MEDICAL COMMISSION

EDUCATIONAL WORKSHOP

Into the Future:

Designing Better Patient Safety Systems

August 22-24, 2012

Capitol Event Center Tumwater, WA

A public service of the Washington State Medical Commission

Washington State Department of Health

Washington State Medical Commission
Educational Workshop 2012

Into the Future: Designing Better Patient Safety Systems

WEDNESDAY – August 22, 2012 – Capital Event Center	
	Breakfast Provided in Main Rooms
8:15 a.m.	Welcome: Mimi Pattison, MD, Chair and Secretary of Health Mary Selecky
8:30 a.m.	**Dennis Turk, PhD** John & Emma Bonica Professor of Anesthesiology & Pain Research University of Washington *Evidence Based Practice*
9:30 a.m.	**Break**
9:45 a.m.	**Jon Thomas, MD, MBA** President, MN Board of Medical Practice, Chair-elect FSMB *Social Media and Medical Practice*
10:45 a.m.	**Jane Ballantyne, MD** Professor of Education and Research University of Washington *Managing Bill 2876*
12:00 p.m. **Lunch Provided**	**Presentation: RADM Patrick O'Carroll, MD** Assistant Surgeon General, USPHS, Region X *The Affordable Care Act* Introduction: Karen Jensen, JD, MS Assistant Secretary, Department of Health
1:30 p.m.	**Networking Break**
2:00 p.m.	Breakout 1 1. **Commission efforts:** Chehalis A *Pain Rule, Demographics, Pilot to Date* 2. **Jon Thomas, MD, MBA:** Chehalis B President, MN Board of Medical Practice, Chair-elect FSMB *Telehealth innovations in Minnesota*
3:00 p.m.	Breakout 2 1. **Commission efforts**: Chehalis A *Pain Rule, Demographics, Pilot to Date* 2. **Jon Thomas, MD, MBA:** Chehalis B President, MN Board of Medical Practice, Chair-elect FSMB *Telehealth innovations in Minnesota*
4:00 p.m.	**Break**
4:15 p.m.	Wrap up and discussion from breakouts, general day wrap

THURSDAY – August 23, 2012 – Capital Event Center	
	Breakfast Provided in Main Rooms
8:15 a.m.	Welcome: Mimi Pattison, MD, Chair
8:30 a.m.	**Gary Kaplan, MD** Chairman and CEO, Virginia Mason Health System *Seeking Zero Defects: Creating a Patient Safety Culture*
9:30 a.m.	**Break**
9:45 a.m.	**Lisa Robin, MLA** Chief Advocacy Officer with Federation of State Medical Boards *Challenges to State Based Licensure*
10:45 a.m.	**Barbara Schneidman, MD, MPH** Clinical Professor of Psychiatry and Behavioral Sciences University of Washington *Sexual Boundary Violations and Board Diversity*
12:00 p.m. **Lunch Provided**	**Presentation: Margaret O'Kane, MHA** President, National Committee for Quality Assurance *Protecting Patients within and without Systems*
1:30 p.m.	**Networking Break**
2:00 p.m.	**Interactive Demonstration:** *Time Out*
2:45 p.m.	Breakout 1 1. **Stuart Freed, MD:** Chehalis A Chief Medical Officer, Wenatchee Valley Medical Center *Systematic Approach to patients with Chronic Non-Malignant Pain* 2. **Lisa Robin, MLA:** Chehalis B *Legislative trends: State level and Federal*
3:30 p.m.	Breakout 2 1. **Stuart Freed, MD:** Chehalis A Chief Medical Officer, Wenatchee Valley Medical Center *Systematic Approach to patients with Chronic Non-Malignant Pain* 2. **Lisa Robin, MLA:** Chehalis B *Legislative trends: State level and Federal*
4:15 p.m.	**Break**
4:25 p.m.	**Closing:** *Workshop Debriefing and Wrap-up*
FRIDAY – August 24, 2012- PPE, Rooms 152 and 153 – Closed Sessions	
8:00 a.m.-12:00 p.m.	Case Reviews

Washington State Medical Commission 2012 Educational Workshop Evaluation

Please select or highlight the choice that best fits your answer.

1. How satisfied were you with the conference materials provided?
    a. Very Satisfied
    b. Satisfied
    c. Neutral
    d. Dissatisfied
    e. Very Dissatisfied
2. Overall, how satisfied were you with the speakers/presenters?
    a. Very Satisfied
    b. Satisfied
    c. Neutral
    d. Dissatisfied
    e. Very Dissatisfied
3. Overall, how satisfied were you with the conference facilities?
    a. Very Satisfied
    b. Satisfied
    c. Neutral
    d. Dissatisfied
    e. Very Dissatisfied
    f. Other comment:
4. Overall, how satisfied were you with the conference food and refreshments offered?
    a. Very Satisfied
    b. Satisfied
    c. Neutral
    d. Dissatisfied
    e. Very Dissatisfied
    f. Other comment:
5. How many sessions did you attend?
    a. 1-3
    b. 3-5
    c. 5-7
    d. All day, August 22
    e. All day, August 23
6. How did you feel about the length of the conference sessions?
    a. Too short
    b. Just about right
    c. Too long
    d. Other comment:

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Washington State Medical Commission 2012 Educational Workshop Evaluation

Please tell us how much you agree or disagree with the following statements:

7. The content of the conference sessions was appropriate and informative.
    a. Strongly agree
    b. Agree
    c. Neutral
    d. Disagree
    e. Strongly Disagree
    f. Other Comment:

8. The conference was well organized.
    a. Strongly agree
    b. Agree
    c. Neutral
    d. Disagree
    e. Strongly Disagree
    f. Other Comment:

9. Conference and Commission staff was helpful and courteous.
    a. Strongly agree
    b. Agree
    c. Neutral
    d. Disagree
    e. Strongly Disagree
    f. Other Comment:

10. What kinds of sessions would you like to see included at future conferences?

11. What did you like most about the conference?

12. What did you like least about the conference?

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Washington State Medical Commission 2012 Educational Workshop Evaluation

13. Approximately how many conferences of this time do you attend annually?
    a. 1-2
    b. 3-4
    c. 5-6
    d. More than 6
    e. Don't usually attend these types of conferences

14. Do you plan to attend the conference again?
    a. Yes
    b. No
    c. Don't know

15. If the conference required registration would you attend?
    a. Yes
    b. No
    c. Don't know

16. If the conference required a fee but granted CME, would you attend?
    a. Yes
    b. No
    c. Don't Know
    d. Other Comment:

17. How would you rate this conference compared to other conferences that you have attended?
    a. Excellent
    b. Very good
    c. Average
    d. Poor
    e. Very poor

18. In what ways could we improve this conference?

Thank you for completing this survey of the 2012 educational workshop. Please place the completed survey in the basket on the registration table or send the completed electronic version to Micah.Matthews@doh.wa.gov.

Washington State Department of Health

Jane C. Ballantyne, MD

Professor of Education and Research

University of Washington Medicine

Dr. Jane Ballantyne is the University of Washington Medicine Professor of Education and Research in the Department of Anesthesiology and Pain Medicine. Born in Bristol, United Kingdom, Dr. Ballantyne graduated with her medical degree from the Royal Free Hospital School of Medicine in London. She is a member of the Royal College of Surgeons for Otolaryngology and Anaesthesia. She is also a member of the Royal College of Anaesthetists. In 1997, she became a Diplomate of the American Board of Anesthesiology.

Beginning in 1990, Dr. Ballantyne began Clinical and Research Fellowships in Pain Management and Anesthesia at Massachusetts General Hospital in Boston. Dr. Ballantyne has received faculty appointments at Harvard Medical School in Boston as an Instructor in Anaesthesia and as Assistant Professor of Anaesthesia. Prior to her appointment at University of Washington, Dr. Ballantyne was Professor of Anesthesia and Critical Care at University of Pennsylvania in Philadelphia.

Dr. Ballantyne is an extensively published author in both US and international publications. She has been an editor in various capacities for the journal Pain and has participated as a committee member in various organizations relating to pain and its treatment. Most recently, she has participated with the American Pain Society, the Federal Food and Drug Administration, and the International Association for the Study of Pain. Dr. Ballantyne has received the Alan Sharp Research Award from Oxford University, the Fellow Teacher of the Year Award from Massachusetts General Hospital Pain Center, and the Will Solimene Award for excellence in medical communication from the American Medical Writers Association. When not instructing, editing, or publishing, Dr. Ballantyne lectures extensively both nationally and internationally.

Stuart D. Freed, M.D.

Medical Director

Wenatchee Valley Medical Center

Stuart D. Freed, MD is the current Medical Director of Wenatchee Valley Medical Center. Dr. Freed attended Pacific Lutheran University for his undergraduate studies and received his medical degree from University of Washington in 1984. Dr. Freed completed his residency in 1987 at the University of Washington/Tacoma Family Medical Center and received his Board Certification from the American Board of Family Practice the same year. Dr. Freed specializes in Sports Medicine.

Prior to relocating to Wenatchee, Dr. Freed spent ten years in private practice in both small clinic and multidisciplinary settings. The location and collegial environment at WVMC enticed him to relocate. When not practicing medicine and spending time with family, Dr. Freed enjoys skiing, running, backpacking, cycling, and kayaking in the Columbia River.

Karen A. Jensen, JD, MS

Assistant Secretary to the Department of Health

Health Systems Quality Assurance

Karen Jensen was appointed as an Assistant Secretary to the Department of Health in August 2008. She leads the Health Systems Quality Assurance Division. This is the department's largest division, with nearly 400 employees. Among other responsibilities, the division licenses more than 300,000 health professionals in Washington State. Karen began working with the department in May 2000 when she was still with the Attorney General's Office. Karen formally joined the department in 2004 and assumed responsibilities as one of the supervising staff attorneys in the division's Legal Service Unit. She worked most recently as the division's policy director and legislative coordinator. Karen has a Bachelor's degree and Master's degree in microbiology from Washington State University, as well as a Juris doctor from Seattle University.

Gary S. Kaplan, MD

Chairman and CEO

Virginia Mason Health System

Gary S. Kaplan, MD, FACP, FACMPE, FACPE, has served as chairman and CEO of the Virginia Mason Health System since 2000. He is a practicing Internal Medicine physician at Virginia Mason.

During Dr. Kaplan's tenure as chairman and CEO, Virginia Mason has received significant national and international recognition for its efforts to transform health care. Recent recognitions include:

- Virginia Mason was named the "Top Hospital of the Decade" for patient safety and quality by The Leapfrog Group, a distinction shared with only one other hospital.
- Virginia Mason received the highest overall score of any reporting hospital in the Pacific Northwest in the 2010 and 2011 surveys by The Leapfrog Group. In 2010, Virginia Mason also had the best safety ratings in Washington State for high-risk procedures, as well as the best overall patient safety ratings among all reporting hospitals.
- Virginia Mason is one of only 238 hospitals out of 6,000 nationwide to receive the 2011 HealthGrades Patient Safety Excellence Award™.
- Virginia Mason was one of five hospitals honored with the 2011 American Hospital Association-McKesson Quest for Quality Prize®, presented annually to honor leadership and innovation in quality improvement and safety.
- Virginia Mason was named a 2011 Distinguished Hospital for Clinical Excellence™ by HealthGrades, placing Virginia Mason among the top 5 percent of hospitals nationwide — the fourth time Virginia Mason had earned this honor.

Virginia Mason is considered to be the national leader in deploying the Toyota Production System to health care management — reducing the high costs of health care while improving quality, safety and efficiency to deliver better, faster and more affordable care.

In addition to caring for patients and serving as chairman and CEO, Dr. Kaplan is a clinical professor at the University of Washington and has been recognized for his service and contribution to many regional and national boards, including:

- The Institute for Healthcare Improvement
- The Medical Group Management Association

- The National Patient Safety Foundation
- The Greater Seattle Chamber of Commerce
- The Washington Healthcare Forum
- The Seattle Foundation
- Special Olympics of Washington

Dr. Kaplan is a founding member of Health CEOs for Health Reform and has been recognized nationally for his health care leadership.

- Modern Physician and Modern Healthcare ranked Dr. Kaplan No. 2 on the 2012 listing of the 50 Most Influential Physician Executives.
- Modern Healthcare ranked Dr. Kaplan No. 33 on the 2011 listing of the 100 Most Influential People in Healthcare.
- Becker's Hospital Review, in 2011, listed Dr. Kaplan as one of the 13 Most Influential Patient Safety Advocates in the United States, and named him as one of 291 U.S. Health and Hospital Leaders to Know.

Some of Dr. Kaplan's other awards and distinctions include:

- The 2009 John M. Eisenberg Award from the National Quality Forum and The Joint Commission for Individual Achievement at the national level for his outstanding work and commitment to patient safety and quality.
- The Harry J. Harwick Lifetime Achievement Award for outstanding contributions to health care from the Medical Group Management Association and the American College of Medical Practice Executives.

Dr. Kaplan received his medical degree from the University of Michigan and is board certified in internal medicine. He is a Fellow of the American College of Physicians (FACP), the American College of Medical Practice Executives (FACMPE) and the American College of Physician Executives (FACPE).

RADM Patrick O'Carroll, MD, MPH

Assistant Surgeon General, U.S. Public Health Service
Regional Health Administrator, Region X, Seattle

States: Alaska, Idaho, Oregon, and Washington

RADM Patrick O'Carroll, a career Commissioned Officer in the U. S. Public Health Service (USPHS), has served as Regional Health Administrator for Region X since January 2003. As RHA, Dr. O'Carroll serves as the Region's senior physician and scientist representing the Assistant Secretary for Health, the Secretary, and the U.S. Department of Health and Human Services.

Dr. O'Carroll received the Doctor of Medicine and Master of Public Health degrees from Johns Hopkins University in 1983. After training in family practice and preventive medicine, he joined the Centers for Disease Control and Prevention (CDC) as an Epidemic Intelligence Service Officer. Initially assigned to work in the area of violence epidemiology, Dr. O'Carroll later led the epidemiology research unit for the prevention of suicide and violence at CDC's National Center for Injury Prevention and Control. He was elected as a Fellow of the American College of Preventive Medicine in 1988.

In 1992, Dr. O'Carroll began work in the field of public health informatics. He co-led the development of *CDC WONDER* (an innovative computer system providing global access to CDC's epidemiologic data) and was lead scientist on the *CDC Prevention Guidelines Database* project. Dr. O'Carroll developed the nation's first training course and first (and only) textbook in public health informatics. As Associate Director for Health Informatics at CDC's Public Health Practice Program Office, he defined, developed and directed CDC's national Health Alert Network program. Under Dr. O'Carroll's leadership, the Health Alert Network grew from an idea into a $50 million annual investment in national public health information and communications infrastructure. He was elected as a Fellow of the American College of Medical Informatics in 2004.

During his 27 years with CDC and USPHS, as an epidemiologist, informaticist, program director and leader, Dr. O'Carroll has worked in many subject areas on a great variety of health and policy challenges. These include immunization; chronic disease; maternal and child health; environmental health; infectious disease epidemic control; behavioral health; global health and disease surveillance; and bioterrorism preparedness. He has received numerous awards and other recognition for his work, including two Outstanding Service Medals. Dr. O'Carroll holds an Affiliate Associate Professor appointment in the Departments of Epidemiology and Health Services at the University of Washington School of Public Health and Community Medicine and is also Affiliate Associate Professor in the Division of Biomedical and Health Informatics, University of Washington School of Medicine.

Margaret E. O'Kane, MHA

President

National Committee for Quality Assurance

Since 1990, Margaret E. O'Kane has served as President of the National Committee for Quality Assurance (NCQA), an independent, non-profit organization whose mission is to improve the quality of health care everywhere. Under her leadership, NCQA has developed broad support among the consumer, employer and health plan communities. About three-quarters of the nation's largest employers evaluate plans that serve their employees using Healthcare Effectiveness Data and Information Set (HEDIS®) data. In recent years, NCQA has received awards from the National Coalition for Cancer Survivorship, the American Diabetes Association and the American Pharmacists' Association.

In addition to her leadership of NCQA, Ms. O'Kane plays a key role in many efforts to improve health care quality. Recently, she was awarded the 2009 Picker Institute Individual Award for Excellence in the Advancement of Patient-Centered Care for her leadership of NCQA and lifetime achievement in improving patient-centered health care. In 1999, Ms. O'Kane was elected as a member of the Institute of Medicine. She also serves as co-chair of the National Priorities Partnership, a broad-based group of high-impact stakeholder organizations, working together to bring transformative improvement to our health care system.

Ms. O'Kane began her career in health care as a respiratory therapist and went on to earn a master's degree in health administration and planning from the Johns Hopkins University.

Lisa A. Robin, MLA

Chief Advocacy Officer

Federation of State Medical Boards

For more than 17 years, Lisa Robin has been active in leading the Federation of State Medical Boards in developing and promulgating policy on a broad range of issues supporting state medical boards in their mission of public protection. Under her oversight, the FSMB has addressed the issues of physician impairment, telemedicine, pain management, scope of practice, professional conduct and ethics, Internet prescribing, the regulation of office-based surgery, and complementary and alternative medicine. Lisa established and currently leads the FSMB's Washington D.C. advocacy office.

A long-time leader in the area of pain management, Lisa guided development of the landmark FSMB policy, *Model Policy for the Use of Controlled Substances for the Treatment of Pain.* She served as project director for development of the book, *Responsible Opioid Prescribing: A Physician's Guide,* which was distributed to more than 160,000 physicians in the United States. A revised and expanded edition of the book was released in April 2012 and is available in print and electronic formats. In 2008, Lisa received national recognition for her work in pain management with a prestigious fellowship from the Mayday Fund and a Presidential Commendation from the American Academy of Pain Medicine.

In addition to her activities in the governmental and policy arenas, Lisa oversees the FSMB's state and federal government relations and policy activities, education, public affairs and communications. She also works closely with the FSMB Foundation, the organization's philanthropic arm. Lisa received her bachelor's and master's degrees from Texas Christian University in Fort Worth, Texas.

Barbara S. Schneidman, MD, MPH

Clinical Professor of Psychiatry and Behavioral Sciences

University of Washington School of Medicine

Barbara S. Schneidman, MD, MPH was the Vice President of Medical Education at the American Medical Association from 2002-2008. Prior to this position she served as the Associate Vice President of the American Board of Medical Specialties (ABMS), from 1993-1998. During 2009 she served as the Interim CEO and President of the Federation of State Medical Boards.

She currently holds the position of clinical professor of psychiatry and behavioral sciences at the University of Washington School of Medicine and is a member of the medical school admissions committee. Dr. Schneidman is a board certified psychiatrist. She is a distinguished fellow of the American Psychiatric Association, fellow of the American College of Psychiatrists (ACP) and chaired the Psychiatry Residency in Training Examination (PRITE) Commission. She is also a member of the ACP Board of Regents where she is currently President-Elect. She is a director of the American Board of Psychiatry and Neurology and the American Board of Medical Specialties. She has been a member of the Illinois Psychiatric Society (IPS) since 1993 and has served as a member of the Fellowship Committee as well as serving as a councilor from 2003-2008. She is currently a member of the Washington State Psychiatric Association where she is serving as President.

Dr. Schneidman has been active in the Washington State Board of Medical Examiners and the Federation of State Medical Boards (FSMB) and also chaired the FSMB Impaired Physician's Task Force, which produced two policy documents on physician impairment. She is currently the chair of the FSMB Reentry to Practice Special Committee. Dr. Schneidman served as the 70th president of the FSMB in 1991-92.

Dr. Schneidman is a graduate of the University of Minnesota Medical School and underwent training as an intern at Providence Hospital in Seattle. Following her internship, Dr. Schneidman received her Masters in Public Health (MPH) from the University of Washington School of Public Health and completed her residency in psychiatry at the University of Washington. She practiced psychiatry in Seattle and taught consultation liaison psychiatry to primary care medicine residents at the University of Washington School of Medicine before joining the ABMS.

Mary C. Selecky

Secretary of Health

Washington State

Mary C. Selecky has been Secretary of the Washington State Department of Health since March 1999, serving under Governor Chris Gregoire and former Governor Gary Locke. Prior to working for the state, Mary served for 20 years as administrator of the Northeast Tri-County Health District in Colville, Washington.

Throughout her career, Mary has been a leader in developing local, state and national public health policies that recognize the unique health care challenges facing both urban and rural communities. As secretary of health, Mary has made tobacco prevention and control, patient safety, and emergency preparedness her top priorities. Mary is known for bringing people and organizations together to improve the public health system and the health of people in Washington.

Mary has served for two terms as the president of the *Association of State and Territorial Health Officials,* receiving the 2010 American Medical Association's Nathan Davis Award for Outstanding Government Service; and is a past president of the *Washington State Association of Local Public Health Officials.* Mary served on the Board of Directors of the *National Association of City and County Health Officials.* A graduate of the University of Pennsylvania, she's been a Washington State resident since 1974.

In 1989, Mary helped create the state's Department of Health, which she now leads. She was also instrumental in developing Washington's nationally recognized *Public Health Improvement Partnership.*

On a statewide level, Mary has made tobacco prevention and control, patient safety, nutrition and physical activity, and emergency preparedness her top priorities. Mary is known for bringing people and organizations together to improve the public health system and the health of people in Washington. Mary graduated from the University of Pennsylvania with a degree in political science and history, and has been a resident of Washington for 38 years.

Jon V. Thomas, MD, MBA

President, Minnesota Board of Medical Practice

Chair-elect, Federation of State Medical Boards

After completing residency at Mayo Graduate School of Medicine in Otolaryngology-Head and Neck Surgery in 1993, Dr. Thomas joined a group of 3 Otolaryngologists in St. Paul, MN. Over the ensuing decade, the group of 3 has grown to a group of 21 through acquisition and merger. Since 2006, Dr. Thomas has served as President and CEO of the combined entity, Ear, Nose & Throat SpecialtyCare of Minnesota. In 2001 Dr. Thomas earned an MBA in Medical Group Management from the University of St. Thomas in St. Paul, MN.

Shortly after completing the MBA program Dr. Thomas was appointed to the Minnesota Board of Medical Practice by Governor Jesse Ventura in 2001. In 2005, he was reappointed by Governor Tim Pawlenty. After a 1 year hiatus he was reappointed by Governor Pawlenty for a 3rd term in 2010. Dr. Thomas chaired the Complaint Review Committee from 2003 - 2006. He was elected Secretary of the Board in 2005, Vice President in 2006 and President in 2007 and 2012. As President he also served on a Work Study Group on Controlled Substances. In 2008 he chaired the Policy and Planning Committee. One of his most enlightening experiences was serving on and chairing the Continuing Competency and Maintenance of Licensure Task Force. In an effort to understand the impact of the movement to Maintenance of Licensure, the Minnesota Board set out to examine the potential impact on its physicians and public.

In addition to his service with the Minnesota Board of Medical Practice, he has also been active nationally with the Federation of State Medical Boards. From 2002 - 2004 he served on the Finance Committee. From 2006 - 2007 he served on the Nominating Committee. In May of 2007 he was a lecturer and panelist at the FSMB annual meeting. The title of the presentation was "Ensuring Public Protection in a Dynamic Health Care Delivery Environment." In 2009 he was elected to the Board of Directors. He served as Chair of the Governance of Committee and member of the Executive Committee of the Board of Directors in 2011 - 2012.

Other activities include service on the board of PreferredOne Physician Associates, a large PPO in Minnesota. He continues to serve on its Medical/Surgical Quality Management Subcommittee. In 2006 he was elected to the Senior Management Team of United Hospital, St. Paul's largest hospital. He served in that capacity until 2009. He then went on to serve as Secretary/Treasurer, Vice-Chief and is currently serving as Chief of Staff. He continues to practice full time.

Dennis C. Turk, PhD

John and Emma Bonica Professor of Anesthesiology and Pain Research

University of Washington

Dennis C. Turk, PhD, is the John and Emma Bonica Professor of Anesthesiology and Pain Research, Director of the Center for Pain Research on Impact, Measurement, & Effectiveness (C-PRIME) at the University of Washington, and a Special Government Employee within the US Food and Drug Administration. He is currently Editor-in-Chief of The Clinical Journal of Pain, Co-director of the Initiative on the Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), and Associate Director of the Analgesic, Anesthetic, and Abuse Clinical Trials Translations, Innovations, Opportunities, & Networks (ACTTION) and FDA-sponsored public-private partnership. His research has been funded continuously by NIH since 1977 and has been funded by the National Center for Health Statistics, the National Center for Medical Rehabilitation Research, as well as by a number of private companies and foundations. Dr. Turk has published over 500 journal articles and chapters in scholarly texts, and has written and edited 20 volumes, most recently, The Pain Survival Guide: How to Reclaim Your Life and Chronic Pain: An Integrated Biobehavioral Approach.

Dr. Turk is the past President of the American Pain Society, and position he held from 2004-2006. He is a fellow of the American Psychological Association, Society of Behavioral Medicine, and Academy of Behavioral Medicine Research. Dr. Turk has received the American Psychological Association, Division of Health Psychology, Outstanding Scientific Contribution Award; the American Association of Pain Management's Janet Travell Award for Outstanding Contribution to Pain Management; and the John C. Liebeskind Research Award for Outstanding Contributions to the Field of Pain. Dr. Turk was identified as one of the Top 10 Leaders in Pain Research and Treatment Development by an international survey conducted by the University of Regina, Saskatchewan, Canada, which was published in "The Pain Clinic" in 2000.

Evidence-Based Practice -- RCTs, Meta-Analyses, & Practice Guidelines:

The GOOD The BAD & The UGLY

Dennis C. Turk, Ph.D.

Disclosures

After this presentation you will wonder how is it possible that I could have a relationship with, Eli Lilly, Endo, Feering, Galderma, OrthoMcNeil-Janssen, Pfizer, Philips Respironics, the National Institutes of Health, and the United States Food and Drug Administration that could be perceived as placing me in a real or apparent conflict of interest in the context of this presentation, but I do!

Acronyms By Which to Practice

EBM/P

RoI

EIM/P

P4P

ACO

CER

PGIC

MID

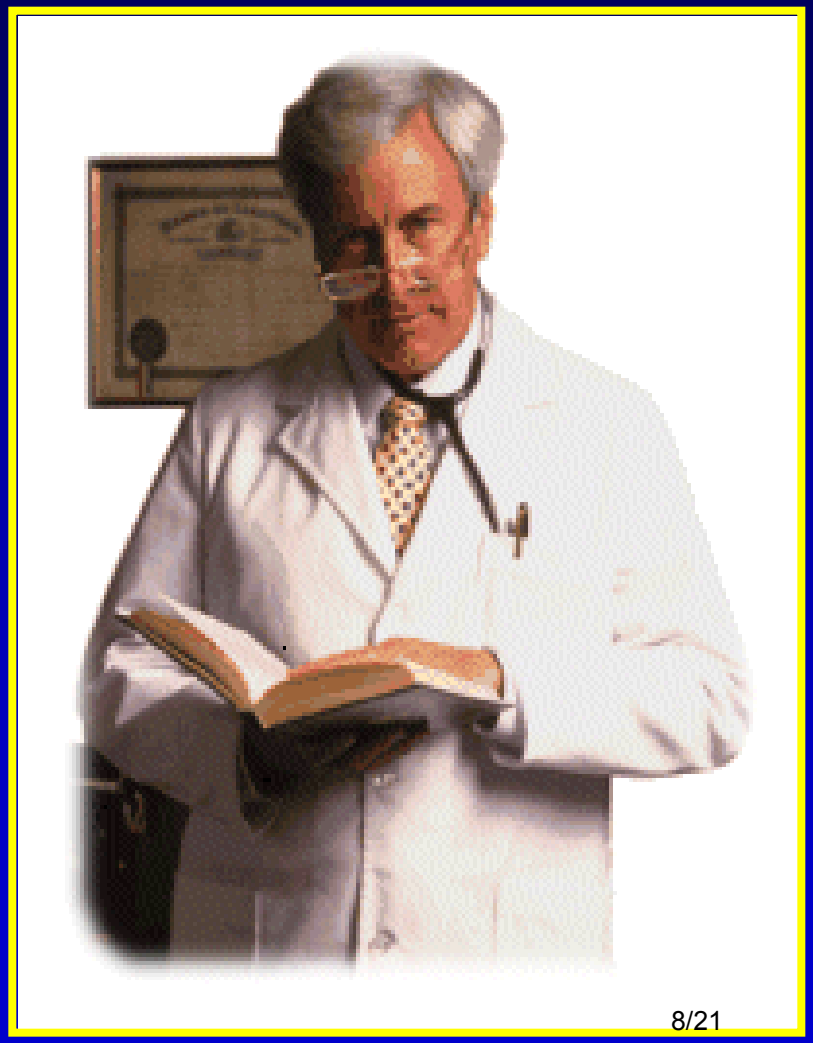
Y U should care

"If there isn't any evidence, we aren't going to pay."

Gary Franklin

How health care progresses….

Eminence-Based Practice: Prestigious, silver-haired health care provider advocates for treatments with which he or she is familiar, and of course he or she knows best.

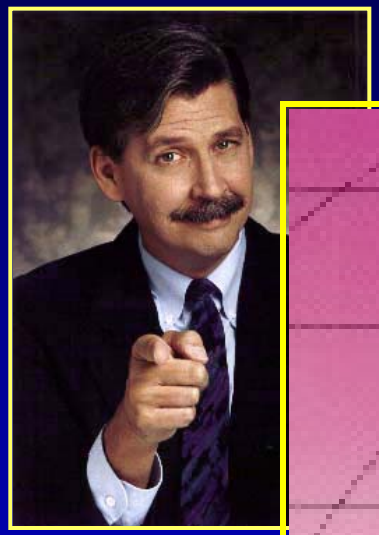


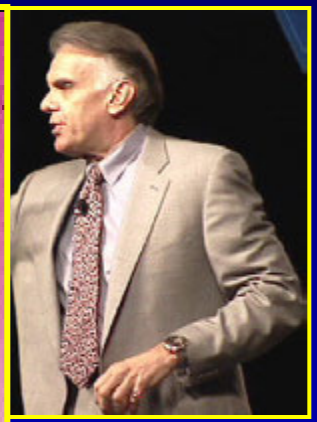
How health care progresses….

Faith-Based Practice: There is no need for evidence for clinical decision-making, just trust in a "higher power" (eg, pharmaceutical representatives detailing you)!

How health care progresses….

Eloquence-Based Practice:





The "Why" Chromosome -- Why Is EBP Needed, Or Is It?

- Rapid advances in knowledge
- Only about 15% of medical interventions are supported by solid scientific evidence
- Rate of publication is voluminous
- Standardization of methods to appraise data across trials

Why Is EBP Needed, Or Is It?

- Promotes more efficient use of available healthcare resources
- Striking variation in clinical practice
- Overcome clinical entropy
- Lag between evidence and practice

Today's dogma is tomorrow's dog meat!

What's the Evidence for Treatment Benefit?

"Evidence is what is evident, based on my experience"

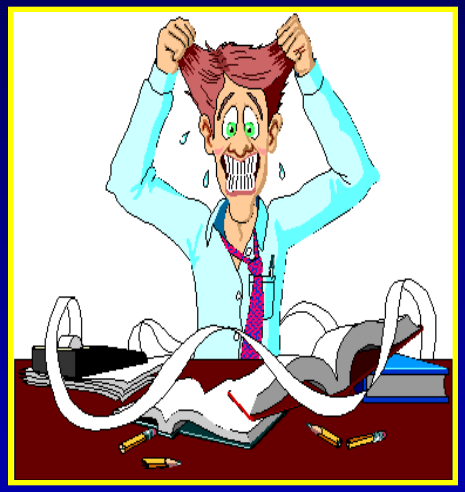
The plural of anecdote is not….

