Implements Outreach for 54 PCPs
    - 90 day ~10,000 outreach events
  - Meaningful Use
  - Insight and Coordinate Implementation
  - Plan to be fully implemented on Remind/Outreach/Insight and Coordinate by October
- Verisk
  - CMS Data Application Front
  - Commercial Data Application Front

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# Learning

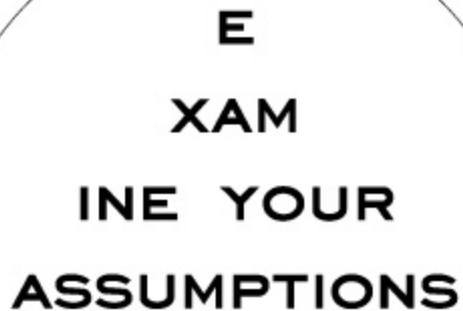
- **Talk is cheaper than infrastructure:** don't underestimate the effectiveness of the bully pulpit
- **Unexpected alignment:** many patients now have “skin in the game” and behave as such
- **Seeing around corners is sometimes possible:** Measuring outcomes of processes that are proxies for reducing the total cost of care is a way to monitor your performance in real time

# Learning

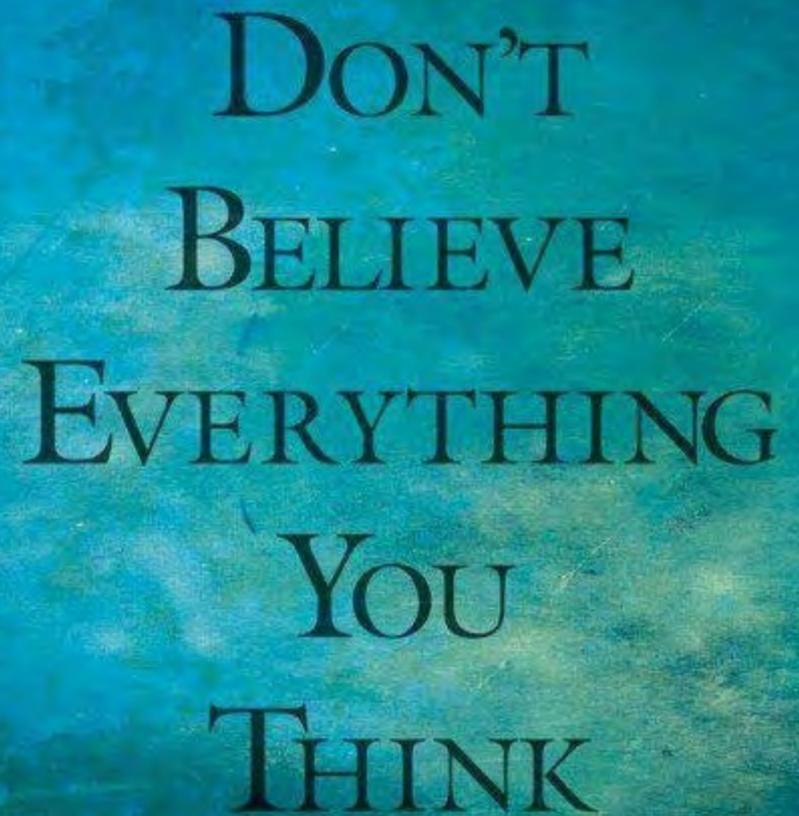
- **Don't let the perfect be the enemy of the good:** directionally correct and timeliness are often more important than precision in pursuing goals
- **Clinical integration and care coordination can be organic processes:** nurture, don't hinder them



Re-Think It



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ASSUMPTIONS



DON'T  
BELIEVE  
EVERYTHING  
YOU  
THINK

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# Patient Safety: How Can the Commission Move from Policy to Results?

Ann Greiner  
Vice President for External Affairs

*October 2, 2013*



NATIONAL  
QUALITY FORUM

# Overview of the Presentation

- Brief introduction to NQF
- Review of our Safety Portfolio
- Ideas About How the Washington State Medical Commission Might Enhance Patient Safety

# NQF's Mission and Structure



# Who We Are

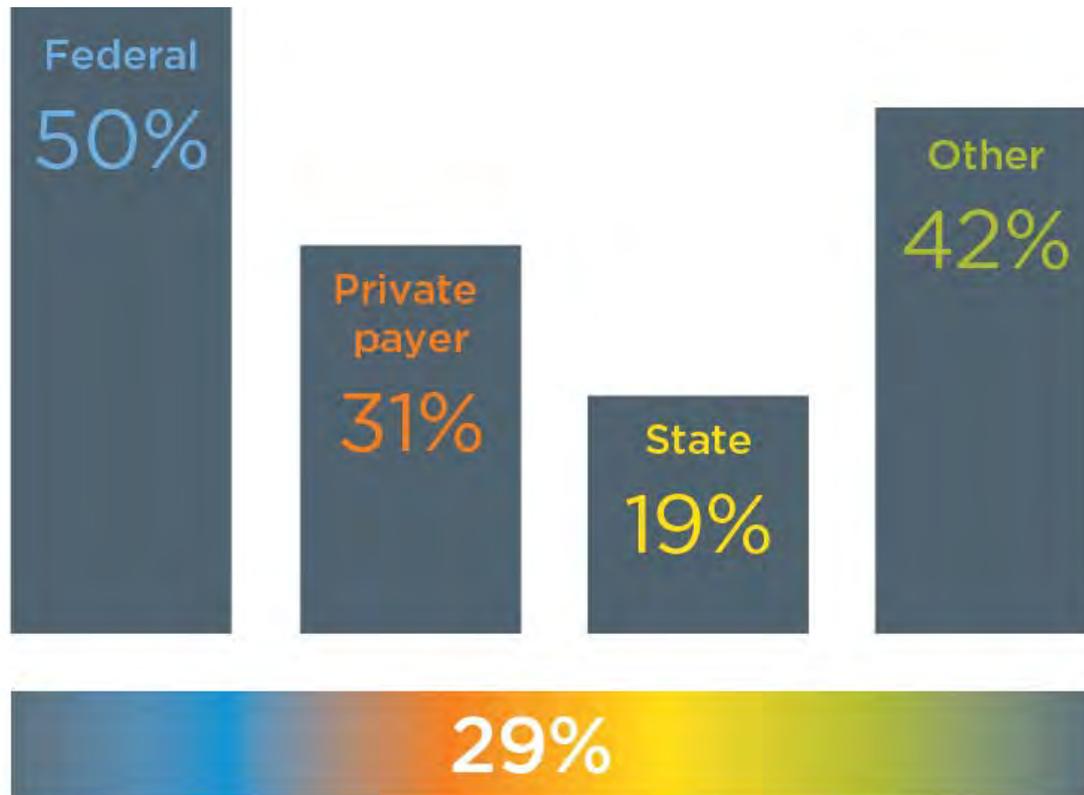
- NQF has more than 400 members from every part of the healthcare system
- Our board has a majority of consumer and purchaser representatives
- Clinicians play a key role:
  - 25% of NQF's membership consists of physician or nursing organizations
  - 59% of those leading committees are doctors

# What We Do

## Catalyze healthcare improvement through:

- Building consensus about what is important to measure and improve
  - In 2012, 822 individuals volunteered time on 41 projects, translating to 55,000 hours of donated time
- Endorsing best-in-class measures
- Recommending and aligning measures across public and private programs

# Using NQF Endorsed Measures



of measures in use represent alignment between two or more key sectors.

# The Value of High Quality Performance Measures

## **NQF endorsement is the gold standard for healthcare quality**

- NQF-endorsed measures—in concert with delivery and payment changes—are:
  - Making patient care safer
  - Improving maternity care
  - Achieving better health outcomes
  - Strengthening chronic care management

# How NQF is Changing

## **We're improving how we engage with the healthcare community to drive quality**

- Streamlining measure development and endorsement – getting to better measures faster
- Considering broadening our focus in terms of kinds of measures and approaches to measurement
- Beginning to engage our membership in novel ways and expanding our base

# Rethinking Our Processes

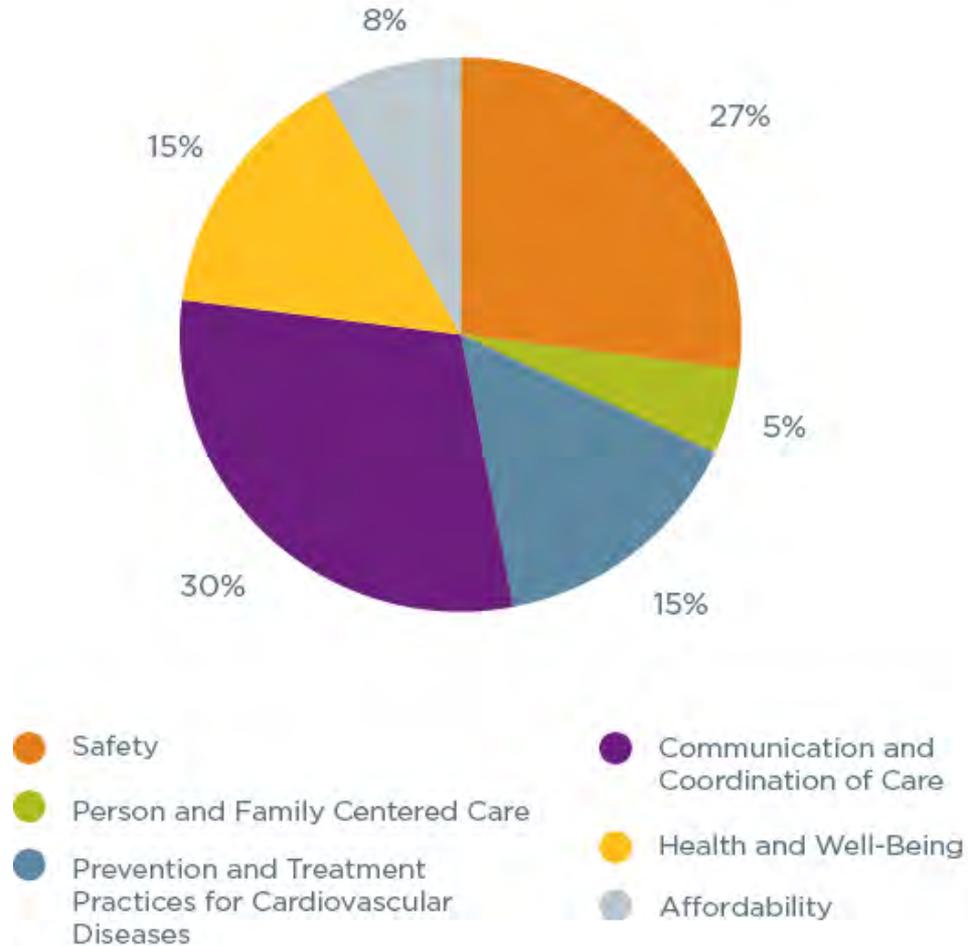
- NQF's Kaizen event (September 9-12, 2013)
  - Brought together a diverse group of stakeholders to envision a new path forward for measure development and endorsement
  - Asked the healthcare community to help us improve internal processes—a major, positive shift from how NQF has typically operated
  - Key finding: getting multi-stakeholder input upstream in the measure development process
- Much more to come in the next six months following this Kaizen event

# The National Quality Strategy (NQS) Shapes NQF's Work



# Safety is a Long Standing Focus of NQF

## Endorsed measures by NQS priority



# NQF-Endorsed Patient Safety Measures

- Endorsed safety measures cover wide range of topic areas:
  - Surgical Events
  - Healthcare-Associated Infections (CLABSI, CAUTI, MRSA, SSI, C. difficile)
  - Complications: falls, pressure ulcers, VTE
  - Medication Safety
  - Radiation Safety
- Closely align with goals of the Partnership for Patients (CMMI)
- Major challenges related to harmonization of competing measures and measurement across sites and providers.

# An Integrated, Focused Set of Safety Measures

- The NQF-convened MAP developed “Families of Measures” to guide stakeholders toward using core sets of measures, which transcend settings and levels of care in pursuit of overall healthcare goals
- The 2012 Families of Measures report focused on safety, care coordination, cardiovascular and diabetes care. Work is underway to define additional Families of Measures
- More than 300 safety measures were reviewed to define the 55 measures in the Safety Family

# MAP Safety Family: Nine Priority Topics

- Healthcare Acquired Conditions (e.g., CLABSI, MRSA, SSI)
- Medication/Infusion Safety (e.g., ADEs)
- Pain Management
- Venous Thromboembolism
- Perioperative/Procedural Safety
- Injuries from Immobility (e.g., pressure ulcers, falls)
- Safety-Related Overuse & Appropriateness (e.g., imaging)
- Obstetrical Adverse Events
- Complications-Related Mortality (e.g., failure to rescue)

# NQF's Patient Safety Work Beyond Measures

- Serious Reportable Events (SREs) – reported by more than half of the states, including the state of Washington
  - Adverse events that are serious, unambiguous, largely if not entirely preventable, and indicative of a systems problem or important for public credibility/accountability
  - Events updated in 2011 and expanded to 3 new settings: offices, long term care, & ambulatory surgery
  - Intended to help providers identify and learn from serious reportable events and to provide important information for consumers
- Safe Practices – 30 evidenced-based practices for clinical settings to reduce adverse events that harm patients

# Challenges for Patient Safety Efforts

- Real-time measurement and tracking of events not routinely assessed
- Safety measures still difficult to capture as valid rates
  - Safety events are uncommon or rare – making comparisons and communicating to patients challenging
  - Few events have standardized definitions
  - Dependence on self-reporting
  - Denominators are frequently poorly defined
  - Handling of “close calls”
- Important gaps remain, e.g., assessing the culture of safety

# What Can the Commission Do to Further Safety?

## ■ **Washington Medical Commission Assets**

- Jurisdiction covers all physicians; contact with doctors is regular and frequent
- Patients have direct input and are a major (primary?) constituent
- The Commission's new statutory authority provides flexibility
- Demonstrated leadership in patient safety and other areas
  - » Collect and publish SREs and other data

## ■ **Potential Liabilities**

- Complaint driven investigations
- Focus is on individual physicians not groups
- Oversight not quality improvement role/reputation

# What Can you Do? -- Focus Communication on Patients and Physicians Simultaneously

- Your website could be used to inform consumers and physicians about overuse/misuse that may cause harm. Help shift the dynamic: more care is not necessarily better care.
- For example, *Choosing Wisely* encourages doctors, patients and others to consider what medical tests/procedures may be unnecessary and harmful
  - To spark these conversations, specialty societies created “Things Physicians and Patients Should Question”
  - Fifty Specialty Societies joined the campaign; *Consumer Reports* is getting the message out to patients

# What Can You Do? -- Leverage Data and MOC to Target Education Efforts

- Leverage existing quality/patient safety data -- SRE, HAI, SCOAP/COAP reporting
  - What steps can you take to encourage more reporting?
  - Consider focusing physician continuing education on areas identified as problematic
  - Can you facilitate a learning community?
- For complaints that are quality/safety related: root case analysis, facilitate QI, and ongoing monitoring
- Board maintenance of certification programs include modules focused on patient safety that could be recognized as meeting licensure requirements

# Questions and Comments

# Disclosure and Resolution Program (DRP) Update

Thomas H. Gallagher, MD

Professor of Medicine, Bioethics & Humanities

Director, UW Medicine Center for Scholarship

in Patient Care Quality and Safety

Director, Program in Hospital Medicine

University of Washington



Transforming Communication in Healthcare

# Background

- Medical injuries common
- Poor team communication as cause of many injuries
- Communication with patient often deficient in response to injuries
  - Disclosure often fails to meet patient expectations
  - Difficult for injured patients to receive fast, fair compensation



# Project Overview

- Created HealthPact Forum
  - Ongoing engagement with trial attorneys, regulators among other stakeholders
- Communication training
  - Team Communication Training
  - Disclosure and Apology Coach Training
- Created and piloting the Disclosure and Resolution Program (DRP)



# What Is The Problem?

- When unanticipated outcomes happen to patients, we struggle to:
  - Communicate with patients and families
  - Provide resolution that is fast/fair when the unanticipated outcome was caused by care that was not reasonable
- Patients often file malpractice claims simply to understand what happened and get basic needs met
- The disclosure and resolution process is especially challenging when multiple providers/institutions/insurers are involved



# The Accountability Gap

- Fear of unpredictable, punitive response by institution and regulators severely chills provider reporting of adverse events
  - Hampers efforts to learn, prevent recurrence
- System does not serve patients' needs
  - Information
  - Acceptance of responsibility
  - Timely compensation
  - Prevention of recurrences
- System stresses providers financially and emotionally



# What is accountability after medical injury?

- Healthcare institutions and providers:
  - Recognize that event has occurred
  - Disclose it effectively to the patient
  - Proactively make the patient whole
  - Learn from what happened
    - Discuss the event across colleagues, institutions
- in a healthcare delivery environment that:
  - Prospectively monitors quality of care
  - Identifies unsafe providers and employs effective remediation
  - Spreads learning across institutions



# Just Culture

- Seeks middle ground between historical “shame/blame-bad apple” approach and “blame-free” model of accountability for medical injury
- Distinguish between “human error” (console), “at-risk behavior” (coach), reckless behavior (punish)
- Conceptually appealing, hard to implement
  - Recent survey of 500,000 healthcare workers, half felt their mistakes were held against them.



# Quality of Actual Disclosures

- COPIC
- 3Rs program for disclosure and compensation, 2007-2009
  - 837 Events
  - 445 patient surveys (55% response rate)
  - 705 physician surveys (84% response rate)

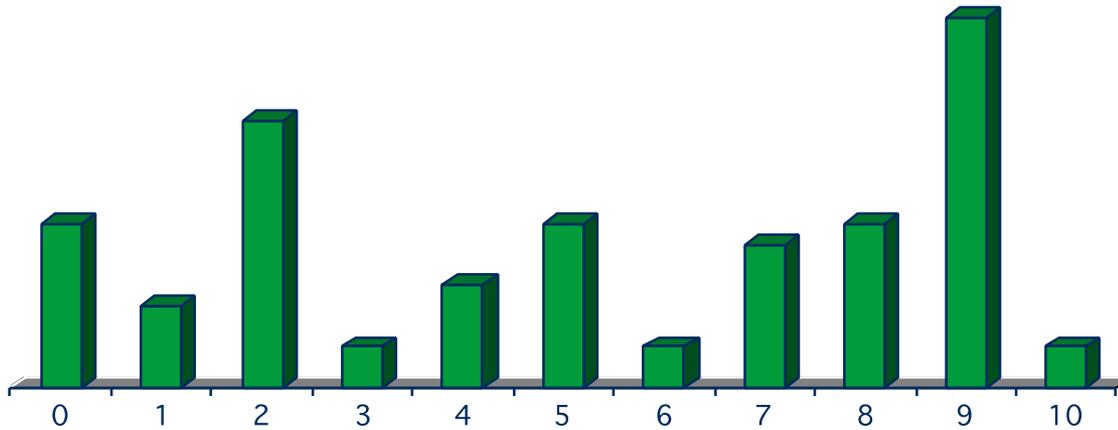
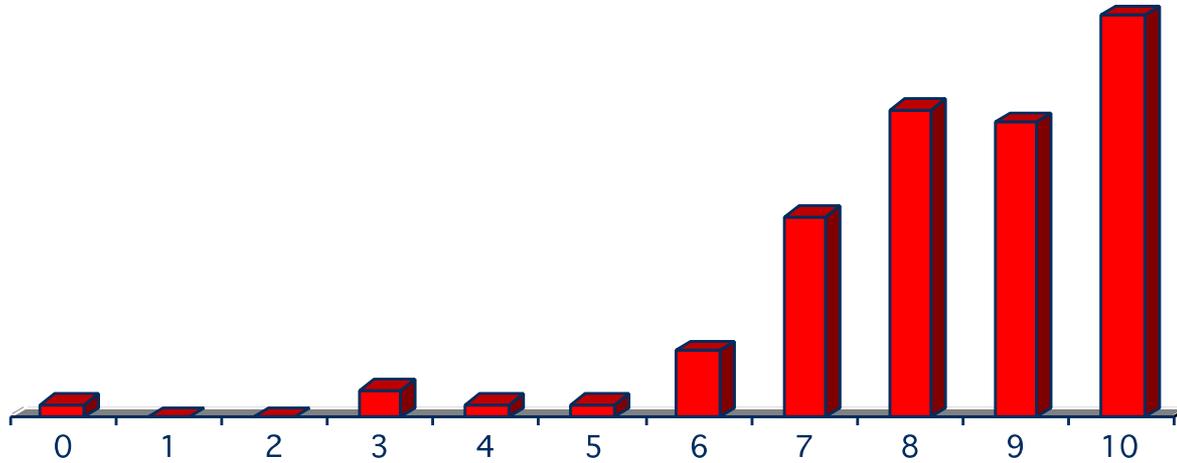


# Event Severity

	Patient Assessment	Physician Assessment
Extremely serious (I might have died)	31%	7%
Very Serious (permanent injury)	25%	25%
Somewhat serious (injury that resolved)	28%	61%
Not at all serious	3%	6%



# Quality of Disclosure



Transforming Communication in Healthcare

# Patient Rating of Disclosure Skills

Skill	Agree
The physician provided a sincere apology to me for this event	66%
The physician had good listening skills	64%
The physician was truthful when explaining the event to me	63%
The physician explained the event using terms I could understand	62%
I trust this physician's clinical competence	59%
The physician told me as much information as I wanted to know about the event	54%
The physician told me why the event happened	50%
The physician told me whether or not the event was preventable, i.e., known complication	44%
The physician assured me that steps would be taken to prevent similar events from happening again	37%

# Cancer patients' experiences of problems in care

- Screened 416 cancer patients for perceived problems in care
  - Something went wrong, what went wrong was preventable, caused harm
- 93 of 416 (22%) screened positive. In-depth interviews with 78 patients
- 28% described problem with medical care; 47% described problem with communication; 24% reported both

# Suffering in silence

- Only once did patient perceived that person responsible had assumed responsibility
- 6% of patients reported receiving a clear explanation of the event
- 13% of patients formally reported the problematic event to the organization
  - Reasons for not reporting
    - Need to focus on own health, put event behind them
    - Belief that reporting would not do any good
    - Concern about impact on relationship with clinicians



# Accountability: More Than Words

- Action that follow the disclosure need to be congruent with the words
  - “If you’re just going to apologize and you’re not going to fix anything, that’s insulting to my intelligence”
  - “There’s got to be accountability. I don’t want to hear ‘I’m sorry.’ ‘I’m sorry is nothing. I want to hear what steps have been taken to correct the problem.”
  - “Don’t tell me you were sorry that the problem occurred. That just puts a band aid on something....I want to see results.”



# Provider Complaints

- Recent study of >10,000 patient complaints to Australian complaints commission
  - 3% of physicians accounted for 49% of all complaints
  - 1% of physicians accounted for 25% of all complaints
- Prior complaints strong predictor of future complaints
- Similar trends found in US data on complaints, malpractice claims
- Physicians with recurrent complaints represents fundamental breakdown in professional self-regulation



# What is the DRP?

The DRP is a voluntary, structured approach to promote collaboration among stakeholders, and communication with patients, following unanticipated outcomes of care.