Evidence

But, there is as much disagreement as to what qualifies as *evidence* as there is to what constitutes good clinical practice.

Gap Between Data and Conclusions

How health care progresses….



Evidence-Based Practice: Published studies, when possible randomized, double-blind, placebo controlled trials. But not always possible.

EBP Not New – Early Comments About Evidence & Need for Clinical Trials

- Old testament, Book of Daniel describes what we now call a "prospective clinical trial" confirming the benefits of a diet of gain and water versus the royal household diet of meat and wine.[1]
- Jewish sage, Maimonides in the 12th century: "If anyone declares to you that he has actual proof, from his own experience, of something that he required for the confirmation of his theory – even though he be considered a man of great authority, truthfulness, earnest words and morality – yet, just because he is anxious for you to believe his theory, you should hesitate."[2]

[1]Holy Bible, Book of Daniel 1:3-20; [2]Maimonides M. Ethical Writings of Maimonides. Weiss RL, Butterworth C, eds. New York: Dover, 1975

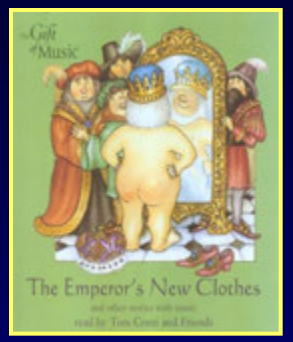
Rapid Spread of EBP

Increasingly advocated for:

- guiding clinical practice
- shaping research agendas
- formulating policy
- allocating financial resources

Eddy DM. Health Affairs 2005;24:9-17; Lambert et al. Soc Sci Med 2006;62:2613-20

What is EBP? Haute Couture or the Emperor's New Clothes?



"Refers to the use of evidence, specifically in the form of quantitative research data, concerning the effectiveness of a variety of medical interventions, to guide decisions about whether to use those interventions in health care practice. … The primary goal of EBM is to improve health outcomes through the deployment of the most effective interventions."

Gupta M. J Evaluation in Clin Pract 2003;9:111-21

Why Resistance to EBP?

- Concern about loss of autonomy
- Belief that will diminish clinical experience and expertise
- Concern that will interfere with provider-patient relationship
- Published results do not represent experience – decontextualizes clinical practice
- Published clinical trials do not represent practice – "grey zones"[1]
- Relies on the "average" and belief that there really is no average patient and patients are complex
- Believe EBP will be used solely for cost – containment (ie, financially motivated)

Naylor DC. Lancet 1995;345:840-2

Why Resistance to EBP?

Promotion of "cook book" medicine[1] – offers more than it can deliver

Crustulibriphobia:

An irrational fear of cookbooks

[1]Sleigh JW. Lancet 1995;348 (8983):1172

Many Interventions Accepted Without Published Clinical Trials

Some examples:

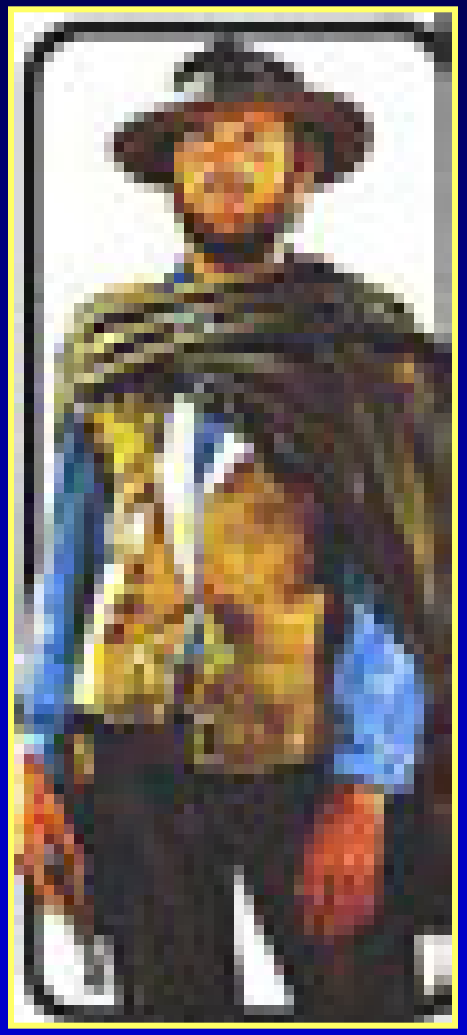
- Insulin for diabetes
- Suturing for large wounds
- Blood transfusion for severe hemorrhagic shock
- Defibrillation for ventricular fibrillation
- Ether for anesthesia
- Some things are so obvious evidence not required…

Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Smith GCS, Pell JP. BMJ 2003;327:1459-61

Conclusion: "Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomized controlled trials."

EBP - The GOOD



“One is instantly reminded of the malign influence of fashion on medicine, more than any other science. Even nowadays it is subject to fads although no science is more profitable.”

Pliny the Elder, 23-79 AD

An Antidote to Anecdotes

- Prevents selectivity (bias?) in studies read
- Alternative to reliance on what learned during training
- Reduces exclusive reliance on mentors & "experts"
- Synthesis of multiple studies that meet established standards and consequently are "carefully designed" -- can improve practice (eg, bed rest for back pain)
- Explicit study inclusion criteria to assure quality control
- "Gold standard" for establishing treatment effectiveness
- Potential sources of bias are minimized (*perhaps*) and likely validity of the conclusion is maximized
- Provides "dispassionate Truth" (?) based on objective science

Steps in EBP

- Formulate question to answer and information needed
- Seek answers supported by best evidence
- Examine the quality of the evidence
- Apply evidence to implement best practice
- Evaluate in health care practice

Sources of Evidence

- Cochrane Collaboration reviews
- Other published meta-analyses and systematic reviews
- Commissioned reviews
- Published studies (different languages) using electronic data bases (eg, MEDLINE, CINAHL, Embase, many, many others)
- Abstracts, unpublished studies, and data
- References in published manuscripts

Judging the Quality of Evidence

Highest

I. Meta-analysis of multiple well-designed controlled studies

II. Well-designed experimental studies

III. Well-designed quasi-experimental studies such as nonrandomized controlled, single-group pre post, cohort, time series, or matched-case controlled studies

IV. Well-designed non-experimental studies such as comparative and correlational, descriptive and case studies

V. Case reports and clinical examples

Lowest

VI. Expert opinion

Judging the Strength of the Evidence

A. There is evidence of type I quality or consistent findings from multiple studies of types II, III, or IV.

B. There is evidence of types II, III, or IV quality, but findings are generally consistent.

C. There is evidence of types II, III, or IV quality, but findings are inconsistent.

D. There is no evidence, or there is type V quality evidence only. Panel consensus: practice is recommended on the basis of the opinions of experts.

EBP -- The BAD

Some Criticisms of EBP

- Oversimplifies the complex and interpersonal nature of clinical care
- May be the gold standard for effectiveness but not adverse effects, prognosis, or diagnosis
- Absence of published studies ("*Absence of evidence is not evidence of absence*!"[1])
- Hampering of innovation if strictly applied to new txs
- Reliability of abstract review and inclusion
- Variability in entry criteria for inclusion, outcome criteria & measures
- Combining marginally-related studies
- Lag from study completion, to manuscript preparation, acceptance, publication – timeliness of updates

[1]Altman DG, Bland JM. BMJ 1995;311: 485

Even More Criticisms of EBP

- Composition panel of experts and sponsor
- Heterogeneity in quality of studies combined. Over 49 systems to rate strength of evidence![1] Choice of evidence criteria and levels can lead to widely discrepant results.
- Studies of interventions likely to have commercial value most likely to be supported (eg, drug trial vs. physical therapy trial), positive, and published – EBP: Economic–Based vs. Evidence-Based Practice
- Generalization from clinical trials to clinical practice ("efficacy" vs. "effectiveness" trials)
- Feasibility of RCTs (eg, SCS vs. repeat surgery)

West et al. Systems to Rate the Strength of Scientific Evidence. Evidence Report/Technology Assessment No. 47. Rockville, MD: AHRQ, 2002. AHRQ Publication 02-E016

And Still MORE Problems with EBP

- Provide information about groups not individual patients (what is relevance of group data for individual patient – eg, Depressed LBP patient with history substance abuse, work loss, and pending litigation)
- Ignores patient preference, societal values, and health care resources

Boston Globe story headline

"Recent studies have challenged the effectiveness of a popular kind of back surgery, yet many patients – and their doctors – say vertebroplasty works" What is the truth?

Kay Lazar. Boston Globe, Monday, August 24, 2009

Yet MORE Problems with EBP

- Exclusive ("evangelical") reliance on RCTs (RCTism) as the sole means to establish The TRUTH
- Idolatry of statistical significance, worship of *P*-value

A Final Problem with EBP

"A difference is not a difference, unless it makes a difference."[1]

Over reliance of statistical significance with Inadequate attention to clinical significance or meaningfulness of the results –

Minimally Important Difference

Although there may be statistically significant differences between treatments, the effect sizes may be small

[1]Huff D. How to Lie with Statistics. New York: W.W. Norton, 1954

EBP - The UGLY

How are Sausage and EBP Alike?

You may not want to know the processes involved in creating the final product

How Sausage, Meta-analyses, and Guidelines Are Made

Subjectivity Inherent

- Inconsistency among conclusions of different reviews even using similar quality ratings[eg,1]
- Variability of results among outcome criteria
- Inconsistency in use of inclusion criteria
- Large number of mechanical errors of data extraction in meta-analyses of pooled trials[2]
- Variability in outcome criteria and measures (ease of measurement vs. relevance)
- How much Evidence-based vs. Belief-based?

[1]Hauser et al. Eur J Pain 2010;14:5-10; [2]Gotzsche et al. JAMA 2007;298:430-7 [Erratum 2007;298:2264]

Subjectivity Inherent

- Technical bias favors research know how to do

Evidence B(i)ased Practice

- Positive results more likely to be published "File-draw problem"[1]
- Industry sponsored trials are more likely to report positive results[4]
- 80% of clinical trials are funded by industry[2]
- Evidence b(i)ased practice – selective reporting of results (eg, data mining)[3-5]

[1]Rosenthal R. Psych Bull 1979;86:638-41; [2]Brezis M. Isr J Psychiatry & Relat Sci 2008;45:83-9; [3]Melander et al. *BMJ* 2003; [4]Sismondo S. Contemp Clin Trials 2008;29:109-13;[5]Vedula et al. New Engl J Med 2009;361:1963-71

Illustration of the Problem: Example of Implantable Devices

Taylor et al[1]

- Only 1 RCT & 72 case series of SCS for CLBP
- Case series were poor quality
- Predictor of success in case series = poor quality, short duration, inclusion of FBSS
- RCT: 37.5% of patients showed 50% or greater pain relief vs. 11.5% for re-operation

Vs.

Cameron[2]*

- 16 studies (616 CLBP patients)
- 2 prospective controlled
- 62% reported >50% pain reduction
- But only 3/8 of the prospective controlled trials of SCS for any pain problem reported any statistically significant benefit

*employee of Advanced Modulation Systems company that manufactures and sells SCS

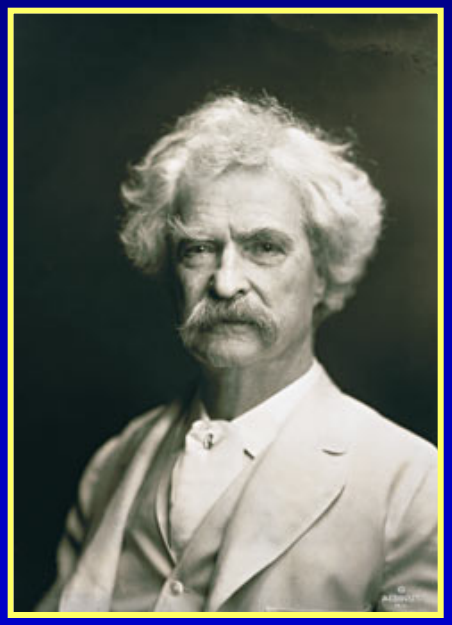
[1]Spine. 2004;30:152-61; [2]Cameron J Neurosurg (Spine 3) 2004;100:254-67

Common Sources of Bias in Research

- Observer bias
- Participant bias
- Instrument bias
- Reporting bias
  - Publication bias
  - Time-lag bias
  - Funding bias
  - Outcome criteria bias

Conclusion from an Eminent Observer

"Lies, damn lies, and statistics"



Mark Twain

Some EBP Paradoxes

- "Only limited evidence has accumulated to show that 'medicine by EBP' is really superior to 'medicine as usual'.[1]
- Case examples of discrepancies of RCT and other "inferior" studies; yet, case reports are low in hierarchy of evidence.
- EBP, which aims to eliminate bias can be a source of bias!
- If all RCTs yielded the same results would not need systematic reviews.

[1]Miles et al. J Eval Clin Pract 2003;9:95-109

Some EBP Paradoxes

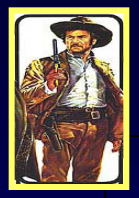
- "Meta-analysis, initially created as a tool intended to ease clinical decision-making, is becoming progressively more complex. The growing complexity is rendering EBP less and less able to offer simple, clear, useful solutions to real-world clinical problems.[1]
- Often more reviews and meta-analyses than RCTs published on the topics.[2-3]
- Reviews often conclude "the quality of the studies are not good enough, effect sizes are too small, and more and better research needed".

[1]Carr DB. Reg Anesth Pain Med 2008;33:229-40; [2]Assendelft et al. Cochrane Database System Rev 2004:CD000447;[3]Hoving et al. Spine 2001;26:196-205;

Some EBP Paradoxes

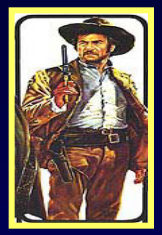
A historical review of heart disease recommendations noted that although the number of guideline recommendations has increased so to has the proportion based on lower levels of evidence or clinical opinion.

Tricoci et al. JAMA 2009;30:831-41



Some Problems With RCTs

- Sample included in clinical trials may not represent clinical practice (eg, volunteers), inclusion/exclusion criteria (eg, exclude women of child-bearing age, limits on age, presence of depression, co-morbid medical conditions)
- Difficulties with “blinding” (eg, surgery, PT)
- Provider willingness to refer
- Patient willingness to be randomized in a placebo trial



Ethical Problems With RCTs

- Use of placebo treatment especially when an efficacious treatment is already available
- Is it ethical to deny patients trials of interventions because the average responses to such interventions did not differ from placebo in earlier published trials?

Some Problems With Clinical Trials

- Method of recruitment will influence representativeness of the sample
- Where trial conducted (eg, US, India, Russia)
- Characteristics of volunteers for clinical trials
- Precision of diagnoses across sites
- Problem of dropouts and loss to follow-up

Some Problems With Clinical Trials

- Short trial duration (typically 3-6 mos.)
- Determining appropriate comparators (eg, SCS)
- Determining primary & most relevant end-points
- How to handle multiple end-points
- Difficult to study complex (multicomponent) treatments (eg, rehabilitation) in RCTs. Sample size and therefore costs may be prohibitive, isolating each component might dilute treatment, blinding may not be possible

The WRONG Question

"Is Tx A effective?"

Creates a false dichotomy:

- **Yes or no**
- **0% response vs. 100% response**

The RIGHT Questions

- "Is Tx A more clinically effective than Tx B?"
- "On what criteria?"
- Delivered how, by whom, when?
- "With what adverse effects?"
- "For whom?" and
- "Is Tx A more cost effective than Tx B?"

Criteria of Success

Importance to society

Importance to employer

Return to work

Importance to payers

Health care utilization

Functional improvements

Importance to HCP

Patient satisfaction

Pain relief

Importance to patient

Evolution of EBP

"The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients"

Sackett et al., 1996[1]

4 years later enter a paradox

"…the integration of best research evidence with clinical expertise and patient values."

Sackett et al., 2000[2]

[1]Sackett et al., BMJ, 1996;312:71-2;[2]Sackett et al. Evidence-based Medicine: How to Practice and Teach EBM, 2nd ed. Edinburgh: Churchill Livingstone

Questions to Consider Regarding Clinical Practice Guidelines & Recommendations

- Who involved in development?
- Who supporting development?
- What was the nature of the development Were patients/practicing clinicians consulted?
- Who conducted computerized searches?
- What dates of study inclusion?

Questions to Consider Regarding Clinical Practice Guidelines & Recommendations

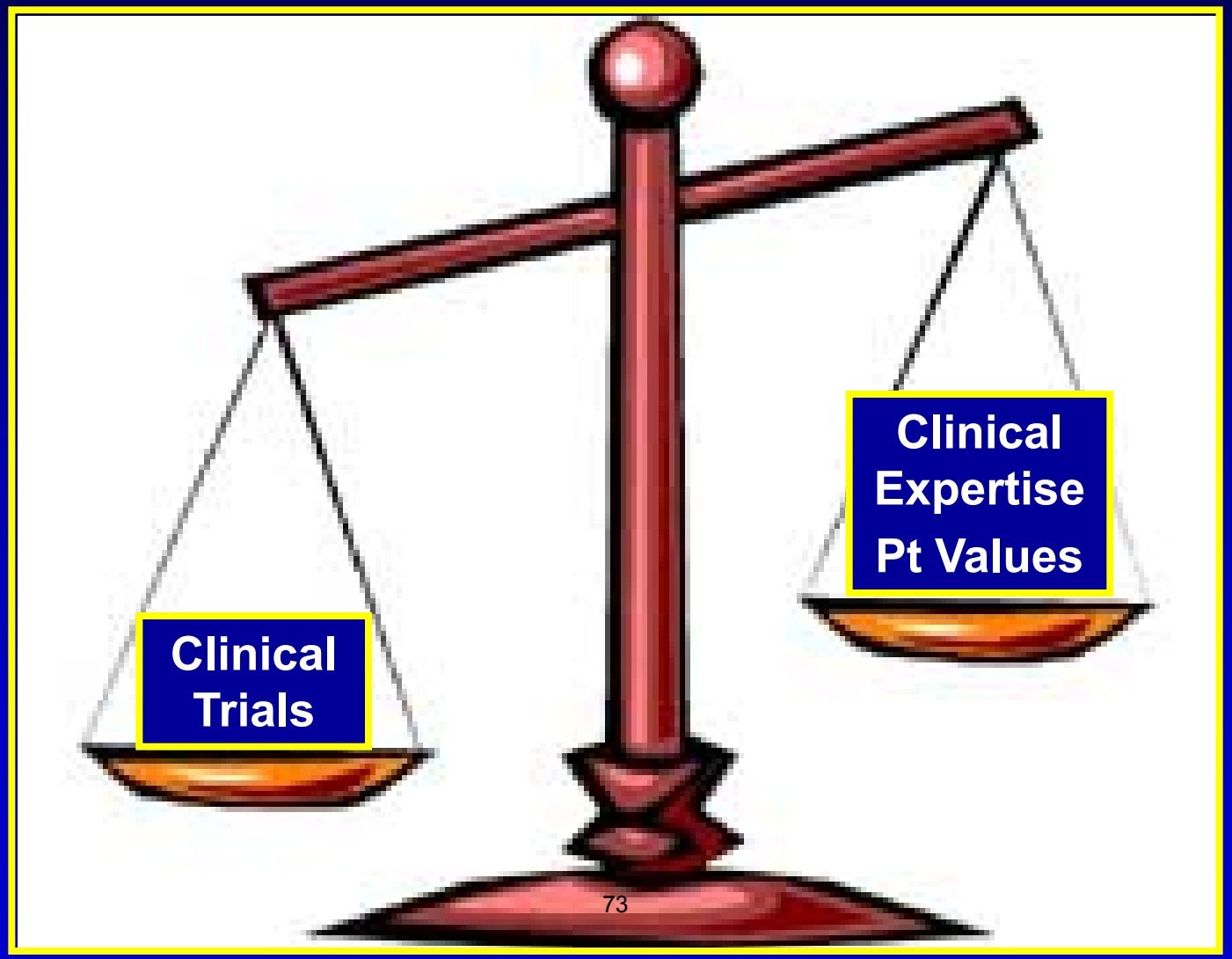
- W
- W
- W
- Ho
- Ho
- Ho
- Ha

not, why and

Warning: Males, avert your eyes

Whose ox do you gore?

Finding the Right Balance



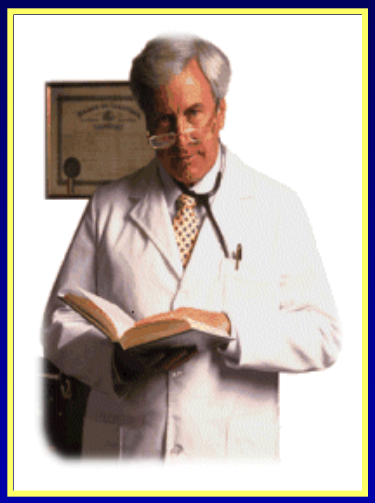
How health care progresses

Evidence-informed Practice

Evidence alone, no matter how clear, is never sufficient to make a clinical decision. The final decision is influenced by clinicians' and patients' weighing of benefits and risks, values, preferences, and expectations, and the inconvenience, availability, and costs of treatments.[1]

[1]Croft et al. Spine 2011;36:E1121-5

You Decide, Which is the Good, the Bad, and the Ugly



- Eminence-based Practice
- Eloquence-based Practice
- Faith-based Practice
- Evidence-based Practice
- Evidence-informed Practice

Conclusion: What EBP Is Not

- Not a textbook
- Not a cookbook
- Not a substitute for clinical judgment
- Not a standard of care (legal issues)
- Not cost-cutting medicine (ethical issues)

Conclusions

- Be cautious in accepting results of RCTs, meta-analyses, and clinical practice guidelines
- Be cognizant of the limitations
- Remember the inherent subjectivity regardless of the technical sophistication reported
- Be wary of a false sense of certainty created by EBP
- Limited EVIDENCE for EBP

CAVEAT EMPTOR!

- Yet, EBP and guidelines are being used in court as the basis for litigation against clinicians and employers.[1]

[1]Davies J. Med Law 2009;28:603-13

Conclusion

EBP is an important tool although is can be over- and mis-applied, it must be balanced with clinical experience, patient preferences, societal values, & resources = **EIP**?

- How to weight and balance?
- Who decides?
- Is EIP testable?
- Does it lead to better outcomes?
- Does including values, preferences, & resources defeat the very rationale of EBP?

Don't throw the babies out with the bathwater!

References Related to Evidence-Based Practices Cited in Presentation

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Federation of STATE MEDICAL BOARDS

PROMOTING THE HIGHEST STANDARDS FOR MEDICAL LICENSURE AND PRACTICE



Protecting
Advocating
Serving

Protecting
Advocating
Serving

Social Media and Medical Practice

Jon Thomas, MD, MBA
President, Minnesota Board of Medical Practice
Chair-Elect, FSMB Board of Directors

Washington State Medical Commission Educational Workshop
August 22, 2012

82

Greetings from the FSMB Board of Directors

Today's Agenda

- **FSMB "New Directions"**
  - Vision and Mission

- **Key Topic:**
  - Social Media and Medical Practice

FSMB Vision & Mission 2010-2015

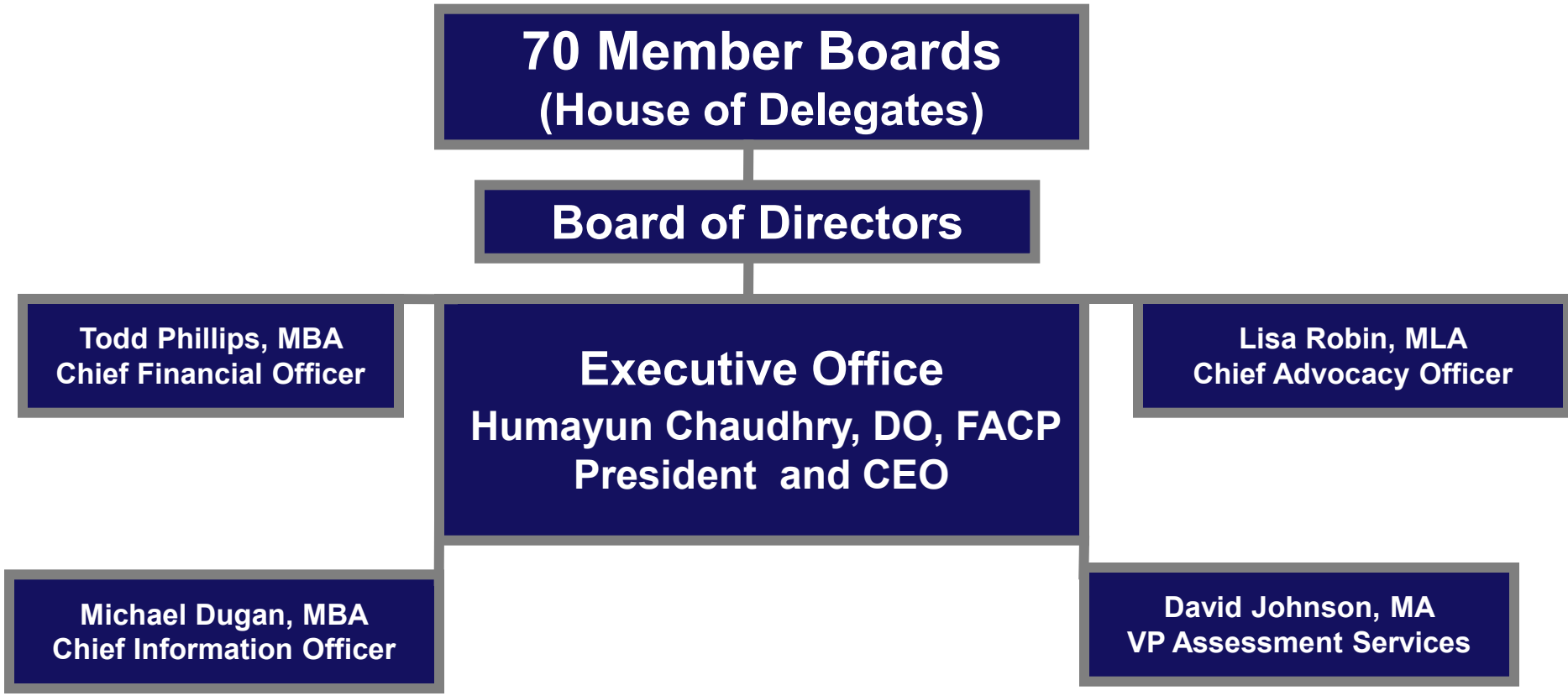
Vision

The Federation of State Medical Boards is the leader in medical regulation, serving as an innovative catalyst for effective policy and standards.

Mission

FSMB leads by promoting excellence in medical practice, licensure, and regulation as the national resource and voice on behalf of state medical boards in their protection of the public.

How FSMB priorities are established



FSMB Committee & Workgroup Structure

Committees Reporting to the House of Delegates	
Bylaws	Reference
Nominating	Rules

Committees & Workgroups Reporting to the Board of Directors	
Standing Committees: Audit Editorial Education Ethics & Professionalism Finance	**Workgroups**: Define a Minimal Data Set Examine Composite Action Index and Board Metrics Innovations in State-based Licensure International Collaboration MOL Implementation Group MOL on Non-Clinical Physicians Office-Based Opioid Treatment Pain Policy
Special Committee on Physician Re-entry for Formerly Impaired Physicians	

Advisory	
Advisory Council of Board Executives	FCVS Advisory Council

Social Media

- The medical community faces both opportunities and challenges as social media and social networking websites play a more active role in health care
- Guidance on the usage of social media is necessary to protect physicians and patients alike
- In 2011, FSMB Chair Janelle Rhyne, MD, directed the Special Committee on Ethics and Professionalism to develop guidelines for state boards to consider for educating licensees on proper usage of social media

The Doctor Will Connect With You Now…

- In 2011, *QuantiaMD* surveyed more than 4,000 physicians and found that 87% use a social media website for personal use and 67% use social media for professional purposes
- Research has also found 35% of practicing physicians received friend requests from a patient or member of their family
- 16% of practicing physicians have visited an online profile of a patient or patient's family member

Where the Problem Lies

- Boundaries of Professionalism
- Violating Privacy and Confidentiality of Patients

- A 2010 survey of state medical board Executive Directors found that 92% had indicated that violations of online professionalism were reported in their jurisdictions, including:
  - Inappropriate contact with patients (69%)
  - Inappropriate prescribing (63%)
  - Misrepresentation of credentials or clinical outcomes (60%)

What Physicians Using Social Media Should Do

- Protect the privacy and confidentiality of patients
- Avoid requests for online medical advice
- Act with professionalism
- Be forthcoming about employment, credentials, and conflicts of interest
- Be aware that information posted online may be available to anyone, and can be misconstrued

Examples of Misuse

A physician comes across the profile of one of his patients on an online dating website and invites her to go on a date with him. The patient feels pressured to accept the invitation because her next appointment with her physician would be awkward if she refuses.

A concerned patient notes that her physician frequently describes "partying" on his Facebook page, which is accompanied by images of himself intoxicated. The patient begins to question whether her physician is sober and prepared to treat her when she has early morning doctor's appointments.

A first-year resident films another doctor inserting a chest tube into a patient. The patient's face is clearly visible. The resident posts the film on YouTube for other first-year residents to see how to properly do the procedure.

Guidelines for the Appropriate Use of Social Media and Social Networking in Medical Practice

- Interacting with Patients
  - Avoid interacting on personal social networking sites
- Discussion of Medicine Online
  - Social networking sites that allow for physicians to gather and share experiences, and discuss medicine and treatments are beneficial. But physicians should ensure that sites are secure and that only verified and registered users have access to information
- Privacy/Confidentiality
  - Never provide any information that can be used to identify patients (including room numbers, code names, and pictures)

Doximity

Guidelines for the Appropriate Use of Social Media and Social Networking in Medical Practice

- Disclosure
  - Reveal conflicts of interest and credentials when posting online
- Posting Content
  - Be aware that anything posted on a social networking site may be disseminated (whether intended or not) to a larger audience, and may be taken out of context or remain publicly available. Do not post ambiguous or false information.
  - Delete inaccurate information or other's posts that violate the privacy and confidentiality of patients or that are of an unprofessional nature

Guidelines for the Appropriate Use of Social Media and Social Networking in Medical Practice

- Professionalism
  - Use separate personal and professional social networking sites and passwords
  - Report unprofessional behavior witnessed to supervisory and/or regulatory authorities
  - Adhere to same professionalism standards both on and offline
  - Cyber-bullying is unprofessional
  - Refer to employer's social media or networking policy for direction on proper use in relation to employment

Medical Board Sanctions and Disciplinary Findings

State medical boards have the authority to discipline physicians for unprofessional behavior relating to the inappropriate use of social networking media, such as:

- Inappropriate communication with patients online
- Use of the Internet for unprofessional behavior
- Online misrepresentation of credentials
- Online violations of patient confidentiality
- Failure to reveal conflicts of interest online
- Online derogatory remarks regarding a patient
- Online depiction of intoxication
- Discriminatory language or practices online

Protecting
Advocating
Serving

Thank you!

Questions/Discussion/Contact Us

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UW Medicine
DIVISION OF
PAIN MEDICINE

MANAGING RULE 2876

Jane C Ballantyne MD FRCA

University of Washington School of Medicine
Seattle, WA

UW Medicine
DIVISION OF
PAIN MEDICINE

1. A bit of history
2. What's wrong with high doses
3. What would the ideal outcome be of Rule 2876
4. What happens to people on opioids
5. What are the current problems with Rule 2876

Doubtful Hope (1875) *by Frank Holl.*
Chemist's shop in London

An 18th century medical report declared: "there was not a village in all that region round but could show at least one shop and its counter loaded with the little laudanum-vials, even to the hundreds, for the accommodation of customers retiring from the workshops on Saturday night"

***Opium and the Opium Appetite,* A Calkins, Lippincott, Philadelphia, 1871 pp 33-5**

Princess Helena
1846-1923

The arrangement was not to prove a very satisfactory one: the Queen was to find Helena (her daughter) - who, like to so many of her contemporaries, became addicted to laudanum - 'difficult to live with'.

Christopher Hibbert in Queen Victoria, a Personal History, Da Capo press 2001, p 393

"No one who thinks of the early nineteenth-century opium addicts in terms of what their position would be today – forced to pester reluctant doctors …. or to pay large sums for illicit supplies … – will be able to understand the frame of mind of someone like Coleridge, who had no obstacles between him and the drug but his own conscience and the reproaches of his immediate family and closest friends ……

Alethea Hayter in "Opium and the Romantic Imagination"

Samuel Taylor Coleridge
1772-1834

The poet, Lord Byron
1788-1824

Walter Scott 1771-1832

William Wilkie Collins
1824-1889

BRITAIN

1920 Dangerous Drug Act
1924 Rolleston Committee

- permissive
- did not punish the user
- not illegal to provide opioid maintenance
- determined UK policies for 40 yrs

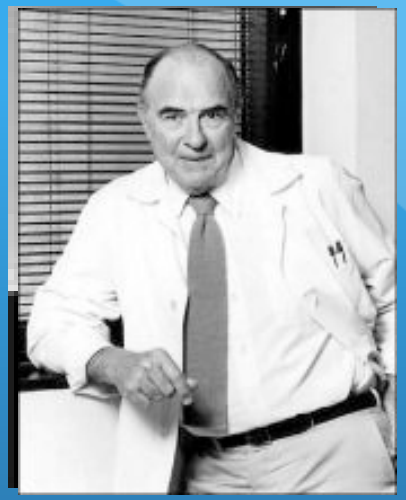
UNITED STATES

1918 Harrison Act
1919 *Webb versus the US*

- repressive
- user subject to harsh penalties
- suppressed maintenance prescribing
- determined US policies for 50 yrs

Advocates for addicts

Marie Nyswander, d 1986



Vincent Dole, d 2006

Mary Jeanne Kreek

1974 Narcotic Addict Treatment Act

- culmination of years of investigation 1966-72 by Nyswander, Dole and Kreek and others
- ended 50 yrs of no prescribing for addiction

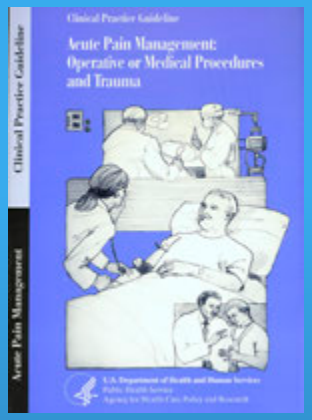
Portenoy and Foley

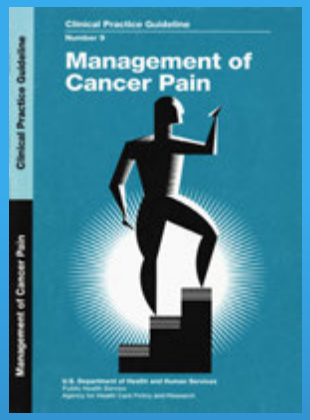
Chronic use of opioid analgesics in non-malignant pain: report of 38 cases

Pain 1986;25:171-86

Russell Portenoy

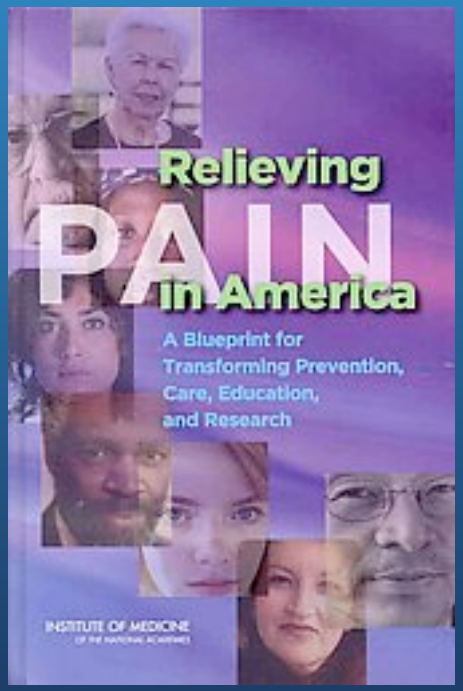
Kathleen Foley





1991-2 Agency for Healthcare Policy and Research

2001 The Joint Commission for the Accreditation of Hospital Organizations



2011 Institute of Medicine

At least 100 million American suffer undertreated pain at a cost of $635 billion in medical bills, lost productivity and missed work. Described as a 'public health crisis'

AHCPR 1992, AHCPR 1994, JCAHO 2001, IOM 2011

Distribution of Prescription Opiates to U.S. Pharmacies, 2000-2010 (DEA data)

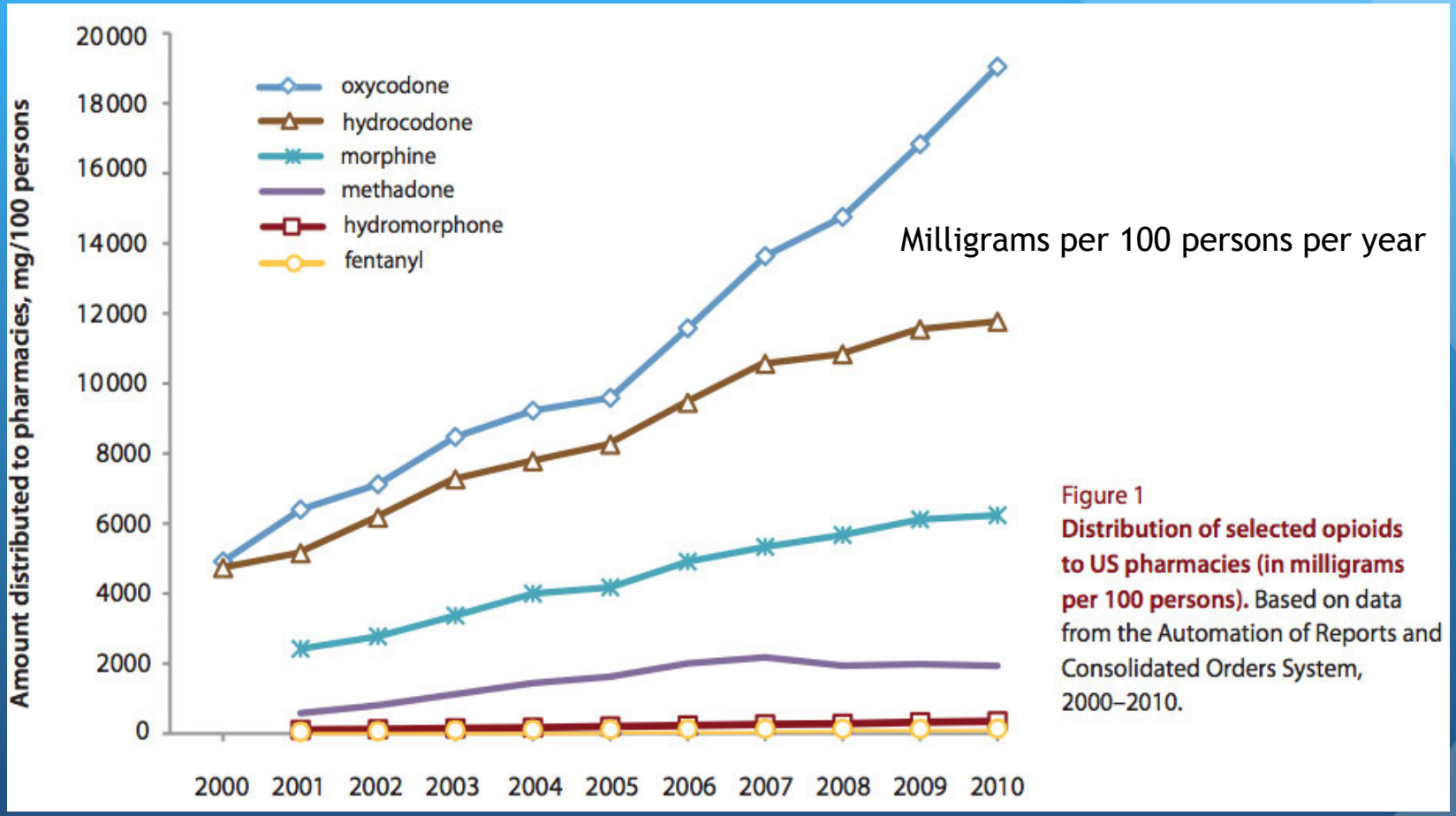


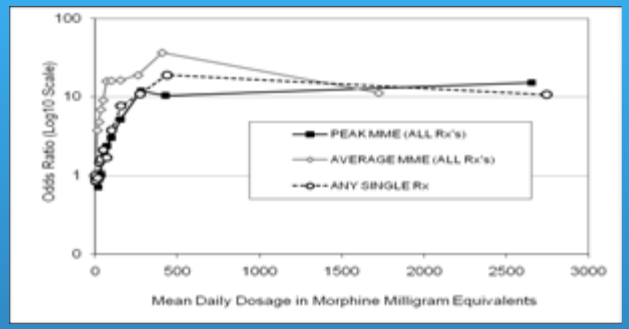
Figure 1
Distribution of selected opioids to US pharmacies (in milligrams per 100 persons). Based on data from the Automation of Reports and Consolidated Orders System, 2000–2010.

Source: Kenan K, Mack K, Paulozzi L. Open Medicine 2012; 6:e41.

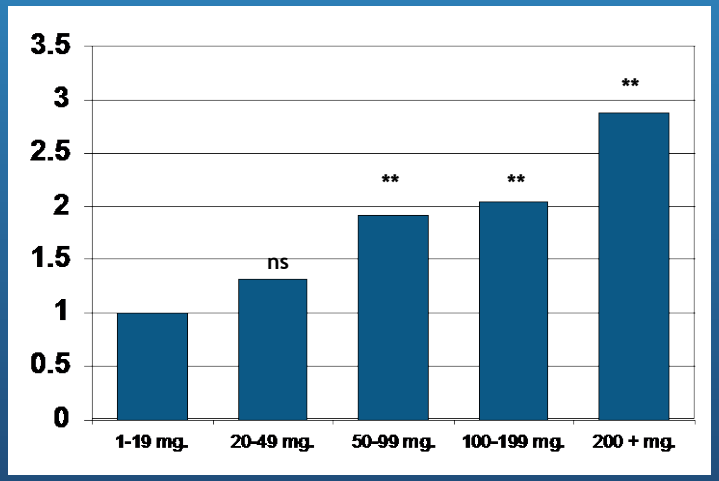
What's wrong with high doses

DEATHS AND HIGH DOSES

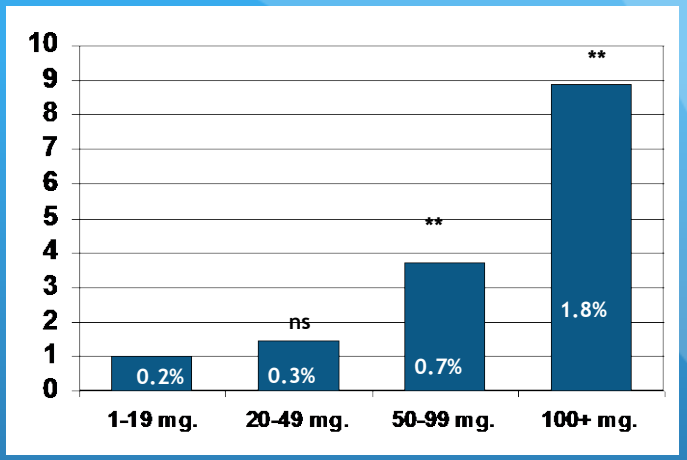
Crude association of daily dosage of opioid analgesics with risk of unintentional drug overdose death,
New Mexico, October, 2006—March, 2008



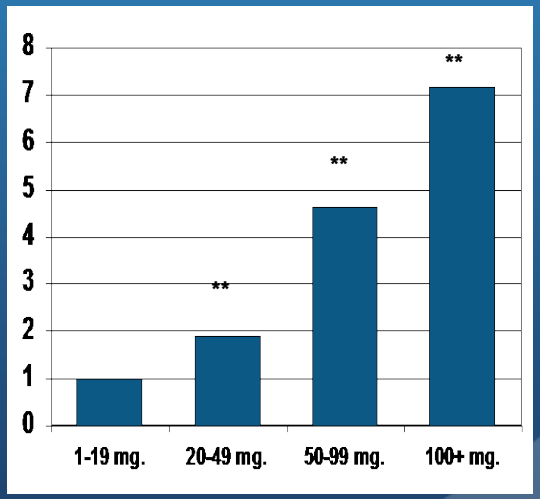
Paulozzi , et al. Pain Med 2012; 13:87-95



Gomes et al., Arch Int Med, 2011



Dunn et al., Annals Int Med, 2010



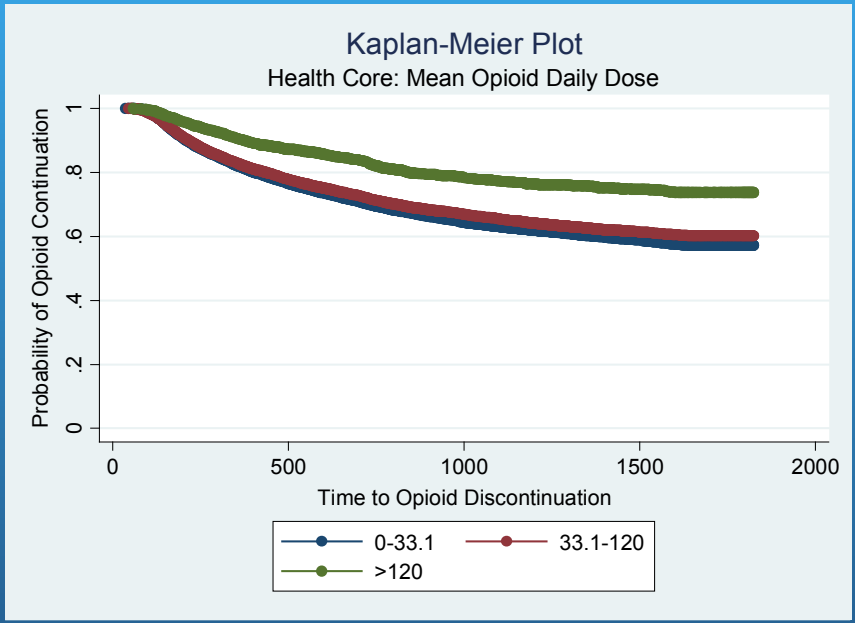
Bohnert et al., JAMA, 2011

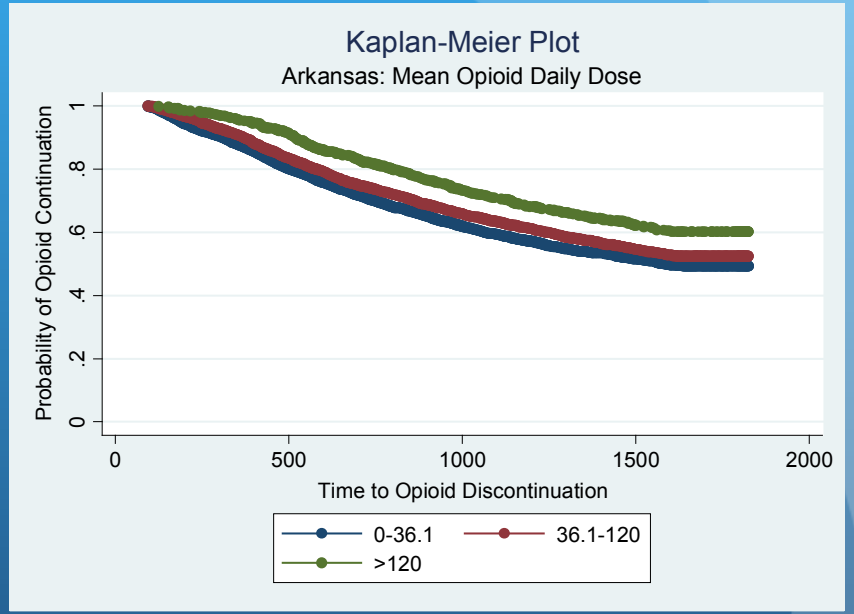
COT discontinuation

- Once started on a course of COT, how long do patients remain on opioids?
- TROUP study of COT recipients (used at least 90 days without a 32 day gap)
- Outcome: 6 months without any opioid Rx

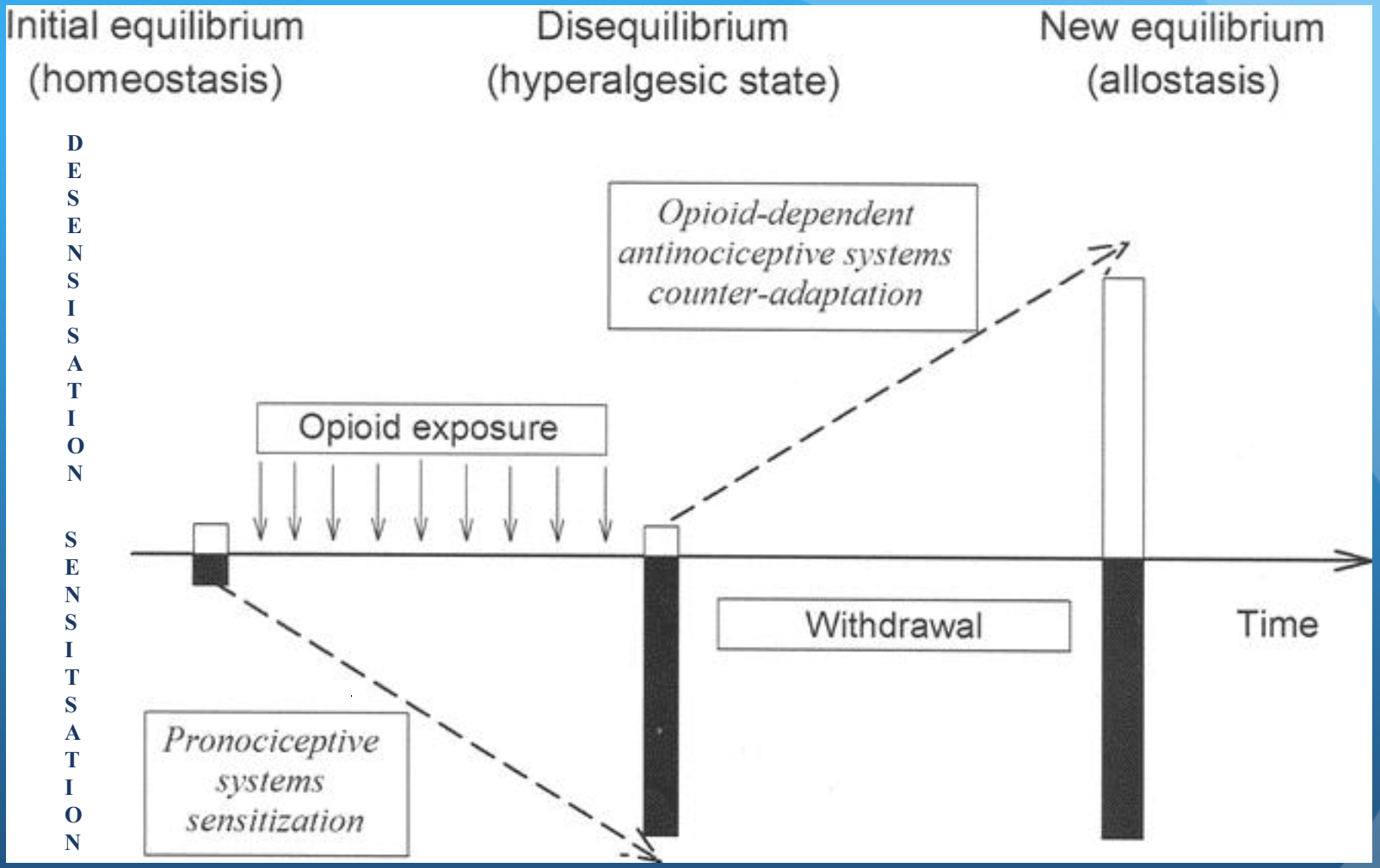
Martin B, et al. , *J Gen Intern Med,* 2011; 26:1450-7.

COT discontinuation





Martin B, et al. , *J Gen Intern Med*, 2011; 26:1450-7.



Model of neuroadaptive changes underlying expression and recovery of opioid-induced hyperalgesia

Angst & Clark Anesthesiology 2006;104:570

Increase in neonatal abstinence

The JAMA Network

From: **Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000-2009**

JAMA. 2012;307(18):1934-1940. doi:10.1001/jama.2012.3951

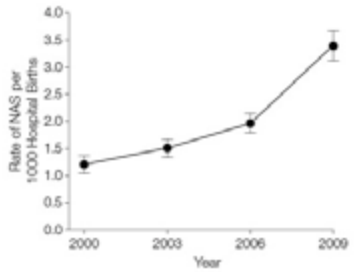


Figure Legend:

NAS indicates neonatal abstinence syndrome. Error bars indicate 95% CI. P for trend <.001 over the study period. The unweighted sample sizes for rates of NAS and for all other US hospital births are 2920 and 784 191 in 2000; 3761 and 890 582 in 2003; 5200 and 1 000 203 in 2006; and 9674 and 1 113 123 in 2009; respectively.

Increase in mothers on opioids

The JAMA Network

From: **Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000-2009**

JAMA. 2012;307(18):1934-1940. doi:10.1001/jama.2012.3951

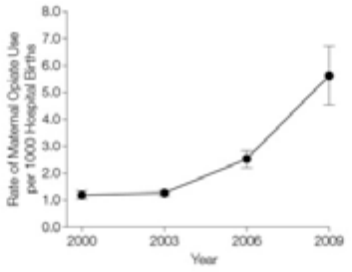
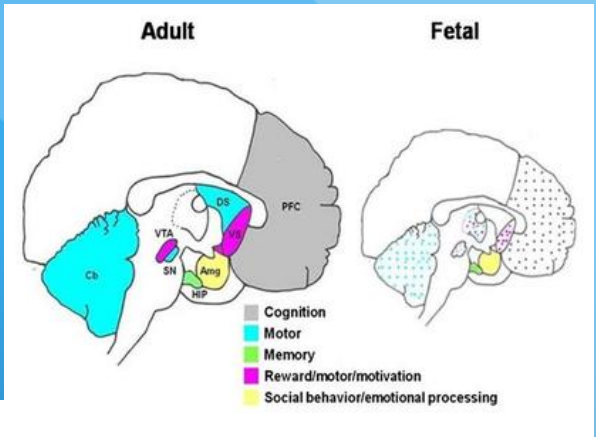


Figure Legend:

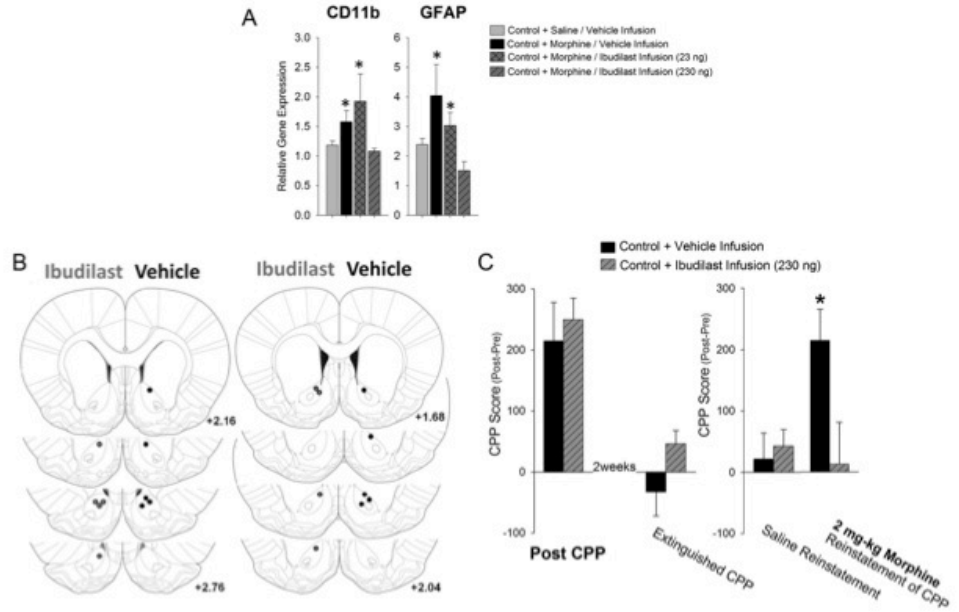
Error bars indicate 95% CI. P for trend <.001 over the study period. The unweighted sample sizes for mothers diagnosed with and without antepartum opiate use are 987 and 833 494 in 2000; 1058 and 849 133 in 2003; 2160 and 879 910 in 2006; and 4563 and 816 554 in 2009; respectively.

The fetal brain is different

New studies suggest that fetal changes change abuse risk later in life



Infusion of ibudilast directly into the NAcc blocks the drug-induced reinstatement of morphine CPP in control rats.



Schwarz J M et al. J. Neurosci. 2011;31:17835-17847

The Journal of Neuroscience

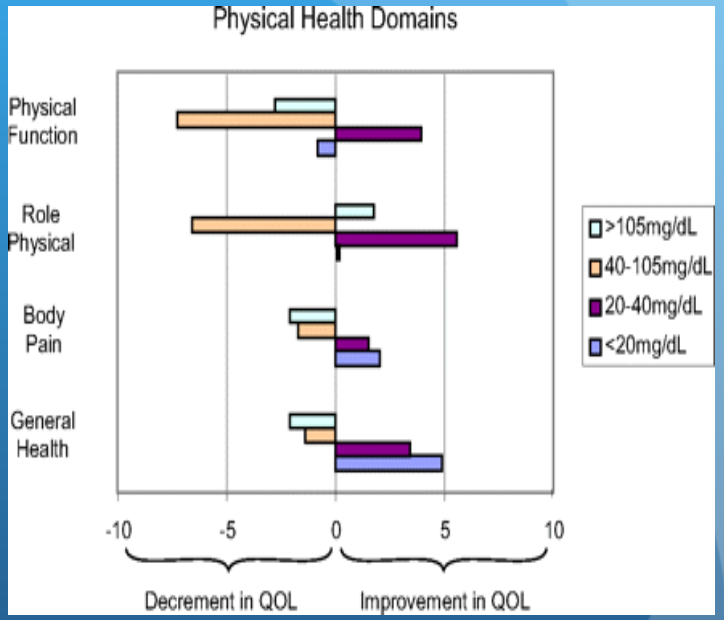
OPIOIDS, FUNCTION AND RETURN TO WORK
Relationship to high dose

Webster et al 2007 after controlling for covariates (including injury severity), mean disability duration, mean medical costs, risks of surgery and later opioid use all increase with MED

Dillie et al 2008 All health domains deteriorate rather than improve at > 40 mg MED, and the only improvement for higher doses are in emotional and mental health

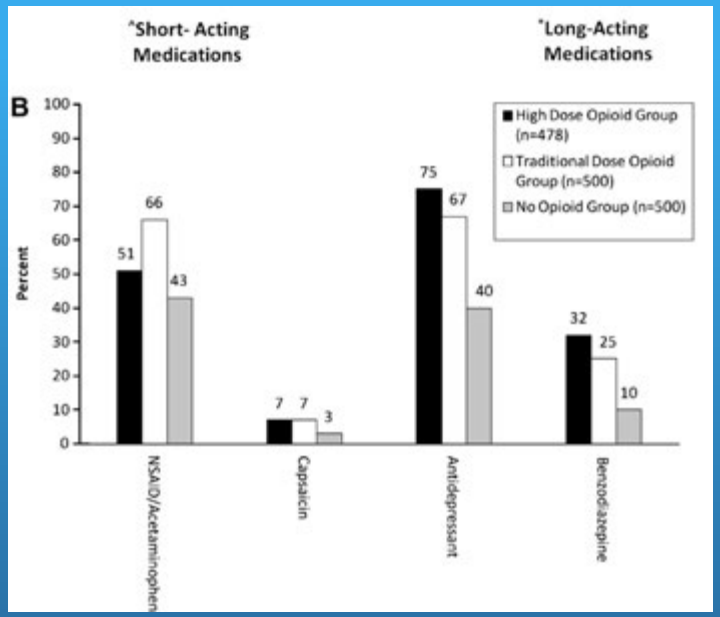
Kidner et al 2009 Both high dose groups (61-120 and >120 mg MED) are significantly related to lower rates of return to work and work retention, higher healthcare utilization and higher disability

CONSORT data 56% of lower dose users (<50 mg MED) are working compare to 39% of moderate dose users (50-99 mg MED) and 36% of higher dose users (>100 mg MED)



Webster et al Spine 2007;32:2127-32
Dillie et al, J Am Board Fam Med 2008;21:108
Kidner et al, J Bone Joint Surg Am 2009;91:919