# What is the DRP?

- ▶ Be candid and transparent about unanticipated care outcomes
- ▶ Conduct a rapid investigation, offer a full explanation, and apologize as appropriate
- ▶ Where appropriate, provide for the family's financial needs without requiring recourse to litigation
- ▶ Build systematic patient safety analysis and improvement into risk management



# AHRQ Grants with DRP Component

State	PI	Core DRP component	Related activities
<u>Demonstration Projects</u>			
IL	McDonald	“Seven Pillars” approach at 10 Illinois Hospitals	Patient compensation card
NY	Kluger/Co hn	CRP in place at 5 NYC hospitals	Enhance culture, AE reporting Judge-directed negotiation
TX	Thomas	DRP in place at 6 UT health campuses	Patient engagement in event analysis, resolution
Ascension Health	Hendrich	CORE program in place at 6 hospitals	Major focus on OB safety
WA	Gallagher	DRP at 6 institutions, Physicians Insurance A Mutual Company	HealthPact-transforming healthcare communication
<u>Planning Grants</u>			
MA	Sands	Create MA collaborative for DRP implementation	Implementation underway using alternate funding.
UT	Guenther	Exploring DRP options in Utah	Collaborative with Utah stakeholders underway
WA	Garcia	Accelerated Compensation Events	

# How have DRPs worked elsewhere?

- University of Michigan (Early settlement model)
  - Since implementing disclosure-with-offer program
    - Claims half as likely, lawsuits 1/3 as likely
    - Time to resolution cut nearly in half
    - Reduced liability costs
- University of Illinois at Chicago (Seven Pillars)
  - Increase in patient safety event reporting from 1,500 to 7,500 per year
  - 50% reduction in new claims
  - Median time to resolution now 12 months compared with 55 months before program



# Who is currently participating in the DRP in WA state?

- Physicians Insurance A Mutual Company
- Providence Sacred Heart Medical Center and Children's Hospital
- Providence Regional Medical Center, Everett
- Providence St. Mary Medical Center
- The Everett Clinic
- The PolyClinic
- The Vancouver Clinic
- Swedish



# Disclosure and Resolution Program Process

## Study Event (SE)

- Care team responds to immediate patient needs and provides information then known
- Involved staff reports SE to Risk Manager



# Disclosure and Resolution Program Process

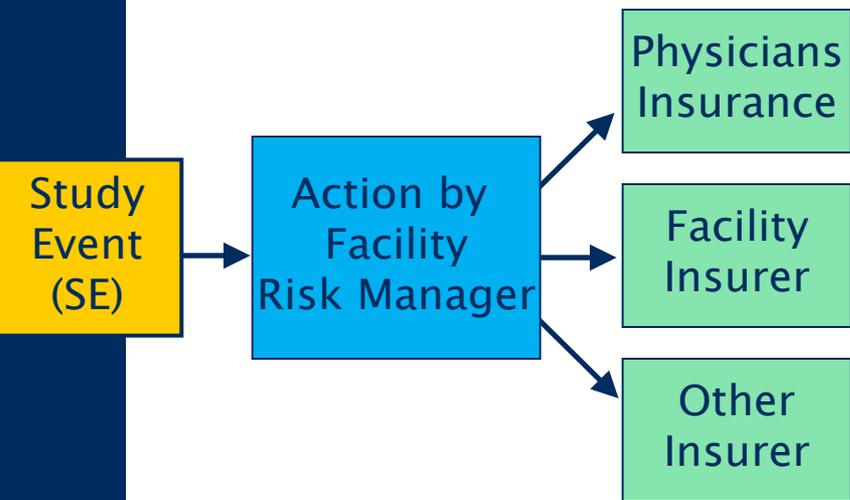
Study  
Event  
(SE)

Action by  
Facility  
Risk Manager

- Initiates QI investigation using Just Culture approach
- Initiates support services for patient/family
- Initiates disclosure coaching and other support services for healthcare team
- Contacts other Partners to explain SE and steps taken and initiates collaboration

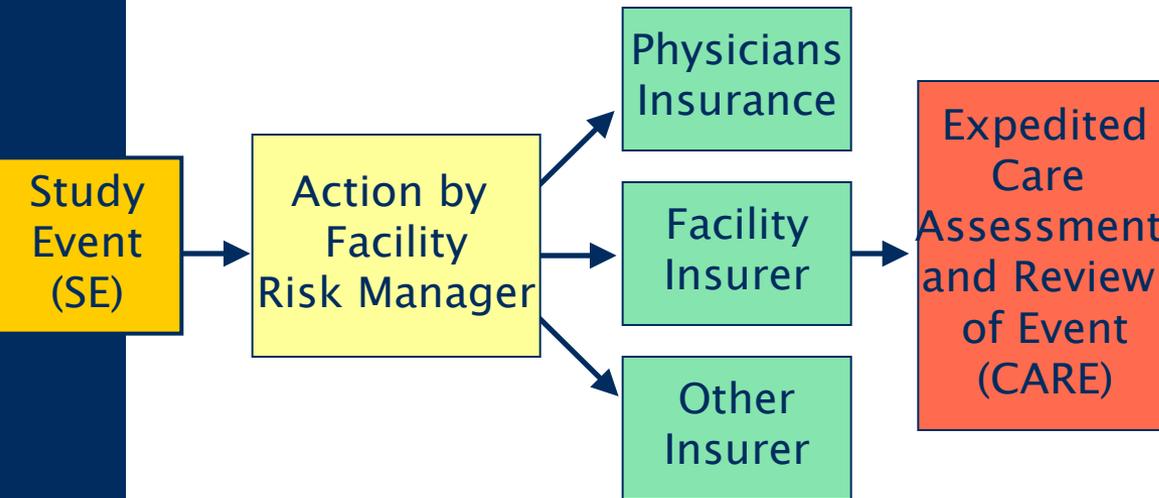


# Disclosure and Resolution Program Process



Partners collaborate on approach to evaluation and resolution

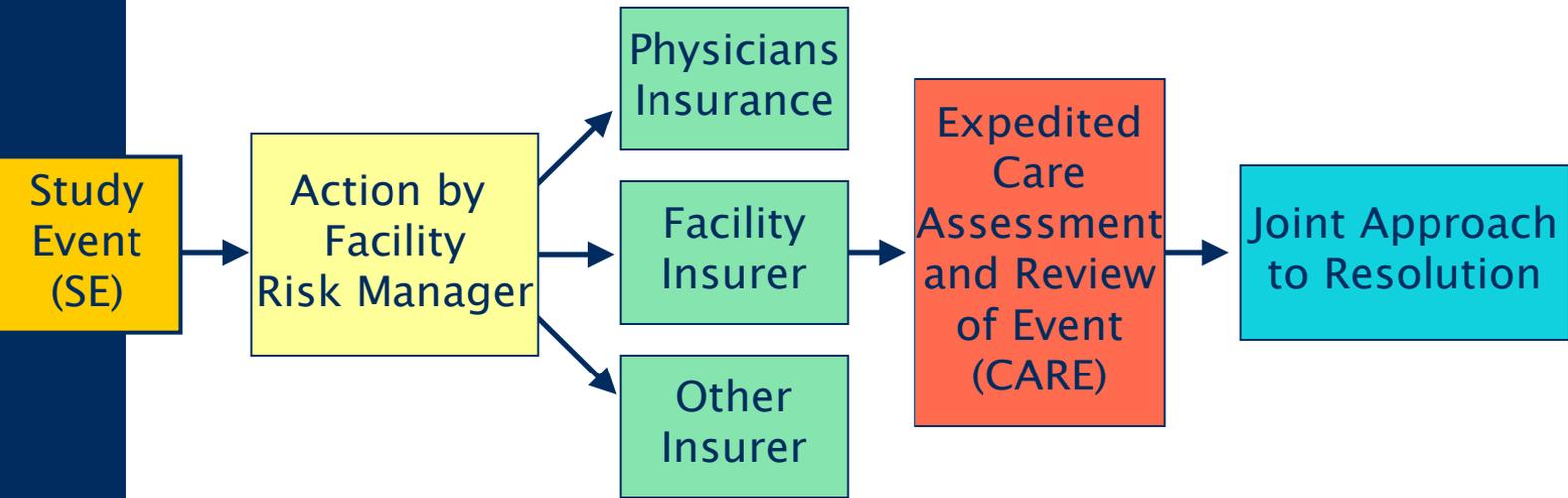
# Disclosure and Resolution Program Process



Partners and involved providers decide on effective approach and timeline for CARE, including internal and/or external expert review to determine:

- Whether care was reasonable
- Whether system improvements are needed to prevent recurrence
- Whether other actions are warranted

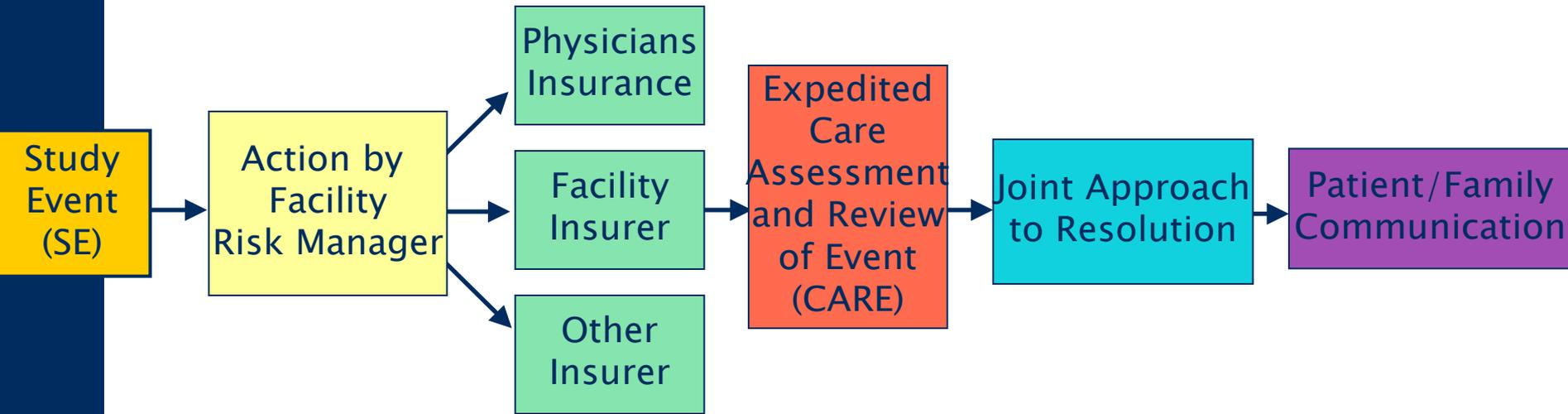
# Disclosure and Resolution Program Process



Partners agree on approach to resolution:

- What are the patient's/family's needs?
- Will monetary compensation or other remedies be offered?
- What will be disclosed to patient/family?
- How will identified system improvements be pursued?

# Disclosure and Resolution Program Process



Patient/family is notified of findings and approach to resolution:

- Full explanation of what happened
- Apology as appropriate
- Offer of compensation and/or other remedies, or explanation of why no offer is being made
- Information about any safety improvements

## The DRP is not:

- A rush to judgment
- A rush to settlement
- Mandatory
- Telling the patient absolutely everything known about an adverse event
- Paying patients when care was reasonable
- Business as usual



# WA DRP Development

- Physicians Insurance grant to support DRP through no-cost extension period
- Swedish joining DRP
- DRP events progressing through system
  - # of events to date less than expected, accelerating
- Providence-PI task force
- DRP workgroup
  - DRP Patient Education
  - Patient representation
  - Offer review panel concept
- Proposed collaboration with MQAC around DRP Certification Concept



# National Developments

- New AHRQ grant secured by national team to develop, pilot test DRP toolkit
  - Likely prelude to national roll-out
- Results of 9 DRP programs presented at recent meeting in Washington DC
- National Collaborative



# DRP Implementation Barriers

- Physician fear of adverse event reporting
  - MD education underway
  - Work with sites around Just Culture
- Lack of trust among key stakeholders
  - Incremental improvement as DRP events progress through system
  - Ongoing outreach to key physician groups affiliates with DRP sites
- Time constraints for quality/safety/risk leaders
- Physician concern about NPDB, MQAC, peer review

# MQAC-DRP Collaboration



Transforming Communication in Healthcare

# Major DRP Challenge: Provider Fear of Reporting

- Providers worry that reporting unanticipated outcome may lead to punitive consequences from institution, regulators
  - Mandatory reporting to Medical Quality Assurance Commission required when patient receives compensation >\$20K in response to medical error
  - Providing fast, fair financial resolution to patients when care was not reasonable is central tenet of DRP process
- Absence of event reporting by providers preventing analysis, learning



# Most Adverse Events Are Not Caused By Incompetent Providers

- Oftentimes, adverse events happen despite high quality care
- When adverse events are associated with care that was not reasonable, usually involve competent provider caught in system failure or who made simple human error



# MQAC's Collaboration With DRP Would Improve Patient Safety, Protect Public

- Addressing provider fear of a punitive response when they report adverse events could dramatically increase reporting, promote learning, improve quality
- Needs to be balanced with vigorous efforts to support provider competence, protect the public



# What Does the Ideal DRP Event Look Like?

- Early event reporting by provider
- Careful analysis by institution-was unanticipated outcome caused by medical error? If so, how can recurrences be prevented?
- Prompt, compassionate disclosure to patient
- Fast, fair resolution for patient
- Learning at individual and institutional level



# DRP Certification Concept

- MQAC retains all current authority
- All current requirements for mandatory reporting to Commission remain in effect
- Important exclusions: Gross provider negligence, provider impairment, boundary violations
- MQAC investigation generally put on hold for events being handled by DRP
- For “DRP Certified Cases”, MQAC would generally not open independent investigation
- Proposed MQAC-DRP collaboration would be statewide
- Hope would be to expand to all providers if pilot successful



# DRP Certification Example

- Skilled provider uses new bedside ultrasound machine incorrectly
  - Incorrect diagnosis leads to patient harm
  - Patient misses 3 months work, needs childcare during recovery.
- Provider promptly reports event to institution. Rapid analysis occurs. Event attributable to provider knowledge gap, need for improved institutional policies.
- Disclosure to patient occurs. Patient provided compensation for lost wages and childcare expenses.
- Provider takes bedside ultrasound course, passes exam. Institution implements policy around use of bedside ultrasound.
- Case reported to DRP. Reviewed by panel, marked as DRP Certified
- DRP Certification report reviewed by MQAC. Case closed without Commission investigation as satisfactorily resolved.



# DRP Near Miss Registry

- DRP focuses on all unanticipated outcomes of care, not just those associated with harmful error
- DRP will encourage providers to report near misses for analysis
- Safety lessons learned will be widely disseminated



# Other Regulatory Challenges: Case Example

- Highly skilled neurosurgeon involved in a wrong site neurosurgery, leaving patient with right arm and hand weakness.
- Root cause analysis suggests multiple system and individual causes, including fact that surgeon rushed through the mandatory pre-procedure time-out because he was behind schedule.
- His department tracks whether operations start on time, allocates OR space and time slots accordingly.
- The hospital proactively settles a claim with this patient for \$30,000. Files required report of surgeon to the state board of medicine and National Practitioner Data Bank.
- The surgeon voices resentment about the “black mark” on his record when the hospital has openly acknowledged that system factors contributed to the adverse outcome



# Unanswered Questions

- What ethical principles should guide state board of medicine, institutional peer review response?
  - How to assess relative contribution of system vs. individual error to adverse event
  - Are sanctions appropriate, and if so who should levy them?
- Should the state board's action be publicly reported?
- Should institution settle case with patient without naming provider, shielding provider from reporting to state board or National Practitioner Databank?



# Related Work Facilitated by RWJ Support

41

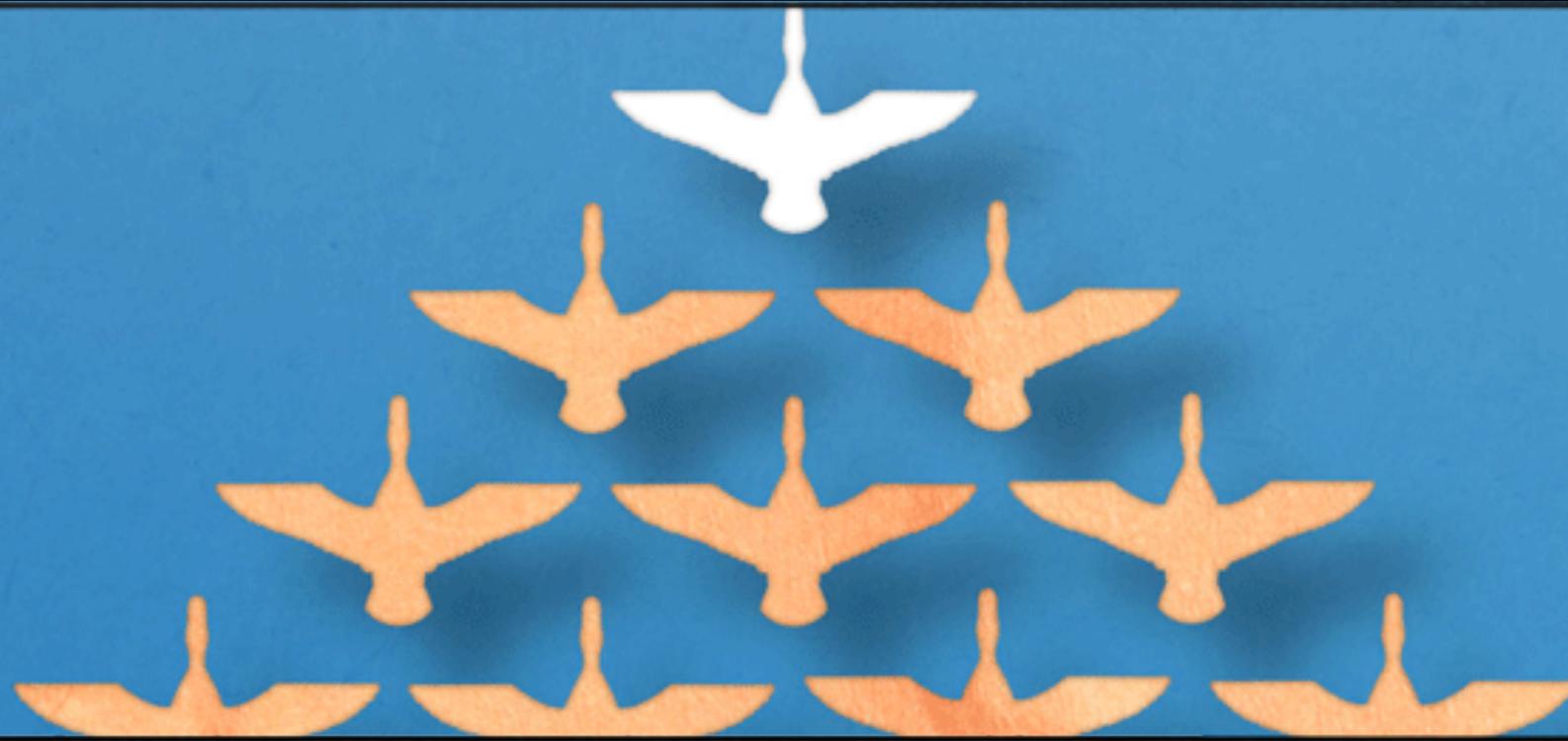
- AHRQ Patient Safety and Liability Reform Demonstration projects
- AHRQ Communication and Resolution Toolkit
- NCI-funded work on cancer patients' experiences of care breakdowns
  - New AHRQ “We Want to Know” study





Medical Commission  
Initiatives Update

Commission Senior Management



# Overview

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- Medical Commission Fiscal Year 2013 Performance Update
- Current Efforts Briefing
  - Strategic Plan
  - Joint Operating Agreement
  - Demographics Legislation
  - Disclosure and Resolution Program
- Policy Briefing
  - Professionalism and Electronic Media
  - Electronic Health Practice

# Commission Pilot Project

---

- Represents a major restructuring of how the Commission performs its business and is now permanent.
- Effective July 1, 2008 and new model made permanent July 1, 2013.
- Gives increased authority to Commission, particularly in personnel and budget, to address case backlog
- Performance Measures
- Sanction rules
- Processing of complaints of sexual misconduct

# Commission Vital Stats-Fiscal Year 2013

---

- **1,493 complaints received**

- 911 cases investigated
- 920 cases completed legal process

- **86 disciplinary orders issued**

- 15 licenses summarily suspended and restricted

- **181 practitioners in compliance monitoring**

- 44 successfully completed compliance

# Performance Update-Fiscal Year 2013

---

- Licensing: PM 1.1
  - FY 2012-99.9%
  - FY 2013-100%
- Licensing: PM 1.2
  - FY 2012 and 2013-100%



# Performance Update-Fiscal Year 2013

---

- Investigations: PM 2.1-Complaints Assessed
  - FY 2012-99.9%
  - FY 2013-99.9%
- Investigations: PM 2.2-Investigations Completed
  - FY 2012-92.1%
  - FY 2013-91.7%

# Performance Update-Fiscal Year 2013

---

- Investigations: PM 2.4-Investigations Open
  - FY 2012-2.3%
  - FY 2013-3.5%
- Investigations: PM 3.1-Investigations vs. Investigator
  - FY 2012-10/month avg.
  - FY 2013-8.6/month avg.

# Performance Update-Fiscal Year 2013

---

- Legal: PM 2.3-Cases Completing Disposition
  - FY 2012-92%
  - FY 2013-95%
- Legal: PM 2.5-Open Cases in Legal
  - FY 2012-30.3%
  - FY 2013-23.7%

# Performance Update-Fiscal Year 2013

---

- Legal: PM 3.2-Staff Attorney Case Load
  - FY 2012-46.8
  - FY 2013-42.8

# Discipline Rules

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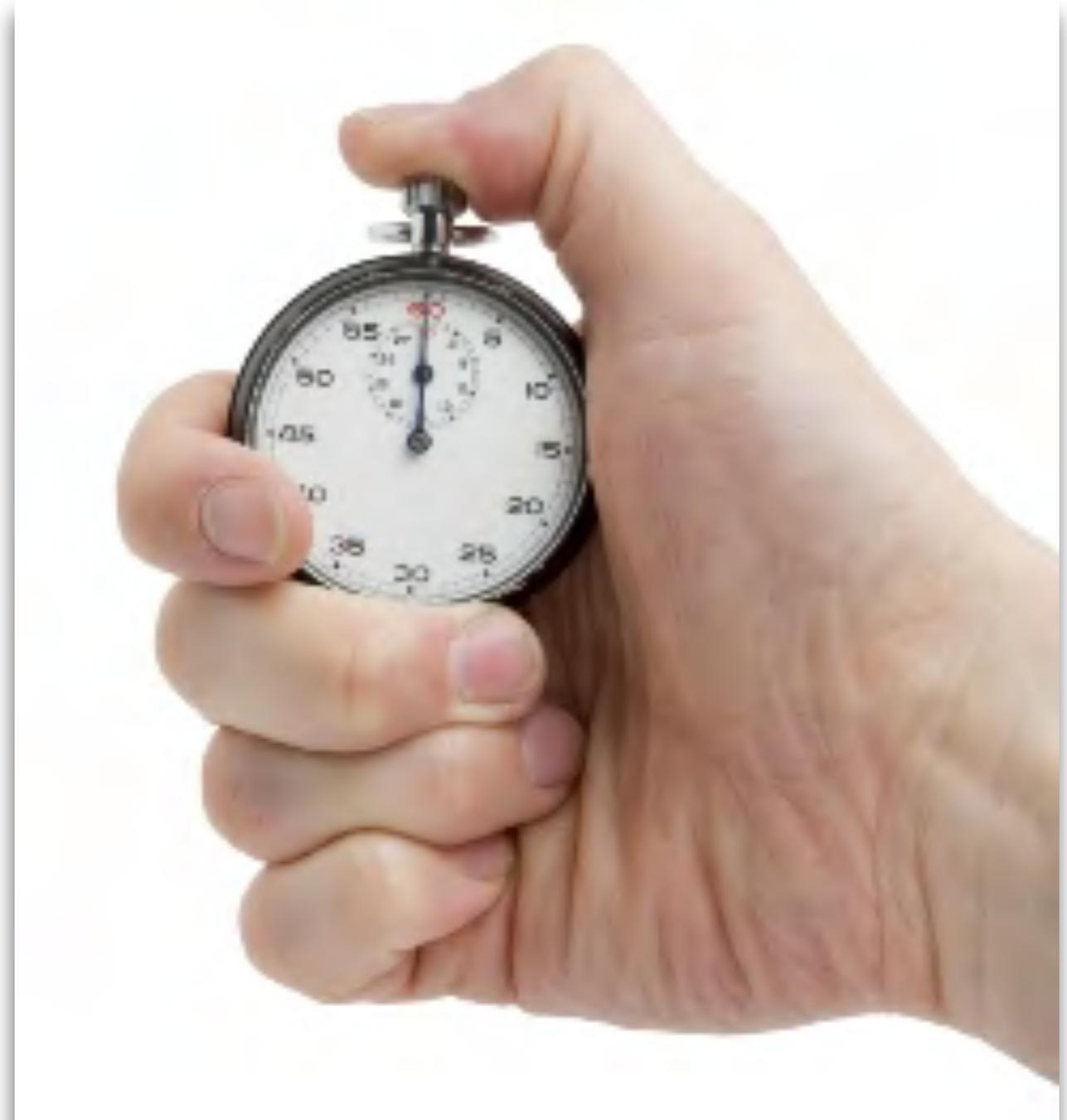
- PM 2.6-Sanction Schedule
  - FY 2012-100%
  - FY 2013-100%
- PM 2.7-Sex Case Transfers
  - FY 2012-100%
  - FY 2013-100%



# Performance Update-Fiscal Year 2013

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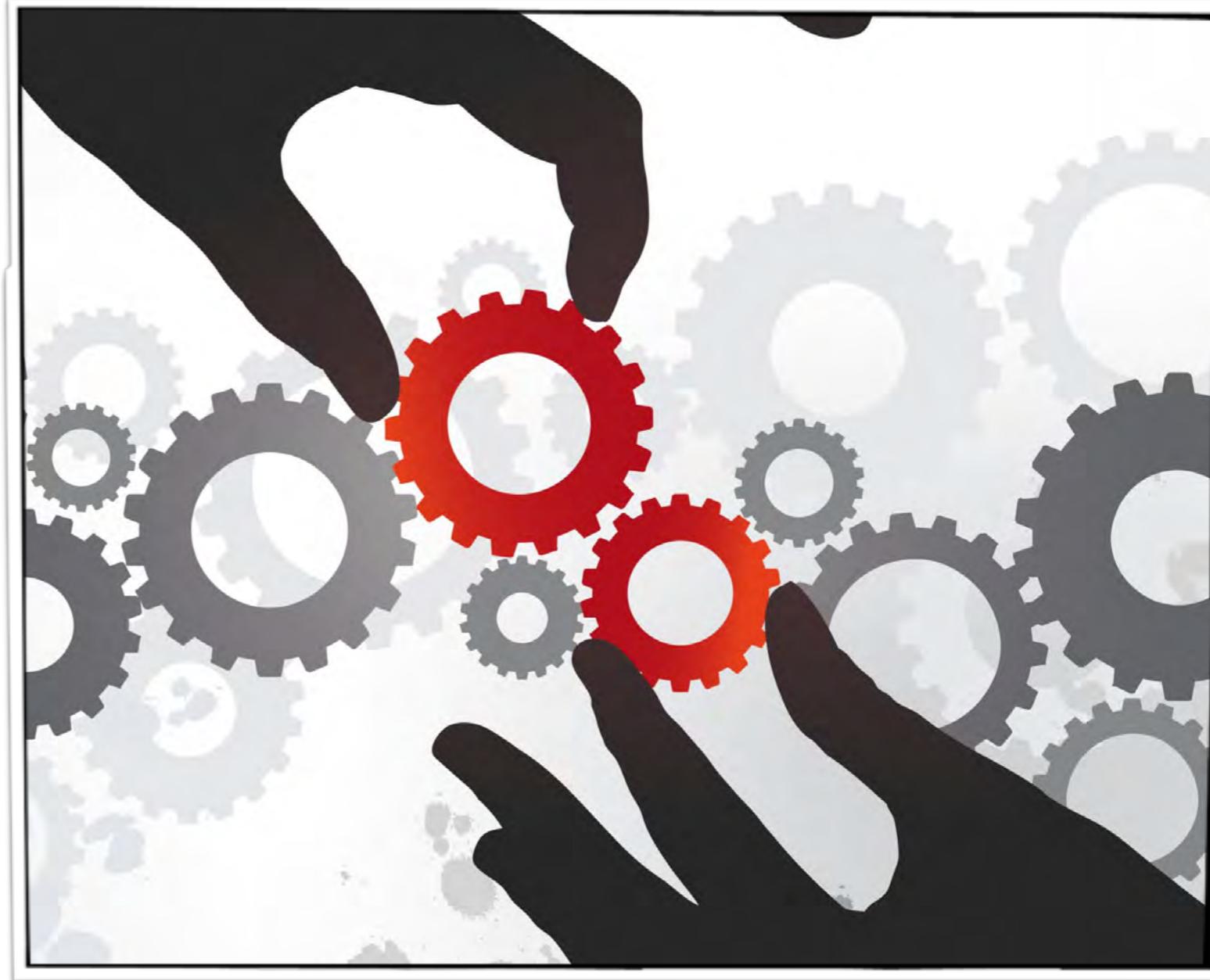
- Case Resolution 2012
  - 0-180: 77.4%
  - 181-360: 15.9%
  - 361+: 6.6%



# Case Timelines 2013

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- Case Resolution 2013
  - 0-180 : 81.9%
  - 181-360 : 12.5%
  - 361+ : 5.5%



# Performance Update-Fiscal Year 2013

---

- Aggregate Performance
  - FY 2012-94.5%
  - FY 2013-95.8%



# Current Initiatives

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Strategic Plan

Joint Operating Agreement



# Strategic Plan

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- First post-Pilot strategic plan
- Acting Director of DOH Performance and Accountability is serving as a facilitator for the process
- Ground up approach
- Looking to incorporate lessons learned and knowledge gained in the last five years

# Joint Operating Agreement

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- Guides how we do business with DOH
- Mandated by statute
- First revision since 2010
- Draft is nearly complete and should be introduced at a Commission business meeting in the near future for consideration and approval

# Current Initiatives

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Disclosure and Resolution Program (DRP)

Demographics Legislation



# Demographics Update

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- **Census started 2012: 3/1 for MDs and 9/1 for PAs**
- **Total returns**
  - MD: 10,699, PA: 939
- **Gender**
  - MD: 69.3% Male, 30.7% Female\*
  - PA: 48.7% Male, 51.7% Female
- **Reside in Washington**
  - MD: 77.7%, PA: 88.5%
- **Practice in Washington**
  - MD: 76.8%, PA: 88.1%

# Demographics Update-2

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- 92% completed an ACGME residency
- 90% of MDs report as ABMS Board Certified
  - Majority are FP, Internal Med, and Pediatrics
- 97% of PAs report of certified
- 65% of PAs work with 1-5 MDs, 18% with 6-10
  - Majority of supervising MDs are FP, Internal Med, Orthopaedic Surgery, and Emergency Med
  - 14% of PAs report practice at remote sites
- 52% of PAs are office based, 17% hospital based

# Demographics Update-3

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- **MD Practice**

- 12% in solo practice
- 20-26% report as single specialty, multi-specialty, hospital employee
- 78% of single specialty groups less than 25 members
- 85% of multi-specialty groups 500 members or less
- 42% of clinical practice is hospital based
- 74% of MDs report having hospital privileges
- Majority of MDs report working 40+ weeks in the last 12 months at an average of 47.2 hours per week

# Demographics Update-4

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- **Practice Areas**

- 9% of MDs report using telehealth with 81% reporting less than 30 hours per week in this area, 12% between 31-40 hours in this setting
- PAs report 5% of telehealth usage with the majority spending less than 5 hours per week in this setting
- 32% of MDs reporting prescribing opioids for chronic non-cancer pain patients, 85% have 50 patients or less
- 45% of PAs reporting prescribing opioids for chronic non-cancer pain patients, 27% have 20 patients or less
- 2% of MDs report practicing non-traditional medicine

# Demographics Update-5

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- **What does this data mean?**

- Total census responses: 11,639
- Total WA licensees: 29,937
- Our response rate is not high enough to be as reliable as we would like
- Data collection for two years under the current model
- We have proposed request legislation in the 2014 session to increase the response rate

# Additional Resources

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## **Medical Commission Homepage**

[www.doh.wa.gov.hsqa/MQAC](http://www.doh.wa.gov.hsqa/MQAC)

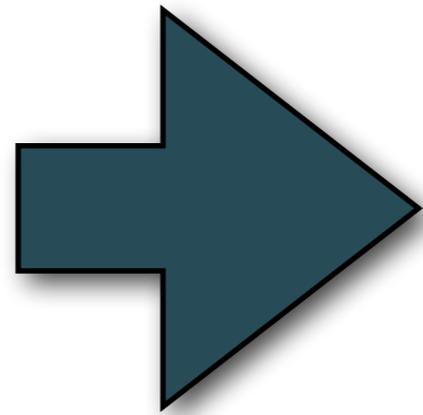
## **Demographics Webpage**

(quarterly reports and online census)

<http://go.usa.gov/2pkm>

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Commission's  
Work



Patient Safety



# The Search for the Holy Grail

Malcolm Sparrow

Harvard, Kennedy School of Government

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## "Risk-Based Regulation"

### **Old Model**

- Enforcement
- Reactive
- Adversarial
- Incident Driven

### **New Model**

- Compliance Assistance
- Preventative
- Partnerships
- Problem Solving

Malcolm Sparrow

Harvard, Kennedy School of Government

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## **People who use the new model find it**

- Different
- Intellectually demanding
- Analytically demanding
- Organizationally awkward
- Unrelentingly difficult
- Extremely effective

# Pain Management Rules

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- Problem
  - Opioid-related overdoses
- Partnership
  - MQAC, Osteopathic Board, Nursing Commission, Dental Commission, Podiatric Board
  - L&I, DSHS, UW, legislature, health care community
- Result
  - 23% decrease in opioid-related deaths 2008-2011

# Disclosure and Resolution Program

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- Problem
  - Medical errors
- Partnership
  - MQAC, Foundation for Patient Safety, institutions state wide
- Result
  - ?