ADVERSE SELECTION AND HIGH DOSE



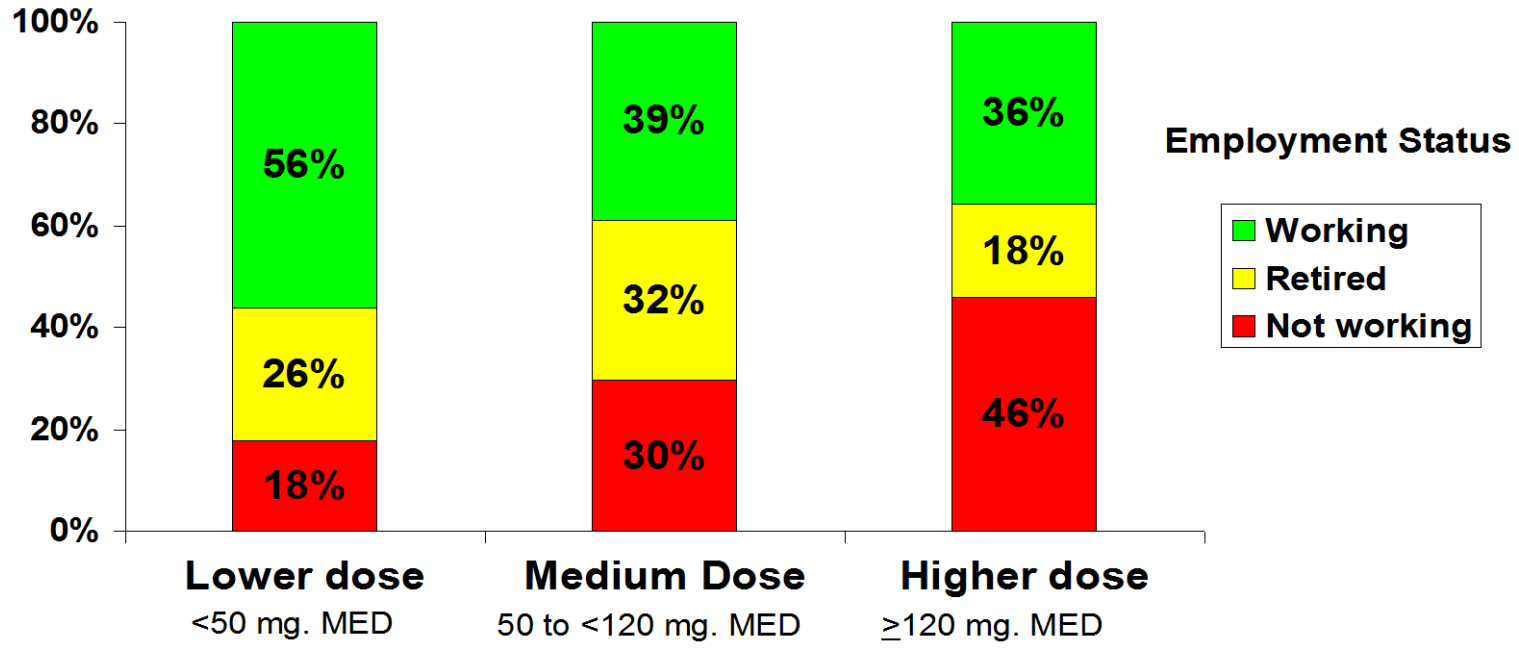
Clinical characteristics of veterans prescribed high doses of opioid medications for chronic non-cancer pain

Morasco et al Pain 2010;151:625

Weisner et al Pain 2009;145:287-93
Morasco et al Pain 2010;151:625
Edlund et al Clin J Pain 2010;26:1-8
Martin et al J Gen Intern Med 2011;26:1450-7
Seal et al JAMA 2012;307:940-7

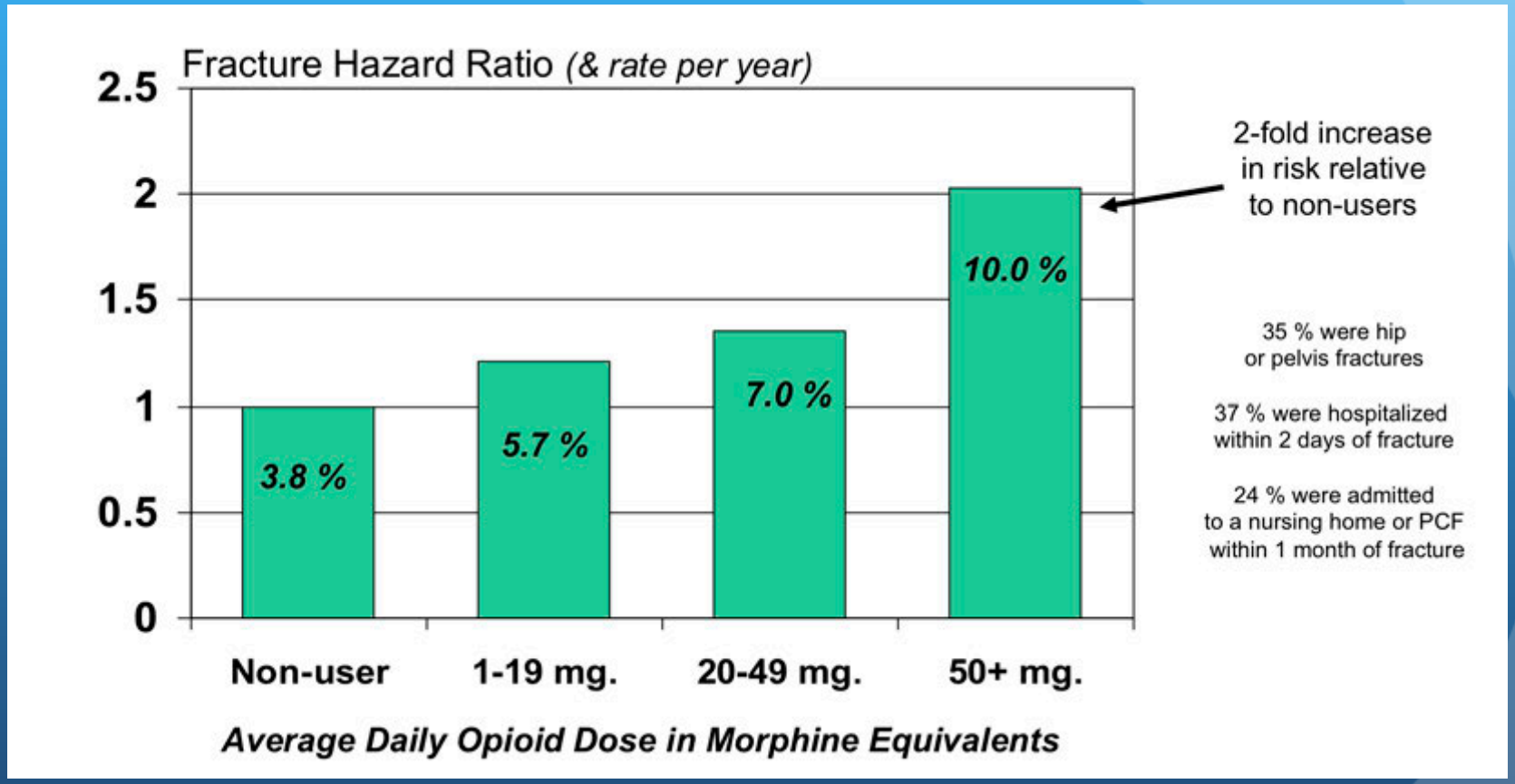
Employment Status
COT Patients by Average Daily Dose

GroupHealth



Source: CONSORT Survey (N=2119) Group Health Cooperative and Kaiser Permanente N CA

Fracture risk by average daily dose of medically prescribed opioids: persons age 60+



Saunders et al, JGIM 2010

SUMMARY - Problems with high dose opioids for the patients themselves

Deaths

Cannot wean

- Significant problems with managing acute pain (surgical pain), as well as pain at the end of life
- Inability to wean during pregnancy a significant problem for neonates, possibly extending into adult life

Not able to work

High association with mental health disorders, accounting in large part for high risk

What would the ideal outcome be of Rule 2876

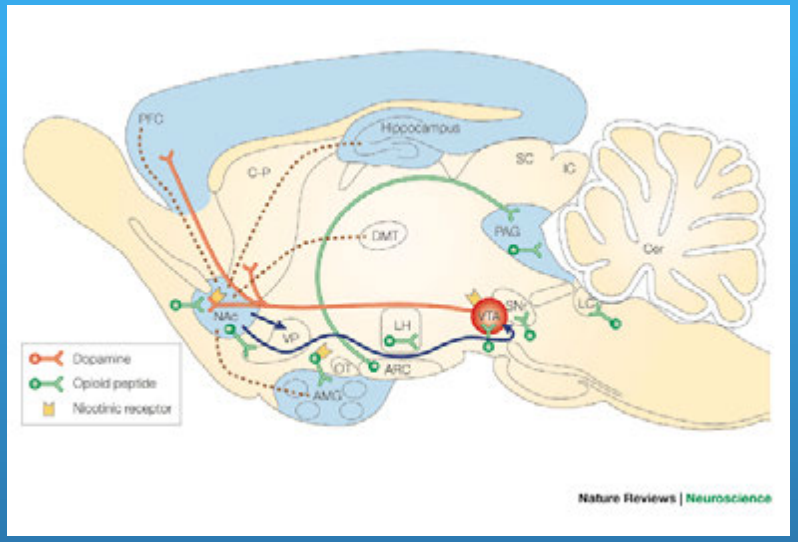
1) 120 mg MED never exceeded when treating chronic pain

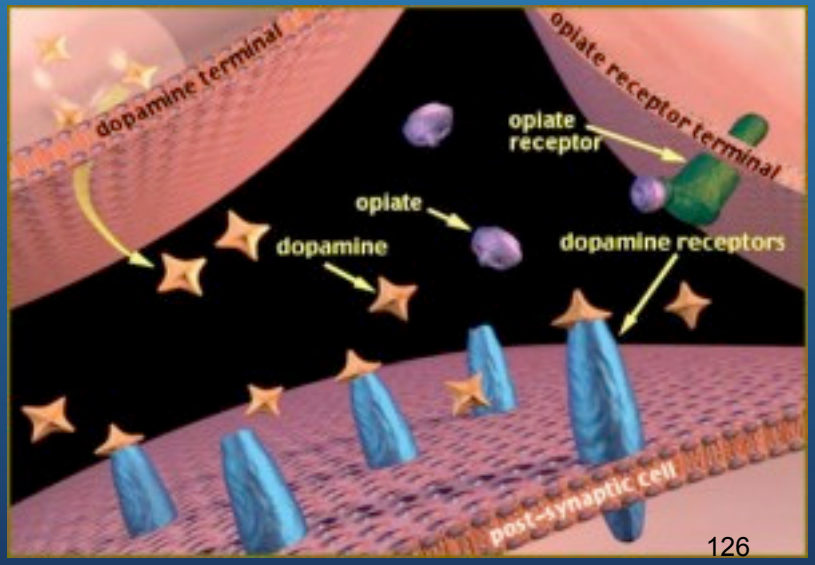
2) those that can be tapered are tapered

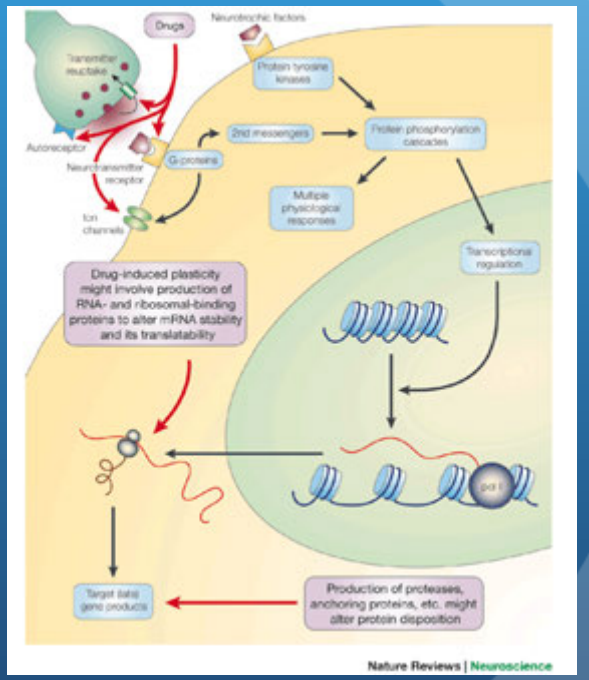
3) those that cannot, get good care (ie dependence treatment

What happens to people on opioids

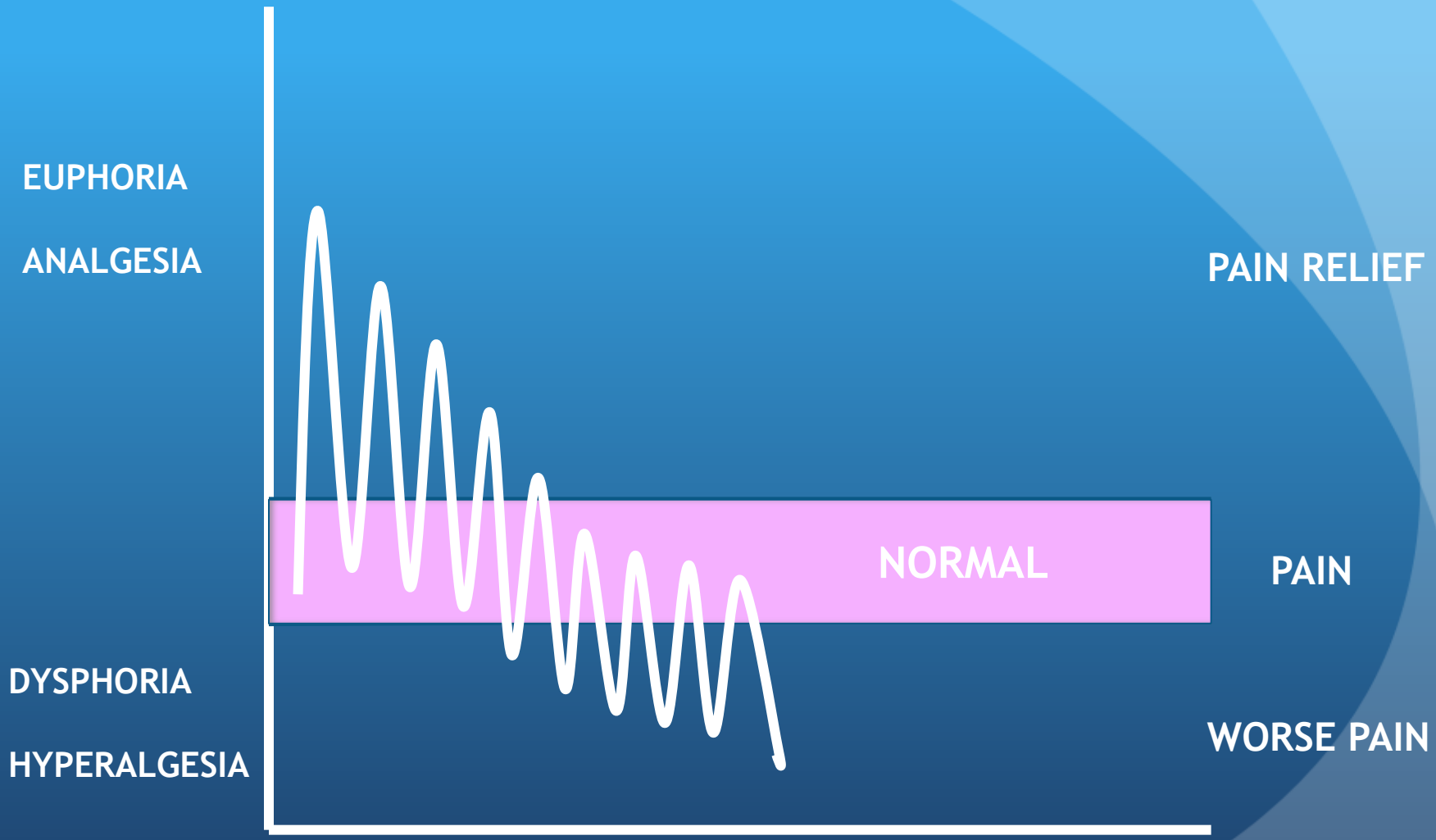
The brain on opioids

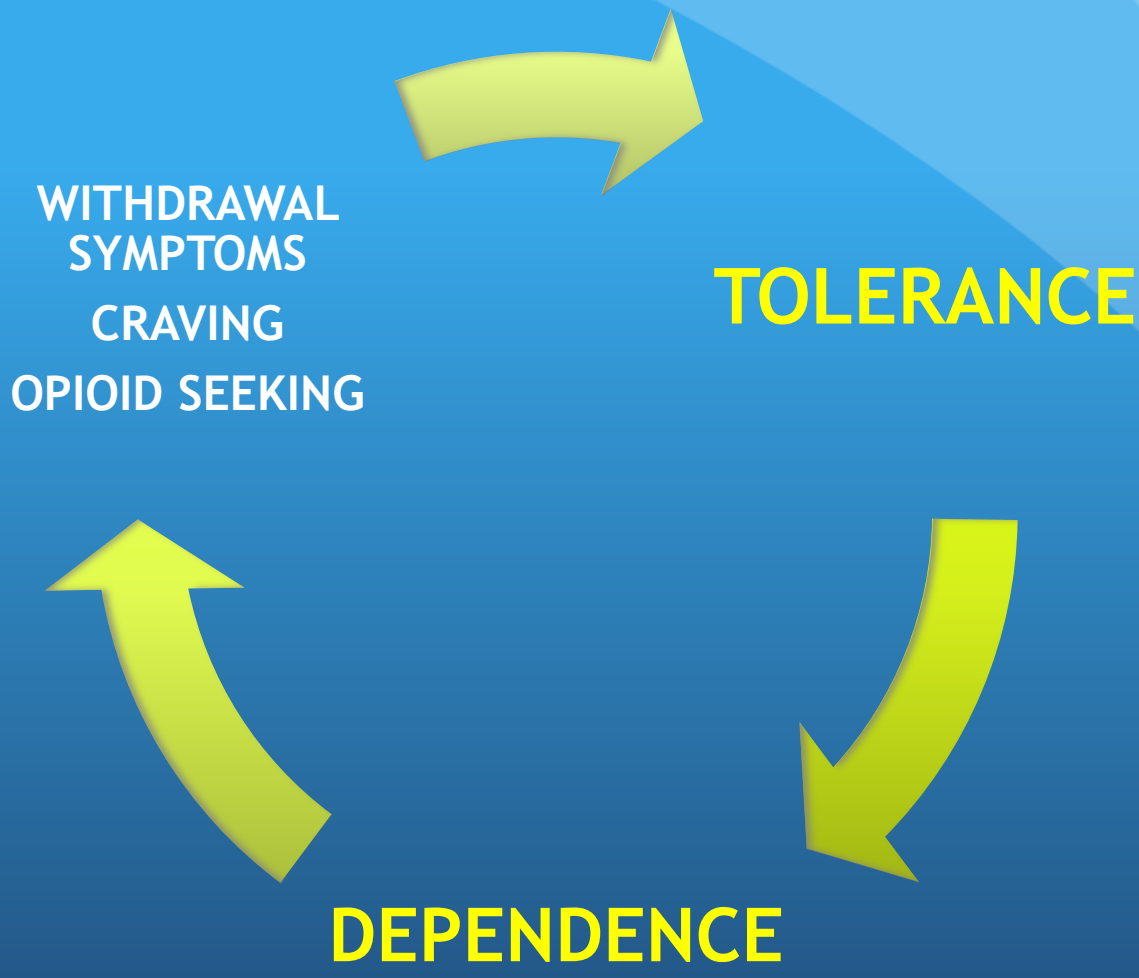


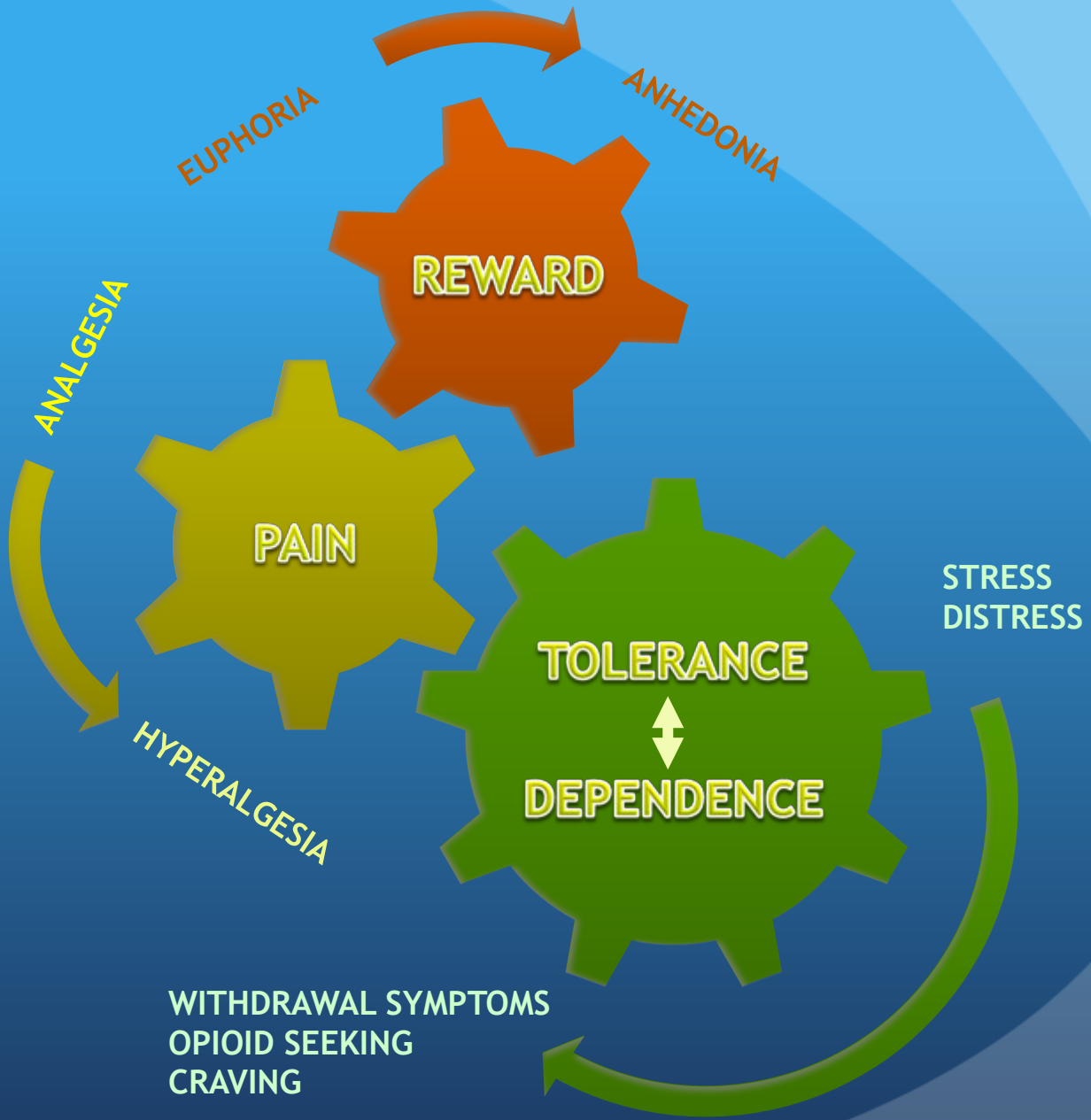




Natural History of Opioid Dependence







Clinical picture of someone stabilized on continuous opioid pain therapy

- Doses tend to be high (> 120 MED)
- Report good analgesia
- Report good function
- Report satisfaction with treatment

BUT

- Pain score remains high
- No dose is enough

Clinical picture of someone trying to taper

- Report worse pain
- Report worse function
- Experience dysphoria/anhedonia
- Desperate to go back up on dose, tearful
- Not satisfied with treatment
- Cannot understand why opioids are being withdrawn
- Are not concerned about safety – would rather die

People doing badly on opioids:

- Demanding
- Miserable
- No dose is enough
- Use up clinic resources

What are the current problems with Rule 2876

Patients already on opioids being denied further prescriptions

- Opioid prescribing not taken over (eg changing provider or relocating)
- Going into withdrawal (even though compliant)
- Being totally discharged from care (when non-compliant)

Physicians refusing to prescribe at all

What are the current problems with Rule 2876

People are being tapered even when they don't need to be ⟶ destabilization

People are being sent for expert consultation even when they don't need to be

Tapering is really hard

We don't have vast experience

What are the current problems with Rule 2876

LESS EASY TO FIX

There is no consensus about what to do with the people already on high doses, even among experts

There are no suitable services for people with dependence on opioid pain medications

CONCLUSIONS

- Restricting high doses is entirely the right thing to do and will reduce adverse outcomes for both patients and society

- We have a clean slate for patients who are not already on high doses

  - given current knowledge, we should not prescribe high doses for chronic pain
  - controlling dose escalation will be the great benefit of Rule 2876

- Knowing what to do with people who are already dependent on high doses is the real challenge

Mimi Pattison, MD, FAAHPM

Commission Chair

Richard Brantner, MD, FAAEM

1st vice Chair

WASHINGTON STATE MEDICAL COMMISSION

Washington State Medical Commission

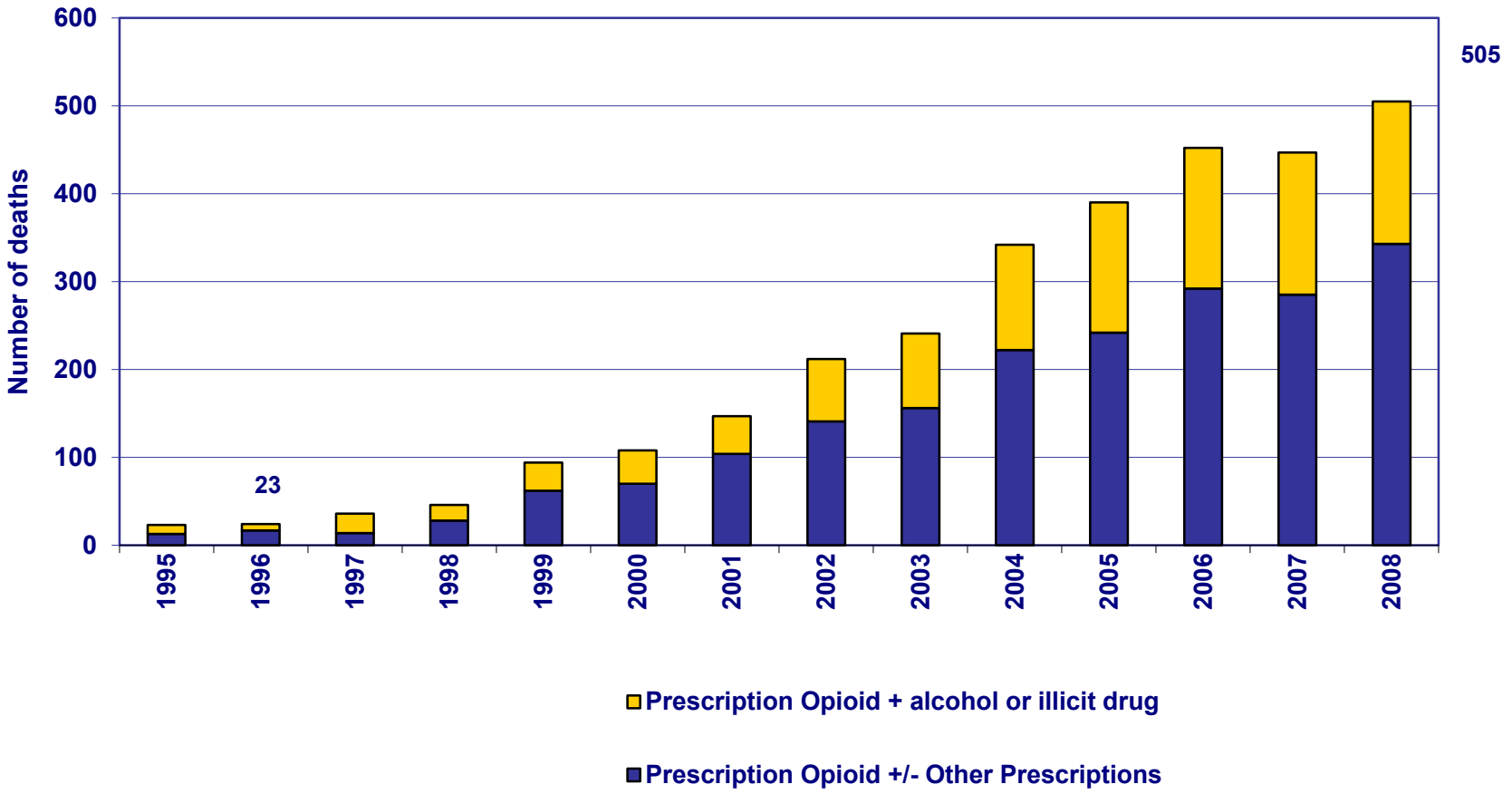
The Medical Quality Assurance Commission promotes patient safety and enhances the integrity of the profession through licensing, discipline, rule making, and education.

Purpose of the Commission

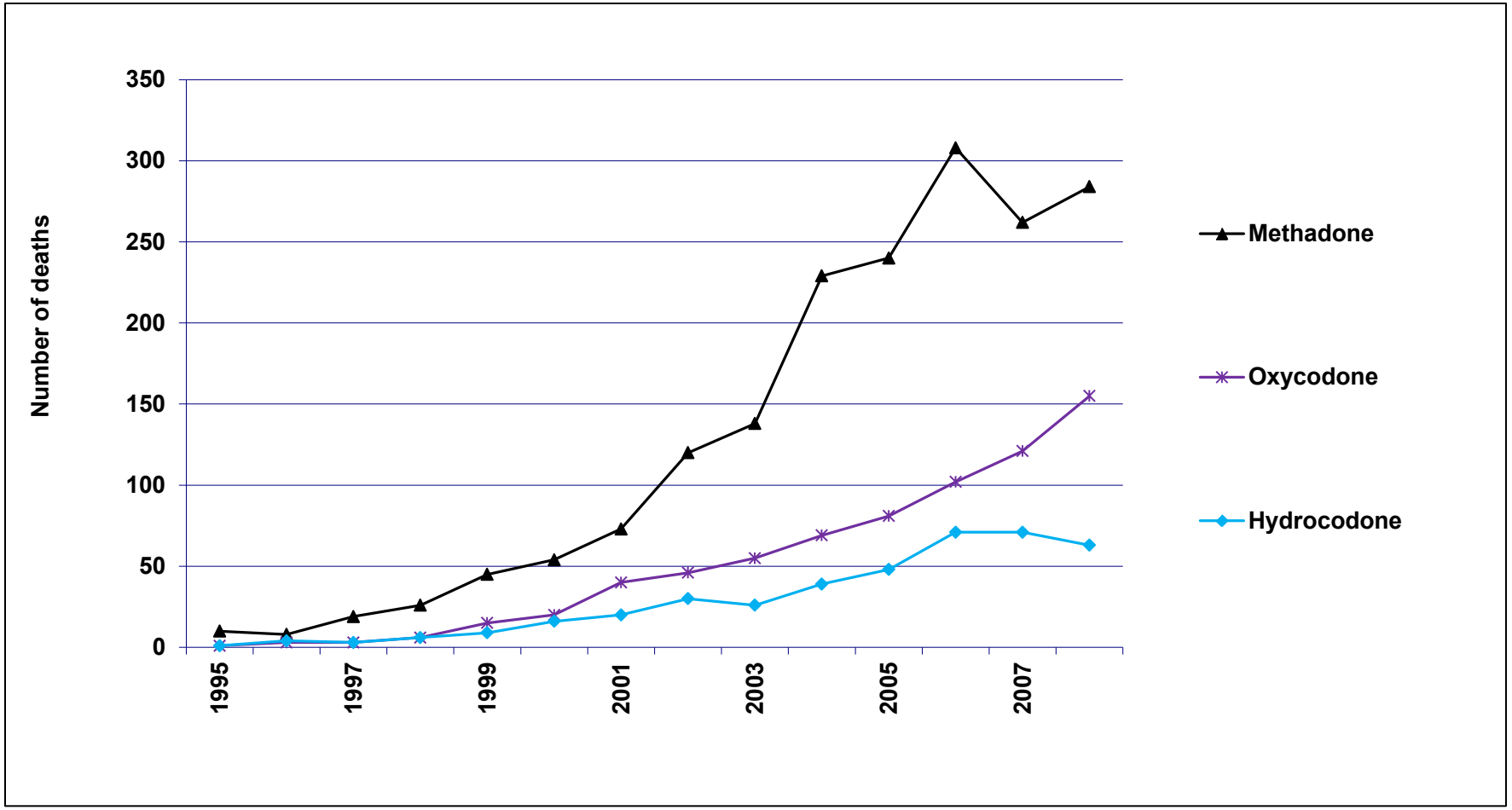
RCW 18.71.002 *"It is the purpose of the* ***medical quality assurance commission*** *to regulate the competency and quality of professional health care providers under its jurisdiction by establishing, monitoring, and enforcing qualifications for licensing, consistent standards of practice, continuing competency mechanisms, and discipline.*

Rules, policies, and procedures developed by the commission must promote the delivery of quality health care to the residents of the state of Washington."

Washington State Opioid Related Deaths



Washington State Opioid Related Deaths



Tipping Point in Southwest Washington

- Three nurse practitioners in one clinic were the focus of media attention
  - In WA, ARNPs may practice and prescribe independently
  - 2,500 patients, 700-900 were chronic pain patients
  - Minimal documentation or history taken, visits were cash based
- Clinic resulted in nearly 60 complaints to the Department of Health and the Nursing Commission
  - Complaints originated from family members, DEA, Labor & Industries, DSHS, Medicare, Medicaid, other prescribers, and pharmacists
  - In March 2009 all three practitioners voluntarily surrendered their DEA registrations
  - In December 2009 the Nursing Commission suspended the schedule II prescribing privileges of one practitioner for 24 months, no action taken on remaining two
- Rep. Jim Moeller, D-Vancouver, an addiction counselor for over 25 years, sponsored ESHB 2876.
  - Mandated rule-making for specific boards and commissions with specific requirements

Washington State Legislation on Opioid Treatment in 2010-ESHB 2876

ESHB 2876 Process

- Five boards and commissions mandated to adopt rules by June 30, 2011
- Cross agency process with public hearings to develop pattern rules
- Four organizations implemented by June 30 deadline
- Medical Commission adopted March 4, 2011
  - Recognized need to educate licensee population and public
  - Decision made to delay implementation until January 2, 2012
- Lesson learned: Semantics matter
  - Adopted vs. Implemented
  - Stakeholder issues arose due to decision to delay

New Rules Must Contain

- Dosing criteria
- Guidance on seeking consultations
- Guidance on tracking progress
- Guidance on tracking use of opioids

Elements of the Rules

- Preamble
- Exclusions
- Definitions
- Patient Evaluation
- Treatment plan
- Informed Consent
- Written agreement for treatment
- Periodic review
- CME requirements
- Consultation requirement
- Exigent and special circumstances
- Definition of pain management specialist

Preamble

- Discusses overall approach to pain management
- Federation of State Medical Boards Model Policy

Exclusions to the Rule

- Hospice care
- Palliative care
  - defined as having a life limiting illness
- Other end of life care
- Acute pain from injury or surgery

Patient Evaluation

- Physician **shall** obtain, evaluate, and document in the health record
  1. Current and past pain treatment
  2. Co-morbidities
  3. Any substance abuse

Patient Evaluation (continued)

- **Should** include:
  1. Review of any available prescription monitoring program (PMP)
  2. Relevant information provided by pharmacist

Patient Evaluation (continued)

- **Shall** include
  1. Physical exam
  2. Pain description
  3. Effect of pain on function
  4. Medications
  5. Risk screening tool

Treatment Plan

- **Shall** state the specific objectives to be used to determine success of treatment and must include functional assessment

Informed Consent

- Physician **shall** discuss the risk, and benefits of treatment options

Written Agreement

- **Should** receive prescriptions from one physician and one pharmacy

- If at high risk
  - **shall** use a written agreement
  - to include 10 elements

CME for Long-Acting Opioids

- Physicians prescribing long-acting opioids **should** have a one-time completion of at least four (4) hours of CME relating to this topic

Consultations

- **Shall** consider referring as necessary
  - especially high risk or patients with multiple co-morbidities

Mandatory Consultations

- 120mg of Morphine Equivalent Dose (MED)
- Mandatory unless the consultation is exempted
  - exigent or special circumstances or exempt practitioner

Mandatory Consultations (continued)

- **Shall** consist of one of the following:
  1. Office visit with pain specialist
  2. Telephone consult with specialist by referring physician
  3. Electronic consultation between pain specialist and physician
  4. Audio-visual evaluation with pain specialist

Exigent and Special Circumstances: No Consultation Required

- Patient following tapering schedule
- Acute pain and expected return to or below baseline dose
- Documented reasonable attempts to refer to specialist
- Physician document pain and function are stable and dose is stable

Physician Exemption from Required Consultation

- Physician is a pain specialist
- Physician has completed in last two (2) years a minimum of 12 hours of CME on chronic pain management with at least two (2) hours dedicated to long-acting opioids and Methadone

Exempt Physician (continued)

- Working in multidisciplinary chronic pain center or academic research facility or
- Has minimum of three (3) years of clinical experience and at least 30% of time is in the current practice of pain management

Pain Management Specialist

- Board eligible or certified by American Board of Medical Specialties (ABMS) approved board or by American Osteopathic Association (AOA)
- Subspecialty certificate in pain medicine by ABMS approved board
- Certificate of added qualification in pain management by AOA

Pain Management Specialist (continued)

- Minimum of three (3) years experience in chronic pain management and
  1. Credentialed in pain management
  2. Successful completion of at least 18 hours of CME in pain management during past two (2) years
  3. 30 percent of current practice is direct provision of pain management care

Summary

- Rules for management of chronic non-cancer pain
  - Adopted June 30, 2011
  - Effective January 2, 2012

Interpretive Statement

- Adopted September 30, 2011
- 6 issues addressed
- To address areas of misunderstanding or over-reaction

Educational Efforts

- Continuing education (CME) package developed and hosted on the Agency Medical Directors Group (AMDG) website (link on the Commission website)
  - 1,582 passing the CME
  - Over 12,891 downloads of the dosing guidelines
- Commission created educational materials
  - Letter to licensees
  - Frequently asked questions and links to pain orgs
  - Patient brochure and links to UW Pain Toolkit
  - Interpretive statement

Educational Efforts (continued)

- Public presentations by Commission members
  - Hospitals
  - Specialty groups
  - Legislative members
  - Public interest/patient groups
- Washington State Prescription Monitoring Program
  - Rules adopted August 27, 2011
  - Accepting input October 7, 2011
  - Accepting queries January 2012

Expectation vs. Reality

- Reality:
  - We did not realize we had actually landed here: "the Zone"
  - Spoon feeding. 1 in 10 had actually read rules or source materials

Medical Quality Assurance Commission

Update!

www.doh.wa.gov/hsqa/mqac Vol. 2, Spring 2012

Message from the Chair

The winter months have seen a flurry of activity for the Commission. Dealing with the January snow storm, implementation of the rule for chronic non-cancer pain, keeping up with the intense activity of this legislative session, and business as usual have been challenging for the Commissioners and staff.

The Commission adopted the pain management rules March 4, 2011 and the rules became effective January 2, 2012. We have continued our educational efforts, speaking at conferences, testifying to both the Senate and

access for persons living with ch
them with the necessary tools to

The Commission regularly recei
concerned individuals about ref
suspected substance abuse probl
understand that these referrals c
the Washington Physicians Heal
calling 1-800-552-7236. The WI
Commission if it is necessary. A
this method of referral should b

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION
PO Box 47866, Olympia, WA 98504-7866

June 15, 2011

Dear Colleague:

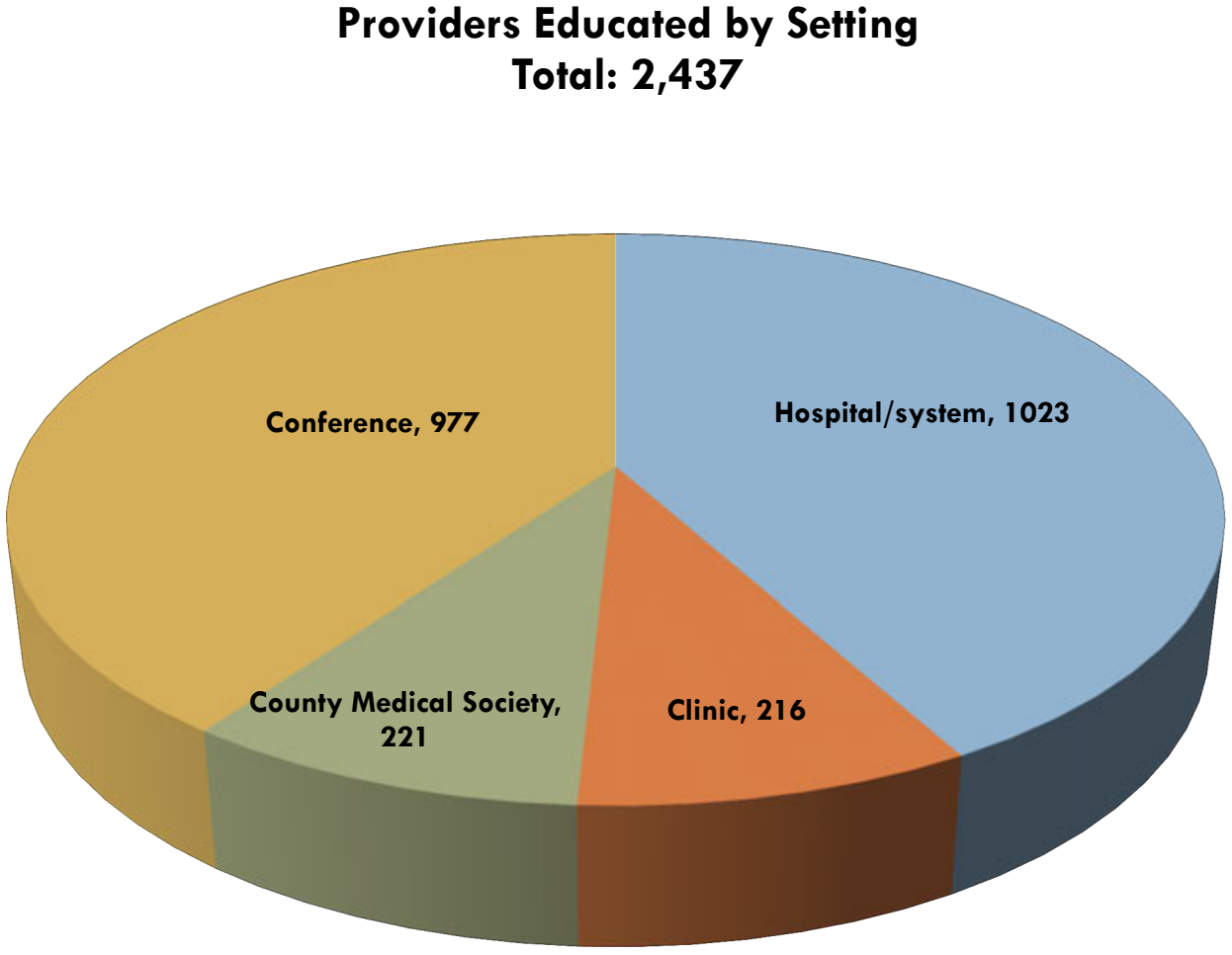
The purpose of this letter is to provide you with information regarding the recently adopted rules for the management of chronic noncancer pain.

In Substitute House Bill 2876, signed into law in March 2010, the legislature required the Medical Quality Assurance Commission, as well as four other boards and commissions, to adopt rules governing chronic noncancer pain management.

Educational Efforts-Strategy

- Active
  - Letter to all licensees informing them of the adoption and implementation dates
  - Four quarterly newsletters all featuring pain rules
    - Winter 2011 edition featured the interpretive statement in its entirety
- Passive
  - Dedicated pain rule email: Medical.PainRules@doh.wa.gov
  - Comprehensive webpage as repository for all resources
    - Three sections: Patient, Provider, Legal

Presentations to Date



Moving Forward with Lessons Learned

- Physician behavioral response
- Realistic Expectations
  - "What is this acronym?"
- We share the Ohio strategy: See What Sticks
  - Talk to other SMBs dealing with these problems
- More engagement with legislative stakeholders
- Unexpected change in the conversation
  - From we have a "pill problem" to we have an issue to treat, ie management of chronic non-cancer pain
- Process has brought more groups to the table to discuss and develop tools and treatments for these cases
- Highlighted the need for the Commission to conduct educational campaigns in other areas

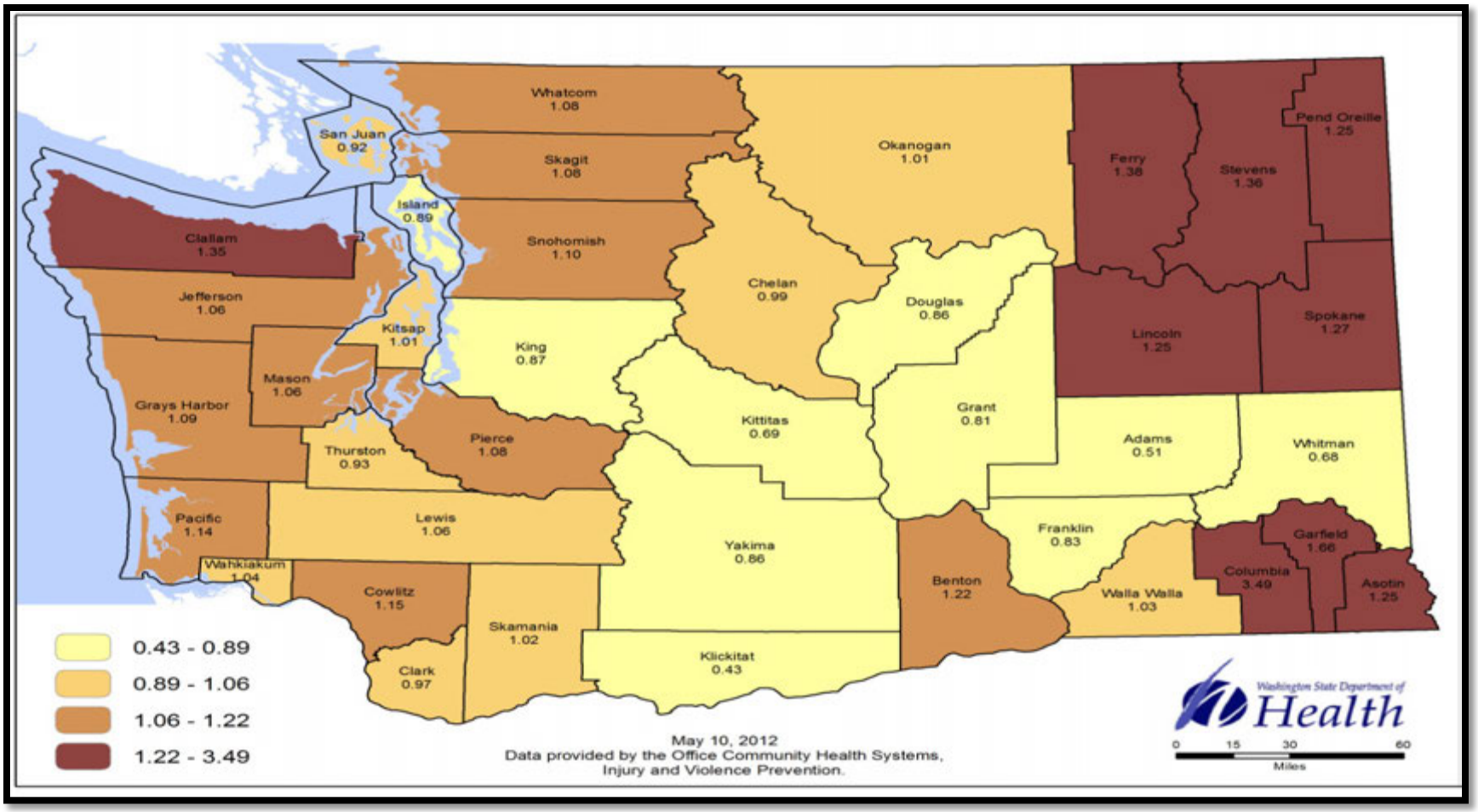
Pain Management in Washington State 2010-2012

- ESHB 2876 passed by 2010 legislature
- Pattern rules created, adopted, and effective January 2, 2012
- Robust educational efforts on behalf of the Commission
- Educational efforts receive Administrators in Medicine top national award, serves as template for other state medical boards
- Health systems quality improvement programs

Pain Management in Washington State 2010-2012

- University of Washington efforts
  - Project ROAM
  - Project ECHO
  - Mentoring of primary care providers-education of Pain Champions
- Washington Prescription Monitoring Program (PMP)

Controlled Substance Prescriptions Filled Per Person Washington State, July 2011-February 2012



Prescribing data: Washington State Prescription Monitoring Program
Population data: Office of Financial Management, 2011 population estimates

Prescription Counts

January 12	February 12	March 12	April 12	May 12	June 12
743,737	957,921	1,021,437	958,702	1,003,384	942,734

Total Rx Count as of 8/1/12 – 10,453,317

Top 10 Drugs by Rx Count

Generic Name	Number of RX	Total QTY	Total Days Supply
HYDROCODONE BIT/ACETAMINOPHEN	1,610,643	85,469,084	19,319,011
OXYCODONE HCL/ACETAMINOPHEN	496,617	28,350,343	5,857,013
ZOLPIDEM TARTRATE	488,368	15,111,889	14,309,962
OXYCODONE HCL	484,646	45,834,260	8,404,616
ALPRAZOLAM	350,090	18,154,695	7,888,567
LORAZEPAM	343,546	15,643,690	6,977,270
CLONAZEPAM	280,968	16,656,010	8,004,081
AMPHET ASP/AMPHET/D-AMPHET	249,605	13,140,244	7,250,387
METHYLPHENIDATE HCL	216,387	11,387,358	6,477,537
MORPHINE SULFATE	177,893	13,337,917	4,151,836

* Run on 8/1/12 for Calendar Year 2012

Registered Users – master accounts

Pharmacist	**1977**
Medical Doctor	**3848**
Medical Limited	**116**
Physician Fellowship	**1**
Teaching/Research	**2**
Osteopathic Physician	**358**
Osteopathic Limited	**8**
Physician Assistant	**702**
Osteopathic Physician Assist.	**13**
Nurse Practitioner	**973**
Dentist	**870**
Dental Community Resident	**0**
Dental UW Resident	**1**
Dental Faculty	**0**
Podiatric Physician	**65**
Naturopathic Physician	**40**
Optometrist	**44**
Veterinarian	**16**

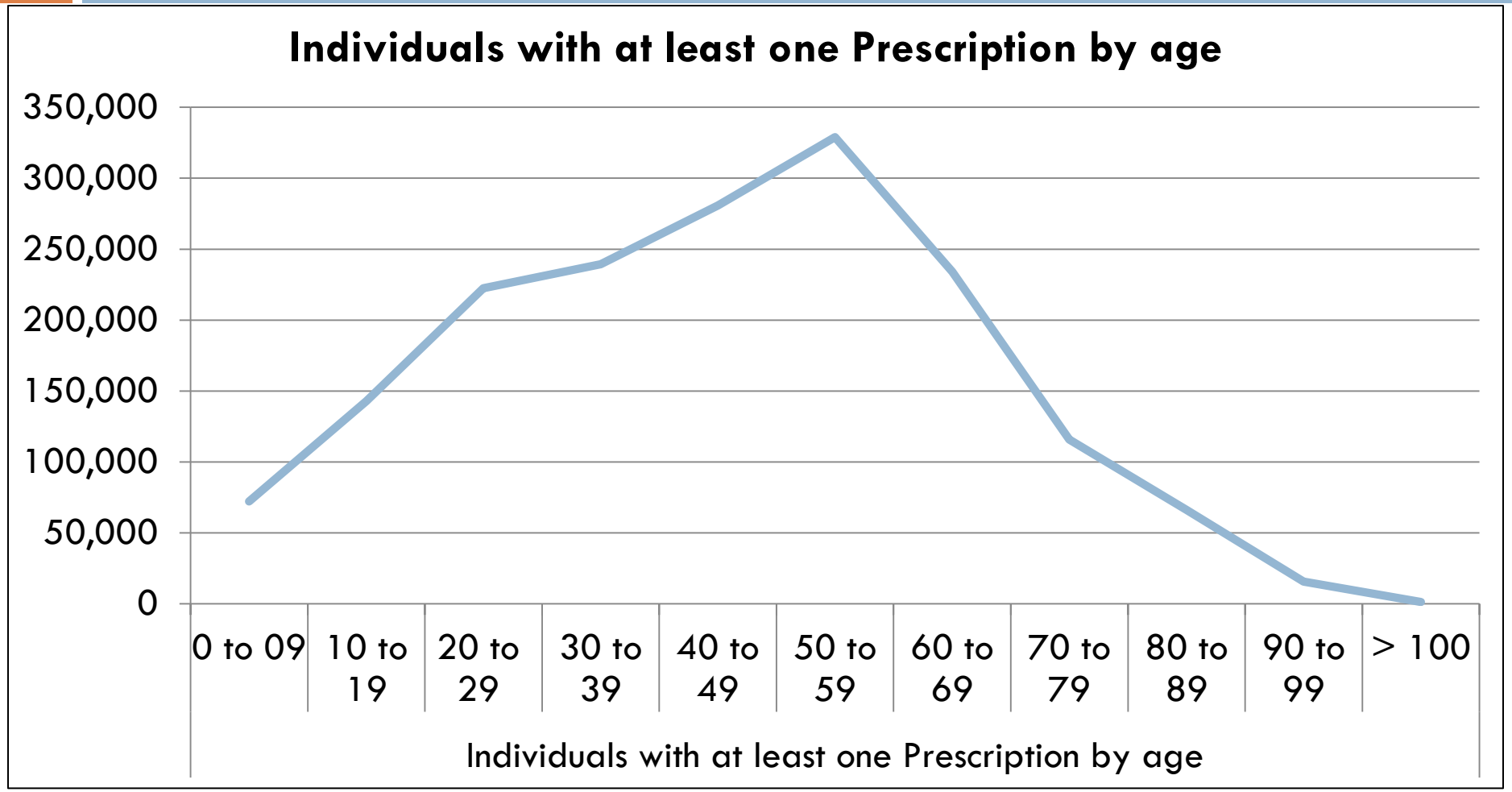
* As of 8/1/2012 - 7,057 total prescribers

Registered Users - Subaccounts

Chemical Dependency Prof.	**6**
Health Care Assistant	**102**
Licensed Practical Nurse	**28**
Registered Nurse	**232**
Nursing Assistant Reg.	**6**
Nusring Assistant Cert.	**2**
Dental Assistant	**4**
Dental Hygienists	**1**
Expanded Function Dental Aux.	**0**
Mental Health Counselor	**2**
Marriage and Family Therapist License	**1**
Psychologist License	**11**
Social Worker Advanced	**3**
Social Worker Associate	**2**
Counselor Agency Affiliated	**1**
X-Ray Technician	**0**

* As of 8/1/2012 – 401 total subaccounts

Individuals with at least one prescription by age decade



* October 1, 2011 to April 30, 2012
* 1,720,217 total individuals

Provider Quotes

"Thanks for setting up this excellent clinical tool. Speaking as a pain specialist, it is a godsend. All our patients are vetted through the system now; my staff finds it very user-friendly. I am certain the community at large will benefit as well as our patients, as we choke off the flow of medication into the black market, and redirect those individuals responsible into treatment. Bravissimo!"

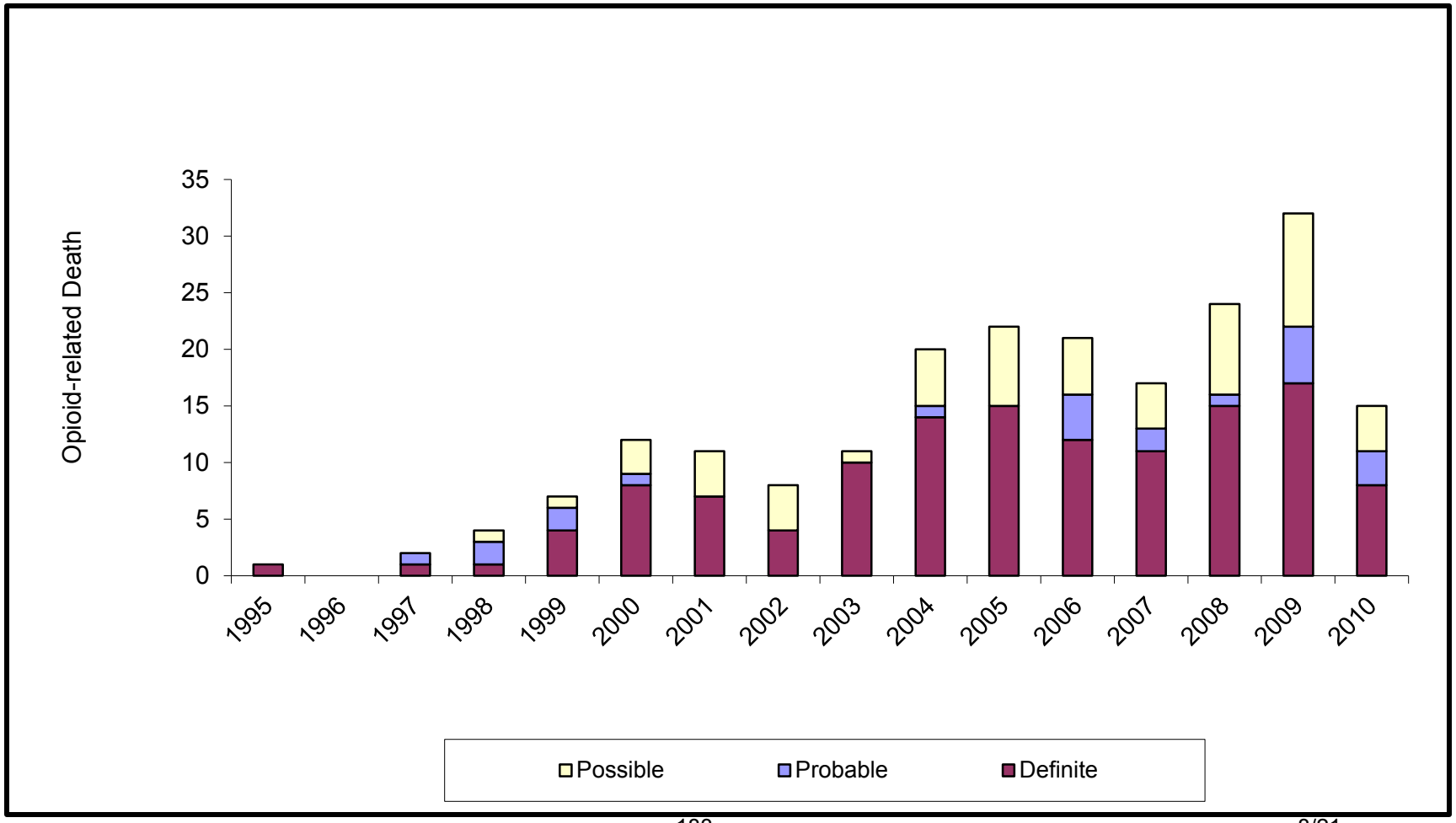
Provider Quotes

"Now that I've started using this system, it's almost hard for me to imagine how I was practicing medicine without it. Whenever I prescribe scheduled meds now, I routinely search the Prescription Monitoring Program database, to ensure that the patient isn't getting similar meds from another provider. It is amazing to me how often this search reveals that the patient actually was getting such meds somewhere else, and just not providing this information. Finding this out helps prevent abuse of the system and thus keep costs down for everyone. Most importantly, it helps to keep patients safe and allows us to get them the help that they truly need."

Across the Nation

- FDA-REMS (Risk Evaluation and Mitigation Strategies)
- Pain Rules in other states
  - Florida (effective)
  - Ohio (effective)
  - Many other states in process

WA Workers' Compensation Opioid-related Deaths 1995-2010



What about opioid related complaints?

- Continue to be for over-prescribing
- Inquiries about being 'cut off' by doctor—usually related to PMP findings
- No complaints related to under prescribing or refusing to prescribe.

Ongoing Monitoring

- Medical Commission direct inquiries
  - Medical.PainRules@doh.wa.gov
- Department of Health direct inquiries
  - painmanagement@doh.wa.gov

Websites

Medical Commission Homepage

www.doh.wa.gov.hsqa/MQAC

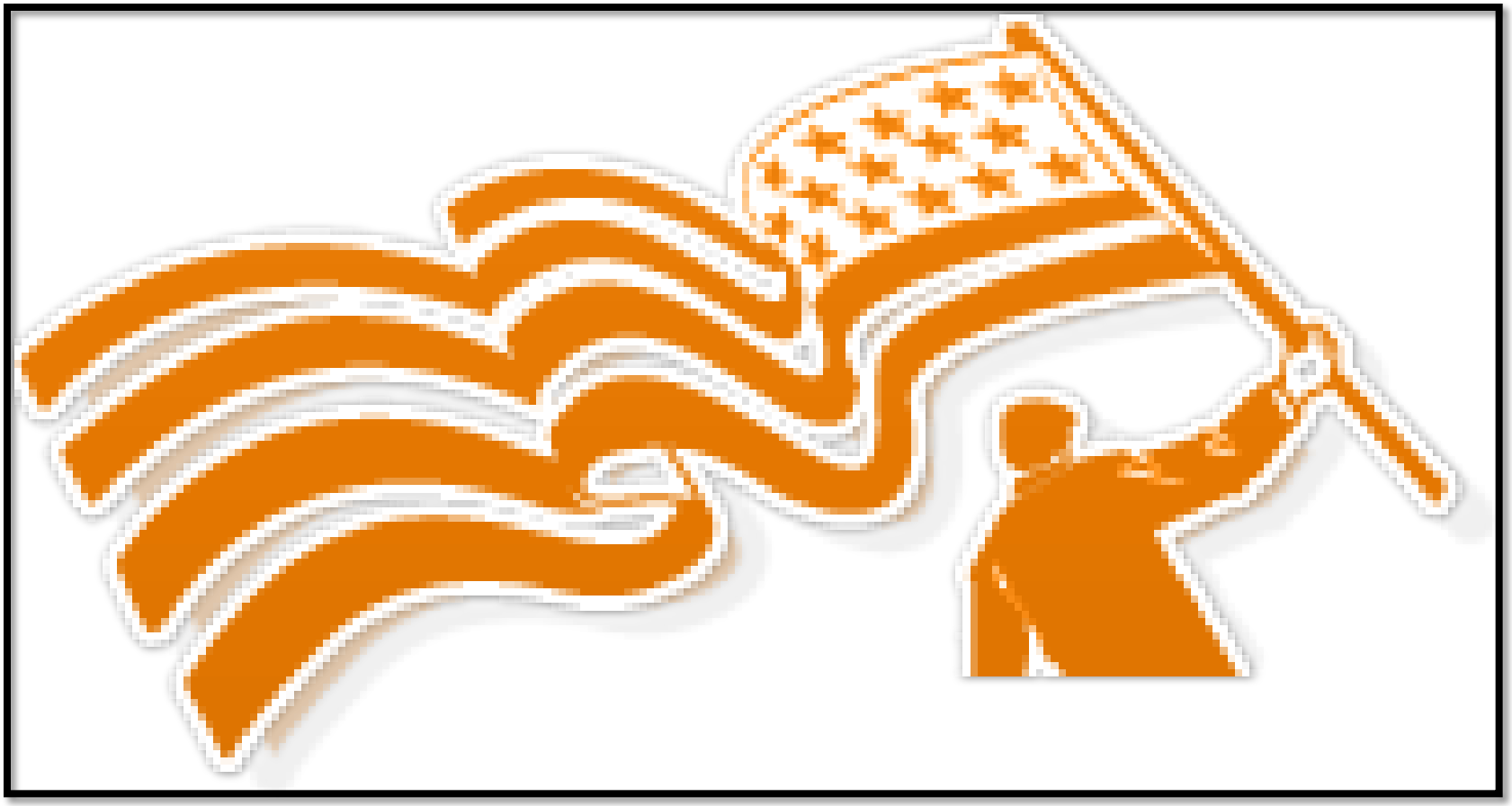
Medical Commission Pain Management page

www.doh.wa.gov/hsqa/mqac/PainManagement.htm

DOH Pain Management Page

www.doh.wa.gov/hsqa/Professions/PainManagement

National Leadership



Pilot to Date

- Performance
- Accomplishments
- Next steps

Professionals Licensed July 2012

- 24,589 Active Physicians (including Retired Active)
- 18,260 In-state active Physicians
- 1,074 Physicians with training/research licenses

- 2,525 Physician Assistants

Medical Commission: Composition

- Semi-Independent body appointed by the Governor
- Governed by Statute (RCW 18.71, 18.71A, 18.130, WAC 246-918, 246-919)
- 21 members
  - 13 MD (each congressional district + 4 at-large), 2 PA, 6 public members
  - Commissioners from all parts of state: rural, urban, east, west, etc.
  - 5 MD, 3 Public pro tem members

Medical Commission: The Staff

- Executive Director
- Medical Director
- Administrative Staff
- Staff Attorneys
- Staff Investigators
- 37 total staff

Medical Commission: Funding for 2011-13 biennium*

- Allotment $14,760,286

*by law, the commission must be self supporting

Basis for Discipline: Uniform Disciplinary Act RCW 18.130

Violations fall into 2 categories:

- **Unprofessional Conduct:** conduct relating to incompetence, negligence, moral turpitude, fraud, sex, or other misconduct.
- **Impairment:** a mental or physical condition making the practitioner unable to practice medicine with reasonable skill and safety.