# The Challenge

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## **Strengthening the Connection**

- Let's be creative
- Partner around risk mitigation
- Collaborate on patient safety initiatives
- Solve problems and reduce risk

# The Goal

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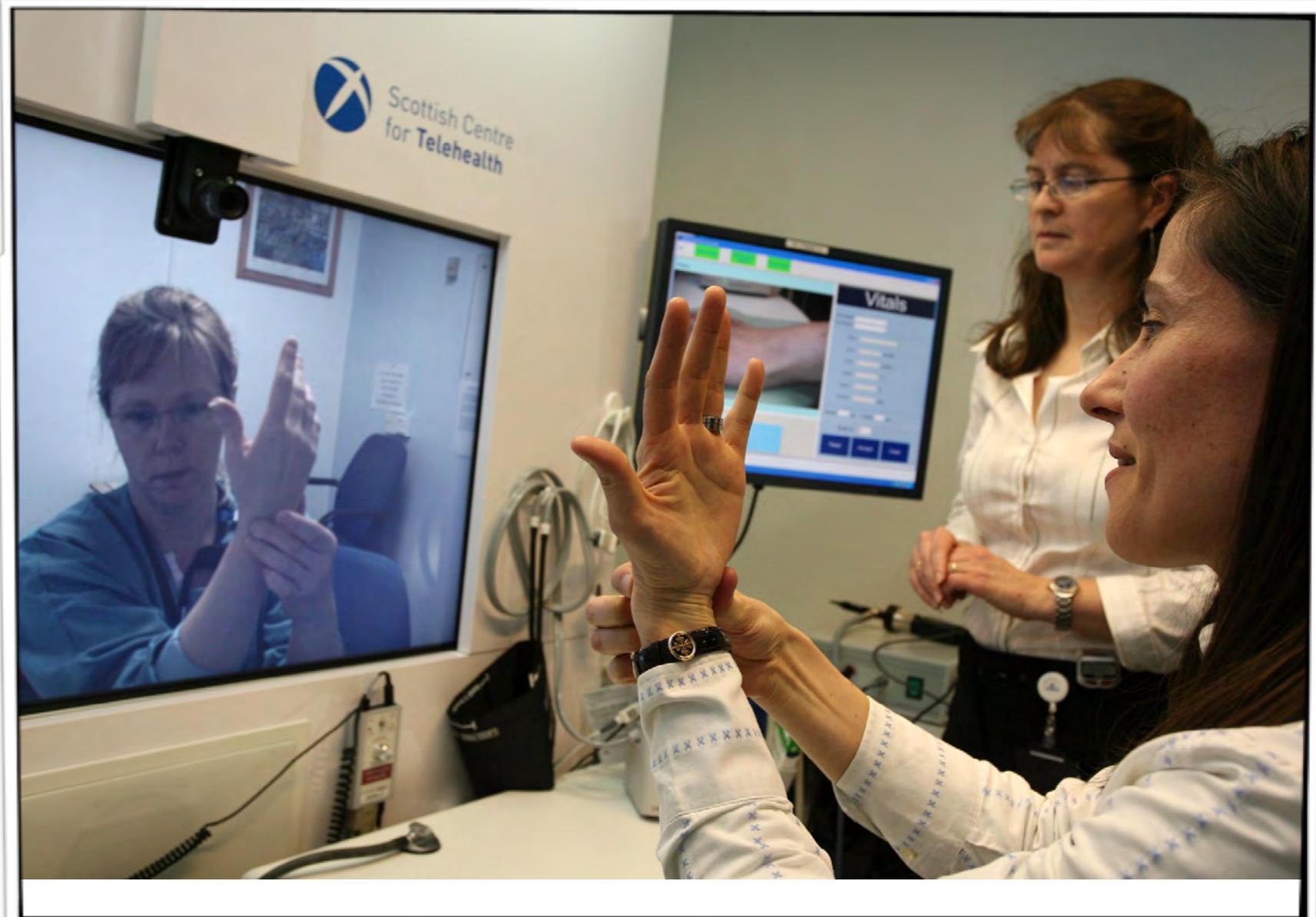
- Demonstrate effectiveness
- Improve patient safety
- Become a better regulator



# Policy Briefing

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- Professionalism and Electronic Media
- Electronic Health Practice (Telehealth)



# Professionalism and Electronic Media

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- Commission is actively developing a guideline
- Focus is on non-clinical interactions
- Best practices communicated through simple examples
- Take home message is professionalism and boundaries don't change





Electronic Health Practice (Telehealth)

# Electronic Health Practice (EHP)

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- In the early stages of development
- Focus on clinical interactions
- Not looking to list what is or is not allowable by telehealth
- Trying to develop a solution that:
  - broadens access to care
  - makes it easier for practitioners to see their regular patients
  - enforces accountability for bad behavior



# Comments or Questions?

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[Michael.Farrell@doh.wa.gov](mailto:Michael.Farrell@doh.wa.gov)



# A View from the Bench on Witness Credibility and the Need for Credibility Findings

**Honorable Thomas McPhee,**

Thurston County Superior Court Judge (Retired)

**Honorable Jeffrey J. Jahns,**

Kitsap County District Court Judge

**Moderator: Tracy Bahm, AAG**



While Commissioners are NOT jurors, and the Health Law Judge instructs the hearing panel on the law and sits with them during deliberations to answer questions on the law, we thought this might be helpful.

## Guidance from the Washington Pattern Jury Instructions

# WPI 1.02

- You are the sole judges of the credibility of the witness. You are also the sole judges of the value or weight to be given to the testimony of each witness.

# WPI 1.02

- In considering a witness's testimony, you may consider these things:
  - the opportunity of the witness to observe or know the things they testify about;
  - the ability of the witness to observe accurately;
  - the quality of a witness's memory while testifying;
  - the manner of the witness while testifying;
  - any personal interest that the witness might have in the outcome or the issues;
  - any bias or prejudice that the witness may have shown;
  - the reasonableness of the witness's statements in the context of all of the other evidence;
  - and any other factors that affect your evaluation or belief of a witness or your evaluation of his or her testimony.

# WPI 1.03

- The evidence that has been presented to you may be either direct or circumstantial. The term “direct evidence” refers to evidence that is given by a witness who has directly perceived something at issue in this case. The term “circumstantial evidence” refers to evidence from which, based on your common sense and experience, you may reasonably infer something that is at issue in this case.
- The law does not distinguish between direct and circumstantial evidence in terms of their weight or value in finding the facts in this case. One is not necessarily more or less valuable than the other.

## WPI 2.06

- The fact that a witness has talked with a party, lawyer, or party's representative does not, of itself, reflect adversely on the testimony of the witness. [A party, lawyer, or representative of a party has a right to interview a witness to learn what testimony the witness will give.]

# WPI 2.10 Expert Testimony

- A witness who has special training, education, or experience may be allowed to express an opinion in addition to giving testimony as to facts.
- You are not, however, required to accept his or her opinion. To determine the credibility and weight to be given to this type of evidence, you may consider, among other things, the education, training, experience, knowledge, and ability of the witness. You may also consider the reasons given for the opinion and the sources of his or her information, as well as considering the factors already given to you for evaluating the testimony of any other witness.



While most of you are not lawyers, we thought it might helpful for you to be aware of some of the court cases that direct how and why you are to make the findings that we ask you to make.

## Case Law

# Cases

- In health professional disciplinary hearings, the Commission is “the fact-finder, entitled to weigh the credibility of each witness and determine the weight to give to each opinion, if any.” *Ancier v. State, Dept. of Health*, 140 Wn.App. 564, 575, 166 P.3d 829 (2007).
- “The trial court's credibility determinations and its resolution of the truth from conflicting evidence will not be disturbed on appeal.” *Frank Coluccio Const. Co., Inc. v. King County*, 136 Wn.App. 751, 770, 150 P.3d 1147 (2007).

# Cases

- “[T]he finder of fact is the sole and exclusive judge of the evidence, the weight to be given thereto, and the credibility of witnesses.” *State v. Bencivenga*, 137 Wn.2d 703, 709, 974 P.2d 832 (1999).
- The trier of facts may give to the testimony of any witness such weight and credence as it believes the evidence warrants. *Segall v. Ben’s Truck Parts, Inc.*, 5 Wn.App. 482, 488 P.2d 790 (1971).
- A Commission panel functions not only as the trier of fact but also as the ultimate decision-maker, not unlike a judge in a bench trial. See *Faghih v. Wash. State Dept. of Health, Dental Quality Assur. Com’n*, 148 Wn. App. 836, 202 P.3d 962, 967 (2009).



# How Does WPHP Help the Physician with Disruptive Behavior?



Medical Quality Assurance Commission  
October 3rd, 2013

Charles Meredith, MD  
Medical Director  
Washington Physicians Health Program  
Clinical Assistant Professor  
UWSOM Department of Psychiatry

# WPHP and the “Impaired” Practitioner



Who are we?  
And what are we to you?



# Department of Health Contract

"WPHP is the qualified provider for potentially impaired physicians, physician assistants, osteopathic physicians, osteopathic physician assistants, podiatric physicians, dentists, and veterinarians and whose objective is to motivate healthcare practitioners to enter treatment and **to recover from their illnesses**, and, in so doing, **will serve to minimize the losses and other negative impacts** that are caused by these illnesses"



# WPHP

- Oversees all MD, DO, PA, DVM, DDS, and DPM (approx. 40,600)
- Includes residents and fellows
- Medical and dental students
- Monitored over 1100 over the last 27 years



# What is WPHP's Purpose?

- Rehabilitate health care providers
- Promote early detection of treatable diseases
- Protect the patients of Washington
- Keep safe and healthy providers in practice



# What Does WPHP Help With?

- Substance use disorders
- Mood disorders
- Anxiety disorders
- Disruptive Behavior
- Are they medically disabled?



# WAC 246-160-200

## Who must report:

- (1) The following persons, entities and businesses must report conduct and conditions as described in WAC 246-16-210:
  - (a) All license holders under the jurisdiction of a disciplining authority listed in RCW 18.130.040;
  - (b) Supervisors and managers of license holders;
  - (c) Group practices of health care providers,
  - (d) Professional associations of health care providers;
  - (e) Insurance carriers providing: professional liability coverage; health care insurance; disability insurance;



# WAC 246-160-200

To report information to the disciplining authority, **or an impaired practitioner program**, which indicates that the other license holder **may not be able to practice his or her profession with reasonable skill and safety** to consumers as a result of a mental or physical condition.



# WAC 246-160-200

- License holders voluntarily participating in the approved programs without being referred by the disciplining authority **shall not be subject to disciplinary action under RCW 18.130.160 for their substance abuse, and shall not have their participation made known to the disciplining authority**, if they meet the requirements of this section and the program in which they are participating.



# Practically speaking:

- HCPs who have a condition that may be affecting their ability to practice safely
- Can get the help they need
- Confidentially
- Endorsement to return to practice
- 90% of WPHP clients are unknown to the disciplinary body



# Who is WPHP currently serving?

- 315 HCPs currently under a monitoring contract throughout WA state
- 84% followed for addictive illness
- 15% followed for psychiatric illness or recurrent disruptive behavior
- <1% followed for other medical illnesses
- Working with roughly 10-20 trainees and 20 students

# Statutory Definition of “Impairment”:

“inability to practice with  
reasonable skill and safety”





# Physician Impairment, Depression, Suicide and Substance Abuse

- **Impairment:** "inability to practice with reasonable skill and safety"
- Clearly defined by DOH in cases of untreated substance dependence
- Less clearly defined for psychiatric conditions such as mood disorders
- *Even* less clearly defined in situations of recurrent "disruptive behavior"



So is the “disruptive” trainee or faculty member *really* “impaired”?



# The Normal Physician

- A moderately well-compensated Obsessive-Compulsive neurotic; with a dominant superego, that is conscientiousness-driven and depression-prone.



Glenn Gabbard, MD



# What Makes a Good Physician?

- Confidence
- Technical Skill
- Knowledge Base
- Rigor
- Authoritative, not authoritarian





# Selection Bias

- Obsessive
- Compulsive
- Confident
- Skilled test-taker
- Good people skills



**Disruptive Behavior** – A HCP who has a PATTERN of being unable, or unwilling, to function well with others to the extent that his or her behavior, by words or action, has the potential to interfere with quality healthcare.

Note: Not limited to Physicians





# The Distressed Physician Behavior Is Frustrating

- Because: They are usually convinced they are right
- Confounded by the fact that there will be some validity to their arguments
- They see us as ignorant, jealous or out to get them
- Patients may sing their praises
- They may truly – but rigidly- champion patient safety

# Behavioral Characteristics



- Inappropriate anger or resentment
- Inappropriate words or actions directed toward another person
- Inappropriate responses to patients needs or staff requests

# Inappropriate Anger or Resentment



- Intimidation
- Abusive language
- Demeaning other staff
- Blames/Shames others for adverse outcomes
- Unnecessary sarcasm or cynicism
- Threats of violence, retribution, or litigation
- Physical abuse
- Throwing charts, instruments
- Loud / cursing





# Inappropriate Words or Actions

- Unwanted sexual comments, jokes, or innuendo
- Unwanted flirtation, sexual harassment
- Seductive, or sexually aggressive, assaultive behavior
- Racial, ethnic, or socioeconomic bias or slurs
- Lack of regard for personal comfort or dignity of others

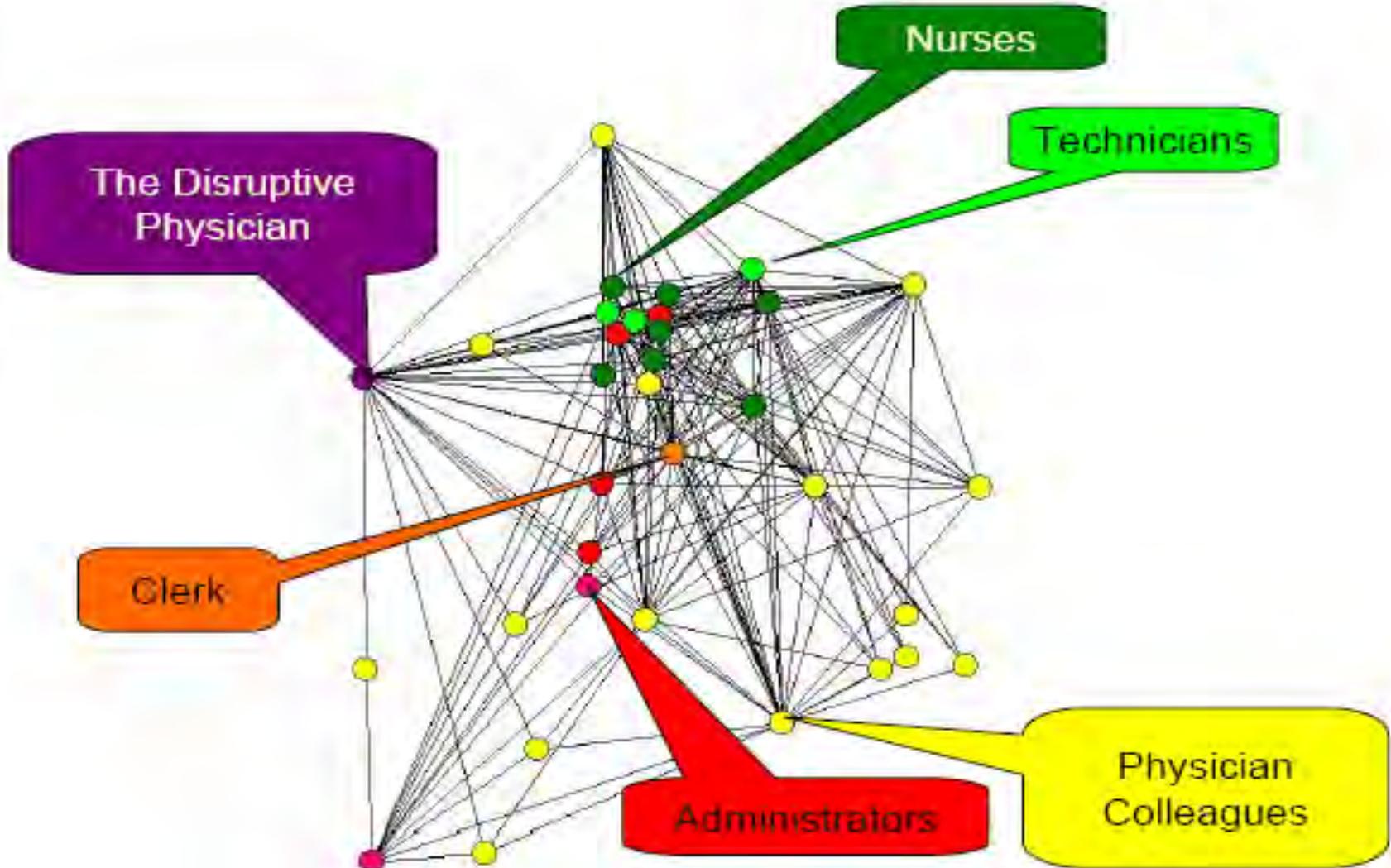


# Inappropriate Responses to Patients/Staff

- Uncooperative, defiant, rigid, inflexible
- Avoidant, unreliable
- Late or unsuitable replies to pages/calls
- Unprofessional demeanor or conduct
- Arrogant, disrespectful, exaggerated responses
- Inadequate communication
- Recurrent conflict – Irrational, oppositional
- Micromanagement, grandiose, self-inflated ego
- Inappropriate examinations



# Impact of Disruptive Behavior





# Impact of Disruptive Behavior

- Subordinates feel manipulated, controlled, harassed, abused
- Decreased morale – “Just because he’s a doctor”
- Increased workplace stress
- Excessive time spent avoiding/appeasing (Added administrative costs)
- Communication breakdown > Important issues
- Increased risk of mistakes/malpractice claim
- Other litigation – i.e. Unsafe work environment



# Impact of Disruptive Behavior

- The physician cannot hear feedback from colleagues and ancillary staff as they try to offer help
  - "Are you sure you want to discharge them without getting another hematocrit?"
- Colleagues and ancillary staff go out of their way to avoid contact and interaction with the physician
  - Preventable crises are not prevented, as no one wants to warn the physician





# Impact on Communication

- Medical teams need to communicate  
“talking to him is a lot like listening”
- Communication correlates to comfort level
- Conflict results in repeated avoidance of the problem
- Less communication with disruptive outbursts



# A Chart Entry

- "I have spoken to nursing supervisor and if necessary I will go to administrator. We are going backwards rather than forward if nurses can't read and follow orders or have the recognition to call if they don't understand an order. Have rewritten orders so that hopefully a child can follow them"



# Why Does It Occur?

- External Reward: System Accommodates
- Internal Reward: Decreased Anxiety



# Disruptive Behavior Reports on the Rise

- Subordinates less willing to tolerate it
- Loss of physician autonomy resulting in increased frustration
- Increased physician stress in rapidly changing medical system
- Modeled behavior
- Medical training de-emphasizes interpersonal skills
- Recent point of patient safety emphasis by Joint Commission



# Differential Diagnosis

- Substance Abuse
- Physical Impairment
- Fatigue/Stress
- Major Psychiatric Illness (ie. Depression, Bipolar Illness, Dementia, Thought Disorders, PTSD, Aspergers Syndrome)
- Personality Traits/Disorders
- Learned Behavior

# The Personality Disorders



- Schizoid, paranoid, schizotypal
- Antisocial, histrionic, narcissistic,  
borderline
- Avoidant, dependent, obsessive  
compulsive



# Medical Staff Responsibility

- Clear Bylaws/Policies & Procedures
- Accurate Documentation
- Informal Intervention
- Formal Intervention
- Refer to Physician Health Program
- Report to MQAC
- AFFORD DUE PROCESS



# Why Refer Them?

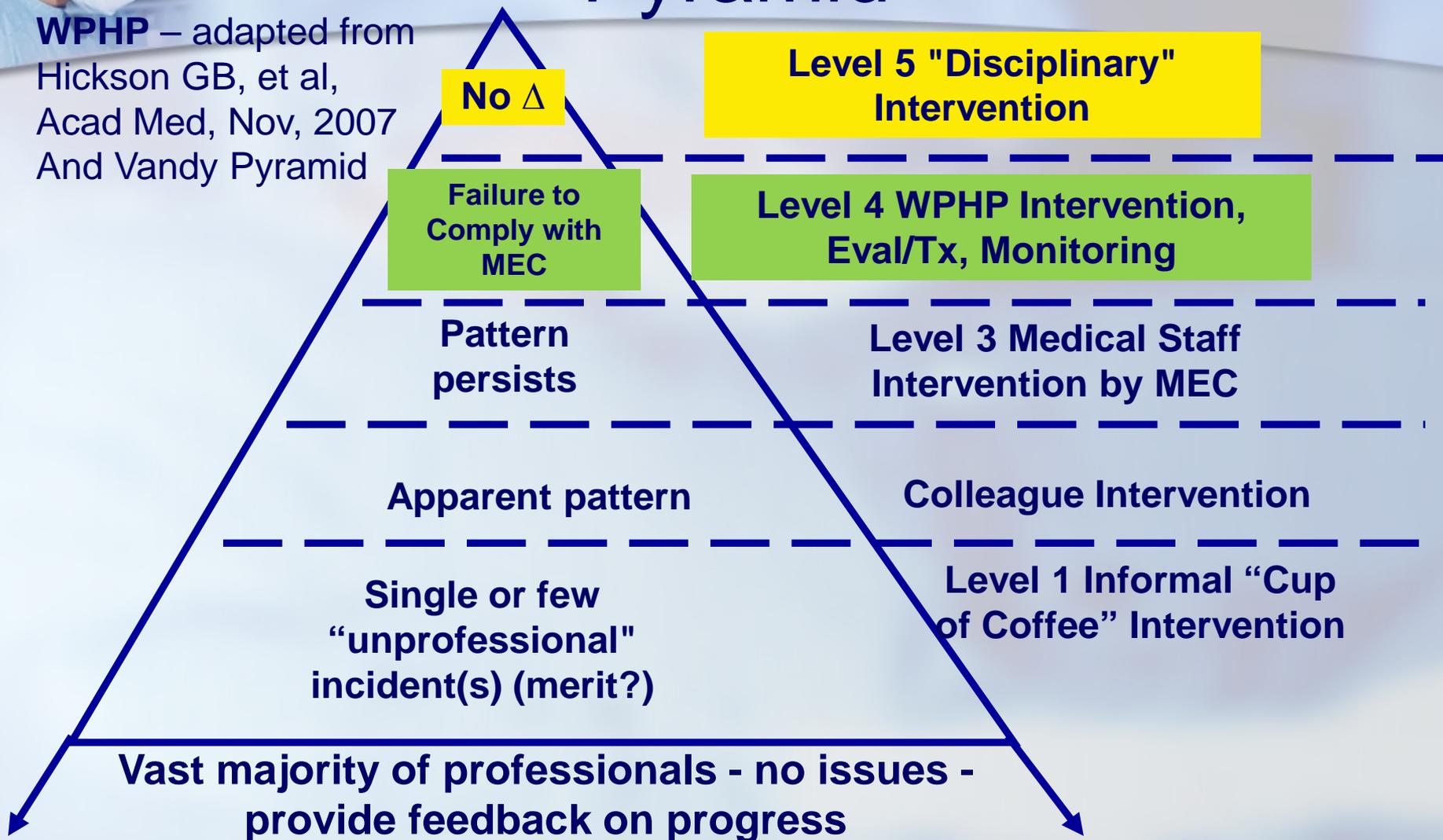
- We have to look like we're doing something
- We want to get rid of them
- We really want them rehabilitated





# Promoting Professionalism Pyramid

WPHP – adapted from  
Hickson GB, et al,  
Acad Med, Nov, 2007  
And Vandy Pyramid