Medical Commission: Workload Fiscal Year 2012

- 1,404 complaints received
  - 1008 cases investigated
  - 1099 cases completed the legal process

- 93 cases resulted in disciplinary action
  - 63 STID (stipulation to informal disposition)
  - 12 Settled with Agreed Order
  - 12 Default Order issued
  - 3 Order following formal disciplinary hearing
  - 11 Summary actions (immediate suspension or limitation of license)

Sanctions by Violation Type: Fiscal 2011

Incompetence, negligence or malpractice	47
Discipline in another state	9
Sexual misconduct or abuse	5
Impairment	7
Moral turpitude, dishonesty or corruption	4
Fail to cooperate or comply	6
Law or rule violation	1
Misrepresentation or fraud	2
Aiding and abetting unlicensed practice	0
Application (failure to meet requirements)	2
Criminal conviction	1

Mission Statement

Promoting patient safety and enhancing the integrity of the profession through licensing, discipline, rule making, and education.

Medical Quality Assurance Commission: 4SHB 1103

- Effective July 1, 2008
- Gives increased authority to commission, particularly in personnel and budget
- Establishes mechanism to adjudicate differences with Dept of Health
- Performance Measures
- Sanction rules
- Processing of complaints of sexual misconduct

Washington State Medical Commission

Thank you! Questions?

Medical.Commission@doh.wa.gov

Micah Matthews, MPA

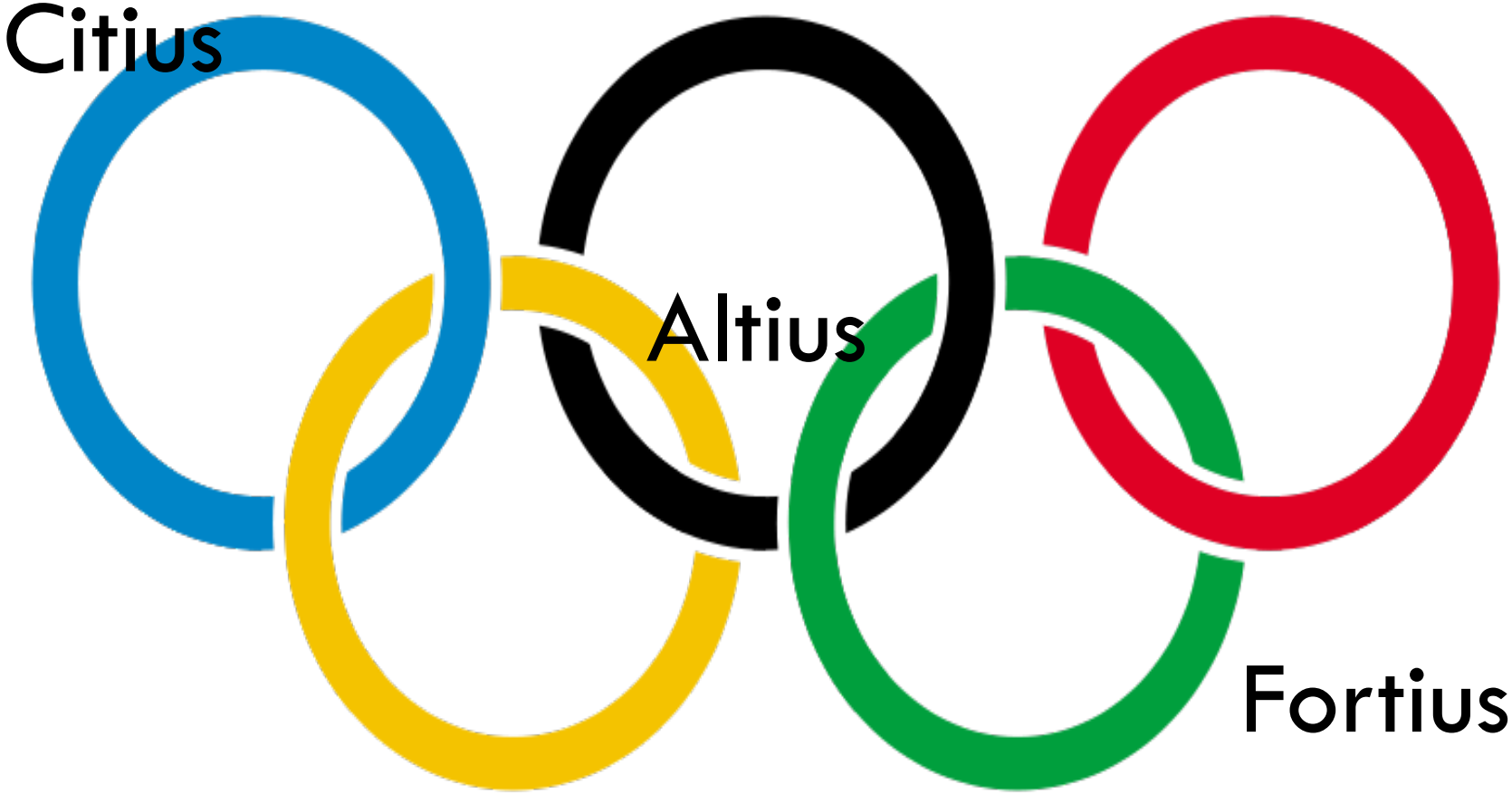
Research & Education Manager

Michael Farrell, JD

Legal Manager

WASHINGTON STATE MEDICAL COMMISSION

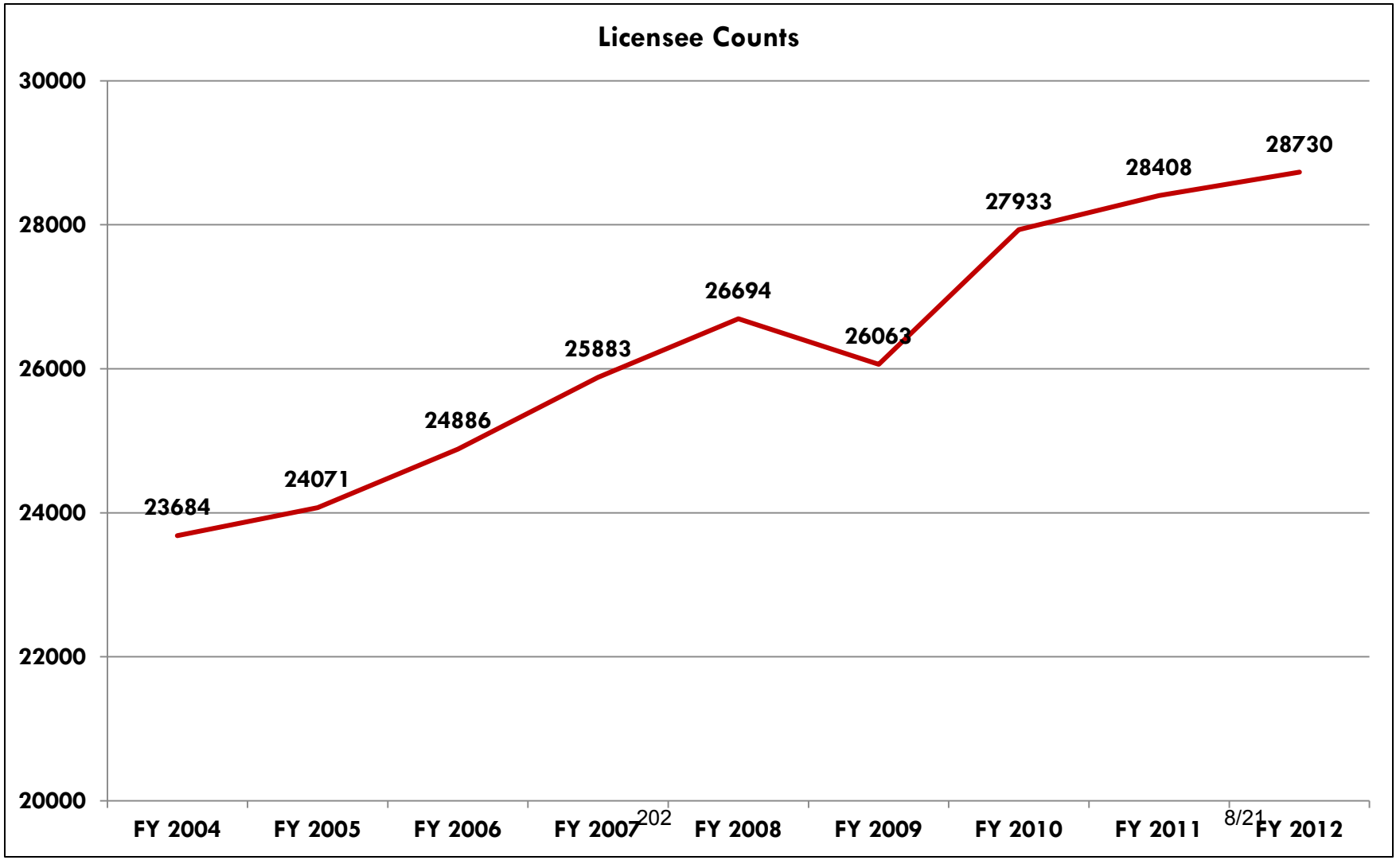
Pilot to Date: Performance



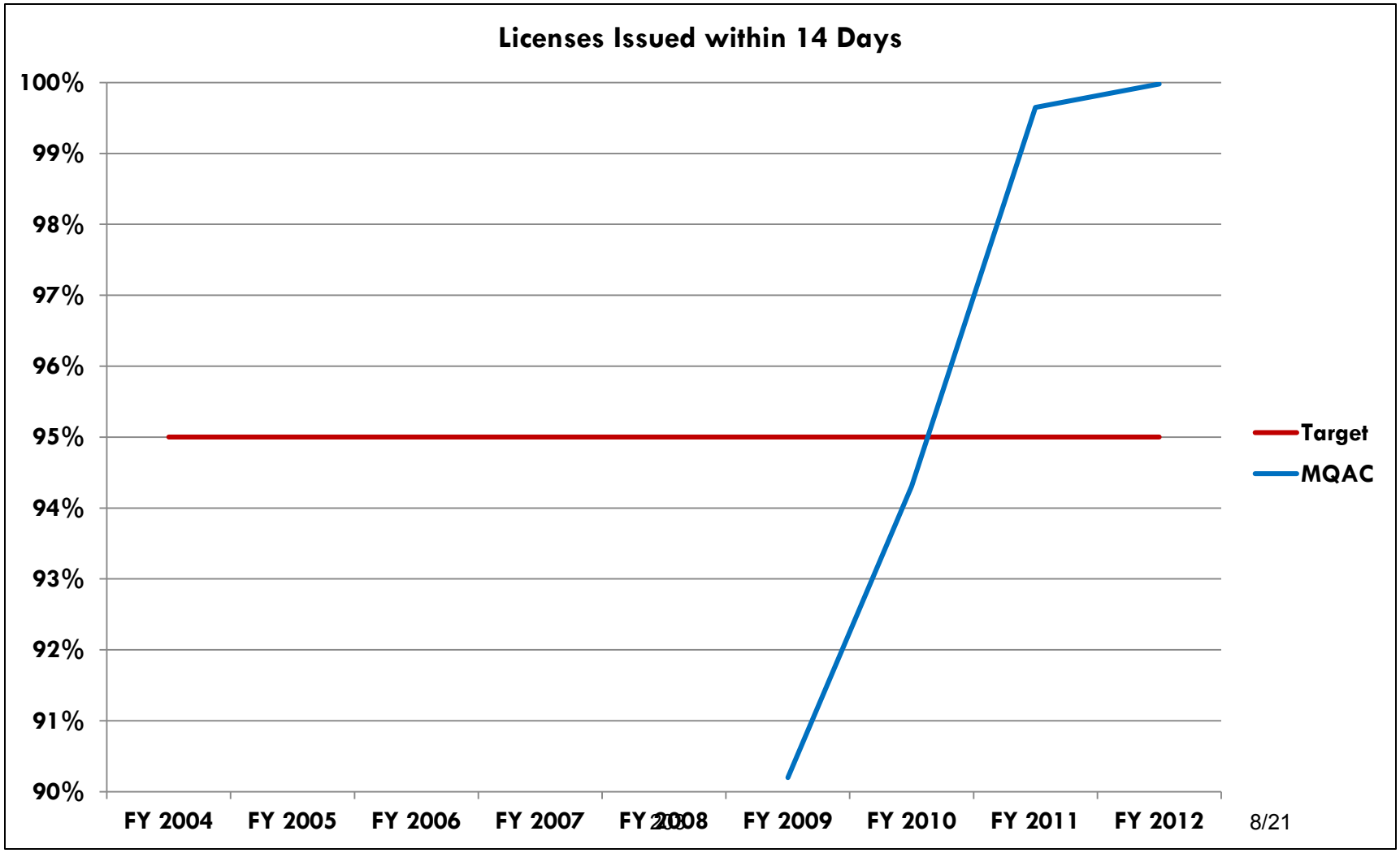
Performance Defined

- As part of the pilot project the Commission negotiated performance measures with the Department of Health.
- These measures track Commission performance in the areas of credentialing, discipline, human resources, and budget
- Theses measures will be used to compare the Medical Commission, Nursing Commission, the Secretary professions, and non-pilot boards and commissions at the conclusion of the project.

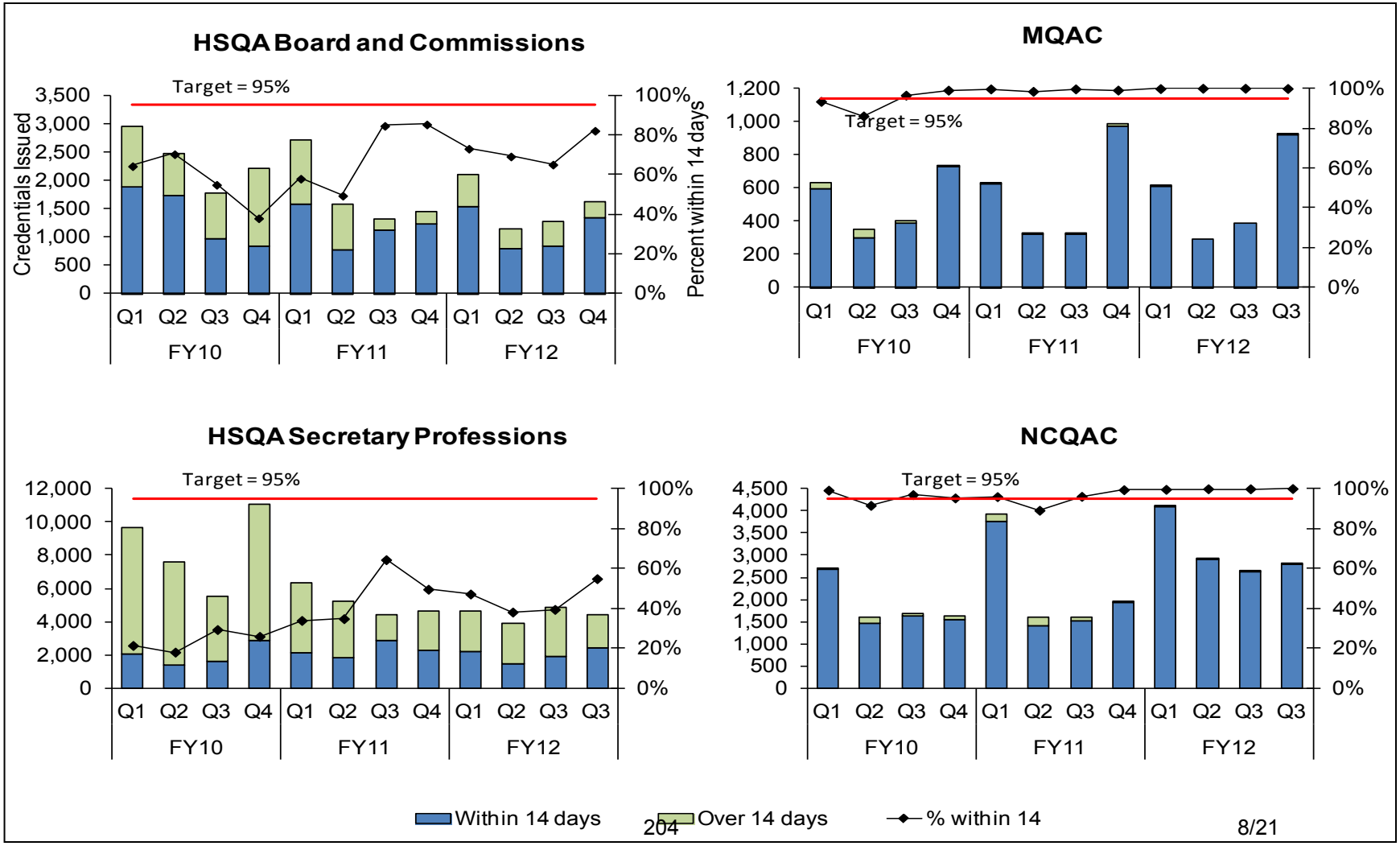
Performance: Licensee Growth



Performance: Credentialing



Performance: Credentialing



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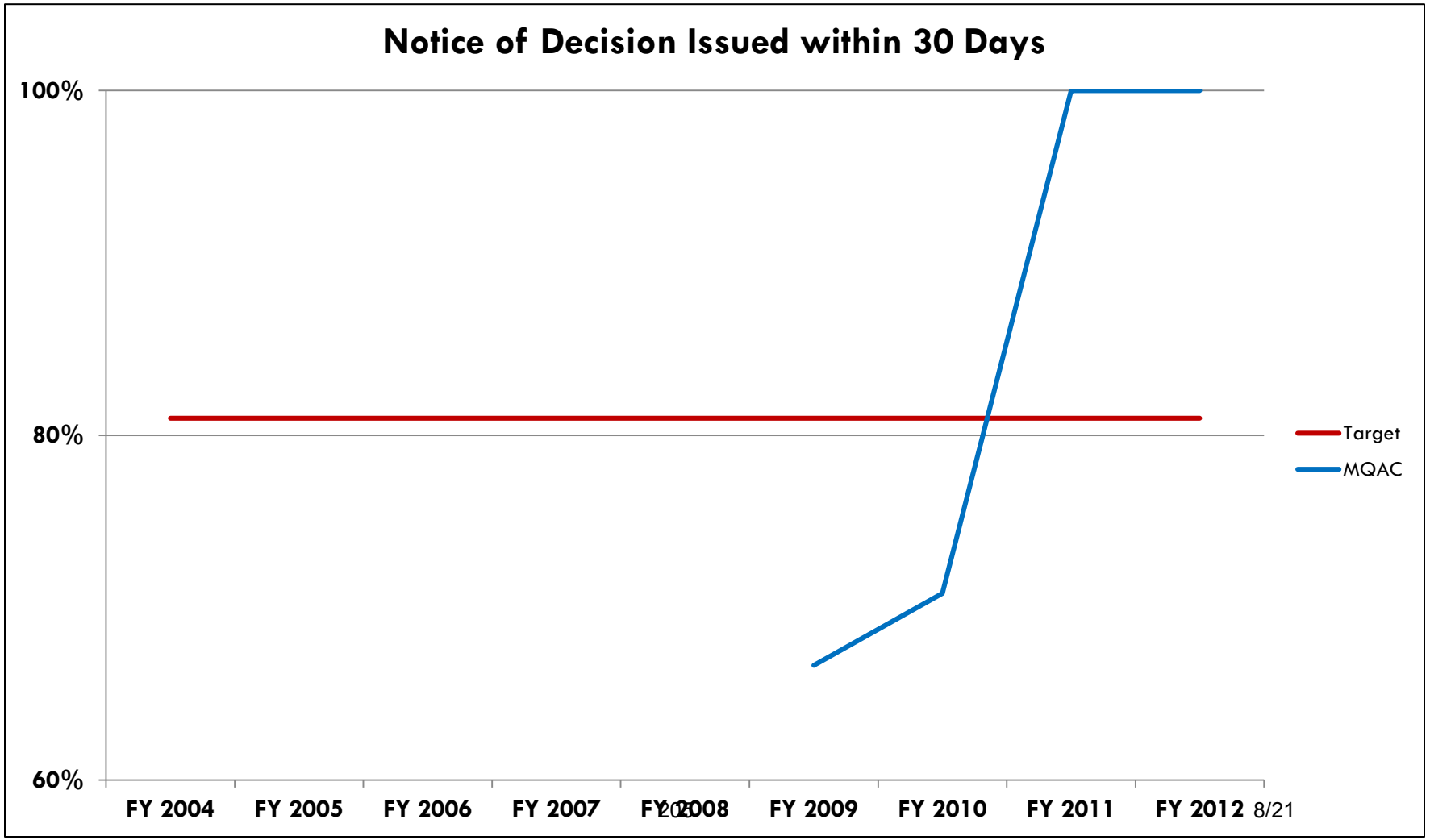
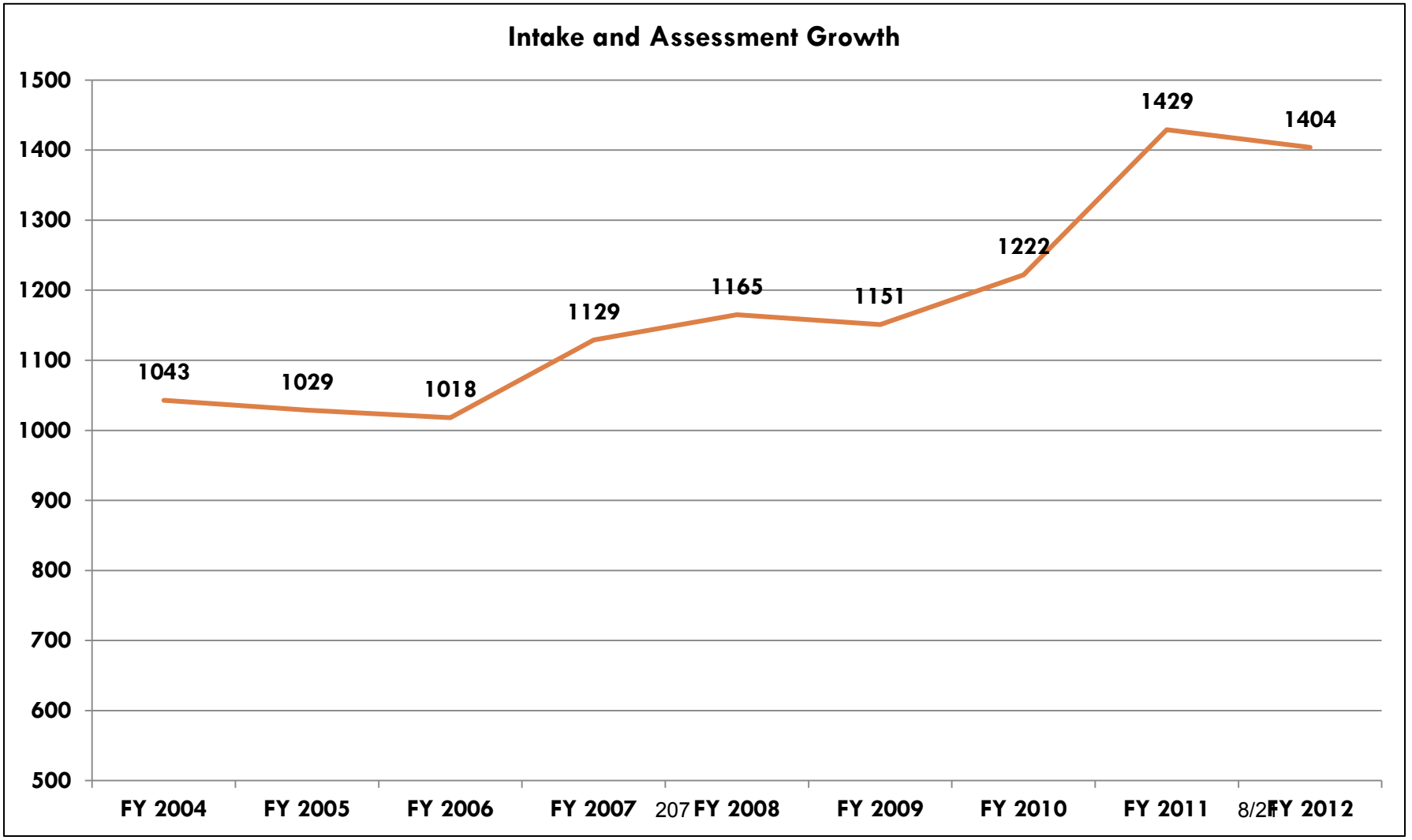
Performance: Credentialing



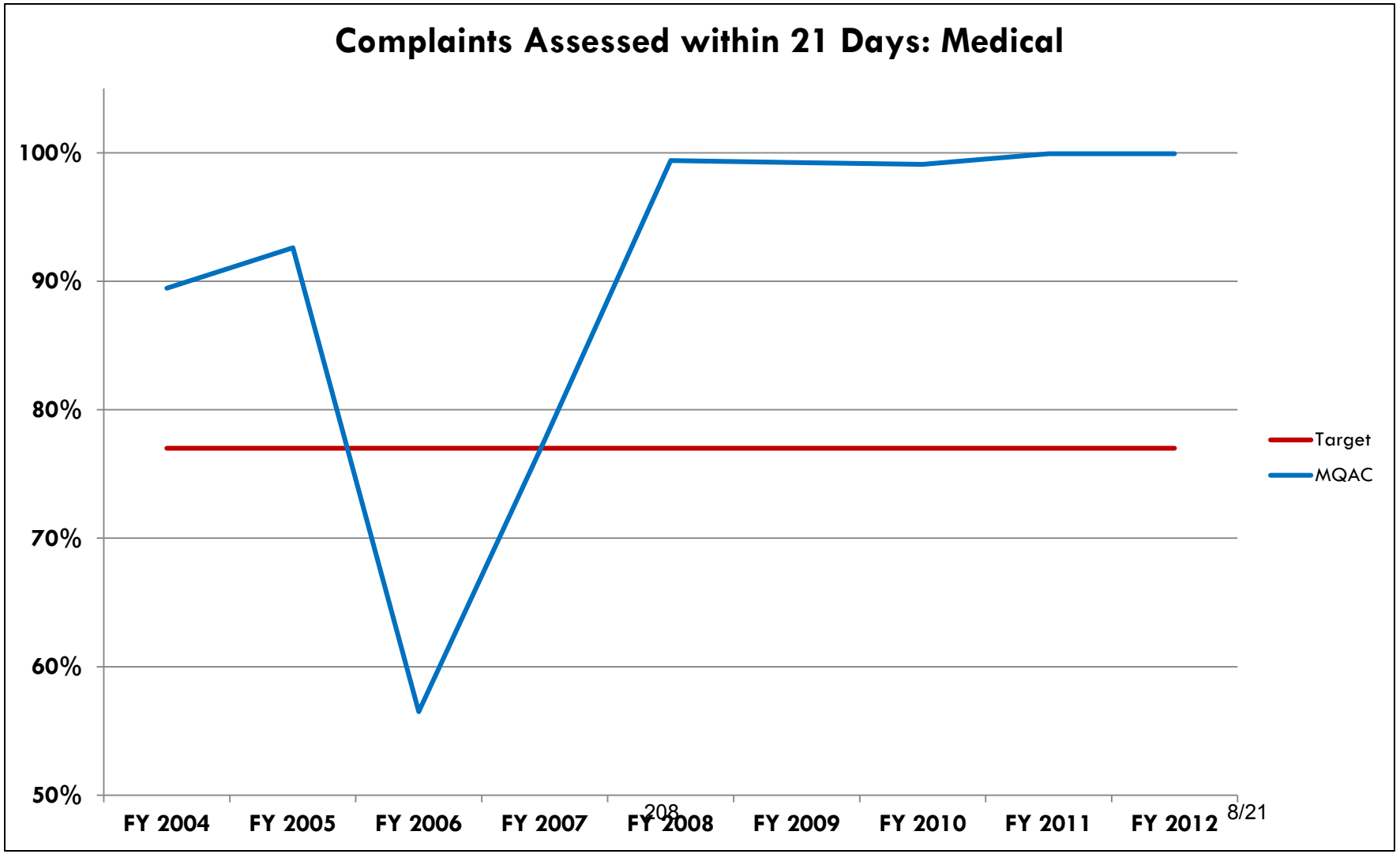
Performance: Credentialing

- Improvements to the Licensing Process
  - Commission established an internal credentialing unit with full control over 90 percent of credentialing functions
  - Adoption of the FSMB Credentials Verification Service
  - Adoption of the FSMB Uniform Application
  - Use of Veridoc for license verifications
  - Online renewals to begin September 16, 2012
- All of these improvements allow credentialing staff to focus on quality control as opposed to data entry tasks.