# What Happens at WPHP?

- The physician meets with our behavioral health team
  - We rule out substance use disorders and psychiatric mood disorders
- Outside evaluation/2<sup>nd</sup> opinion if needed
  - Local forensic experts
  - Multidisciplinary evaluation at specialty centers for physician health
- Clearance to return to work once clearly fit for duty
  - WPHP monitoring agreement as indicated
  - Outpatient therapy
  - Professional job coaching
  - 360' monitoring and supportive mentorship

# What Helps?



## ■ Psychotherapy

- Improves insight
- Improves ability to manage anxiety
- Improves ability to manage anger

## ■ Communications Coaching

- Improves ability to read others
- What signals are you sending off?
- Explicit skills to say/do "the right thing"
- How to listen

## ■ Psychoeducation

- Professionalism courses



# Expectation Management

- Management vs cure – especially with personality disorders
- Change is gradual and incremental
- There will be backslides
- Goal is improved motivation, accountability, insight and anxiety-mediation skills



# When and How to Make Referrals

- Any concern is appropriate for discussion
- Document concerns, especially regarding “disruptive” behavior
- You’re helping your trainee or faculty member, not “getting them in trouble”



## How to contact me:

Washington Physicians Health Program

206-583-0127

800-552-7236

**Call us to “discuss the situation”!**

[cmeredith@wphp.org](mailto:cmeredith@wphp.org)

[www.wphp.org](http://www.wphp.org)

# Integrative Medicine

“Between a Rock and a Hard Place”:  
Mitigation of Risk

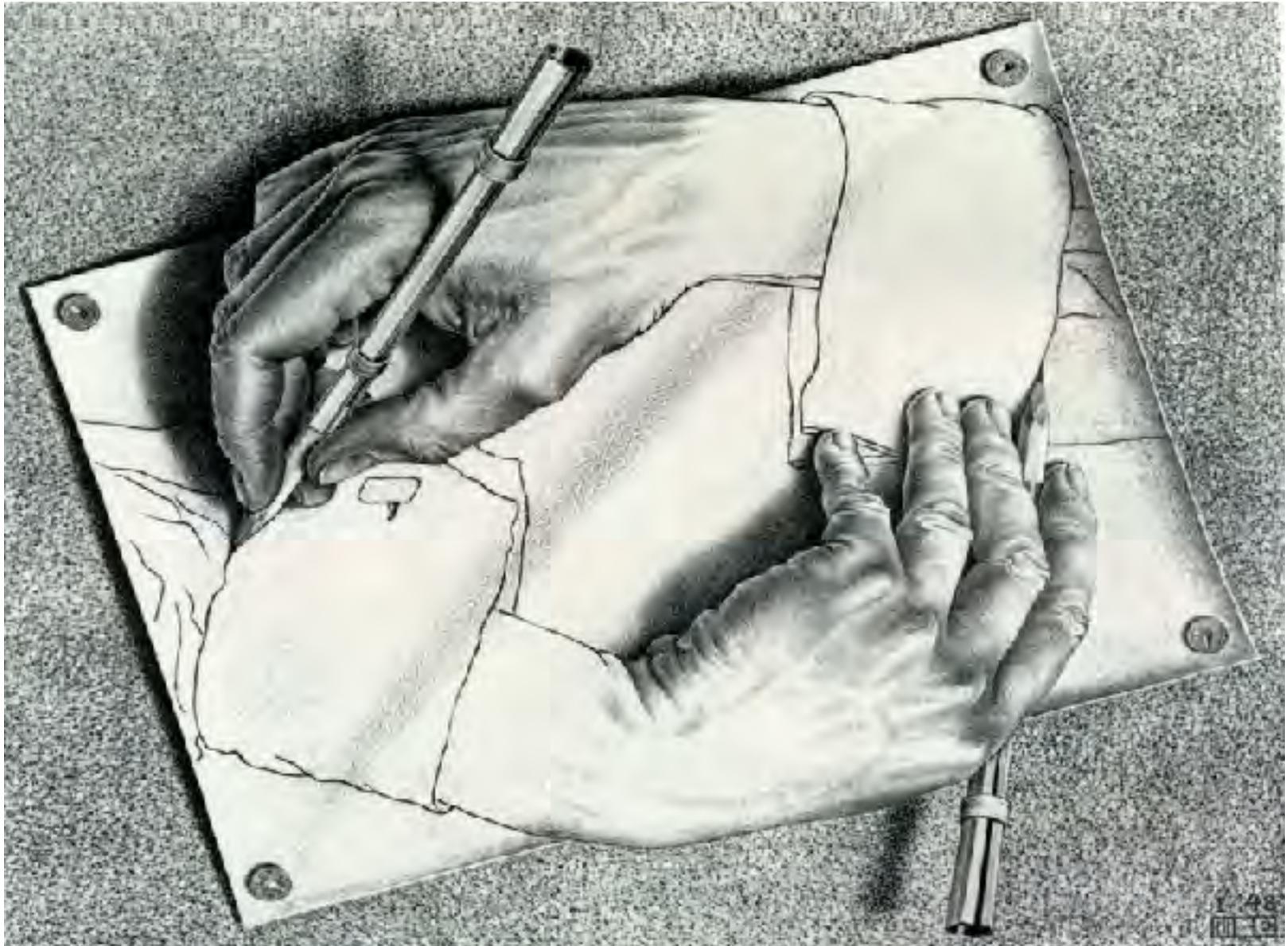
Heather Tick MA, MD  
Clinical Associate Professor  
of Family Medicine  
and Anesthesia & Pain Medicine

UW Medicine  
DIVISION OF PAIN MEDICINE

# Disclosure

- Consultant for USANA (nutritional company)

# Drawing Hands, Escher





- Why do patients turn to CAM or IM and spend upwards of 33 billion out of pocket in 2007 and rising.(adults only)  
(NHIS 2007)



OCTOBER 27, 2008 www.time.com AOL Keyword: TIME

BIRD FLU ■ HARRIET MIERS ON TRIAL ■ THE NEW ODD COUPLE

# TIME

DR. ANDREW WEIL ON

## LIVING BETTER LONGER

- The secrets of sounder SLEEP
- EXERCISES to make you feel younger
- How SEX makes you healthier
- The wellness DIET

# Fads?

# THE HUFFINGTON POST

TOP NEWS AND OPINION



## Good Housekeeping Looks at Chiropractic

# Newsweek



**People** weekly

April 15, 2014 \$5 Cents

**IN THIS ISSUE**

**Representative Wilbur Mills**  
He's after Nixon to pay more taxes

**Henry & Nancy Kissinger**  
He forgot to pay the judge

**Frank Sinatra**  
It was a quick reinvention

**Acupuncture gets popular**

**Jeckyl Mary Dack**  
Looks like an angel, rides like the devil

**Peter Benchley**  
Another best actor from a famous family

**Alice Faye & John Payne**  
They're 'Good News'

**Dr. Sheldon Segal**  
Male contraception via a year-long pill

**Actor Lorne Greene**  
Needles cured his pain

Customer Service?

Better patient  
experience?



Convenience?

Availability

Affability

Ability

# Convenience?

Close to home

Evening and weekend hours

Less waiting in the office

# More access to online information?

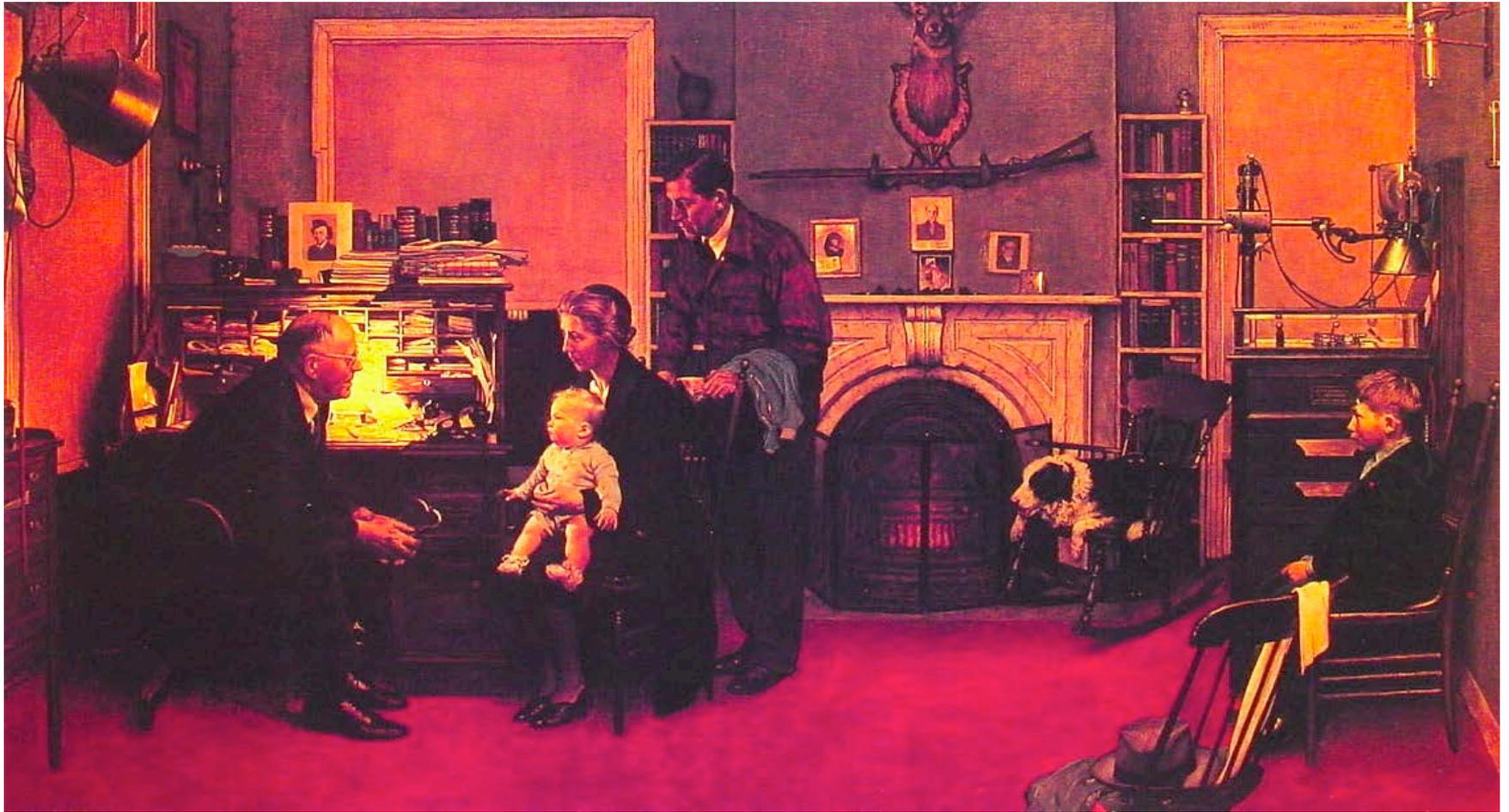


**UPWORTHY**

# Gap In Services?

- CAM-IM offers different services that people are seeking

# Trust?



Are they stepping towards CAM/IM?

Are they stepping away from their experiences of Allopathic practice?

# What Can We learn From the Data?

Consumers/patients are the ones experiencing the different systems of medicine .

CAM/IM must be fulfilling a purpose since its popularity continues to grow.

Average length of appointment is...

10.7 minutes

Average length of time patient gets to speak before being interrupted.....

18 seconds



Beckman and Frankel, Annals of Internal Medicine, Nov 1984

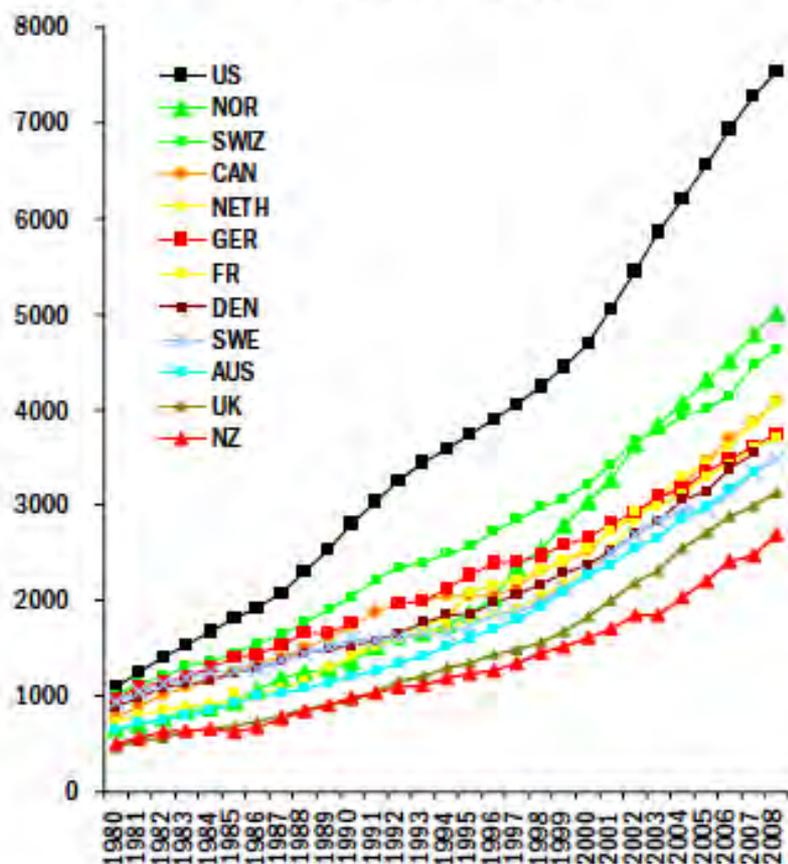
# Costs

- US healthcare system is the costliest in the world, spending nearly twice as much as the next candidate.

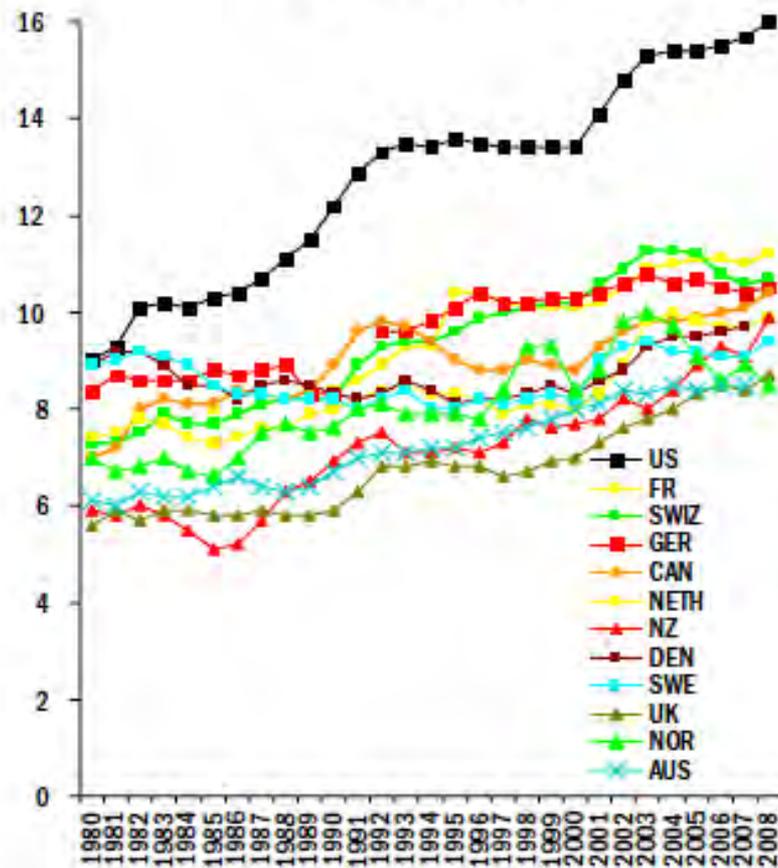


## Exhibit 2. International Comparison of Spending on Health, 1980-2008

### Average spending on health per capita (\$US PPP)



### Total expenditures on health as percent of GDP



Note: PPP = purchasing power parity—an estimate of the exchange rate required to equalize the purchasing power of different currencies, given the prices of goods and services in the countries concerned.

Source: OECD Health Data 2010 (Oct. 2010).

# Value

- We are ranked 51st in health in the world behind some emerging economies

World Factbook: <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2012rank.html>

# IOM Report: *U.S. Health in International Perspective: Shorter Lives, Poorer Health.*

- 30 years of data, 16 peer countries

Even relatively well-off Americans who do not smoke and are not overweight may experience inferior health in comparison with their counterparts in other wealthy countries.... a pervasive disadvantage that affects everyone, and it has not been improving

pp ix-x

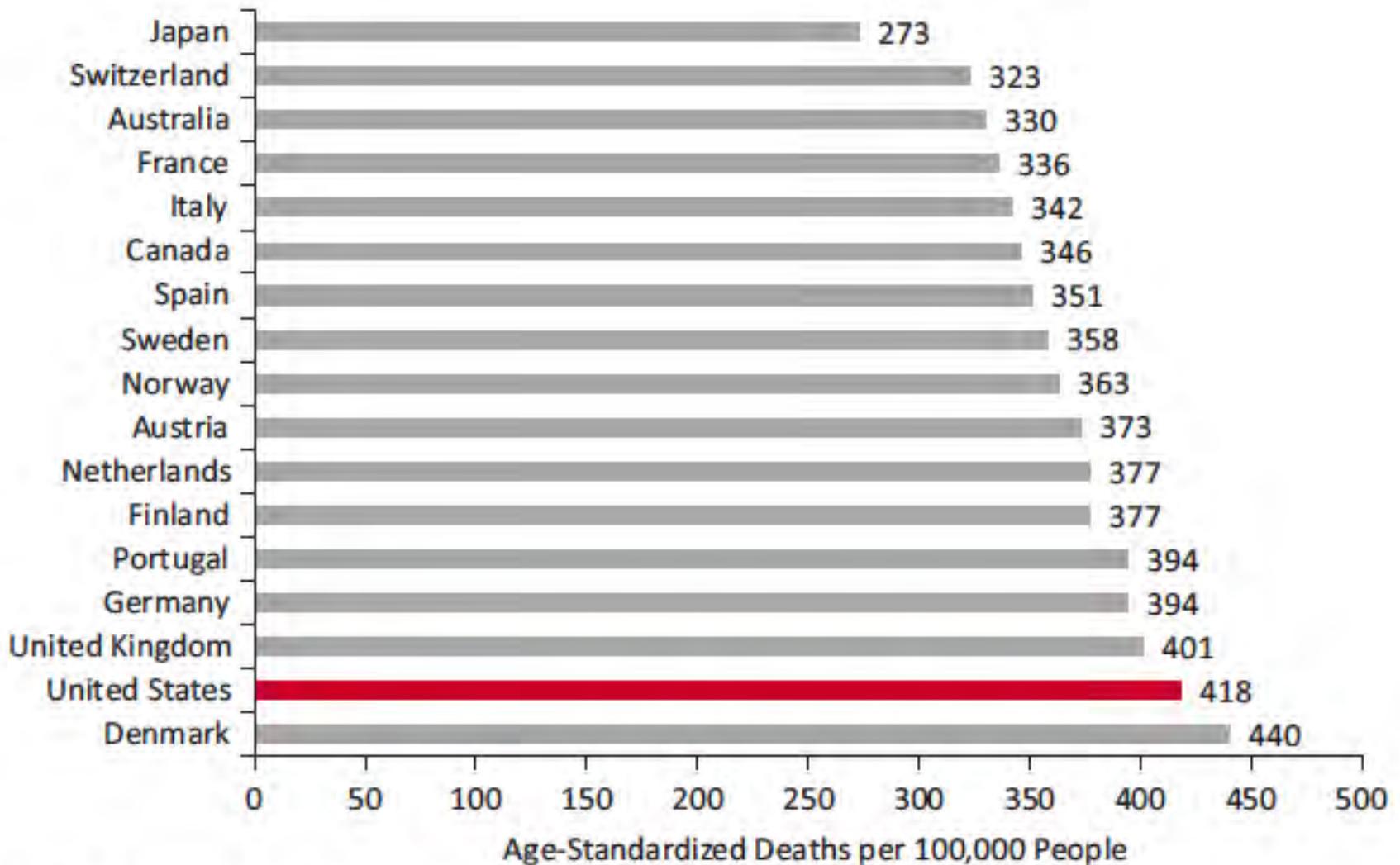


FIGURE 1-1 Mortality from noncommunicable diseases in 17 peer countries, 2008.  
SOURCE: Data from World Health Organization (2011a, Table 3).

TABLE 1-3 Life Expectancy at Birth in 17 Peer Countries, 2007

Males			Females		
Country	LE	Rank	Country	LE	Rank
Switzerland	79.33	1	Japan	85.98	1
Australia	79.27	2	France	84.43	2
Japan	79.20	3	Switzerland	84.09	3
Sweden	78.92	4	Italy	84.09	3
Italy	78.82	5	Spain	84.03	5
Canada	78.35	6	Australia	83.78	6
Norway	78.25	7	Canada	82.95	7
Netherlands	78.01	8	Sweden	82.95	7
Spain	77.62	9	Austria	82.86	9
United Kingdom	77.43	10	Finland	82.86	9
France	77.41	11	Norway	82.68	11
Austria	77.33	12	Germany	82.44	12
Germany	77.11	13	Netherlands	82.31	13
Denmark	76.13	14	Portugal	82.19	14
Portugal	75.87	15	United Kingdom	81.68	15
Finland	75.86	16	United States	80.78	16
United States	75.64	17	Denmark	80.53	17

NOTE: LE = life expectancy at birth (years), or  $e^0$ .

SOURCE: Ho and Preston (2011, Table 1).

# “The US health disadvantage”

“What accounts for the paradoxical combination in the United States of relatively great wealth and high spending on health care with relatively poor health status and lower life expectancy?”

IOM Report: *U.S. Health in International Perspective: Shorter Lives, Poorer Health*

# How Many Die From Medical Mistakes in U.S. Hospitals?



<http://www.propublica.org/article/how-many-die-from-medical...>

# Healthcare Risk

Every year in the US there are:

- 12,000 deaths from unnecessary surgeries;
- 7,000 deaths from medication errors in hospitals;
- 20,000 deaths from other errors in hospitals;
- 80,000 deaths from infections acquired in hospitals;
- 106,000 deaths from FDA-approved correctly prescribed medicines.

The total of medically-caused deaths in the US every year is 225,000 (hospitalized patients)

# Healthcare Risk

- This makes the medical system the third leading cause of death in the US, behind heart disease and cancer.

(Starfield B. JAMA ,July 26, 2000)

From: **Chronicle of an Unforetold Death**

Arch Intern Med. 2012;172(15):1174-1177. doi:10.1001/archinternmed.2012.2204

---

## **Table 1. Lessons From Barbara's Death**

---

Lack of coordination—providers are not notified of sudden and unexpected deaths

Underreporting of possible adverse drug events

Multimorbidity—best appreciated by primary care physicians

Inadequacy of randomized controlled trials

Potential bias in randomized controlled trials sponsored and supported by the pharmaceutical industry

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**Figure Legend:**

From: **Chronicle of an Unforetold Death**

Arch Intern Med. 2012;172(15):1174-1177. doi:10.1001/archinternmed.2012.2204

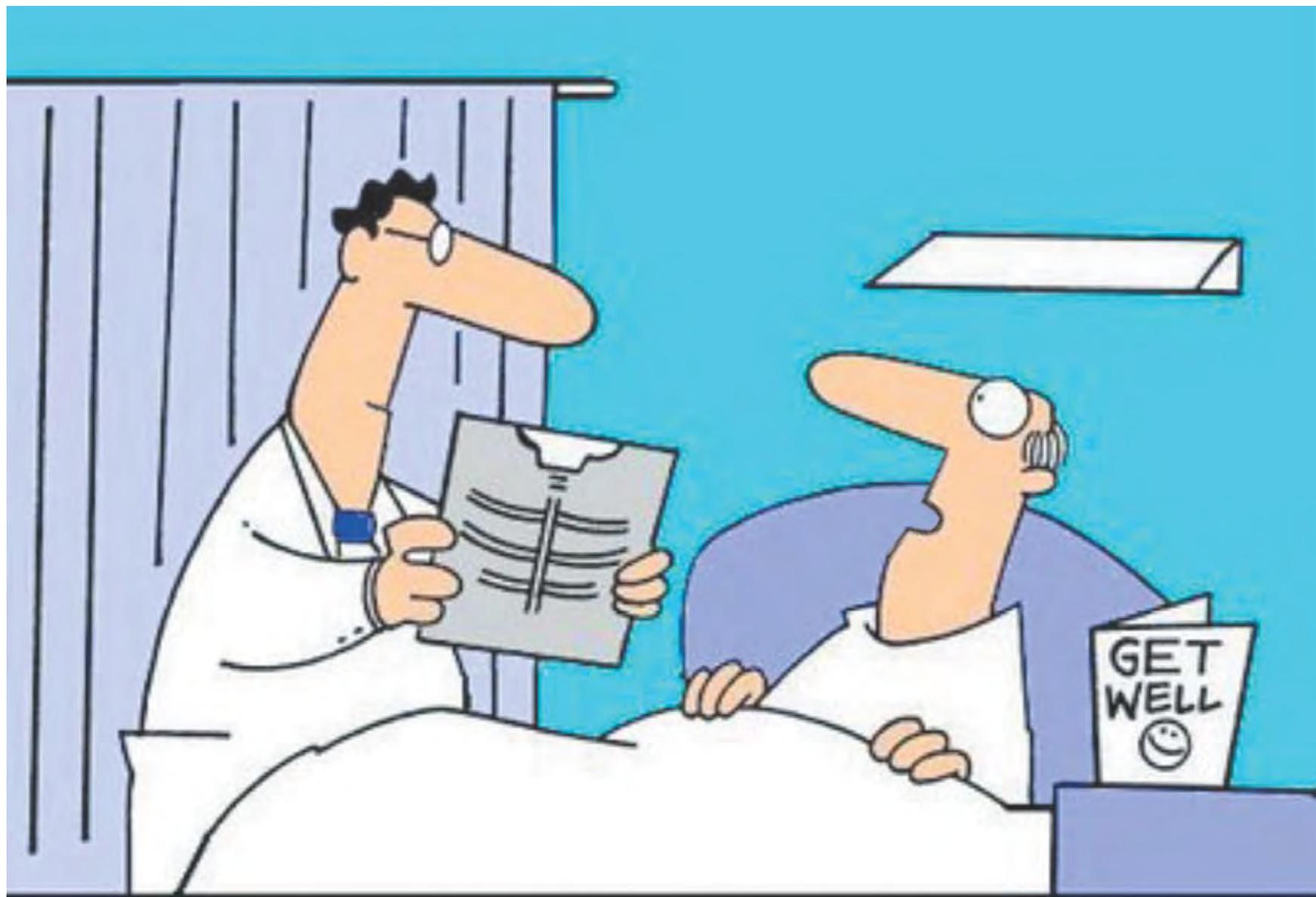
“Specialization, fragmentation, drug-orientation, and profit-seeking help make American medical care the most expensive in the world, but not the safest or most effective.”

Neil A. Holtzman, MD, MPH  
([nholtzma@jhsph.edu](mailto:nholtzma@jhsph.edu)).

# Strength of Allopathic medicine



- Acute conditions: trauma, fractures, CVA etc
- Warrant highly invasive, costly, risky interventions



**“I think I see the problem. Most of me is missing.”**

# Chronic Disease

- Chronic diseases cause 7 in every 10 deaths each year in the United States.
- About 133 million Americans—nearly 1 in 2 adults—live with at least one chronic illness.
- More than 75% of health care costs are due to chronic conditions.

<http://www.cdc.gov/chronicdisease/resources/publications/aag/chronic.htm> (accessed 9.15.13)

# Allopathic Medical Education

What we do not focus on:

- Nutrition,
- Exercise,
- Sleep,
- Stress management (our own or others),
- Work life balance
- Myofascial pain=the commonest cause of pain

# Preventable Diseases?

- 93% Diabetes
- 81% Heart attacks
- 50% Strokes
- 36% Cancers

# EPIC: European Prospective Investigation into Cancer and Nutrition

23,000 people

- Not smoking
- Exercise 3.5 hr/week
- Healthy diet: veg, fruit, beans, whole grains, nuts, seeds, low meat consumption
- BMI <30

# EPIC: European Prospective Investigation into Cancer and Nutrition

Mean follow up of 7.8 years- reduction of

- 93% Diabetes
- 81% heart attacks
- 50% strokes
- 36% all cancers

E. S. Ford et al., “Healthy Living Is the Best Revenge: Findings from the European Prospective Investigation into Cancer and Nutrition — Potsdam Study,” *Archives of Internal Medicine* 169, no. 15 (2009): 1355–62.

# Evidence in Allopathic Practice

- How does this influence patients choices of care?



# Evidence Based Therapies

- Vioxx: known to cause increased cardiac risk before it was approved (160,000 excess CV and CVA events before withdrawn)

# NSAIDS

- Small-bowel injury was seen in 71% of **asymptomatic** NSAID users compared with 10% of controls ( $P < .001$ ) **Visible small-intestinal mucosal injury in chronic NSAID users.**

Graham DY - *Clin Gastroenterol Hepatol* - 01-JAN-2005;  
3(1): 55-9

# NSAIDS

- Annually, the side effects of long-term NSAID use cause 103,000 hospitalizations and 16,500 deaths. (just with RA and OA patients)

Singh G. Am J Ther 2000;7:115-121.

# Proton Pump Inhibitors

- FDA black box warning: advising against use for over 3 months.
- Risks of prolonged use: Profound Mg, Ca, B12 defic, osteoporosis, hyper-gastrinemia, rebound hyper-acidity, protein malabsorption, dysbiosis, C diff, food poisoning, malignancies, and NO reduction of Ca esophagus

Yu-Xiao Y, Metz DC, *Gastroenterology*, Volume 139, Issue 4 , Pages 1115-1127, October 2010

# Statins

- Most systematic reviews support use for secondary prevention
- Most widely used for primary prevention
- Number needed to treat-over a hundred
- Endpoints vary widely

Thompson A, Temple N. “The case for statins: has it really been made?” *Journal of the Royal Society of Medicine*, 2004; 97: 461-464

# Hyperlipidemia

- World Medical Association in the Declaration of Helsinki. advocated placebo for drug trials should be **'best current prophylactic, diagnostic, and therapeutic methods,'**
- For statins this means lifestyle factors and not sugar pills

(Lewis JA, Jonsson B, Kreutz G, Sampaio C, van Zwieten-Boot B. Placebo-controlled trials and the Declaration of Helsinki. Lancet, 2002;359:1337–40)

# Hyperlipidemia

- European Atherosclerosis Society 1987 guidelines made dietary management ‘the sole therapy for the majority of people with elevated levels [of blood lipids]’

European Atherosclerosis Society. Strategies for the prevention of coronary heart disease: a policy statement. Eur Heart J 1987;**8**:77–88

# Hyperlipidemia

- US National Cholesterol Education Program stated: 'Drug therapy is likely to continue for many years, or for a lifetime. Hence, the decision to add drug therapy to the regimen should be made only after **vigorous efforts** at dietary treatment have not proven sufficient.'

The Expert Panel. Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Arch Intern Med 1988;148: 36–69

# Statins

- HMG-CoA Reductase inhibits CoQ10 which is essential for mitochondrial function
- Myopathies (common), rhabdomyolysis (rare)
- CoQ10 highest in heart, liver, kidney
- CoQ10 deficiencies related to CNS dysfunction documented for cerebellum

# Statins

- “Our data show that the treatment with HMG-CoA reductase inhibitors lowers both total cholesterol and CoQ10 plasma levels in normal volunteers and in hypercholesterolemic patients. CoQ10 is essential for the production of energy and also has antioxidative properties. A diminution of CoQ10 availability may be the cause of membrane alteration with consequent cellular damage.”

Ghirlanda G. et al, J Clin Pharm, Mar 1993

# Statins

- Pharmacology and biochemistry literature discusses the use of CoQ10 supplementation and the risks of depletion of CoQ10 levels with statins-increased oxidative cell damage and mitochondrial dysfunction
- Cardiology literature notes there is depletion of CoQ10, admits that there is **no risk** to taking CoQ10 but **advises against** it pending more research

# What do Patients want to hear? From whom?

What do patients think when they find out

- NNT for their drug is 100
- Potentially serious side effects that may not have been disclosed.
- Supplement that could reduce their risk of side effects and they learned about in a magazine and not in their doctors office.

# IM Research

# Omega 3: DHA and EPA

- Omega 3's anti-inflammatory prostaglandin pathways
- >3 gm DHA + EPA/day reduced pain



Maroon et al, *Surg Neurol.*2006;65:326-331

# Omega 3: side effects

Effective for: Lowering TG

Likely: Reduced risk of dying of heart disease

Possibly: Reduced risk for HT, RA, Dysmenorrhea, ADHD, Raynauds, Stroke, Osteoporosis  
IgA nephropathy etc



<http://www.nlm.nih.gov/medlineplus/druginfo/natural/993.html>

# Vitamin D

- Low vit D levels correlated to higher opioid use (2x) and longer duration of use (2x)
- “vitamin D inadequacy may represent an under-recognized source of nociception and impaired neuromuscular functioning among patients with chronic pain”

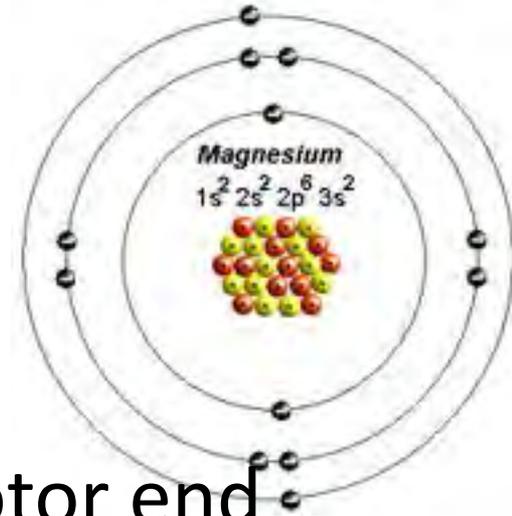
Turner et al, Mayo Clinic [Pain Med.](#) 2008 Nov;9(8):979-84

# Vitamin D Side Effects



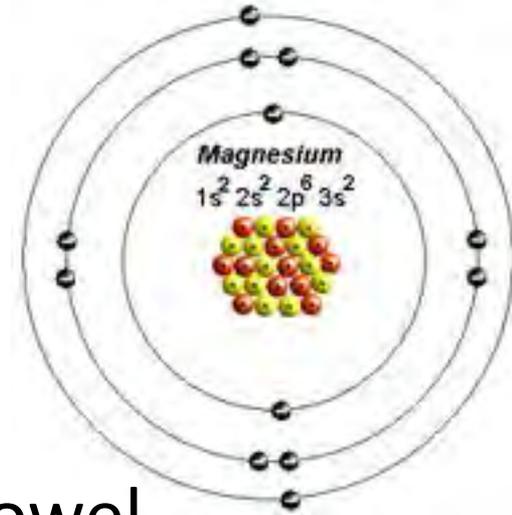
- Decreased inflammation
- Increased bone density
- Less susceptibility to infections such as flu
- Less diabetes
- Less auto-immune disorders
- Possible role in cardiac and brain health
- Overdose extremely rare (over 150ng/ml)

# Magnesium



- Mg inhibits release of Ach from motor end plates -muscle relaxation
- Conversely, magnesium depletion facilitates neuromuscular excitability, producing tremor, cramps, and tetany. Cohen S et al, Anesthesiology 2004; 101:495–526
- Recent rat studies on mechanisms NMDA receptors and nerve pain

# Magnesium



## Side effects:

- Improves constipation and irritable bowel
- Sleep disorders
- Pain conditions—FM, MFPS, cramps
- Bone health
- Collagen formation
- Adverse effect- diarrhea with overdose

# Vitamin B12

- Vitamin B12 in low back pain: a randomised, double-blind, placebo-controlled crossover study daily injections of 1000mcg
- Reduction of pain in both active arms of the crossover

Mauro GL, *Eur Rev Med Pharmacol Sci* - 01-MAY-2000; 4(3):  
53-8

# Vitamin B12-side effects

- Powerful methylator (mitochondria and detox)
- Improved sleep
- Associated with preservation of brain volume
- Co factor for methionine synthase: lowers homocysteine
- Possibly helpful: Diabetic neuropathy
  - Fatigue
  - Fractures(Mayo Clinic)

# Turmeric (*Curcuma longa*)



# Turmeric (*Curcuma longa*)

- 107 knee OA patients: 800 mg/d ibuprofen=2g/d curcumin for pain

Kuptniratsaikul V et al, J Altern Complement Med 2009;  
15(8):891-7

- Laparoscopic cholecystectomy: Less pain and fatigue and analgesic use in curcumin group vs placebo (500mg q6h) DBPC RCT

Agarwal KA, et al, Surg Endosc 2011; June 14

# Turmeric –Side Effects

- Neuroprotective- animal models
- Studied in Alzheimers prevention and improved function in Alzheimers patients

# Glucosamine

Studies 1500 mg/d

- Might reduce progression by 54% meta-analysis: Poolsup N, Ann Pharmacother 2005 June;39(6): 1080-7
- Cochrane: Clinical trials show that taking glucosamine sulfate orally significantly improves symptoms of pain and functionality compared to placebo in patients with osteoarthritis of the knee in studies lasting up to 3 years.” Towheed, Cochrane Database Syst Rev, 2005

# Myofascial Pain

- Myofascial pain is the commonest cause of pain (ref)
- CAM/IM practitioners have many ways to treat MF pain and most allopathic schools do not teach about it or have a systematic way to treat.
- Gap in supply and demand

**Denervation  
supersensitivity  
is now physiologic  
Disuse Supersensitivity**

THE  
SUPERSENSITIVITY  
OF DENERVATED  
STRUCTURES

*A Law of Denervation*

BY

WALTER B. CANNON

*Late George Higginson Professor of Physiology, Emeritus  
Harvard University*

AND

ARTURO ROSENBLUETH

*Head of the Department of Physiology and Pharmacology  
Instituto Nacional de Cardiología de México*

NEW YORK

THE MACMILLAN COMPANY

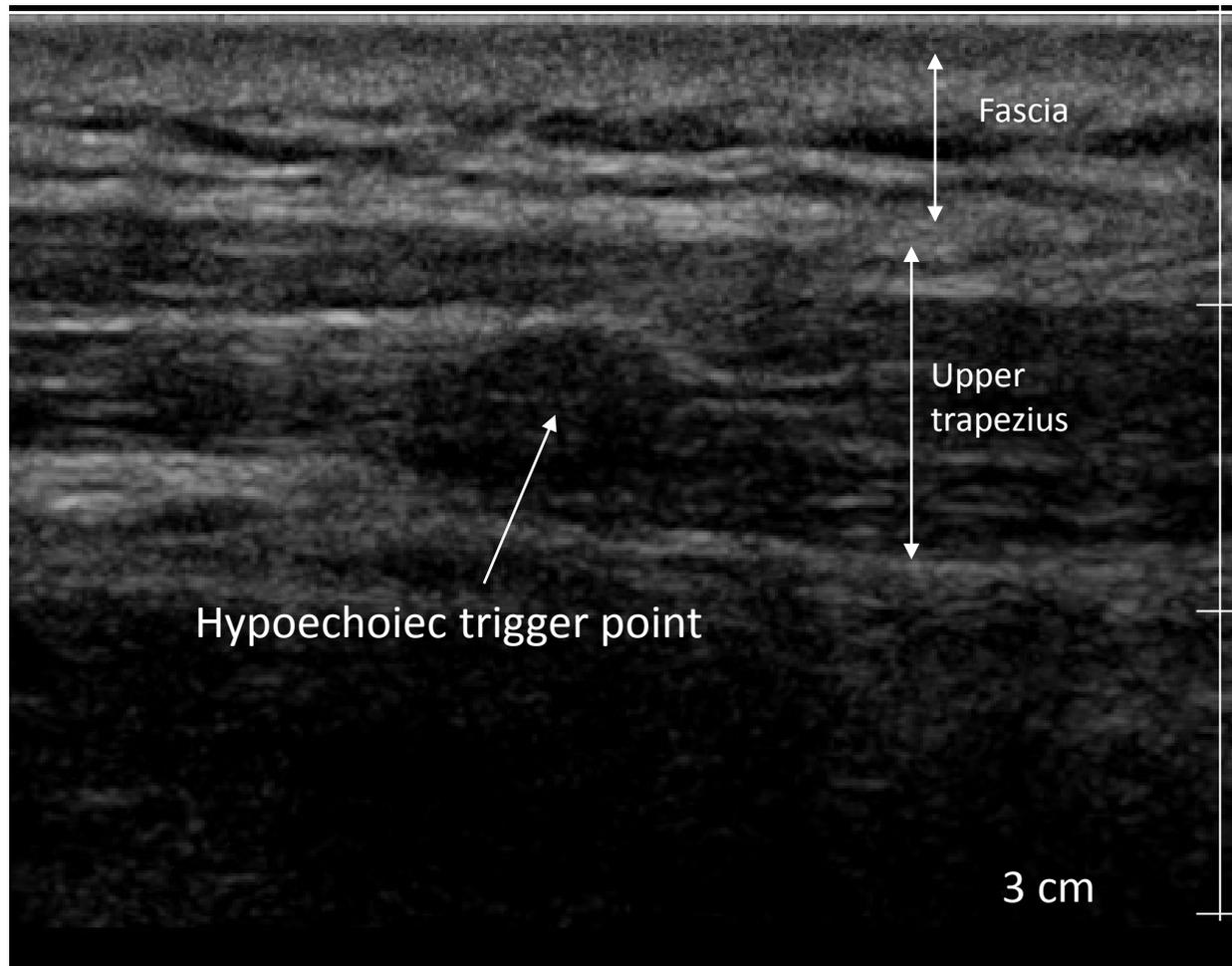
1949

# Myofascial Pain

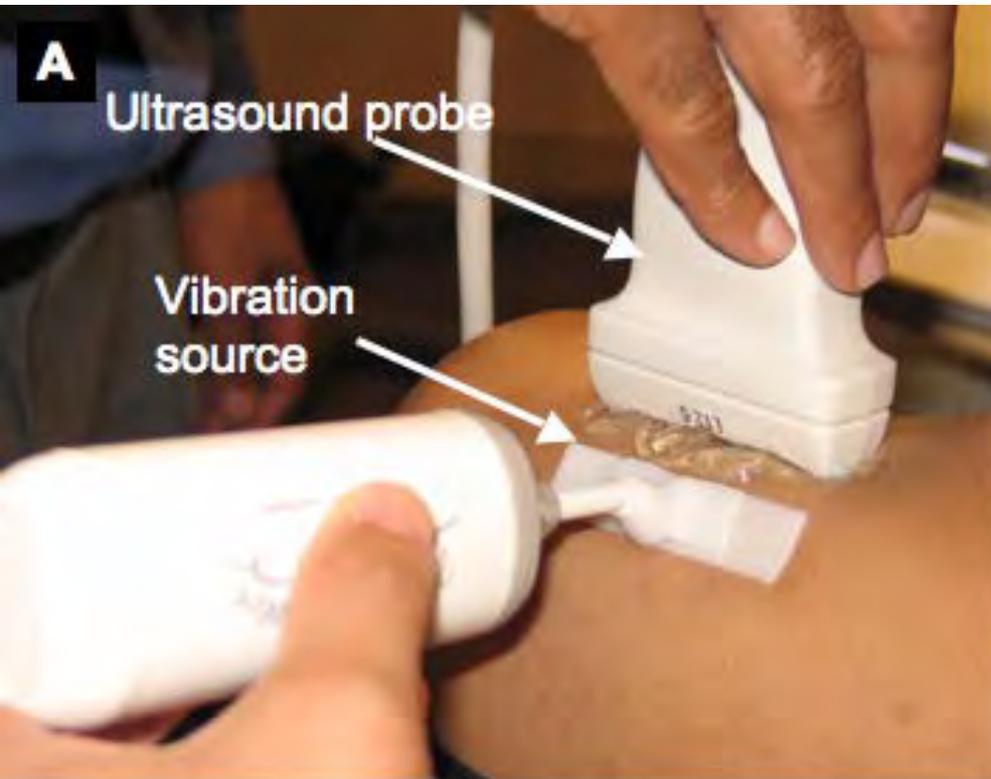
- Back pain patients who were disabled for long periods had tenderness over muscle motor points in affected myotomes.
- Tender motor points=indicators of radicular involvement/irritation at the nerve root and differentiate rapidly healing low back strain from one that is slow to improve

Gunn CC, Milbrandt WE. Tenderness at motor points-a diagnostic and prognostic aid for low back injury. *J Bone joint Surg* 1976; 58A:815-825.

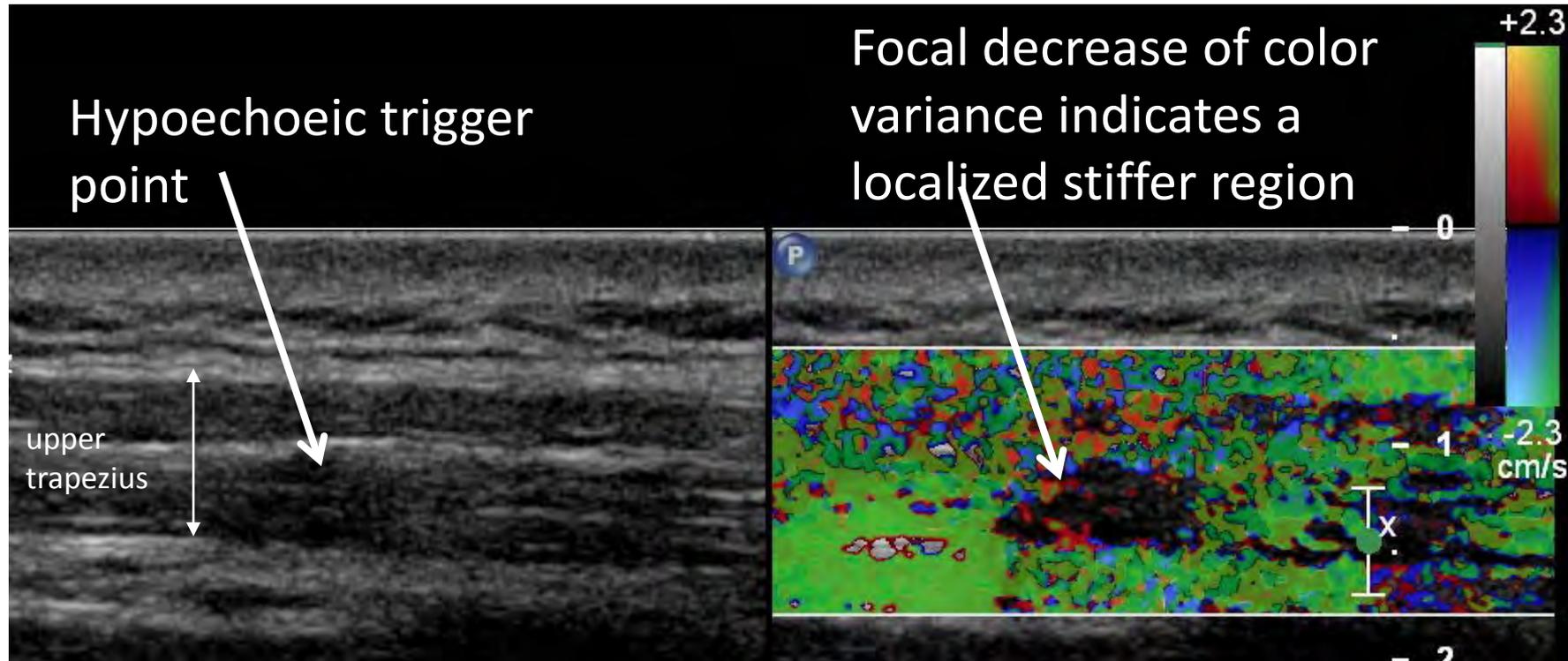
# Upper Trapezius Muscle with Myofascial Trigger Point (MTrP)



# Vibration Applicator

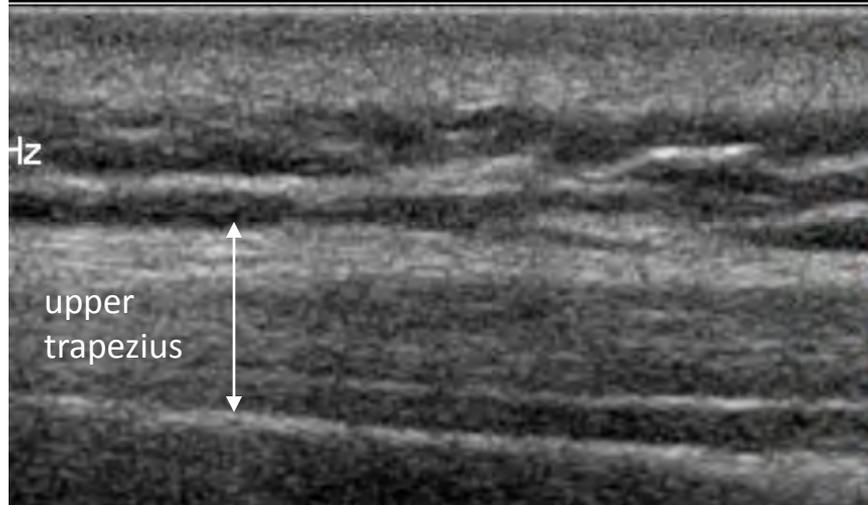


# Vibration Sonoelastography of Muscle with MTrP

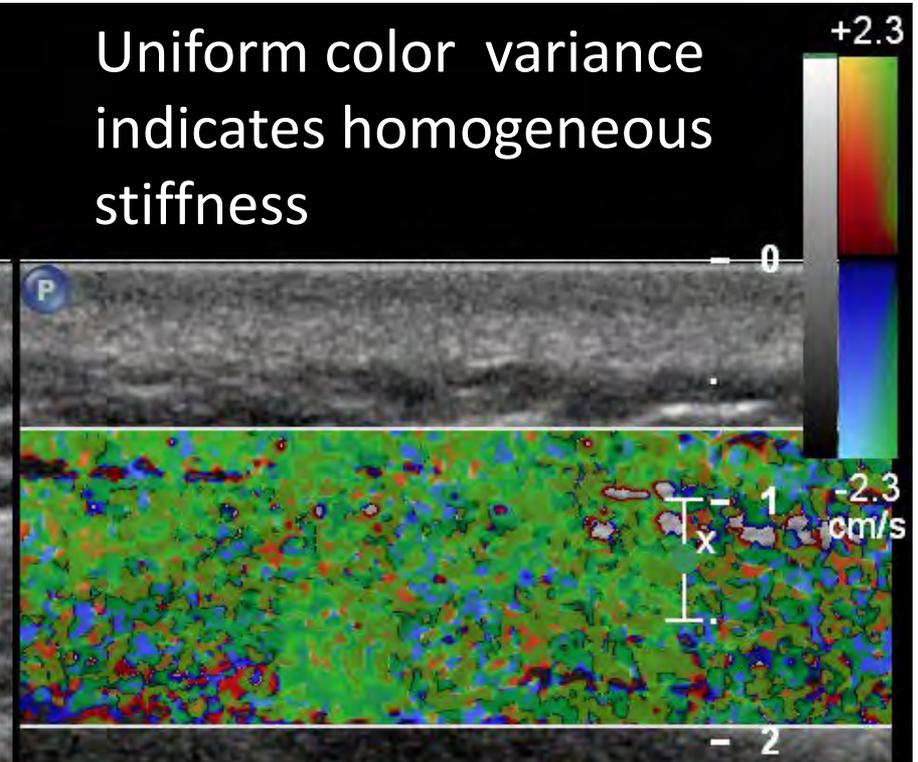


# Vibration Sonoelastography of Uninvolved Muscle

Uniform echogenicity in uninvolved muscle



Uniform color variance indicates homogeneous stiffness



# Muscles: source of pain and the focus of treatment

- Even when there is underlying arthritis or herniated discs, there is often muscle tightening in addition.
- The muscle tightness and its consequences are treatable and, in most cases, when the tight muscles are released there is some relief of the pain.