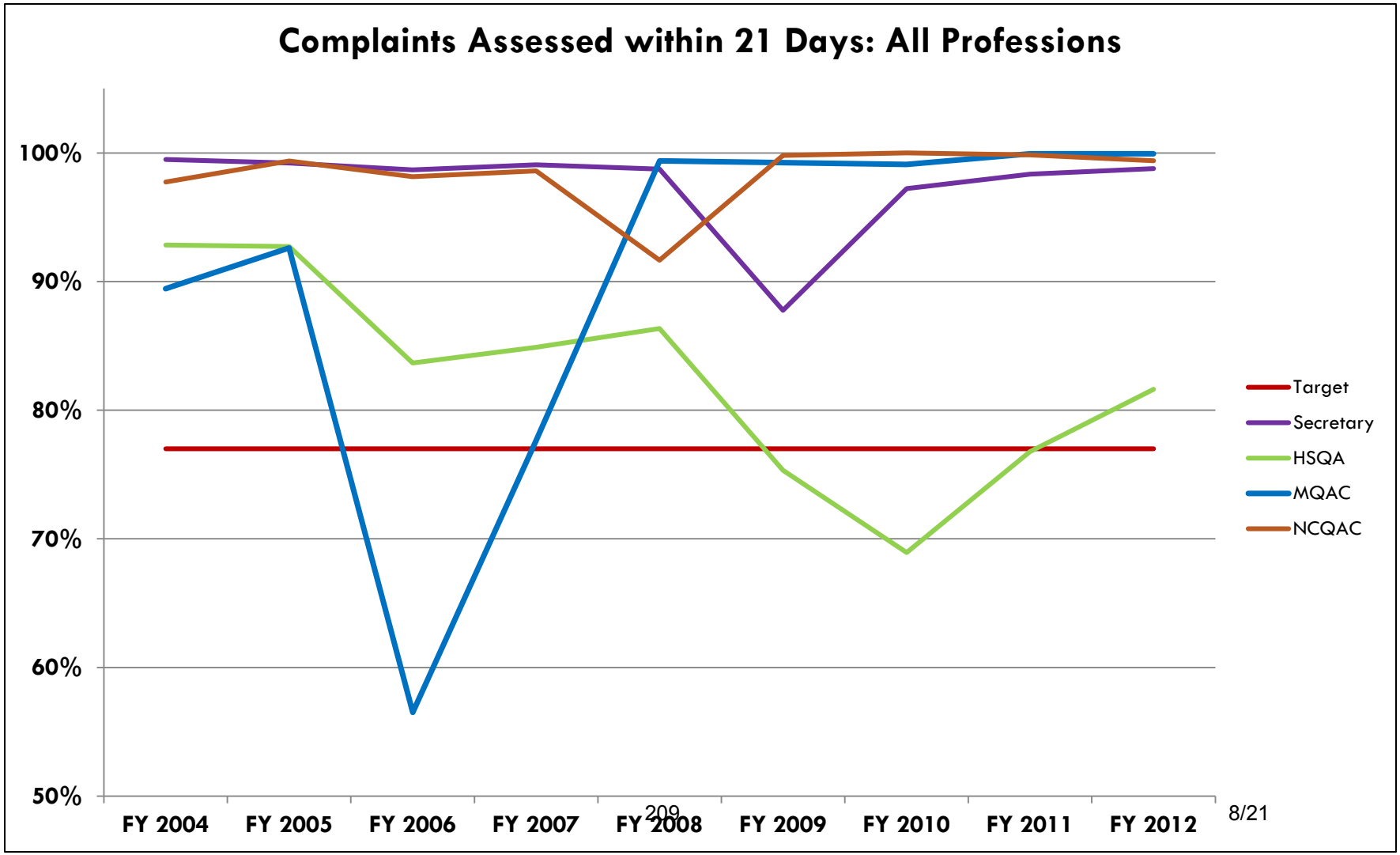
Performance: Complaint Growth



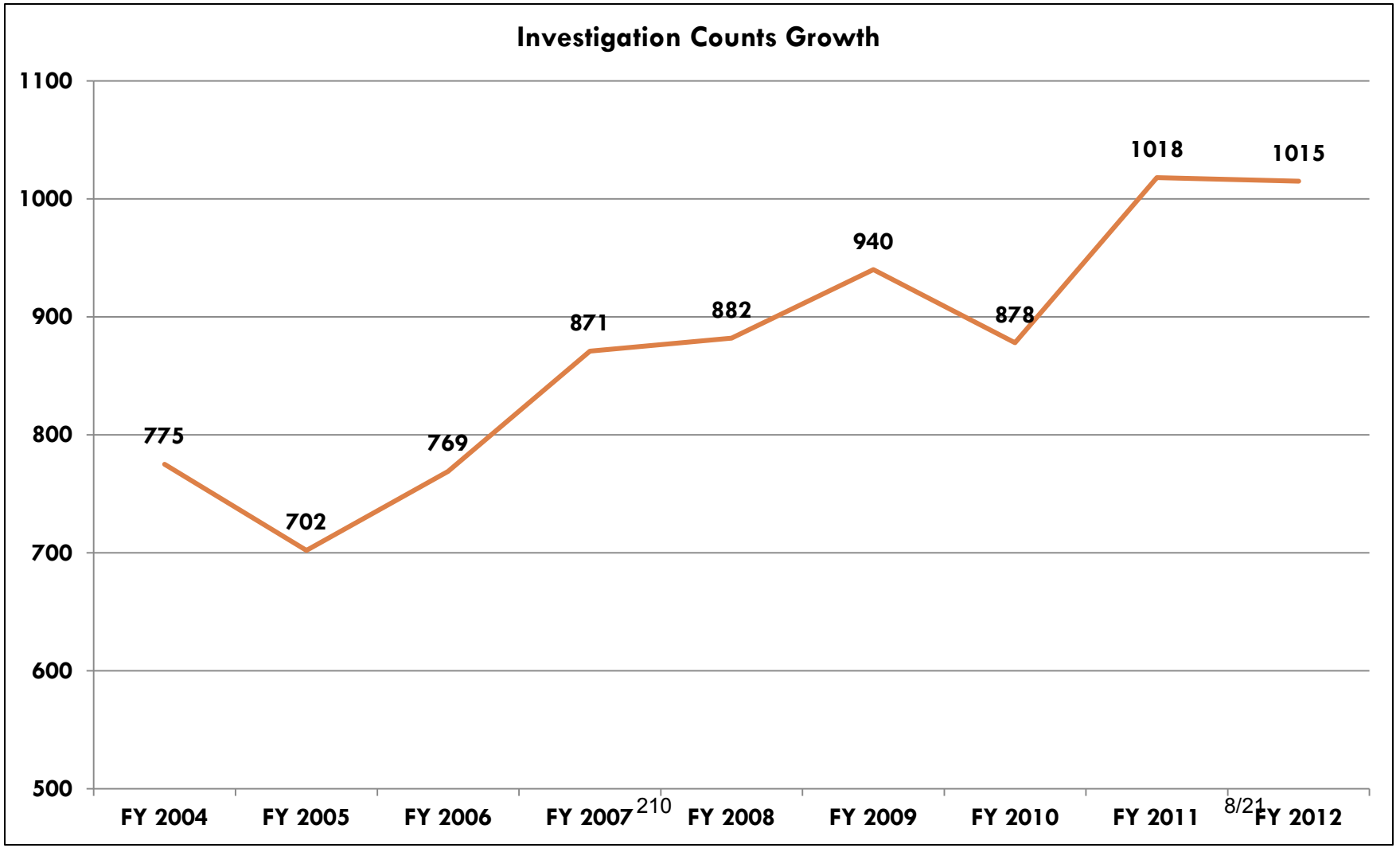
Performance: Discipline



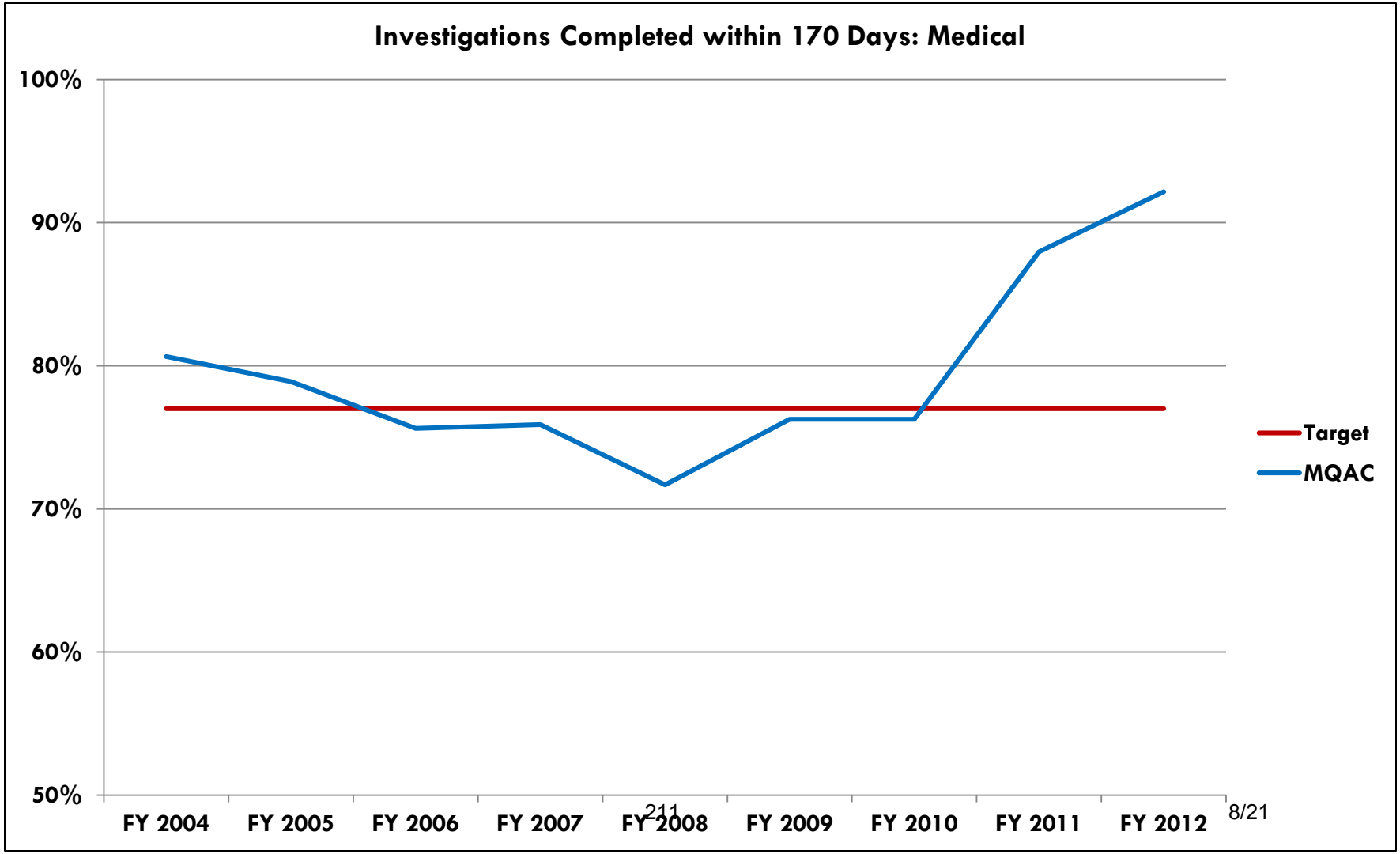
Performance: Discipline



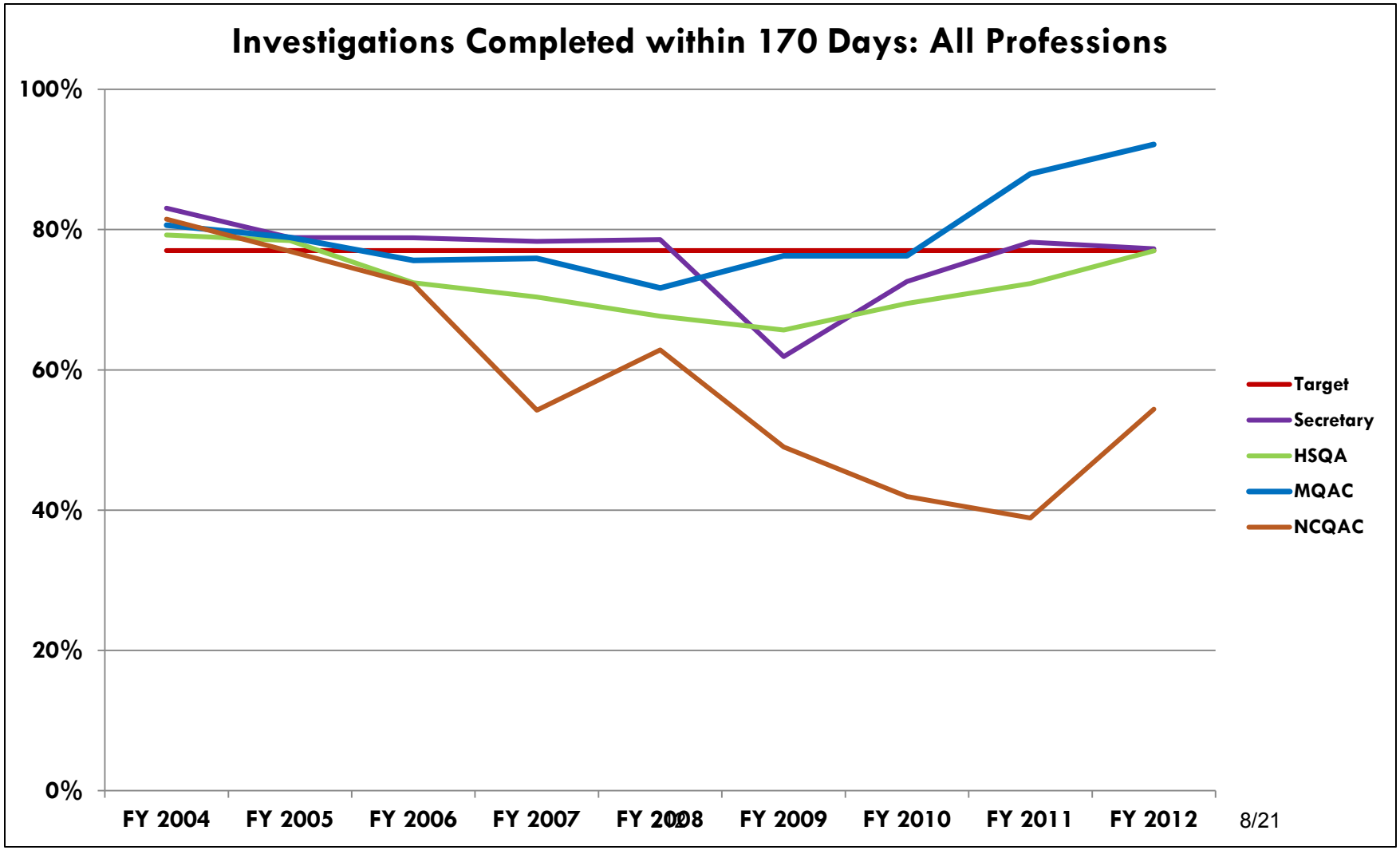
Performance: Investigation Growth



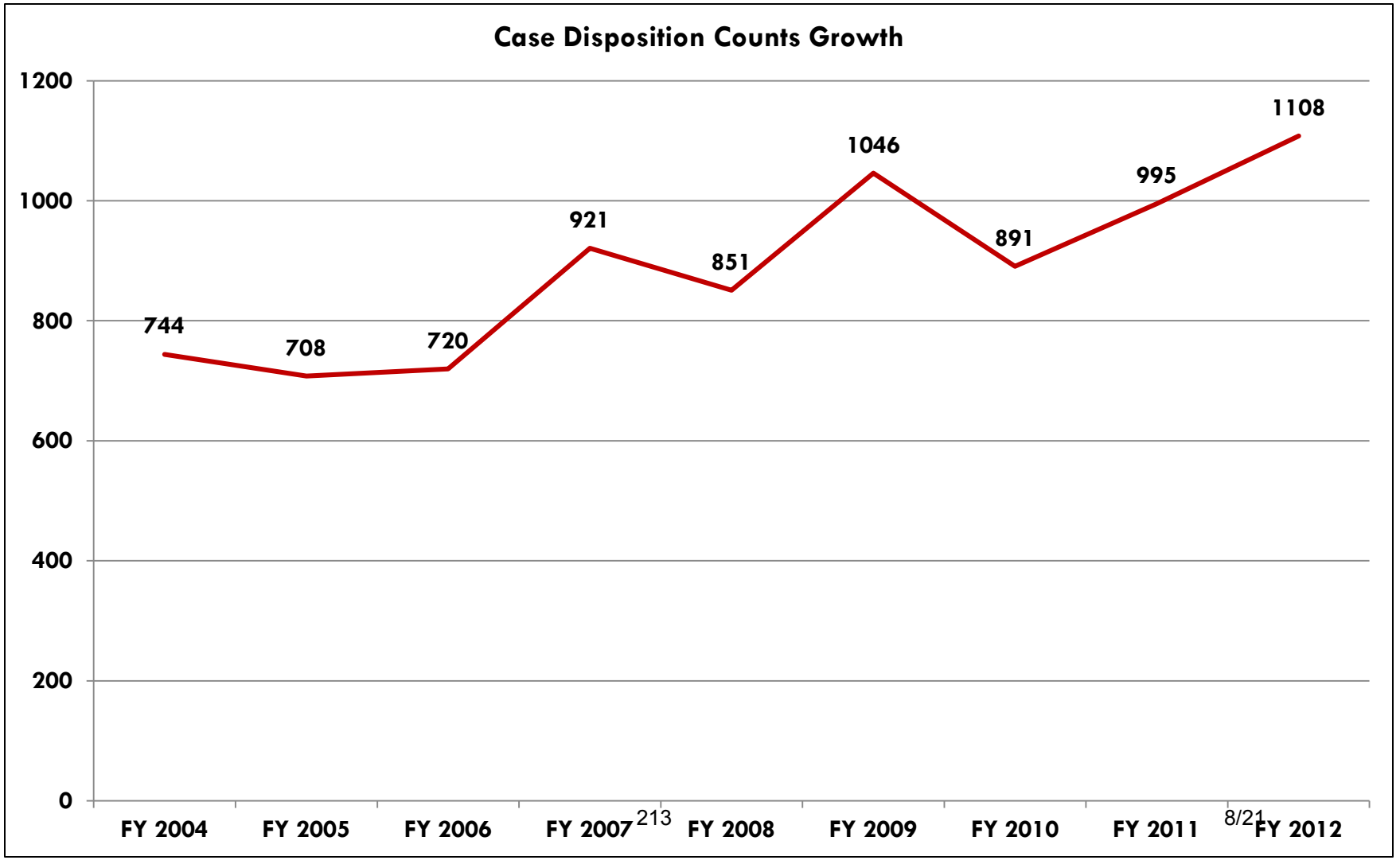
Performance: Discipline



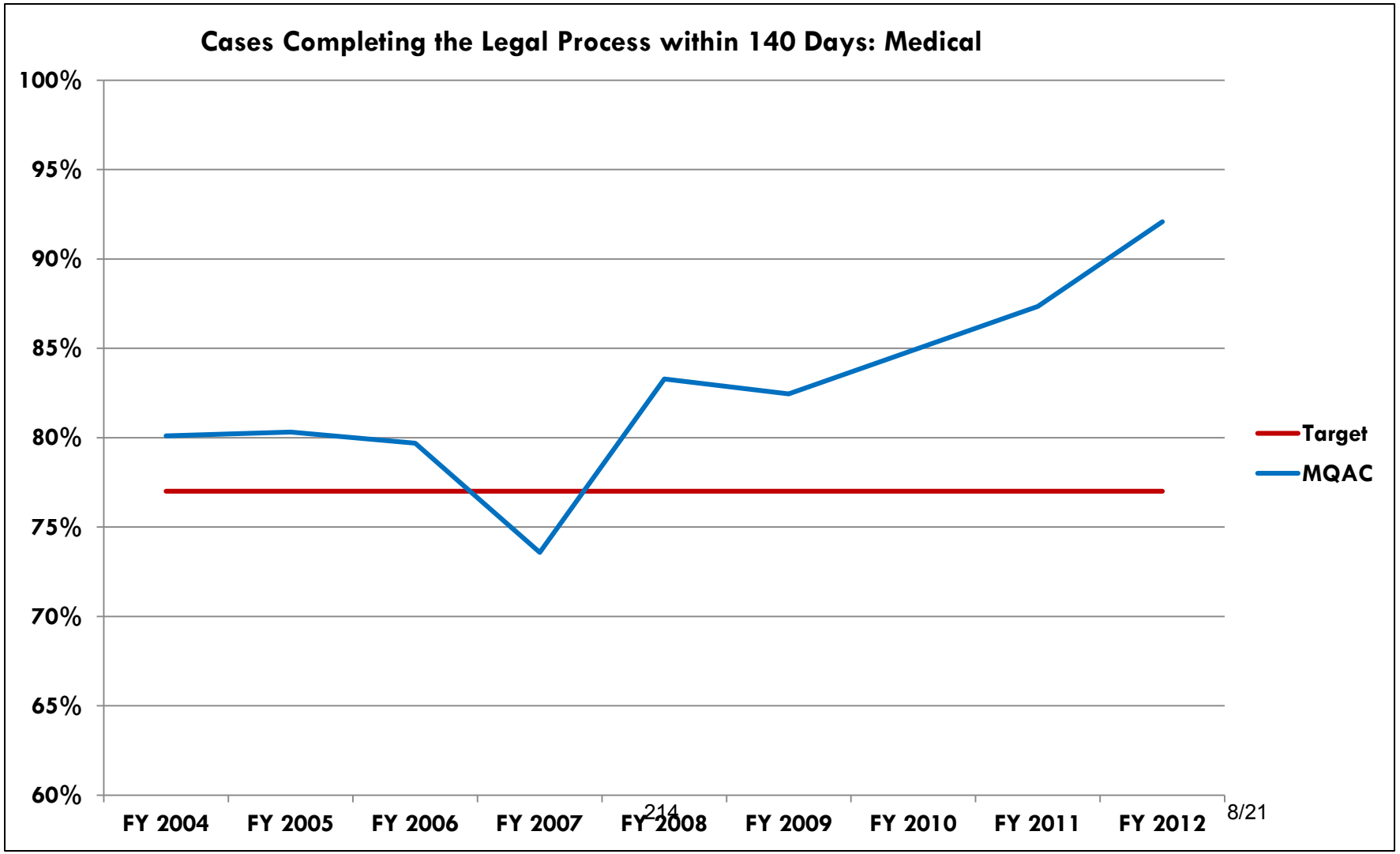
Performance: Discipline



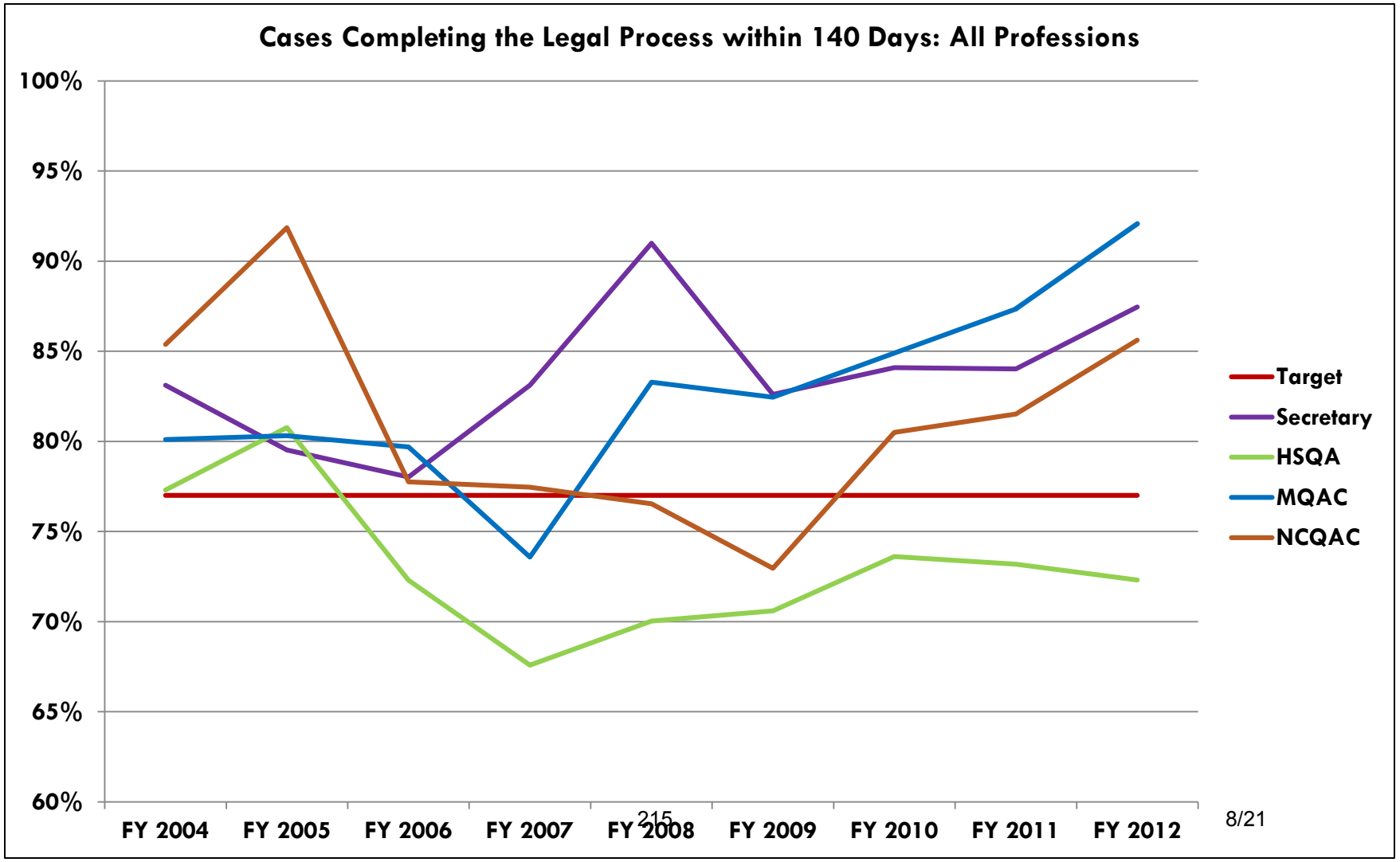
Performance: Legal Cases Growth



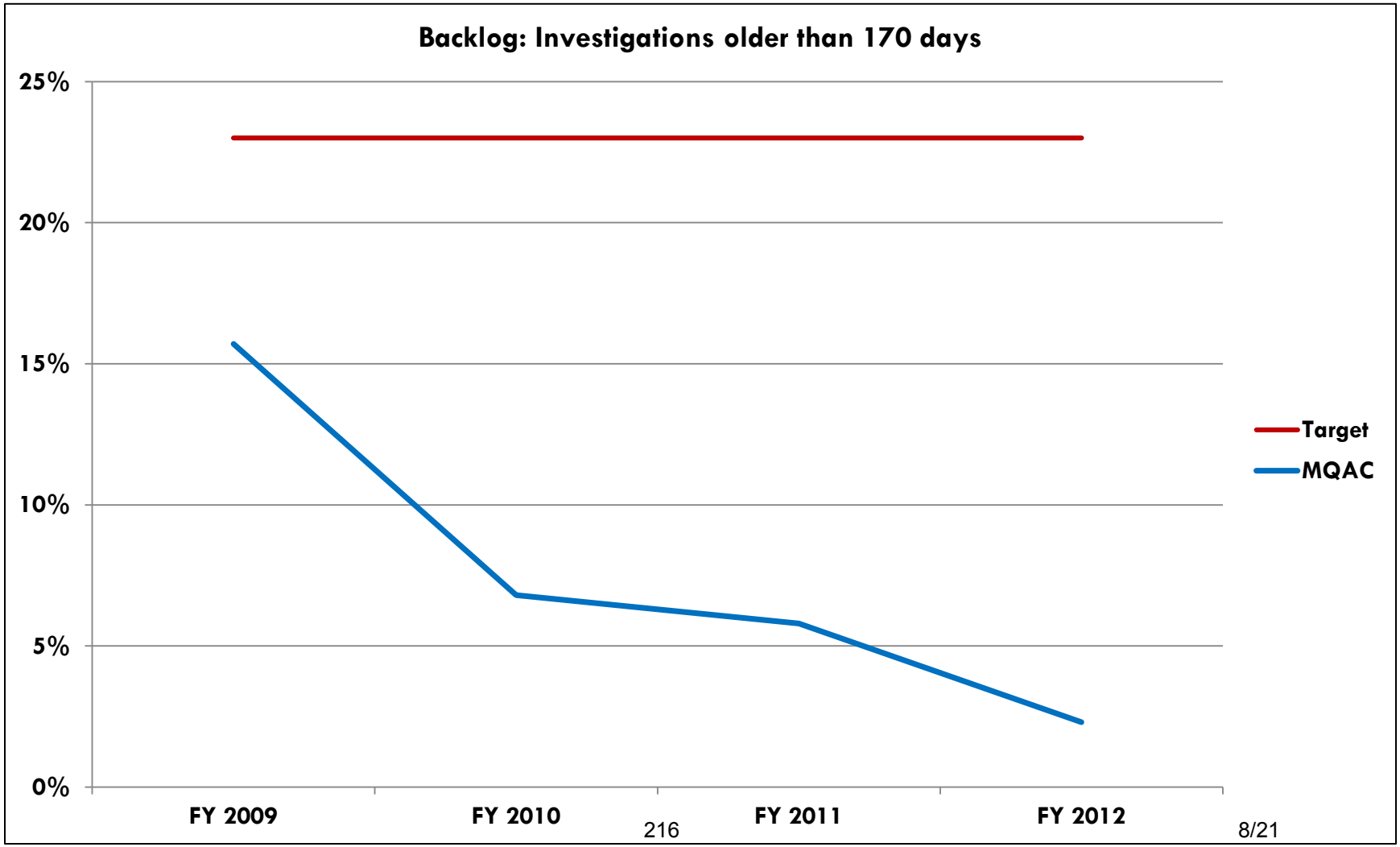
Performance: Discipline



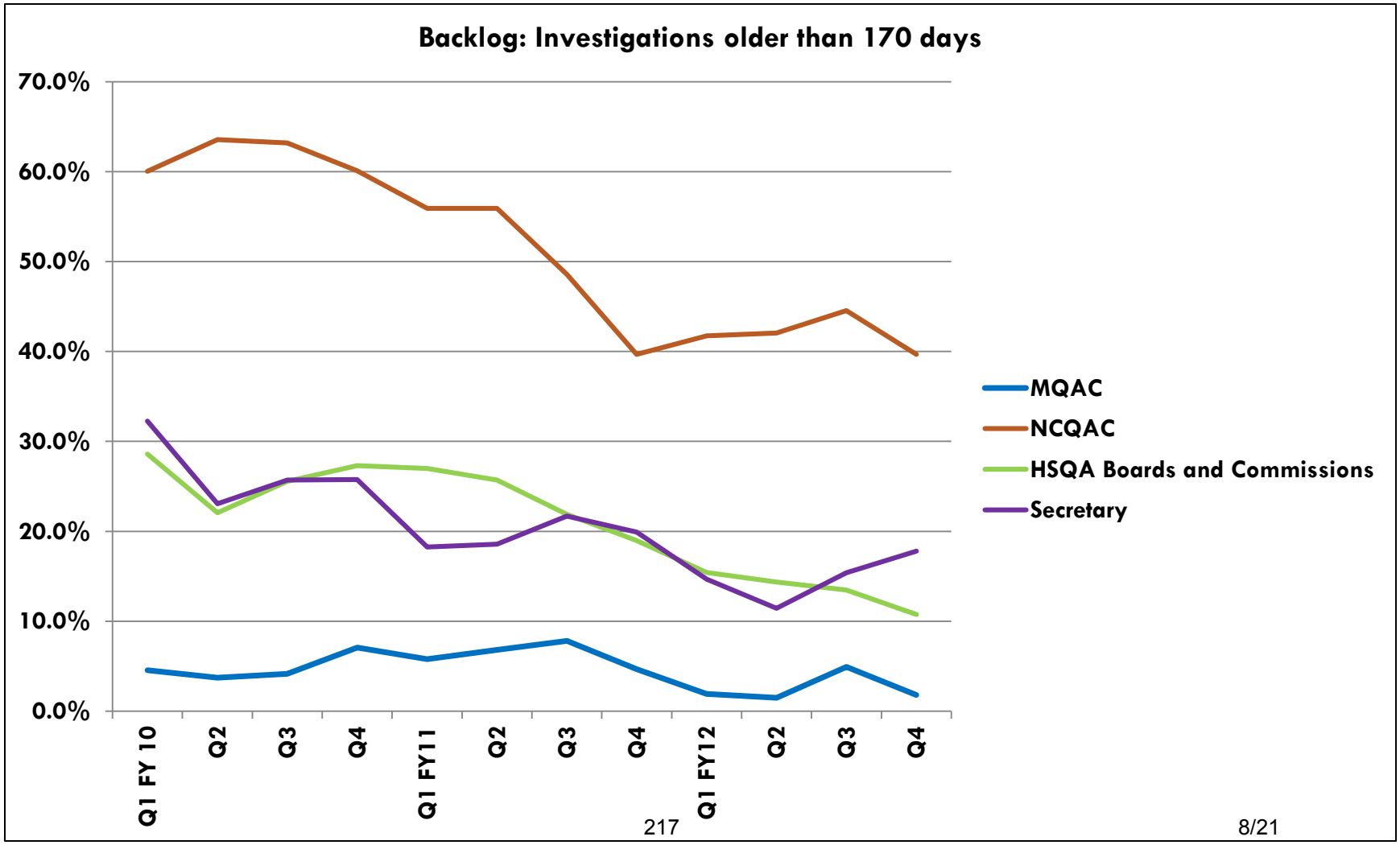
Performance: Discipline



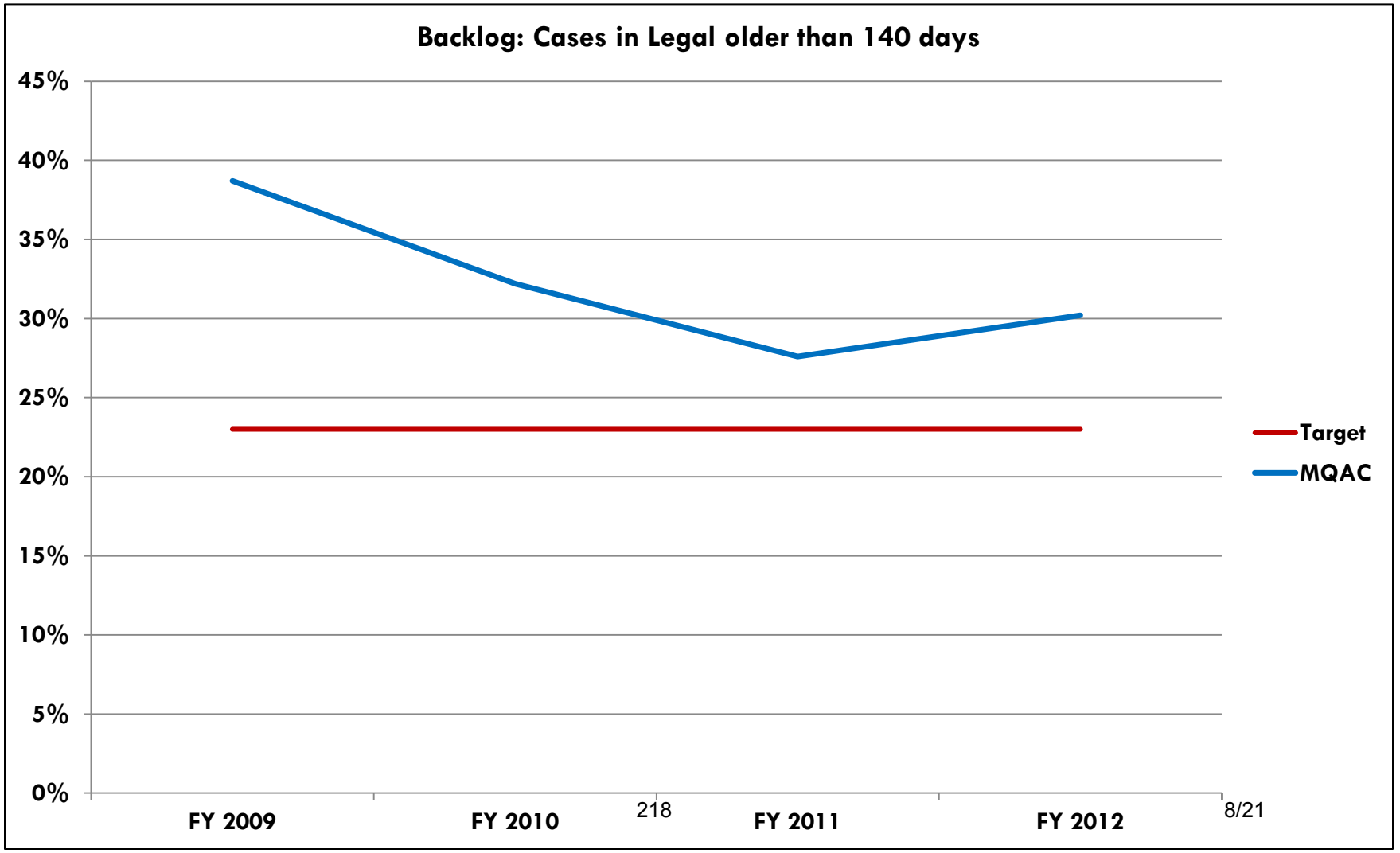
Performance: Investigation Backlog



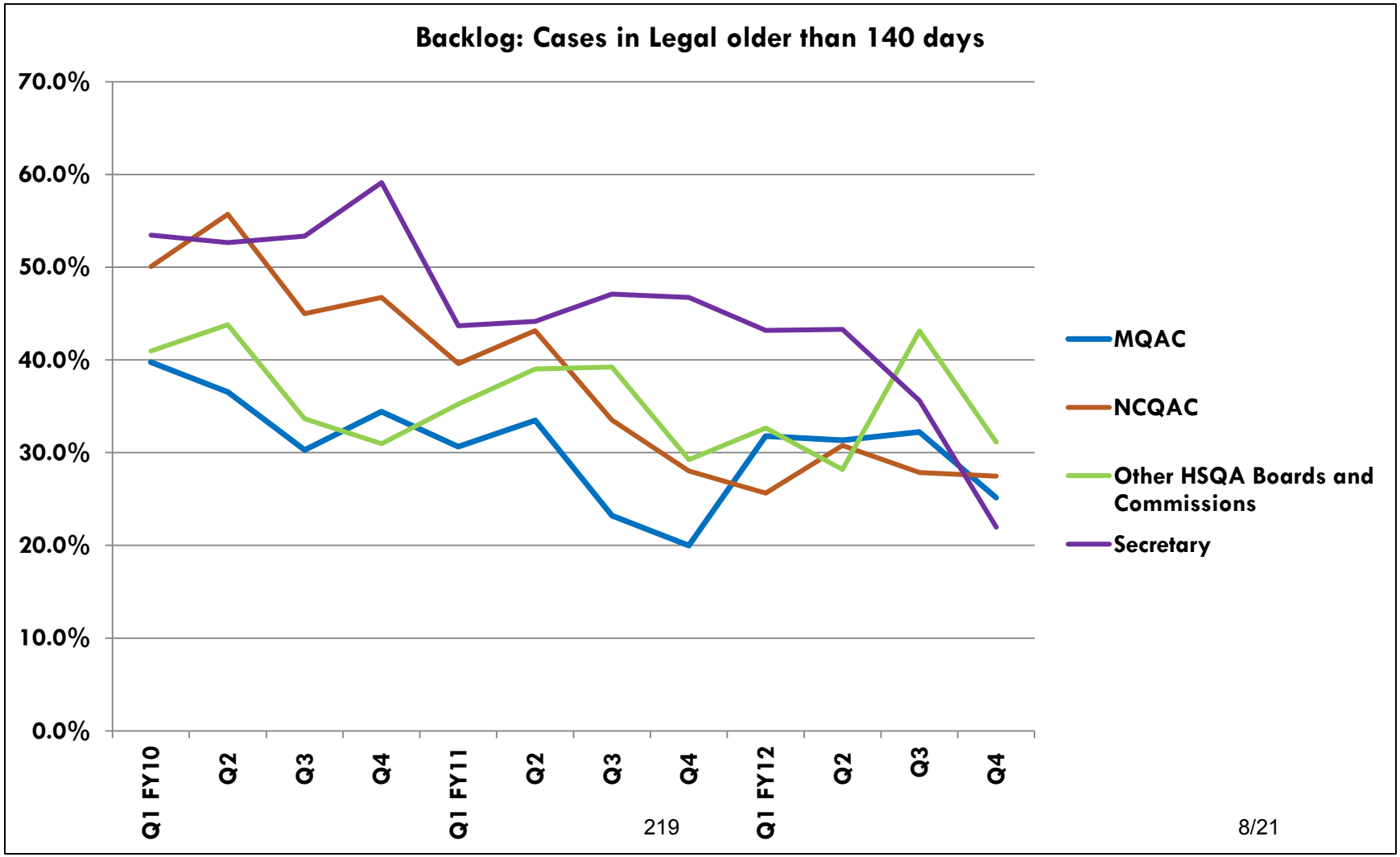
Performance: Investigation Backlog



Performance: Legal Backlog



Performance: Legal Backlog



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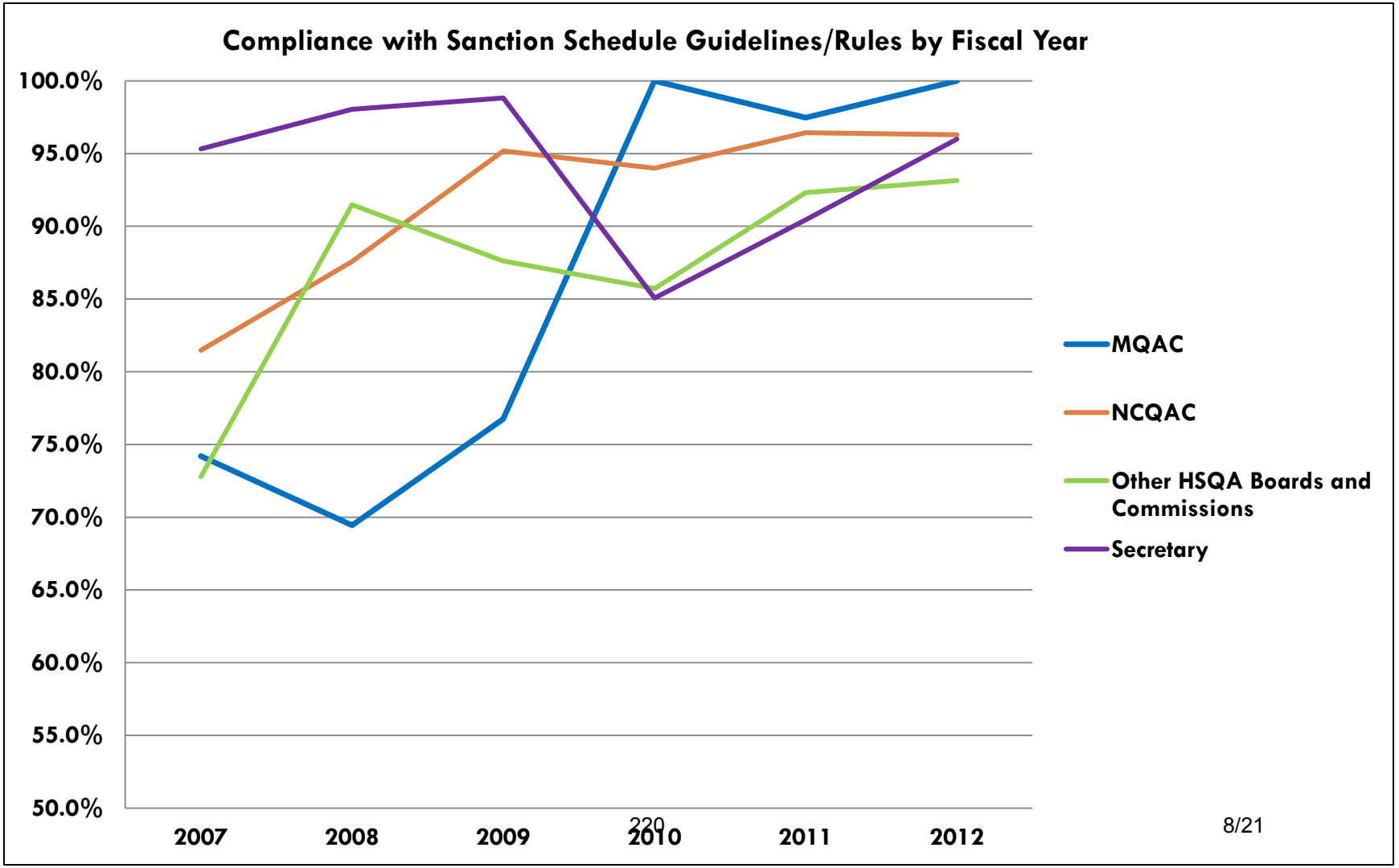
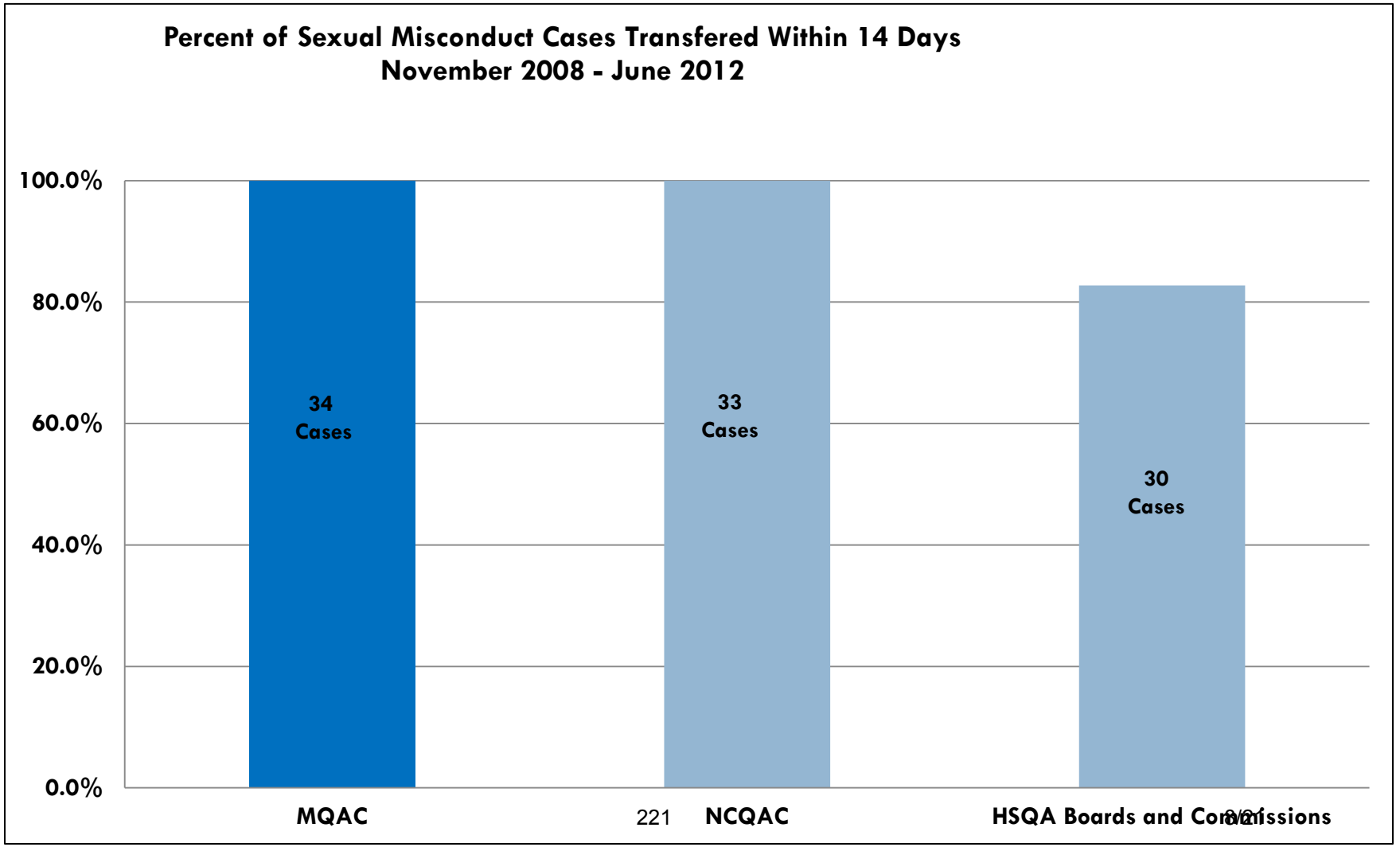
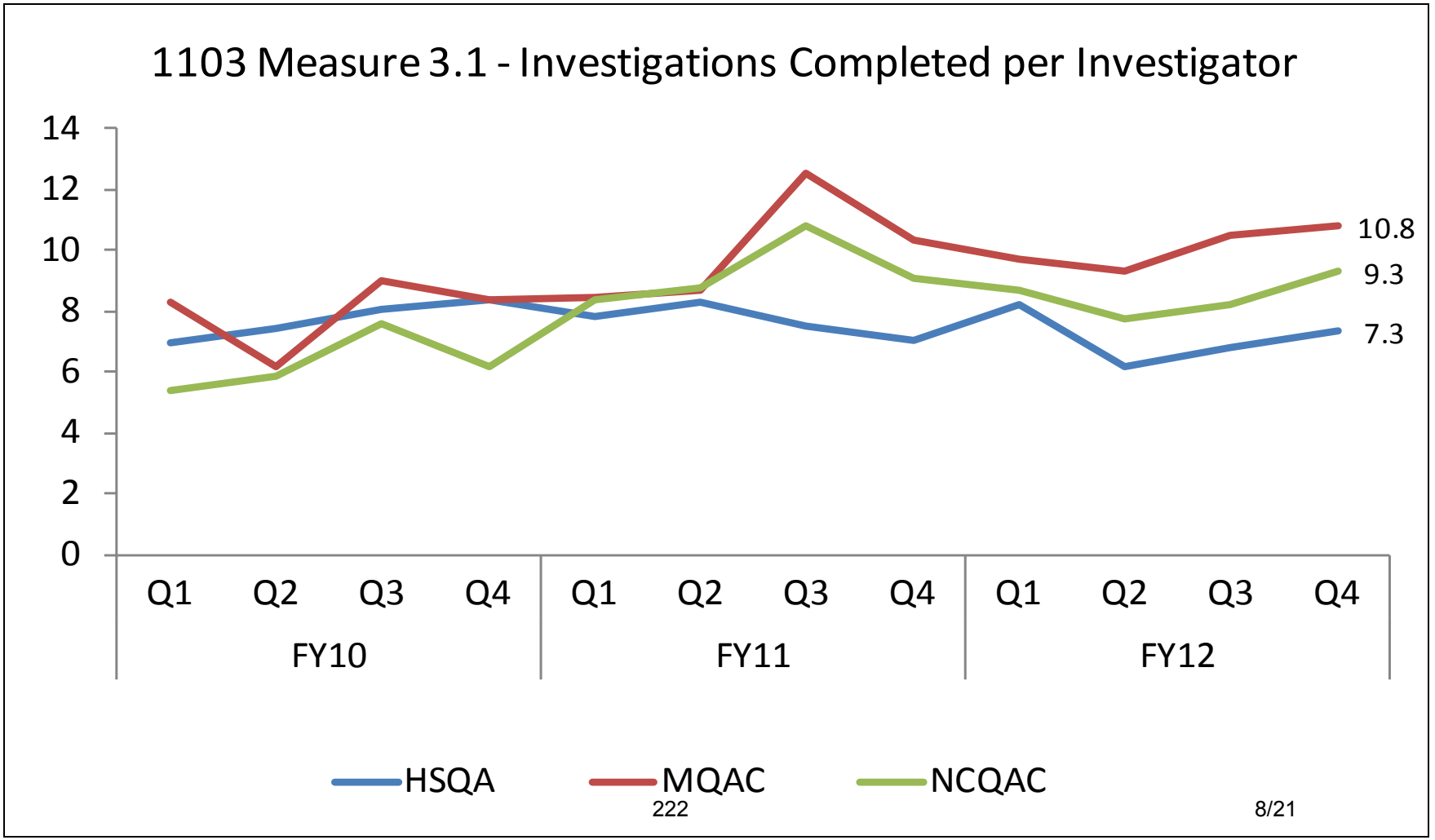
Performance: Consistent Discipline



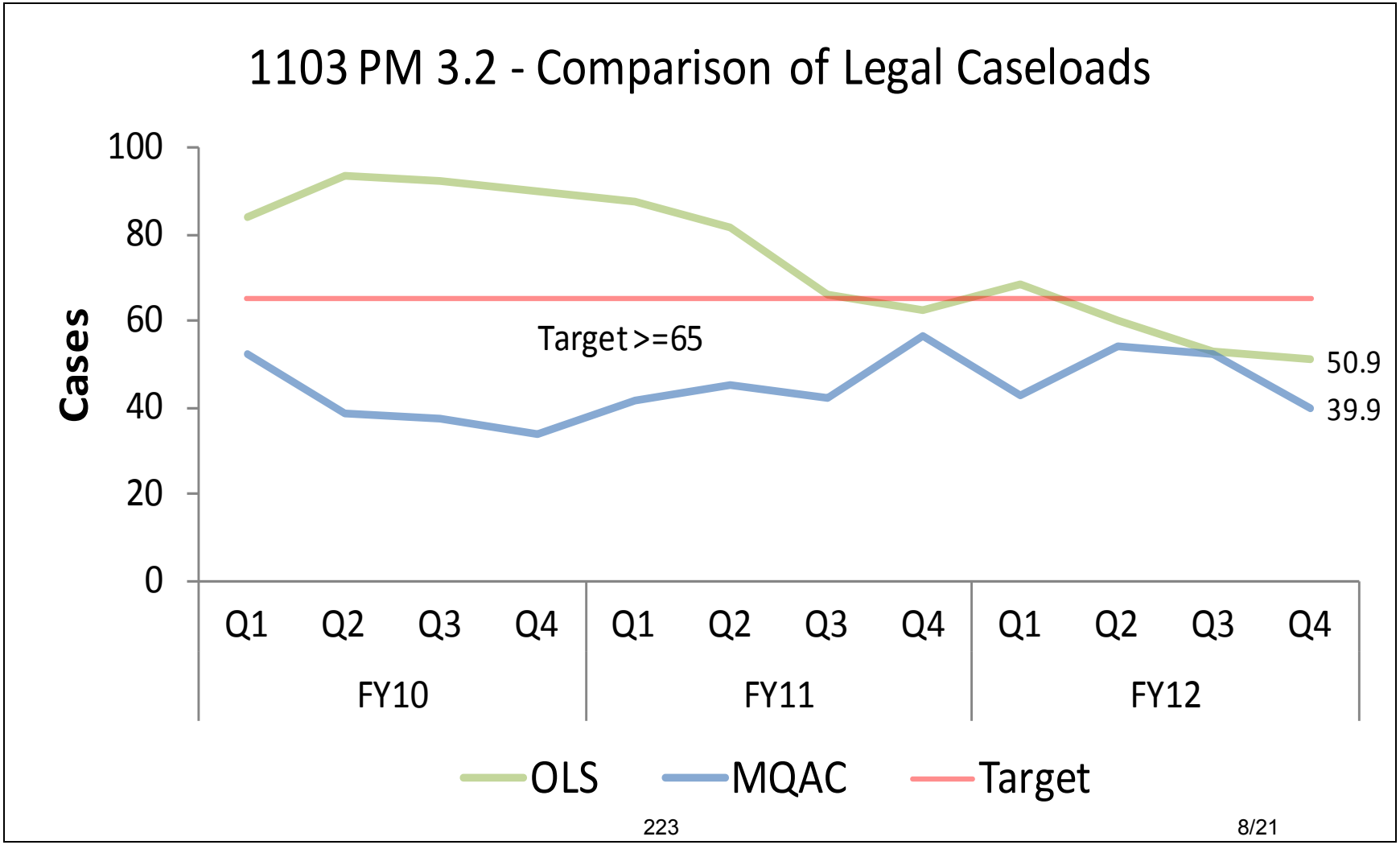
Performance: Discipline



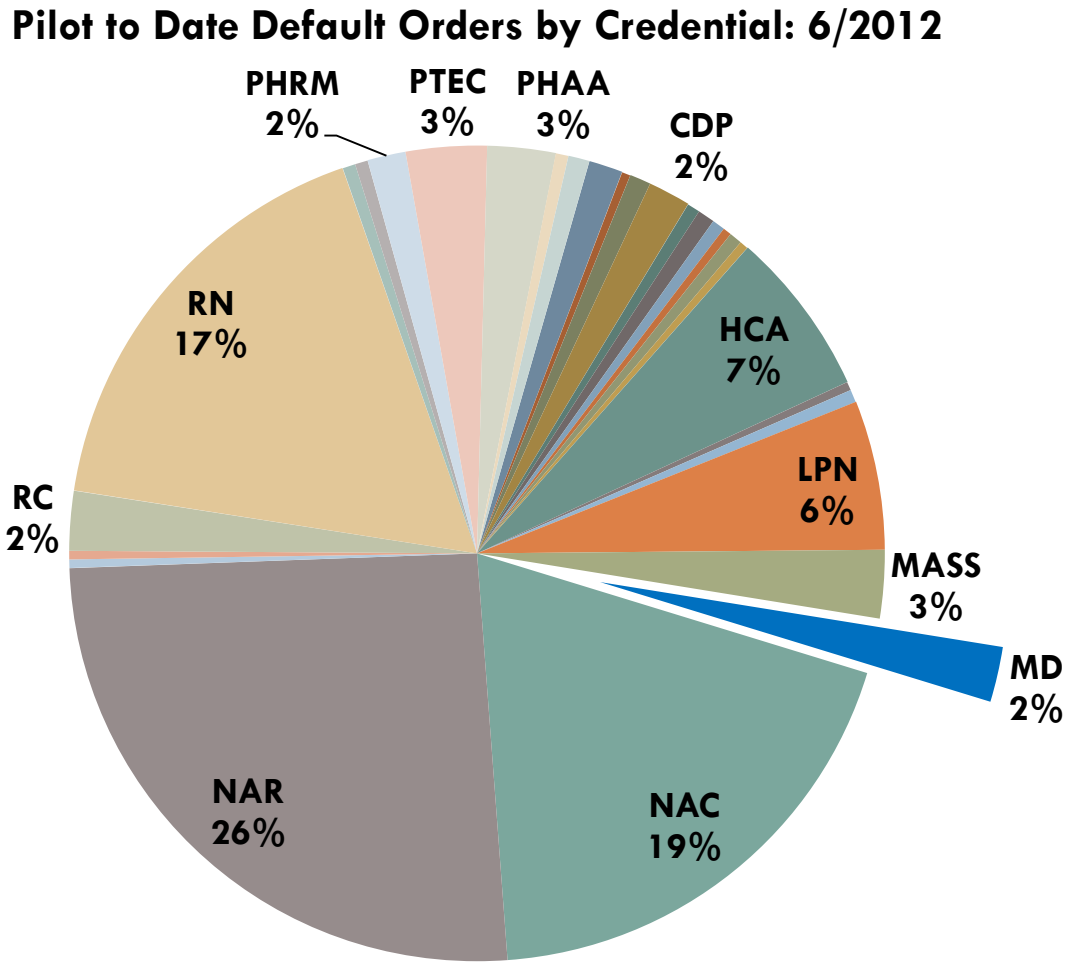
Performance: Investigator Workload



Performance: Legal Workload



Performance: Default Comparison



Demographics: Snapshot

- 67.8% male
- Demographic age ranges:
  - 1900-1946: 14%
  - 1946-1964: 56%
  - 1965-1982: 30%
  - 1983-2001: 0%
- 90.6% ABMS Board Certified
- Top 3 Specialties:
  - Internal Medicine
  - Family Medicine
  - Pediatrics

- 43% practice in a specialty group (single and large)
- 21% are employed by a Hospital or Clinic
- 74% have hospital clinical privileges
- 10% practice Telehealth
- 67% do not prescribe opioids for chronic non-cancer pain
- 37% of medical practices speak English and another language

*Data used is from surveys received between March 1, 2012-August 9, 2012

Reconsideration: One Year Later

- Requests jumped from 15 in FY11 to 74 in FY12
  - 50-50 above investigation and below investigation thresholds
- Over 200 hours to date spent working on Requests for Reconsideration.
  - below threshold cases costs: $44/case
  - primary staff costs: $362/month
  - Above threshold costs: $251-720/case