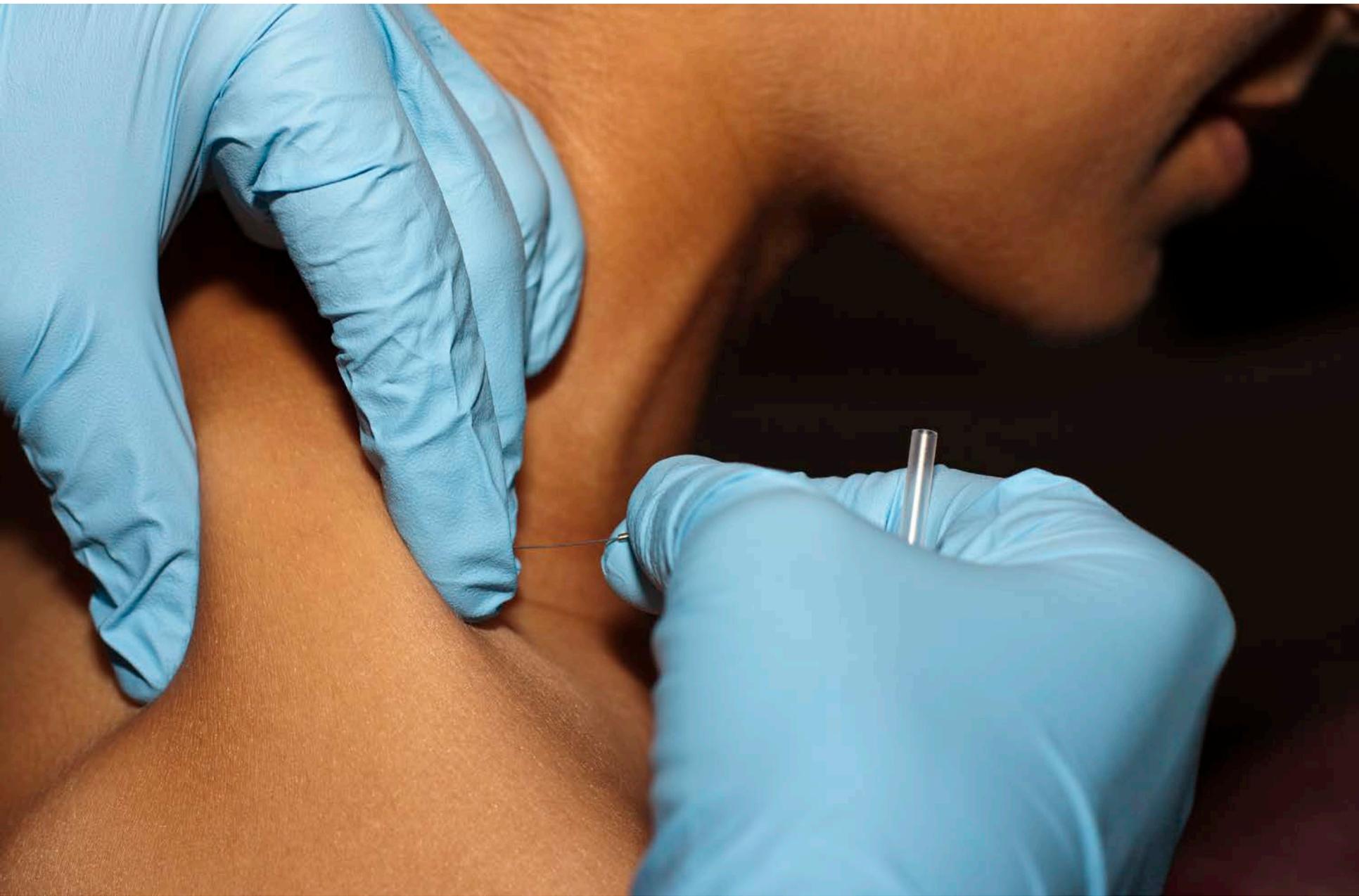
# Intramuscular Stimulation Technique: GunnIMS

placement of acupuncture needles into myofascial trigger points

solid core needle/not a bevel edge hypodermic.

transmits the nature of the tissue penetrated to the operator. Procedure is diagnostic AND therapeutic.

Increased resistance to needle insertion and often local twitch response





**Fats, Oils & Sweets**  
**USE SPARINGLY**

**KEY**

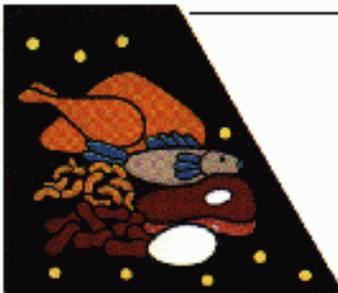
- Fat (naturally occurring and added)
- ▼ Sugars (added)

These symbols show fats and added sugars in foods.

**Milk, Yogurt & Cheese Group**  
**2-3 SERVINGS**



**Meat, Poultry, Fish, Dry Beans, Eggs & Nuts Group**  
**2-3 SERVINGS**



**Vegetable Group**  
**3-5 SERVINGS**

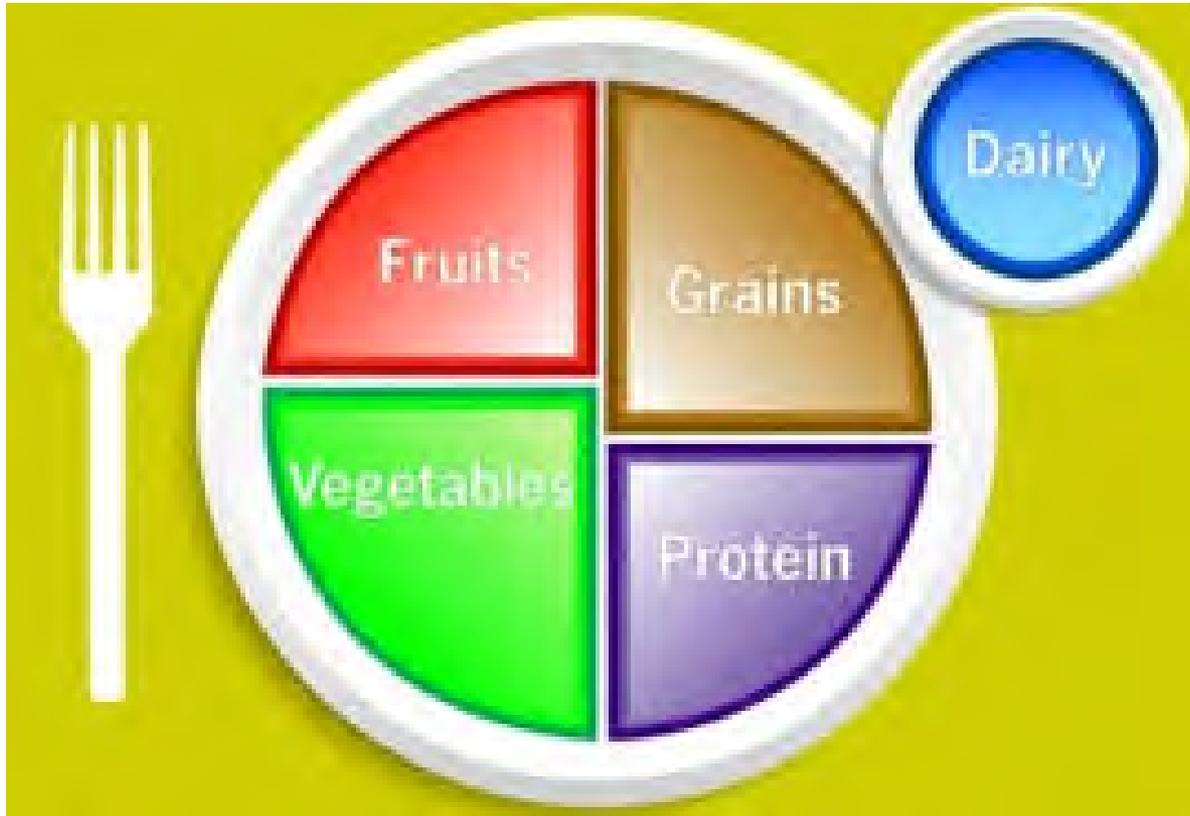


**Fruit Group**  
**2-4 SERVINGS**



**Bread, Cereal, Rice & Pasta Group**  
**6-11 SERVINGS**





At least half the grains whole.....



SLOW FOOD

# VOTE for Small Farms & Local Food

Join  
Slow Food  
U.S.A.



Eating is an agricultural act



Wendell Berry





# Anti-inflammatory Diet

- High in fresh foods, fruits, vegetables, whole grains minimally processed
- Proteins: legumes, pulses, fish, organic meats, eggs
- Healthy oils
- You change your body chemistry every time you eat.

# INFLAMMATION

“Chronic inflammation lies at the root of virtually every disease process known to modern man – from weight gain, obesity & heart disease to autoimmune disorders like lupus, MS and rheumatoid arthritis.”

Dr. Chris Lydon, Yale University

# HIGH GLYCEMIC FOODS?

- **85 to 90% of the carbohydrates** adults and children are consuming in the US and Canada are considered to be high-glycemic.
- Bread, rice, boxed cereals, and potatoes actually spike your blood sugar faster than if you were eating table sugar.

# Data on Risks in IM

## Diet changes

- Decreased inflammation, BP, Chol, insulin resistance etc

# Data on Risks in IM

- Acupuncture: 86 deaths in Europe over 45 years
- British Acupuncture Council 1/10,000 adverse reactions

# Data on Risks in IM

## Vitamin and Mineral Supplements

- Bronstein AC, et al. 2011. "2010 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 28th Annual Report". Clinical Toxicology (Philadelphia, Pa.). 49 (10): 910-41.  
[www.poison.org/stats/2010%20NPDS%20Annual%20Report.pdf](http://www.poison.org/stats/2010%20NPDS%20Annual%20Report.pdf). (Accessed April 6, 2013).
- Based on this report there were: **No deaths due to multiple vitamins, A, B, C, D, E or any other vitamin. No deaths on amino acid or other dietary supplements. (pg. 137-139)**

# How to vet the data

- For many CAM topics there is inconclusive data.
- But some of the data for allopathic medicine is not clear either.
- What is the risk of each?
- What is the risk of continuing the status quo?

# Cost of inaction

- Widening gap between health of US and its peers
- Escalating costs of drugs and procedures
- Increasing costs of chronically ill population

# Is There a Double Standard for Evidence?

Bias within the system favors:

- Higher risk
- Higher cost

# What is the Alternative?

- How to balance the standards for acceptable evidence with the potential for risk?
- What is the tolerable risk of a therapy?
- Should the standard for evidence be different if the risk is low?

What do we need to do to reverse the  
US health disadvantage?

# IOM

- Steven Woolf, chair of the IOM Committee stated that we don't need to wait for more research to take action. This has been a steady deterioration for over 30 years. Holding onto this idea that we are the best, is not getting us what we want. We already know what to do; we need to do it.

# Army Surgeon General Task Force

- Mandated Culture Change
- Fully integrative system of care
- Flipped therapeutic order with acupuncture, yoga and chiropractic before drugs and procedures.

# Guiding principles

## The Triple Aim

- Better Health
  - Improving the health of populations
- Better Care
  - Improving the patient experience of care (including quality and satisfaction)
- Lower Cost
  - Reducing the per capita cost of health care

More information at the Institute for Healthcare Improvement:

<http://www.ihl.org/offerings/Initiatives/TripleAim/Pages/default.aspx>

# Sexual Misconduct in the Physician-Patient Relationship

Glen O. Gabbard, M.D.

Gabrielle S. Hobday, M.D.

The Gabbard Center

Bellaire, Texas

# Books

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- Medical Marriages (1988)
- Physician as Patient: A Clinical Handbook for the Mental Health Professional (2008)
- Professionalism in Psychiatry (2012)

# 3 CATEGORIES OF SEXUAL MISCONDUCT BY PHYSICIANS

---

- Sexual impropriety
- Sexual transgression
- Sexual violation proper

# SEXUAL IMPROPRIETY

---

- Refers to gestures or expressions disrespectful to the patient's privacy and sexually demeaning to the patient
  - Many cases of sexual harassment involving unwanted advances, sexually explicit remarks, and denigrating comments would fall under this category.
-

# SEXUAL TRANSGRESSION

---

- Involves sexualized and inappropriate touching of the patient that falls short of actual sexual relations
  - Kissing, touching of the breasts or genitals not appropriate for the exam, or performing a physical exam without gloves
-

# SEXUAL VIOLATION PROPER

---

- Refers to physician-patient sexual relations
  - It makes no difference who initiates the contact and whether or not love has been professed
  - Oral sex, anal intercourse, genital intercourse, and mutual masturbation
-

# THE WIDE RANGE OF SITUATIONS COVERED BY THE TERM “SEXUAL MISCONDUCT”

- Predatory physicians with serious personality disorders who systematically attempt to seduce patients
  - Those who claim to use sex for therapeutic purposes
  - Cases involving abuse of the physical examination procedure
-

# Inappropriate behavior during exam

- ❖ Altering or removing a patient's clothing without patient consent
- ❖ Not allowing the patient the privacy to undress or dress and not providing gowns or drapes
- ❖ Examining sensitive areas when not indicated by reason for visit

# THE WIDE RANGE OF SITUATIONS COVERED BY THE TERM “SEXUAL MISCONDUCT” *(cont.)*

- Situations in which a physician asks the patient on a date during the visit to his or her office or to an emergency department
  - Cases in which a longstanding physician-patient relationship evolves into an intense lovesickness or infatuation
-

# THE WIDE RANGE OF SITUATIONS COVERED BY THE TERM “SEXUAL MISCONDUCT” *(cont.)*

- Situation in which a rural general practitioner who is the only physician in town dates a patient because virtually anyone who is a potential romantic partner is also a patient
-

# THE WIDE RANGE OF SITUATIONS COVERED BY THE TERM “SEXUAL MISCONDUCT” *(cont.)*

- Cases in which patients are raped or fondled (while awake or under anesthesia in the operating room or office)
  - Cases related to sexual harassment in which the physician makes erotic or suggestive comments to the patient
-

# WHY IS SEX BETWEEN PHYSICIANS AND PATIENTS UNETHICAL?

- Presence of power differential
  - Transference to doctor makes it difficult to say no
  - Breach of fiduciary duty to treat patient
  - May harm patient's ability to trust physician
  - A physician cannot provide objective care when a sexualized relationship exists
-

# Power Differential

- Sexual misconduct in the doctor-patient relationship is always unethical and always the physician's responsibility
- Power differential is always one-way even when patient is seductive, bullying, or threatening



Why Can't Women Say No?

# White Coat Silence



- Like White Coat Hypertension
- Defined as a reluctance of patients to question their doctors.

# Why would this be?

- Paternalistic dynamic between physician and patient
- Strange and unfamiliar surroundings and faces
- Feelings of anxiety, intimidation, pain, and vulnerability.

# White Coat Silence (Cont')

- Patients may remain silent out of fear of being labeled a “difficult” patient.
- Patients perceive that physicians can easily alter the level of services they provide.
- Fear of asking for more time, being a burden to a busy physician.

# Transference

- The displacement of attributes belonging to past figures to the physician
- Authority figures like physicians typically draw parental transferences

# Transference (cont')

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- Transference is gender and role related
- The patient's knowledge and intelligence are immaterial

# Regression to a Dependent State

- Role suction into a dependent state
- Sucked into a “know nothing” role
- Because of transference, patients don't want to upset the power gradient or their doctor

# Fear

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- Regression engenders fear
- Fear of having serious illness
- Fear of not getting good care
- Fear of retribution

# “Is this really happening ?”



- Freezing during trauma - deer in the headlights
- What did I do wrong?
- How do I understand this situation?

# Clinical Examples

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- Pelvic Exam scenario
- Physician presents with a sore throat

It's my fault. I brought this on  
myself"



- ◆ Tendency to self-blame
- ◆ "I must have been asking for it."
- ◆ A woman who exudes sexuality

# The Sitting-Duck Syndrome

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- Repetition Compulsion
- 20% of women have been sexually abused as children
- You do not know which of your patients are in this category

# Movie Clip



“The Waitress”

# Attracted to the Doctor

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- Becoming powerful by being able to seduce or “be loved” by a powerful figure
- Romanticized notion of being the “chosen one”

# Who Commits Sexual Misconduct?

- There is no single profile
- Occurs in different types of physicians for different reasons
- Some have strong records of ethical behavior

# Who Commits Sexual Misconduct?

---

- Approximately 80% male
- Approximately 20% female
- Same sex misconduct is common

# Who Commits Sexual Misconduct?



- Predators with narcissistic and antisocial features
- Lisak “undetected rapists”

# Who Commits Sexual Misconduct?

- Bully-Victim Paradigm
- Lovesick Doctor
- Drug/alcohol-related
- Dementia or Psychosis

# Who Commits Sexual Misconduct?

---

- ◆ Mental Gymnastics
- ◆ Self-Deception
- ◆ Moral Hypocrisy

# Assessment



- ◆ A subgroup are similar to “sex offenders” but many are not
- ◆ Assessment is crucial
- ◆ Importance of collateral information

# Static 99

- Based on studies of rapists and child molesters
- Ten factors related to recidivism
- Accuracy of prediction of sexual violence using Static 99 is controversial

# Assessment (cont')

- Each case needs to be assessed individually to determine punishment, treatment/rehab, and return to practice
- What motivated their behavior / category of boundary violation is paramount to determining the above

# Post-Termination Sex

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- Psychiatry—never acceptable
- Other specialties—It depends

# AMA Council on Ethical and Judicial Affairs

- “Sexual contact or a romantic relationship with a former patient may be unethical under certain circumstances” -1991
- Case review required to determine if there is exploitation of continued emotional dependency

# Sexual Misconduct in the Physician-Patient Relationship

Glen O. Gabbard, M.D.

Gabrielle S. Hobday, M.D.

The Gabbard Center

Bellaire, Texas



**THE  
SLIPPERY  
SLOPE  
PHENOMENON**



# Place and Space

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- Hospital
- Clinic
- Private Office

# TIME

---

- ◆ Length of appointments
  - ◆ Time of appointments
-

# ACCEPTANCE OF LARGE GIFTS

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- ◆ Expectation of special treatment
  - ◆ Unconscious bribe
-

# SELF-DISCLOSURE

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- Role reversal
  - Burdening the patient with personal problems or family matters
-

# STUDY ON PHYSICIAN SELF-DISCLOSURE

- Self-disclosure in primary care was studied in 113 patient visits.
- Primary care physicians disclosed information about themselves or their family in 34% of new visits with unannounced, undetected, standardized patients.
- There was no evidence of positive effect of these self-disclosures—some appeared disruptive to the doctor-patient relationship.

- *McDaniel et al, Archives of Internal Medicine 2007*

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**Language**

# Confidentiality

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- What you hear in the consulting room stays in the consulting room
- Need for compartmentalization
- Legal exceptions

# Business Transactions

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- The fundamental problem with dual relationships
- Exchange of fee should be the limit

# Physical Contact

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- Handshake is usually limit
- Cultural differences
- The problem of the hug



Intent vs. Impact

# MENTALIZATION

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- The capacity to recognize one's own perception may be different than another's perception of the same event
  - The imaginative ability to read faces and know what is going on in the mind of another
-

# Texting and Email

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- ◆ Time of day
- ◆ State of mind
- ◆ Content and context
- ◆ Written vs spoken word

# Social Media



“Physicians are discouraged from interacting with current or past patients on *personal* social networking sites such as Facebook.”

“Use separate personal and professional social networking sites.”

“Physicians should only have online interaction with patients when discussing the patient’s medical treatment with the physician-patient relationship.”

-Federation of State Medical Boards

## Responsible Opioid Prescribing & Prescription Drug Abuse

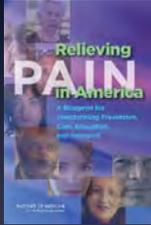


Scott M. Fishman, MD  
 Charles and Patricia Fullerton Endowed Chair in Pain Medicine  
 Professor and Chief, Division of Pain Medicine  
 Exec. Vice Chair, Dept. of Anesthesiology and Pain Medicine  
**Univ. of California, Davis School of Medicine**

## Disclosures

- I have NO Direct Financial Relationships with drug companies
- I receive NO compensation from industry speakers or consultation programs
- I receive payment from publishers of books I have authored / edited
- I participate in official CME programs
- I authored *Responsible Opioid Prescribing* by The Federation of State Medical Boards
- I am...
  - Past President of The American Academy of Pain Medicine
  - Past Chair of Board for The American Pain Foundation
  - Current Chair of the Pain Care Coalition [ASA, APS, AAPM]
- I am not a lawyer and do not offer legal advice

## The Problem of Inadequately Pain



- WHO: Undertreated pain is America's #1 health problem
- # of patients with chronic pain in the U.S. exceeds diabetes, heart disease and cancer combined
- 2011 IOM Report: *Relieving Pain in America*
- *Difficult to justify "UNDERTREATMENT"*
  - Excessive prescribing of opioids in US

National Center for Health Statistics, Health, United States, 2006 with Chartbook on Trends in the Health of Americans. Hyattsville, MD: US Department of Health and Human Services; 2006:68-71

## The Epidemic of Prescription Drug Abuse




- Excessive reliance on opioids for treating chronic pain despite weak evidence for efficacy and clear evidence of risks
- Escalating rates of unintended overdose deaths associated with opioids

## Generalized View of Opioid Therapy for Chronic Pain



- Opioid are not for everyone
  - Opioids seem to work for some
  - Opioids seem to be ineffective for some
  - Opioids seem to be problematic for some
- It may be difficult to know who is in which group

## Generalized View of Opioid Therapy for Chronic Pain



- Data on Long Term Benefits
  - Weak to Inadequate
  - Short Duration
  - Low Dose
- Data on Risks
  - Clear and Convincing
  - Growing
  - Proportional with Dose
  - Special Populations at Additional Risk

### FDA: September 10, 2013

New safety labeling changes and postmarket study requirements for ER & LA opioid analgesics  
 New boxed warning to include neonatal opioid withdrawal syndrome




### FDA: Re-Labeling ER Opioids and Chronic Pain






### FDA: (1 of 3) Re-Labeling ER Opioids and Chronic Pain

#### How Labeling Will Change

1. "Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."
2. Not intended for use as an "as-needed" pain reliever
3. Other, less potentially addictive, treatment options should be considered first
  - "Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve [Tradename] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to

### FDA: (2 of 3) Re-Labeling ER Opioids and Chronic Pain

#### How Labeling Will Change

4. Patients in pain should be assessed not only by rating on a pain intensity scale, but also based on a more thoughtful determination that their pain—however it may be defined—is severe enough to require daily, around-the-clock, long-term opioid treatment, and for which alternative treatment options are inadequate
5. FDA-approved labeling already describes the effects on newborns of exposure to these drugs while in mother's womb and warns against use by women during pregnancy and labor and nursing.
  - The new labeling will provide more detail and elevate the risk of neonatal opioid withdrawal syndrome (NOWS) to the most prominent position in labeling—a boxed warning.
  - Symptoms of NOWS may include poor feeding, rapid breathing, trembling, and excessive or high-pitched crying

### FDA: (3 of 3) Re-Labeling ER Opioids and Chronic Pain

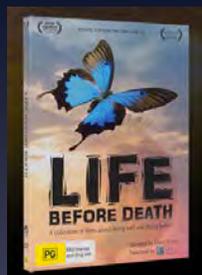
#### How Labeling Will Change

6. Postmarket Studies:
  - Require drug companies to conduct longer term studies and trials of ER/LA opioid pain relievers on the market
  - Evaluate long-term use, assessing known serious risks, including misuse, abuse, addiction, overdose, death, and increasing sensitivity to pain
7. Education to Reduce Risk
  - Modify educational materials for patients and health care professionals to reflect new labeling for ER/LA opioids
  - Opioid manufacturers also must revise a paper handout patients receive with their prescription.
  - The ER/LA Opioid REMS will also be updated

*"Prescriptions for opiates (hydrocodone and oxycodone products) have escalated from around 40 million in 1991 to nearly 180 million in 2007, with the U.S. their biggest consumer. The U.S. is supplied 99 percent of the world total for hydrocodone (e.g., Vicodin) and 71 percent of oxycodone (e.g., OxyContin)."*

Statement of Nora D. Volkow, M.D., Director, NIDA/NIH:  
 To US Senate Committee on Judiciary March 12, 2008  
[http://judiciary.senate.gov/hearings/testimony.cfm?renderforprint=1&id=3199&wit\\_id=7038](http://judiciary.senate.gov/hearings/testimony.cfm?renderforprint=1&id=3199&wit_id=7038)

## The Problem of Undertreated Pain



## Growing Media Attention



## The Oxycontin Express "South Florida: the Columbia of prescription drugs"



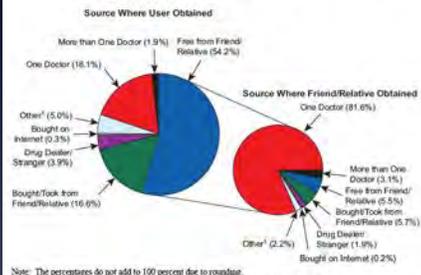
Current TV (AI Gore): Vanguard Program: Peabody Award-winning television documentary series (Laura Ling and Euna Lee)

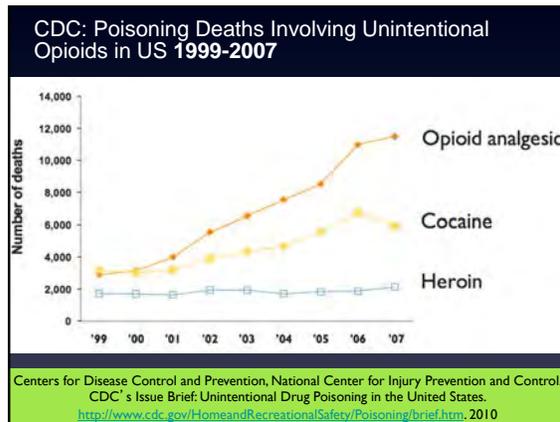
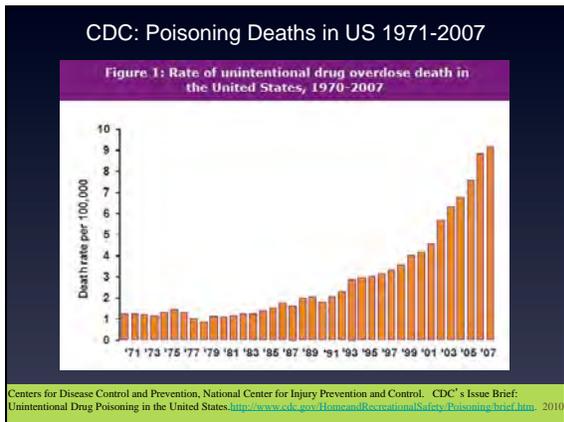
## DEA Facts on Prescription Drug Abuse

- Nearly 7 million Americans are abusing prescription drugs
  - More than the number who are abusing cocaine, heroin, hallucinogens, Ecstasy, and inhalants, combined
  - 80 percent increase in just 6 years
- Prescription pain relievers are new drug users' drug of choice, vs. marijuana or cocaine

## 2011 National Survey on Drug Use and Health: DHHS & SAMHSA

Figure 2.14 Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2010-2011





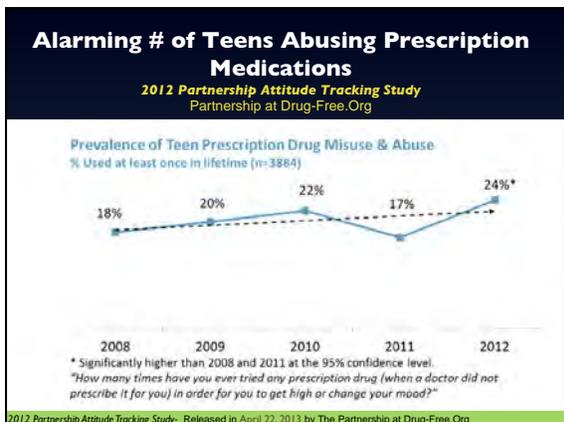
### Prescription drug abuse by teens up sharply: study

WASHINGTON — More parents need to talk with their teens about the dangers of abusing Ritalin, Adderall and other prescription drugs, suggests a new study that finds discouraging trends on kids and drug use.

When teens were asked about the last substance abuse conversation they had with their parents, just 14 percent said they talked about abusing a prescription drug, said the report released Tuesday by The Partnership at Drugfree.org.

"For parents, it really comes down to not using the power they have because they don't think this is an immediate problem, meaning their own home, own neighborhood kind of thing," says Steve Passerl, president of the partnership. "They believe that this is probably a safer way, not as bad as illegal street drugs."

April 23, 2013



### Alarming # of Teens have False Sense of Security About Safety of Abusing Prescription Medications

2005 Partnership and Attitude Study from: Partnership for a Drug-Free America

- 19% of teens report abusing prescription medications to get high
- 40% believe that prescription medicines are "much safer" to use than illegal drugs
- 31% believe there's "nothing wrong" with using prescription medicines without a prescription "once in a while"
- 29% believe prescription pain relievers are not addictive

18th annual study of teen drug use and attitudes - Released in April 2006 by The Partnership for a Drug-Free America

### Alarming # of Teens Abusing Prescription Medications

2012 Partnership Attitude Tracking Study  
Partnership at Drug-Free.Org

Teens who have learned "a lot" or "a little" from their parents/grandparents are less likely to abuse Rx drugs over their lifetime than teens who have learned "nothing."

% Teens used at least once in lifetime	How Much Learned From Parents/Grandparents		
	A lot (A) (n=1405)	A little (B) (n=1497)	Nothing (C) (n=768)
Rx Drugs	19%	21%	33% AB
Pain Relievers	12%	15%	24% AB
Ritalin	10%	10%	20% AB

*Note: A, B, C indicates a significant difference at the 95% confidence level.*

*\*In your lifetime, how many times have you used any prescription drug in order for you to get high or change your mood/a prescription pain reliever like Vicodin or OxyContin/the prescription drugs Ritalin or Adderall when a doctor did not prescribe it for you?*

*\*\*How much have you learned about the risks of drugs from each of the following: Parents or grandparents?*

2012 Partnership Attitude Tracking Study - Released in April 22, 2013 by The Partnership at Drug-Free.Org

### Alarming # of Teens Abusing Prescription Medications

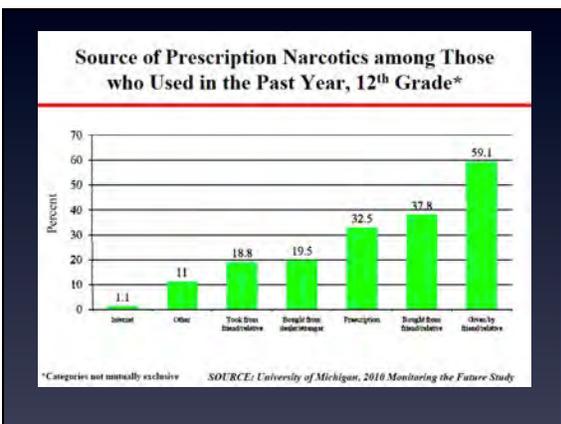
2012 Partnership Attitude Tracking Study  
Partnership at Drug-Free.Org

#### Discussed Drugs with Parents - Trended

% Discussed Drugs with Parents	2010	2011	2012
Rx Pain Relievers without prescription	23%	17%	16%*
Any Rx Drug without prescription	22%	16%	14%*

\* Indicates a significant difference from 2010 at the 95% confidence level.  
"The last time one or both of your parents talked to you about drugs, what specific drugs did they talk about?"

2012 Partnership Attitude Tracking Study - Released in April 22, 2013 by The Partnership at Drug-Free.Org



### Medscape Today NEWS

From News Alerts > Medscape Medical News  
**FDA Issues Warning on Fentanyl Patches**  
Susan Jeffrey  
Posted: 04/19/2012

April 19, 2012 — The US Food and Drug Administration issued a warning to healthcare professionals and the public underlining the appropriate storage, use, application and disposal of fentanyl patches, including Duragesic (Janssen Pharmaceutical Inc) and generic patches, to prevent life-threatening harm from accidental exposure to fentanyl, particularly by children.

The warning comes after FDA evaluated a series of 28 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, the agency notes in a statement issued April 18. Of these, 10 cases resulted in death and 12 in hospitalization. Sixteen cases occurred in children 2 years of age or younger.

"Young children are at particular risk of accidental exposure to fentanyl patches," the FDA statement notes. "Their mobility and curiosity provide opportunities for them to find lost patches, take improperly discarded patches from the trash, or find improperly stored patches, all of which may result in patches being placed in their mouths or sticking to their skin."

### The New York Times U.S.

WORLD | U.S. | N.Y. REGION | BUSINESS | TECHNOLOGY | SCIENCE | HEALTH | SPORTS | OPINION

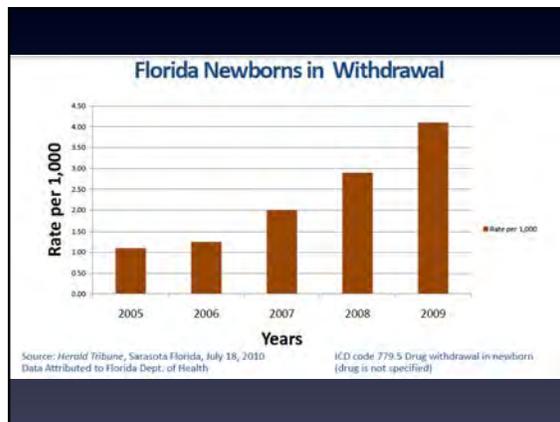
#### Newly Born, and Withdrawing From Painkillers

A nurse administered morphine to MITCHELL, 4 weeks old, at a medical center in Bangor, Me., while he was held by his father.

By ARRY GOODENOUGH and NATHI ZIZIMA  
Published: April 9, 2011

BANGOR, Me. — The mother got the call in the middle of the night: her 3-day-old baby was going through opiate withdrawal in a hospital here and had to start taking methadone, a drug best known

New York Times  
Sunday April 10, 2011





### WV Data on Opioid Poisoning

Hall et al: **Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities.** JAMA, 2008; 300(22):2613-2620

- WV experienced largest increase in drug overdose mortality rates from 1999-2004
- Study looked at OD deaths in year 2006
  - 295 decedents ages 18 – 54
  - 63 % involved diversion
    - Largely Male: 2/3= males
    - Largely Younger: > in ages 18 -24 years
    - Decreased across each successive age group
    - >> association with illicit contributory drugs

### WV Data on Opioid Poisoning

Hall et al: **Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities.** JAMA, 2008; 300(22):2613-2620

- OD deaths in year 2006
  - Evidence of doctor shopping in 21% (1 in 5)
    - Prescriptions for CS from  $\geq 5$  clinicians in the year prior to death
      - Largely Female: F > M (~2:1 , 31% to 17%)
      - Largely Older: 71% age > 35
    - Negative association between drug diversion + doctor shopping
      - Only 8% met criteria for both

### WV Data on Opioid Poisoning

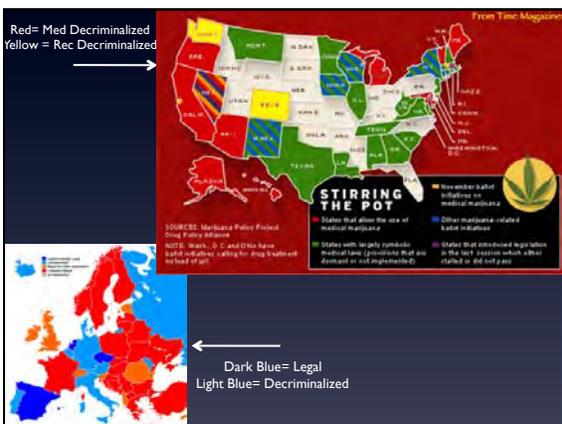
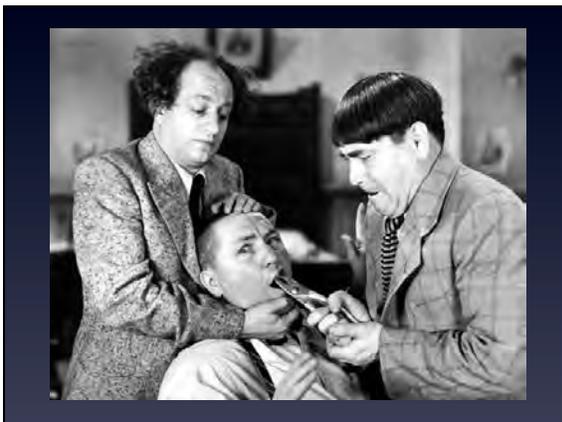
Hall et al: **Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities.** JAMA, 2008; 300(22):2613-2620

- OD deaths in year 2006
  - Methadone
    - Most attributed opioid in single-drug deaths
    - Involved in more deaths than any other drug (40% all deaths)
  - 95% w/ indicators of substance abuse
  - 79% of all cases associated with multiple contributory substances
  - 93% of all cases involved opioid analgesics
    - 66% did not have a prescription
    - 34% had prescription

### WA State Data on Opioid Poisoning

Dunn KM et al: **Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study.** Ann Intern Med. 2010; 152 (2):85-92

- 9940 people w/3 or more opioid prescriptions within 90 days for chronic non-cancer pain between 1997 and 2005 (8 yrs)
- Measures
  - Avg daily opioid dose over the previous 90 days from automated pharmacy data
  - Nonfatal and fatal overdoses identified through diagnostic codes from inpatient and outpatient care and death certificates (confirmed by medical record review)
- 51/9940 opioid-related overdoses and 6 deaths
- Patients receiving  $\geq 100$  mg/d = ~ 9X increase in OD risk compared with Patients receiving 1-20 mg/d
  - Patients receiving 50-99 mg/d had a ~4X increase in OD risk



USA TODAY: MARIJUANA LEGALIZED

Washington Monitor: With a puff of smoke, pot becomes legal in Washington: How will this work?

ABC NEWS: Push to Legalize Pot as 'Tipping Point,' Experts Say

October 12, 2011  
HUFF POST SAN FRANCISCO  
THE INTERNET NEWSPAPER, NEWS BLOGS VIDEO COMMUNITY

**Obama's War On Weed: White House Launches Crackdown On Medical Marijuana**

First Posted: 10/11/11 04:24 PM ET, Updated: 10/12/11 11:00 AM ET

**CHRONIC PAIN? IT'S THE LAW!**

Medical Marijuana Physician Evaluations MEDICAL CLINIC

Anorexia... CHRONIC PAIN... Arthritis... Migraine, or any other illness for which marijuana provides relief

IT'S YOUR RIGHT!  
CA Health & Safety Code 11362.2 (Prop 215)  
(415) 681-0820 www.potdoc.com

**No pot for pain, high court says**

By David G. Savage and John M. Gilman  
Los Angeles Times

WASHINGTON — The Supreme Court on Tuesday rejected California from its policy giving marijuana to people who are sick and in pain.

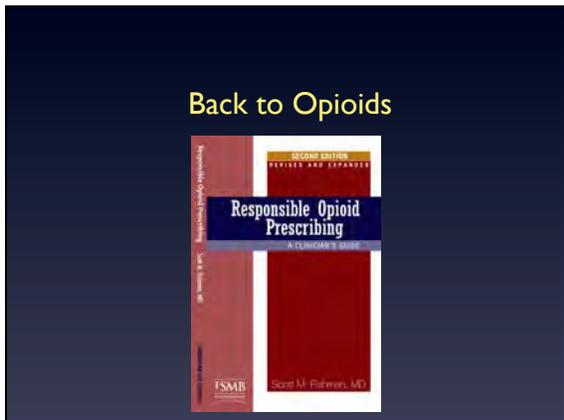
The emergency order holds, at least for now, at that. Physicians' patients' doctors handed down last month that covered the way for distributing medicinal to those for whom it is a "medical necessity."

Justice four years ago. California voters passed that state's government's plan to allow people with a doctor's recommendation. However, private drug growers and local jurisdictions have worked out ways to distribute the drug to people who

INSIDE  
New UC center will study medical marijuana and its potential for pain relief

Page A1

- Many court rulings on MJ
- 2 supreme court rulings
- Restrict physicians and patients
- Many States legalize medical MJ
- 2 states legalize recreational use of MJ
- ?? Federal vs. State
- Supreme Court verdict on PAS



- ### Addiction vs. Analgesia
- Patients with addiction take increasing amounts of abusable drugs
    - » Function does not improve
      - Usually worsens
  - Patients with analgesia usually find a stable (moderate) dose and **Improved QOL**
    - » Pain doesn't completely abate
      - balance of least pain/most function
    - » Function improves
      - DOES NOT DECREASE

- ### Paradigm Shift in Opioid Prescribing
- Competing Public Health Crises
    - » Under Treated Pain
    - » Prescription Drug Abuse
  - Dramatically Increased Need for Safe & Effective Pain Management

### Criminal Charges For Overtreatment of Pain

- Numerous High Cases
  - few cases
    - Relative to the # of MD
      - Almost all are extreme
    - **Good clinicians**
      - Practicing at extremes of the normal curve
    - **Well intentioned clinicians**
      - Practicing below standard of care
    - **Clinicians practicing outside of medicine**
      - Illegal activities

*The New York Times Magazine*

**When Is a Pain Doctor a Drug Pusher?**

By TINA ROSENBERG  
Published: June 17, 2007

*The Washington Post* Politics Opinions Local Sports National World Business Tech

**Health & Science** July 13, 2012

**Calif. pain doctor duped by dog X-ray arrested in undercover sting; the 'patient' had a tail**

The Los Angeles Times reports the physician examined the X-ray and asked if she wanted Vicodin, oxycodone, Valium or Xanax



Federation of State Medical Boards  
of the United States, Inc.  
Model Policy for the Use of Controlled  
Substances for the Treatment of Pain




August 2013  
Available [www.fsmb.org](http://www.fsmb.org)

**FSMB Model Policy**  
Basic Tenets



- Pain management is important and integral to the practice of medicine
- Use of opioids may be necessary for pain relief
- Use of opioids for other than a legitimate medical purpose poses a threat to the individual and society

**FSMB Model Policy**



- Physicians have a responsibility to minimize the potential for abuse and diversion
- Physicians may deviate from the recommended treatment steps based on good cause
- Not meant to constrain or dictate medical decision-making

**FSMB Model Policy**



- Complete patient evaluation
- Written treatment plan
- Informed patient consent and agreement for treatment
- Periodic review of the course of treatment
- Willingness to refer
- Maintenance of complete and current medical record

**2013 FSMB Model Policy**



- The revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following:
  - Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain
  - Inadequate monitoring during the use of potentially abusable medications
  - Inadequate attention to patient education and informed consent
  - Unjustified dose escalation without adequate attention to risks or alternative treatments
  - Excessive reliance on opioids, particularly high dose opioids for chronic pain management
  - Not making use of available tools for risk mitigations

## 2013 FSMB Model Policy Guidelines



- Understanding Pain
- Patient Evaluation and Risk Stratification
- Development of a Treatment Plan & Goals
- Informed Consent and Treatment Agreement
- Initiating an Opioid Trial
- Ongoing Monitoring and Adapting the Treatment Plan
- Periodic Drug Testing
- Consultation and Referral
- Discontinuing Opioid Therapy
- Medical Records
- Compliance with Controlled Substance Laws and Regulations

## 2013 FSMB Model Policy Guidelines

- **Understanding Pain:**
  - The diagnosis and treatment of pain is integral to the practice of medicine

## 2013 FSMB Model Policy Guidelines

- **Patient Evaluation and Risk Stratification:**
  - Document presence of one or more recognized medical indications for prescribing an opioid analgesic
  - Reflect an appropriately detailed patient evaluation
  - Complete Evaluation before a decision is made as to whether to prescribe an opioid analgesic

## 2013 FSMB Model Policy Guidelines

- **Patient Evaluation and Risk Stratification:**
  - Initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated
  - Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use
  - Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation

## 2013 FSMB Model Policy Guidelines

- **Patient Evaluation and Risk Stratification:**
  - Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse should be part of the initial evaluation
    - ~ Ideally completed prior to a decision as to whether to prescribe opioid analgesics
  - This can be done through a careful clinical interview
    - ~ Also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse

## 2013 FSMB Model Policy Guidelines

- **Patient Evaluation and Risk Stratification:**
  - Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R] or the Opioid Risk Tool [ORT], or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk
  - All patients should be screened for depression and other mental health disorders, as part of risk evaluation
    - ~ Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose

### 2013 FSMB Model Policy Guidelines

- **Patient Evaluation and Risk Stratification:**
  - Patients with a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse
  - Treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed)

### 2013 FSMB Model Policy Guidelines

- **Patient Evaluation and Risk Stratification:**
  - Patients who have active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional
  - Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction
    - Including the role of replacement agonists such as methadone and buprenorphine.
    - For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment

### 2013 FSMB Model Policy Guidelines

- **Patient Evaluation and Risk Stratification:**
  - Information provided by the patient is a necessary but insufficient part of the evaluation process
  - Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible
  - Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers

### 2013 FSMB Model Policy Guidelines

- **Patient Evaluation and Risk Stratification:**
  - If possible, the patient evaluation should include information from family members and/or significant others
  - Where available, the state PDMP should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record
    - In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance
  - The physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community

### 2013 FSMB Model Policy Guidelines

- **Development of a Treatment Plan & Goals:**
  - The goals of pain treatment include
    - Reasonably attainable improvement in pain and function
    - Improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety
    - Avoidance of unnecessary or excessive use of medications
  - Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient

### 2013 FSMB Model Policy Guidelines

- **Informed Consent and Treatment Agreement [1 of 3]:**
  - A shared decision between physician and patient
  - Discuss the risks and benefits of the treatment plan
    - Including any proposed use of opioid analgesics
  - Counsel on safe ways to store and dispose of medications
  - Use of a written informed consent and treatment agreement (sometimes referred to as a "treatment contract") is recommended

## 2013 FSMB Model Policy Guidelines

### ■ Informed Consent and Treatment Agreement [2 of 3]: Expected Elements

- Risks and anticipated benefits of chronic opioid therapy
- Potential long/short-term AEs (ie. constipation and cognitive d/o)
- Likelihood of tolerance & physical dependence
- The risk of drug interactions and over-sedation
- The risk of impaired motor skills (affecting driving and other tasks)
- The risk of opioid misuse, dependence, addiction, and overdose
- The limited evidence as to the benefit of long-term opioid therapy
- Prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement)

## 2013 FSMB Model Policy Guidelines

### ■ Informed Consent and Treatment Agreement [3 of 3]: Joint Responsibilities

- The goals of treatment, in terms of pain management, restoration of function, and safety
- The patient's responsibility for safe medication use
  - e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication
- Patient's responsibility to obtain prescribed opioids from single physician or practice
- The patient's agreement to periodic drug testing
- Physician's responsibility to be available to care for unforeseen problems and prescribe scheduled refills
- Informed consent documents and treatment agreements can be part of one document for the sake of convenience

## 2013 FSMB Model Policy Guidelines

### ■ Initiating an Opioid Trial:

- Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain
- Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points
- The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety
- When initiating opioid therapy, the lowest dose possible should be given to an opioid naive patient and titrate to affect
- It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated
- Continuing opioid therapy beyond the trial period should reflect a careful evaluation of benefits vs AEs and/or potential risks

## 2013 FSMB Model Policy Guidelines

### ■ Ongoing Monitoring and Adapting the Treatment Plan [1]:

- Regularly review the patient's progress
  - Including any new information about the etiology of the pain or the patient's overall health and level of function
- When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP
- The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted
- As the patient is stabilized, f/u may be scheduled less frequently
  - However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed

## 2013 FSMB Model Policy Guidelines

### ■ Ongoing Monitoring and Adapting the Treatment Plan [2]:

- At each visit, the results of chronic opioid therapy should be monitored by assessing the "5As" of chronic pain management"
  1. Analgesia: determination of whether the patient is experiencing a reduction in pain
  2. Activity: demonstrated improvement in level of function
  3. Adverse Effects
  4. Aberrant Behaviors: ie. substance-related behavior
  5. Affect: mood of the individual

## 2013 FSMB Model Policy Guidelines

### ■ Ongoing Monitoring and Adapting the Treatment Plan [3]:

- Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of
  1. Evidence of the patient's progress toward treatment objectives
  2. Absence of substantial risks or adverse events, such as overdose or diversion
- Satisfactory response to TX indicated by
  1. Reduced level of pain
  2. Increased level of function
  3. Improved quality of life Information from family members or other caregivers

## 2013 FSMB Model Policy Guidelines

### ■ Periodic Drug Testing [1 of 7]:

- Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs
- Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others
- Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing
- Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing

## 2013 FSMB Model Policy Guidelines

### ■ Periodic Drug Testing [2 of 7]:

- When testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed
- Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based)
  - Which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug
  - If necessary, this can be followed up with a more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites
- It is important to identify the specific drug not just the drug class

## 2013 FSMB Model Policy Guidelines

### ■ Periodic Drug Testing [3 of 7]:

- Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately
  - I.e. When ordering UDT, important to include the opioid being prescribed
- Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist
- Immunoassay, point of care (POC) testing has utility in making temporary and “on the spot” changes in clinical management, its limitations in accuracy have recently been the subject of study
  - Use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained [high rate false positives and negatives]

## 2013 FSMB Model Policy Guidelines

### ■ Periodic Drug Testing [4 of 7]:

- Test results that suggest opioid misuse should be discussed with the patient in a positive, supportive fashion
- Both the test results and subsequent discussion with the patient should be documented in the medical record

## 2013 FSMB Model Policy Guidelines

### ■ Periodic Drug Testing [5 of 7]:

- Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications).
- Consulting the state’s PDMP before prescribing opioids for pain and during ongoing use is highly recommended.
  - A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers
- If the patient’s progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed

## 2013 FSMB Model Policy Guidelines

### ■ Periodic Drug Testing [6 of 7]:

- Evidence of misuse of prescribed opioids demands prompt intervention by the physician
- Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician’s knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors
- The presence of illicit or unprescribed drugs, (drugs not prescribed by a physician) in drug tests similarly requires action on the part of the prescriber.
- Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan

## 2013 FSMB Model Policy Guidelines

### ■ Periodic Drug Testing [7 of 7]:

- Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response
  - Failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67].
  - For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives

## 2013 FSMB Model Policy Guidelines

### ■ Consultation and Referral:

- The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed
- Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed

## 2013 FSMB Model Policy Guidelines

### ■ Discontinuing Opioid Therapy:

- Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential **benefits and risks** of continued treatment
- If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use
- Reasons for discontinuing opioid therapy include
  - Resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use

## 2013 FSMB Model Policy Guidelines

### ■ Discontinuing Opioid Therapy:

- If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen
- Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist
- The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate
- **Providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement**

## 2013 FSMB Model Policy Guidelines

### ■ Medical Records:

- Every physician who treats patients for chronic pain must maintain accurate and complete medical records
- Information that should appear in the medical record includes:
  - Copies of the signed informed consent and treatment agreement
  - The patient's medical history
  - Results of the physical examination and all laboratory tests.
  - Results of the risk assessment, including results of any screening instruments used
  - A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity)

## 2013 FSMB Model Policy Guidelines

### ■ Medical Records:

- Information that should appear in the medical record includes:
  - Instructions to the patient, including discussions of risks and benefits with the patient and any significant others
  - Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement
  - Notes on evaluations by and consultations with specialists
  - Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors
    - These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers
  - Authorization for release of information to other treatment providers

## 2013 FSMB Model Policy Guidelines

- **Medical Records:**
  - The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned
  - Written instructions for the use of all medications should be given to the patient and documented in the record
  - The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed
  - Records should be up-to-date and maintained in an accessible manner so as to be readily available for review
  - Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary
  - Even if the outcome is less than optimal, thorough records protect the physician as well as the patient

## 2013 FSMB Model Policy Guidelines

- **Compliance with Controlled Substance Laws and Regulations:**
  - To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations
  - Physicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* (and any relevant documents issued by the state medical Board) for specific rules and regulations governing the use of controlled substances.
    - ~ Additional resources are available on the DEA's website (at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)), as well as from (any relevant documents issued by the state medical board)

## Risk Management with Opioids

- Requires understanding Risk Management
  - Functional outcomes
    - ~ Improved function → Efficacy
    - ~ Unchanged or decreased function → ??
      - ~ ? Efficacy ? Toxicity
  - Universal Precautions
    - Standardized programs that apply to all
      - ~ Consistent risk management practices
      - ~ Persistent vigilance
      - ~ Minimized bias

## 2013 SAMHSA OPIOID OVERDOSE ToolKit For :

- Prescribers
- 1<sup>st</sup> Responders
- Patients and Family Members
- OD Survivors and Family Members
- Community Members

## INFORMATION FOR PRESCRIBERS

*At the time a drug is prescribed, patients should be informed that it is illegal to sell, give away, or otherwise share their medication with others, including family members.*

*The patient's obligation extends to keeping the medication in a locked cabinet or otherwise restricting access to it and to safely disposing of any unused supply.*

(visit <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm> for advice from the FDA on how to safely dispose of unused medications)

## INFORMATION FOR PRESCRIBERS

### CONSIDER PRESCRIBING NALOXONE ALONG WITH THE PATIENT'S INITIAL OPIOID PRESCRIPTION

- With proper education, patients on long-term opioid therapy and others at risk for overdose may benefit from having a naloxone kit to use in the event of overdose
- Also may be advisable to suggest that the at-risk patient create an "overdose plan"
  - to share with friends, partners and/or caregivers
  - Plan would contain information on the signs of overdose and how to administer naloxone or otherwise provide emergency care (as by calling 911)

## INFORMATION FOR PRESCRIBERS

SAMHSA  
Opioid Overdose  
**TOOLKIT:**  
Information for Prescribers

**Candidates For Prescribing Naloxone Along With Opioids :**

- Taking high doses of opioids for long-term management of chronic malignant or nonmalignant pain
- Receiving rotating opioid medication regimens (and thus at risk for incomplete cross-tolerance)
- Discharged from ED following opioid intoxication or poisoning
- At high risk for overdose because of a legitimate medical need for analgesia, coupled with a suspected or confirmed history of substance abuse, dependence, or non-medical use of prescription or illicit opioids
- Completing mandatory opioid detoxification or abstinence Programs
- Recently released from incarceration and a past user or abuser of opioids (and presumably with reduced opioid tolerance and high risk of relapse to opioid use)

## INFORMATION FOR PRESCRIBERS

SAMHSA  
Opioid Overdose  
**TOOLKIT:**  
Information for Prescribers

Additional information on prescribing opioids for chronic pain

[www.opioidprescribing.com](http://www.opioidprescribing.com)

- Sponsored by the Boston University School of Medicine, with support from SAMHSA

[www.pcass-o.org](http://www.pcass-o.org) or [www.pcassb.org](http://www.pcassb.org)

- Sponsored by the American Academy of Addiction Psychiatry in collaboration with other specialty societies and with support from SAMHSA

<http://www.medscape.org/viewarticle/770687> and <http://www.medscape.org/viewarticle/770440>. CME

- 2 course modules sponsored by NIDA & posted on Medscape.com

## IN Nasal Naloxone Delivery Applicators

Atomized Mist

New York City nasal naloxone device

Denver Health Paramedics Administering Nasal Naloxon

BLS provider administration of the naloxone

## Intra-Nasal Naloxone

Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects

Harmreduction.org

## Injectable Naloxone

Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects

Harmreduction.org

Administering Injectable Naloxone

Injectable naloxone comes packaged in several different forms—a multi-dose vial and single-dose prefilled syring. While all formulations of naloxone, it is important to check the expiration date and make sure to keep it from light. It is not stored in a box. If someone has an injectable formulation of naloxone, all of the steps in recognizing and responding to an overdose are the same except how to give the naloxone.

These are the steps to use injectable naloxone:

1. If the person isn't breathing, do rescue breathing for a few quick breaths first.
2. Pop off the orange top from the vial.
3. Draw up 1cc of naloxone into the syringe (cc=1ml=100%). Use a long needle. Top 18 inch (called an IM or intramuscular needle)— syringe access programs and pharmacies have these needles.
4. Inject into a muscle— thigh, upper outer quadrant of the butt, or shoulder are best. If possible, clean the skin where you are going to inject with an alcohol swab first. It is okay to inject directly through clothing if necessary. Inject straight in to make sure to hit the muscle.
5. If there isn't a big needle, a smaller needle is OK to inject under the skin; however, it is better to inject into a muscle whenever possible.
6. After injection, continue rescue breathing 3 minutes.
7. If there is no change in about 3 minutes, administer another dose of naloxone and continue to breathe for the person. If the second dose of naloxone does not revive them, something else may be wrong— either it has been too long and the heart has already stopped, there are no opioids in their system, non-opioid drugs are the primary cause of overdose (even if they have also taken opioids), or the opioids are unusually strong and require more naloxone (can happen with fentanyl, for example).

## STRATEGIES TO PREVENT OVERDOSE DEATHS

SAMHSA  
Opioid Overdose  
**TOOLKIT:**  
Facts for Community Members

STRATEGY 1: Encourage providers, persons at high risk, family members/others to learn how to prevent and manage opioid OD

STRATEGY 2: Ensure access to treatment for individuals misusing or addicted to opioids or with other substance use disorders

STRATEGY 3: Ensure ready access to naloxone

STRATEGY 4: Encourage the public to call 911. An individual who is experiencing opioid

STRATEGY 5: Encourage prescribers to use state Prescription Drug Monitoring Programs (PDMs)

**STRATEGIES TO PREVENT OVERDOSE DEATHS**

SAMHSA  
Opioid Overdose  
**TOOLKIT:**  
Facts for Community Members

**STRATEGY 1:**  
Encourage providers, persons at high risk, family members and others to learn how to prevent and manage opioid overdose

- Providers should keep current knowledge about evidence-based practices for the use of opioid analgesics to manage pain, as well as specific steps to prevent and manage opioid overdose
- Federally funded CME courses available to providers at no charge at [www.OpioidPrescribing.com](http://www.OpioidPrescribing.com) (5 funded by the SAMHSA and on MedScape (2 funded by the National Institute on Drug Abuse)
- Helpful information for laypersons on how to prevent and manage overdose is available from Project Lazarus at <http://projectlazarus.org/> or from the Massachusetts Health Promotion Clearinghouse at [www.maclearinghouse.org](http://www.maclearinghouse.org)

**STRATEGIES TO PREVENT OVERDOSE DEATHS**

SAMHSA  
Opioid Overdose  
**TOOLKIT:**  
Facts for Community Members

**STRATEGY 2:**  
Ensure access to treatment for individuals misusing or addicted to opioids or with other substance use disorders

- Effective treatment of substance use disorders can reduce the risk of overdose and help overdose survivors attain a healthier life
- Medication-assisted treatment, as well as counseling and other supportive services, can be obtained at SAMHSA-certified and DEA-registered opioid treatment programs (OTPs), as well as from physicians who are trained to provide care in office-based settings with medications such as buprenorphine and naltrexone
- Information on treatment services available in or near your community can be obtained from state health departments, state alcohol and drug agencies, or from SAMHSA

**STRATEGIES TO PREVENT OVERDOSE DEATHS**

SAMHSA  
Opioid Overdose  
**TOOLKIT:**  
Facts for Community Members

**STRATEGY 3:**  
Ensure ready access to naloxone

- Opioid OD deaths preventable with timely naloxone admin
- Naloxone not effective in TX OD of benzodiazepines, barbiturates, clonidine, Elavil, GHB, ketamine, or stimulants
- However if opioids are taken in combination with other sedatives or stimulants, naloxone may be helpful
- Naloxone injection FDA approved and used for > 40 years by emergency medical services (EMS) to reverse opioid overdose
- Naloxone has no psychoactive effects or abuse potential
- Injectable naloxone is inexpensive
  - Typically kit with two syringes at ~ \$6/ dose and \$15 per kit
- important to determine if local EMS personnel/ first responders have been trained to care for overdose, and whether they are allowed to stock naloxone in their drug kits

**STRATEGIES TO PREVENT OVERDOSE DEATHS**

SAMHSA  
Opioid Overdose  
**TOOLKIT:**  
Facts for Community Members

**STRATEGY 4:**  
Encourage the public to call 911. An individual who is experiencing opioid overdose needs immediate medical attention.

- An essential first step is to get help from someone with medical expertise as quickly as possible
- Members of the public should be encouraged to call 911
- All they have to say is, "Someone is not breathing" and give a clear address and location

**STRATEGY 5:**  
Encourage prescribers to use state Prescription Drug Monitoring Programs (PDMPs)

**Monitoring Adherence**

**ADHERENCE**

- History, Presentation, Side Effects
  - YELLOW & RED LIGHTS
- Diaries
- Questionnaire based screens
- Drug Testing
  - Urine, Serum, Hair, Markers (e.g. Phenobarbital, Digitalis)
- Opioid Agreements / Contracts
- PMPs

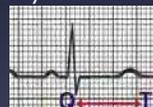
## Methadone and OD Deaths

- Approximately 1/3 of the annual 15,500 prescription drug OD deaths in US involve methadone
  - According to CDC
- 2% of all opioids prescribed for pain in US
- 30% of opioid OD deaths in US



## Methadone

- Different Analgesic vs Plasma half lifes
- Equianalgesic Dosing
  - Opioid Naïve
  - Opioid Tolerant
- Unstable Biometabolism
- Arrhythmia Potential



### ACP - QTc Interval Screening in Methadone Treatment

Mori J. Krantz, MD; Judith Martin, MD; Barry Stimmel, MD; Davendra Mehta, MD; and Mark C.P. Haigney, MD  
Ann Intern Med. 2009;150

- **Recommendations 1-5**
  - **1 - Disclosure:**
    - Clinicians should inform patients of arrhythmia risk when they prescribe methadone
  - **2 - Clinical History:**
    - Clinicians should ask patients about any history of structural heart disease, arrhythmia, and syncope

### ACP - QTc Interval Screening in Methadone Treatment

Mori J. Krantz, MD; Judith Martin, MD; Barry Stimmel, MD; Davendra Mehta, MD; and Mark C.P. Haigney, MD  
Ann Intern Med. 2009;150

- **Recommendations 1-5**
  - **3 - Screening:**
    - Pretreatment electrocardiogram for all patients to measure the QTc interval
    - Follow-up electrocardiogram within 30 days
    - Follow-up electrocardiogram annually
    - Additional electrocardiography recommended if methadone dosage >100 mg/d or if patients have unexplained syncope or seizures

### ACP - QTc Interval Screening in Methadone Treatment

Mori J. Krantz, MD; Judith Martin, MD; Barry Stimmel, MD; Davendra Mehta, MD; and Mark C.P. Haigney, MD  
Ann Intern Med. 2009;150

- **Recommendations 1-5**
  - **4 - Risk Stratification:**
    - QTc interval 450 ms -500 ms
      - Discuss potential risks and benefits with patients and monitor more frequently
    - QTc interval >500 ms
      - ? Discontinuing or reducing the methadone dose
      - ? Eliminating contributing factors, such as drugs that promote hypokalemia
      - ? Change to an alternative therapy

### ACP - QTc Interval Screening in Methadone Treatment

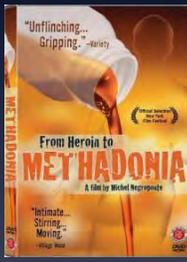
Mori J. Krantz, MD; Judith Martin, MD; Barry Stimmel, MD; Davendra Mehta, MD; and Mark C.P. Haigney, MD  
Ann Intern Med. 2009;150

- **Recommendations 1-5**
  - **5 - Drug Interactions:**
    - Clinicians should be aware of interactions between methadone and other drugs that possess QT interval-prolonging properties or slow the elimination of methadone.

## Methadone and Abuse

*Is methadone less abusible?*

- Maybe
  - Compared with some
- Still is abusible
- Alarming statistics on methadone abuse and deaths in US



## Abuse Resistant Formulations

### Agonist/Antagonist

- Sequestered antagonist
- Bioavailable antagonist
- Antagonists are released only when agent is crushed for extraction
  - eg. Oral-formulation sequestered antagonist becomes bioavailable only when sequestering technology is disrupted; targeted to prevent intravenous abuse

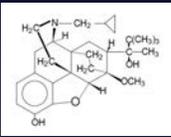



## Remaining Questions About Abuse Resistant Compounds

- How much does the barrier approach deter the determined
- How much do Agonist/Antagonist compounds retain efficacy
- How much do Agonist/Antagonist compounds pose serious adversity
- How to deter over use without manipulation

## Buprenorphine

### An Abuse-Resistant Opioid?



- Antagonist of Kappa opioid receptor
- Agonist of Mu opioid receptor
  - Tightly binds to mu receptor with less respiratory depression and withdrawal



U.S. News & World Report article: "When Children's Scribbles Hide a Prison Drug" (Nov 19, 2011). The article discusses how a drawing of a fish was used to hide a prison drug.

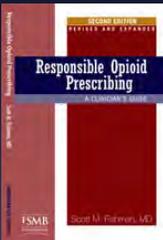
## FDA: Road Ahead for Opioids and Chronic Pain



News articles from The Washington Post and American News Report. Topics include: "Senator warns FDA on danger of newest painkillers" (Alamy, N.Y. AP) and "Living with Pain: Rescheduling Hydrocodone" (American News Report).

## Conclusions

- Responsible opioid prescribing requires **Risk Management**
- Risk:Benefit Analysis [RBA]
  - **Benefits**
    - Evidence is weak or inadequate
  - **Risks**
    - Evidence is strong and mounting
- Increasingly difficult to support benefits over risks in most cases of chronic pain

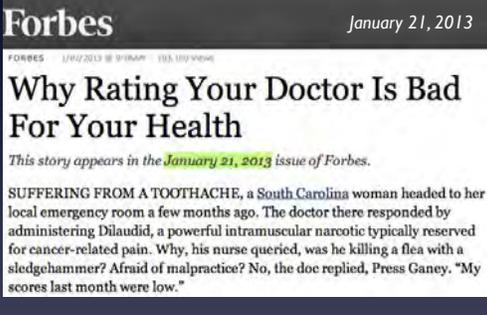


## Why Do We Use So Much Opioid?



**Harper's Bazaar**  
- 1856

## Why Do We Use So Much Opioid?



## Why Do We Use So Much Opioid?

- **Limited Resources**
  - Few available effective treatments for many patients
  - Poor reimbursement for non-medicine/procedure Tx'
  - Covered benefit vs other Tx that may help but aren't covered
- **Time**
  - Much faster to give a prescription than almost anything else
- **Patient Satisfaction**
  - Expect a prescription
  - Some seek dissociation / sedation from life
    - Oriented to
- **Lack of education**
- **Some (few) prescribers are crooks**

## Pharmaco-Vigilant Prescribing

### Risk Stratification and Management

- **Prepare in Advance**
  - Use opioids for CNCP only when safer options have failed
  - Opioids should not be mainstay of Tx
  - Clear Objective Tx Outcomes / End Points
    - Follow-up functional goals
  - **Risks**
    - Assess and agree Prior to Prescribing
- **Benefits must Outweigh Risks!!**
  - **Not the common case of chronic pain**

## Pharmaco-Vigilant Prescribing

### Risk Stratification and Management

- **Real Informed Consent**
  - **Based on Risks & Benefits**
    - **Benefits are not proven by science**
    - **Risks are significant increase with dose**
    - Addiction, abuse, chemical coping and other problems associated with opioids are not uncommon
    - Some patients have difficulty discontinuing therapy
    - Some pain doesn't get better or can worsen with opioids
    - Taking other substances/drugs with opioids (i.e. benzodiazepines) can cause serious adversity

## Pharmaco-Vigilant Prescribing Risk Stratification and Management

- Screen for Risk Before Prescribing
  - Multifactorial aspects including physical, psychological & social domains
  - Consider co-morbidities that increase risks
    - ie. COPD, CHF, sleep apnea, substance abuse, elderly, or renal or hepatic dysfunction, Mental Illness
- Recognize and share with patients that **risks increase with dose**
  - When much is given much should be expected

## Pharmaco-Vigilant Prescribing Risk Stratification and Management

- Never increase the opioid dose because you have no other options for pain relief
  - The opioid must meet its own outcome targets
- Don't Prescribe if you are not willing /able to STOP
  - Before Prescribing
    - Have clear limits in mind
    - Have a clear plan for discontinuation that is shared with the patient
- Opioids rarely mainstay of long term pain mgt
  - Beware if they are

## Consumer Education is Essential

- Educating patients is an essential prescriber role
  - Does not need to be overly burdensome
    - Education must be anticipated prepared for in advance
  - Can make a profound difference in the lives of patients, their loved ones, and society as a whole
  - Opportunity to improve treatment agreement and informed consent
- Proactively educating patients is simply good medicine

## Consumer Education is Essential

- Responsible opioid prescribing requires clinicians to fully educate patients about the many issues
  - Safe use
  - Storage
  - Disposal
  - Pregnancy
  - Driving

## CDC Recommendations to Health Care Providers

- Use opioid medications for acute or chronic pain only after determining that alternative therapies do not deliver adequate pain relief. The lowest effective dose of opioids should be used.
- In addition to behavioral screening and use of patient contracts, consider random, periodic, targeted urine testing for opioids and other drugs for any patient less than 65 years old with noncancer pain who is being treated with opioids for more than six weeks.
- If a patient's dosage has increased to  $\geq 120$  morphine milligram equivalents per day without substantial improvement in pain and function, seek a consult from a pain specialist.
- Do not prescribe long-acting or controlled-release opioids (e.g., OxyContin®, fentanyl patches, and • methadone) for acute pain.
- Periodically request a report from your state prescription drug monitoring program on the prescribing of opioids to your patients by other providers.

Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. CDC's Issue Brief: Unintentional Drug Poisoning in the United States. [http://www.cdc.gov/HomeandRecreationalSafety/Persons/IssueBrief\\_10\\_13/](http://www.cdc.gov/HomeandRecreationalSafety/Persons/IssueBrief_10_13/)

## National Summit on Opioids

Project ROAM (University of Washington Department of Family Medicine) and Physicians for Responsible Opioid Prescribing (support- Group Health Foundation) October 31 and November 1, 2012

### Principles for All Chronic Non-Cancer Pain Patients

- Self-care is the foundation for effective chronic non-cancer pain care
- Your relationship with the patient supports effective self-care
- Guide care by progress toward resuming activities
- Prioritize long-term effectiveness over short-term pain relief

## National Summit on Opioids

Project ROAM (University of Washington Department of Family Medicine) and  
Physicians for Responsible Opioid Prescribing (support- Group Health Foundation)  
October 31 and November 1, 2012

### Principles When Considering Long-term Use of Opioids

- Put patient safety first
- Think twice before prescribing long-term opioids for axial low back pain, headache and fibromyalgia
- Systematically evaluate risks
- Consider intermittent opioid use
- Do not sustain opioid use long-term without decisive benefits
- Keep opioid doses as low as possible

## National Summit on Opioids

Project ROAM (University of Washington Department of Family Medicine) and  
Physicians for Responsible Opioid Prescribing (support- Group Health Foundation)  
October 31 and November 1, 2012

### Principles for Patients Using Opioids Long-term

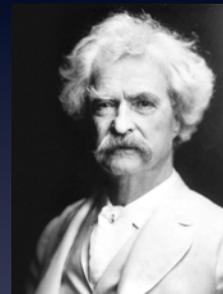
- Clearly communicate standardized expectations to reduce risks
- Adhere to recommended precautions
- Avoid prescribing opioids and sedatives concurrently
- Revisit discontinuing opioids or lowering dose
- Identify and treat prescription opioid misuse disorders

## Conclusions

- Prescribers are largely Untrained
- Opioid Prescribing Requires Great Caution
  - Risk Management
  - **WEIGH RISKS AGAINST BENEFITS**

*"I am all for progress.  
It's change I object to."*

-Mark Twain



**PROMOTING THE HIGHEST STANDARDS FOR  
MEDICAL LICENSURE AND PRACTICE**



Protecting  
Advocating  
Serving

Protecting  
Advocating  
Serving

# FSMB Policy: MOL and Telehealth

**Jon V. Thomas, MD, MBA**

Board Chair, Federation of State Medical Boards

Washington State Medical Commission 2013 Educational Conference

Tumwater, Washington

October 3, 2013

Federation of  
STATE  
MEDICAL  
BOARDS

# Greetings from the FSMB Board of Directors



# Maintenance of Licensure (MOL)



# FSMB House of Delegates 2004 Policy Statement

*“State medical boards have a responsibility to the public to ensure the ongoing competence of physicians seeking relicensure.”*

# What is Maintenance of Licensure (MOL)?

A process by which a licensed physician provides, as a condition of license renewal, evidence of participation in **continuous professional development** that:

- Is practice-relevant
- Is informed by objective data sources
- Includes activities aimed at improving performance in practice

# MOL Guiding Principles

(adopted 2008; modified 2010)

- Support commitment to lifelong learning, facilitate improvement in physician practice
- SMBs should establish MOL requirements; should be administratively feasible, developed in collaboration with other stakeholders
- MOL should not compromise patient care or create barriers to physician practice
- Flexible infrastructure with variety of options for meeting requirements
- Balance transparency with privacy protection

<b><i>MOL Framework</i></b>	<b><i>Recommended Tools</i></b>
<b>COMPONENT 1:</b> <b><i>Reflective self-assessment</i></b>	<ul style="list-style-type: none"> <li>• MOC/OCC</li> <li>• Self-review tests</li> <li>• Simulations</li> <li>• CME in practice area</li> <li>• Literature review</li> </ul>
<b>COMPONENT 2:</b> <b><i>Assessment of knowledge and skills</i></b>	<ul style="list-style-type: none"> <li>• Practice-relevant exams (MOC/OCC)</li> <li>• Procedural hospital privileging</li> <li>• Standardized patients</li> <li>• Computer-based case simulations</li> <li>• Patient/peer surveys</li> <li>• Observation of procedures</li> </ul>
<b>COMPONENT 3:</b> <b><i>Performance in practice</i></b>	<ul style="list-style-type: none"> <li>• Performance improvement CME &amp; projects (Surgical Care Improvement Project, Institute for Healthcare Improvement, Improving Performance in Practice, Healthcare Effectiveness Data and Information Set)</li> <li>• MOC/OCC</li> <li>• AOA Bureau of Osteopathic Specialists' Clinical Assessment Program</li> <li>• Analysis of practice data</li> <li>• CMS measures</li> <li>• 360° evaluations</li> </ul>

# Challenges

- Will impact all licensed physicians
  - Clinically inactive physicians
  - Re-entry physicians
  - Non-board certified physicians
- Financial resources/support currently in short supply
- Variable state laws and regulations
  - Possible amendments to Medical Practice Act
- Reciprocity/similar requirements across states
- Periodicity

# MOL Pilot Projects

- Advance understanding of the process, structure and resource requirements necessary to develop an effective and comprehensive MOL system
  - Impact on state boards
    - Readiness to implement
    - Impact on license renewal process
    - Verification of participation in appropriate activities
  - Supporting physicians' participation
  - Communication issues



# Update on Pilot Work

- Pilots launched in October 2012
  - State Readiness Inventory Survey
    - Completed December 2012
  - Physician Acceptability Survey
    - Distributed to practicing physicians in Colorado & Virginia

## Other MOL Activities

- FSMB MOL Workgroup on Clinically Inactive Physicians
  - Defined the clinically inactive physician
  - Identified responsibilities and guidelines for physicians, state medical boards and the FSMB to facilitate clinically inactive physicians' participation in MOL
  - Final report adopted by the FSMB HOD in April 2013

# Ongoing Communication

- MOL eUpdate
- MOL Information Packet
  - Distributed fall 2012
    - State Medical Boards, Medical/Osteopathic Schools, State Medical/Osteopathic Associations, AOA, AOA BOS
- Peer-Reviewed Articles
  - *Annals of Internal Medicine*
    - Vol. 157, No. 4, August 21, 2012
  - *New England Journal of Medicine*
    - Vol. 367, No. 26, December 27, 2012
  - *FSMB Journal of Medical Regulation*
    - Vol. 99, No. 1 - Evidence and Rationale for MOL

# FSMB Journal Article

## The Evidence and Rationale for Maintenance of Licensure

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Humayun J. Chaudhry, DO, MS; Frances E. Cain, BA; Mark L. Staz, MA; Lance A. Talmage, MD; Janelle A. Rhyne, MD, MA; and Jon V. Thomas, MD, MBA

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**ABSTRACT:** Fulfilling a statutory responsibility to protect the public within their jurisdictions, state medical boards have been working with the Federation of State Medical Boards (FSMB) and collaborating organizations to thoughtfully explore pathways and procedures by which Maintenance of Licensure (MOL) may be implemented for physicians in the years ahead. As a better understanding emerges of the types of continuing medical education (CME) and continuous professional development (CPD) activities physicians already engage in, and the resources that may be necessary for state boards to meaningfully implement MOL, questions have sometimes arisen about the value of these activities in contributing to quality health care and improved patient outcomes. Though MOL has not yet been formally implemented, there is a growing body of compelling evidence and rationale for the educational activities that could meet a state board's requirements for MOL. This article summarizes the recent literature on the subject, including CME and CPD, and recent policy statements of organizations and thought leaders from the house of medicine.

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*"When I graduated from Cornell University Medical College in 1941, I thought I was brimful of knowledge, ready to be a doctor and to bring my skills to patients. Little did I know*

Maintenance of Licensure (MOL), a system of continuous professional development (CPD) that includes practice-relevant CME, to better assure the public that only those physicians

# Future Direction

- Ultimate Goals:
  - Assess physicians in the context of their practice and patient population
  - Demonstrate physicians' effort and success in measurably improving their patient care processes and outcomes
  - Shift profession to a culture of objective and continuous improvement in a constructive, verifiable and creditable manner

# Four Important Points about MOL

- There will not be a mandatory, secure, high stakes examination for MOL
- State medical boards will not require specialty board certification, nor MOC or OCC, as a condition for medical licensure
- MOL is not the same as MOC or OCC, though all value the concept of physician accountability and continued professional development
- Participation in MOC or OCC should substantially count, however, for any state's MOL requirements

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# Exploring the Development of an Interstate Compact for Medical Licensure

# FSMB Special Meeting on License Portability January 17-18, 2013 in Dallas, Texas



Thursday, January 17, 2013  
8:15 - 10:30 a.m.  
Panel Discussion: Existing and Possible State-based Medical Licensure Models  
Mari Robinson, JD  
Ralph C. Loomis, MD  
Thomas H. Ryan, Jr., MPA  
Randall C. Manning, MBA  
Cindy deGroot



# 101<sup>st</sup> Annual FSMB Meeting and Conference Boston, MA



# FSMB's House of Delegates Vote to Support Study of an Interstate Licensure Compact



## Resolution 13-5

- FSMB House of Delegates unanimously adopted *Resolution 13-5: Development of an Interstate Compact to Expedite Medical Licensure and Facilitate Multi-State Practice (HOD 2013)*
- Directed FSMB to convene representatives from state medical boards and special experts to explore the formation of an interstate compact to enhance license portability

# The Need for License Portability

- **Environment of medicine rapidly changing**
  - *Rise of telemedicine and technology*
  - *More physicians practicing in multiple states*
  - *Passage of Affordable Care Act and need for greater access to care*
- **In this environment, PORTABILITY of medical licenses is critical and must be facilitated**
- **Goal: Enhance portability, while ensuring medical quality and patient protection**

# FSMB's License Portability Activity

- **FSMB has long been a proponent for enhanced portability of licenses**
  - *Nearly two decades of action*
- **Major Initiatives**
  - *FSMB License Portability Project (w/HRSA)*
  - *Uniform Application (UA)*
  - *Federation Credentials Verification Service (FCVS)*
- **Interstate Compact for Medical Licensure is latest step in FSMB's efforts**

# The Compact Development Project

- **Launched a feasibility study of the Interstate Compact concept**
  - *Multi-stakeholder planning group*
- **All dimensions of Interstate Compacts being explored**
  - *What has worked for others, and why?*
  - *What operational/administrative models are possible?*
  - *What timeframe is realistic?*
- **All discussion is exploratory and conceptual; no model has been proposed**

# Consensus Principles

- Participation in an interstate compact for medical licensure will be strictly voluntary.
- Participation in an interstate compact should not require modification of a state's Medical Practice Act.
- The practice of medicine occurs where the patient is located at the time of the physician-patient encounter and therefore requires the physician to be under the jurisdiction of the state medical board where the patient is located.
- An interstate compact for medical licensure will establish a mechanism whereby any physician practicing in the state will be known by, and under the jurisdiction of, the state medical board where the practice occurs.

# Consensus Principles (cont.)

- Regulatory authority will remain with the participating state medical boards, and will not be delegated to any entity that would administer a compact.
- A physician practicing under an interstate compact is bound to comply with the statutes, rules and regulations of each compact state wherein he/she chooses to practice.
- The privilege/license to practice can be revoked by any or all of the compact states.

# Overarching Priorities

- **Patient protection is the primary duty of state medical boards and it must be maintained in the new system as a top priority.**
- **Only qualified physicians will be able to participate in the new system.**
- **States will continue to control their licensing activities.**
- **States will maintain their jurisdictional authority.**
- **Any state's participation is voluntary.**

# Timeline to Date

- **May 2013: In consultation with Council of State Governments (CSG) staff, FSMB outlined a project plan and timeline**
- **Confirmed availability of HRSA grant funds that could be dedicated to the project**
- **June 2013: Hosted interstate compact planning meeting at the FSMB Texas office –**
  - Included executive directors from a diverse collection of states in terms of population, size, and geographic region (CSG provided consultation)
- **July 2013: Held first in a series of teleconference meetings to discuss critical content elements of a proposed framework for an interstate medical licensure compact**
- **September 2013: Interstate Compact Taskforce Meeting in D.C.**

# Key Topics Under Discussion

- **In studying an initial framework for an interstate compact for medical licensure, key topics under consideration include:**
  - Compact development process
  - Projected level of adoption among the states
  - Expectations for how a compact could be utilized by state medical boards to expedite licensing for qualified physicians seeking to practice in multiple jurisdictions
  - Critical content areas such as qualifications, credentialing requirements, information sharing and licensing fees
  - Key stakeholders

# Next Steps

- **Provide a forum for representatives from state medical boards to deliberate on the compact framework, which will include:**
  - Physician eligibility requirements for participation in the compact
  - Disciplinary process
  - Funding options for a self-sustaining compact
  - Gauging level of interest among states for adoption
- **Assemble drafting team with support of Council of State Governments that will begin drafting model legislation based on an agreed upon framework**
- **Submit interim report to the FSMB House of Delegates in April 2014**

# Protecting Advocating Serving

Thank you!