- Six cases where Medical Commission took additional action
- No additional disciplinary actions were taken as a result of new law in year one

Accomplishments

- Enhanced Patient Safety
- National Recognition
- Faster, more efficient, more consistent disciplinary process
- Increased transparency/more consumer friendly
- Individual Awards or Accomplishments
- Current Projects

Enhance Patient Safety

- Office-based Surgery rules
- Pain Management rules
- Policy on Reducing Medical Errors
- Policy on Preventing Wrong-site Surgery
- Policy on the Transmission of Time Critical Medical Information
- Policy on Practitioners Exhibiting Disruptive Behavior

National Recognition

- 2012 AIM Best of Boards award for Pain Management Rules education program.
- Public Citizen: 44th to 9th in ranking from 2008 to 2012.
- The Urban Institute Study. FSMB awarded a collaborative research grant of $30,000.

Faster, more efficient and more consistent disciplinary process

- 92% of cases are processed within timelines
- Reduced investigation outliers by ninety-nine percent
- Reduced legal outliers by seventy-four percent
- Adopted policy on processing completed investigations more efficiently (June 2011)
- Improved consistency:
  - 99% of orders comply with sanction rules
  - Policy on consistent approach to wrong-site surgery cases

Individual Awards or Accomplishments

- Samuel Selinger, MD, won the FSMB's John H. Clark Leadership Award in 2011. He also gave a TED talk on professionalism.
- Leslie Burger, MD, is a member of the Federation of State Medical Boards Foundation.
- Frank Hensley serves on the FSMB's Finance Committee.
- Larry Berg serves on the Editorial Board for the FSMB Journal.
- Ellen Harder, PA-C, was appointed by the FSMB to the National Commission on Certification of Physician Assistants.
- Maryella Jansen, ED, was invited by the FSMB to a meeting on the Uniform Application Process and a meeting in Washington, D.C. to address the future of medical regulation.
- Jim McLaughlin asked to speak at national conference on the Commission's pain rules.
- Legal Unit Manager, Michael Farrell, served on an AIM assessment team to evaluate the North Carolina Medical Board.

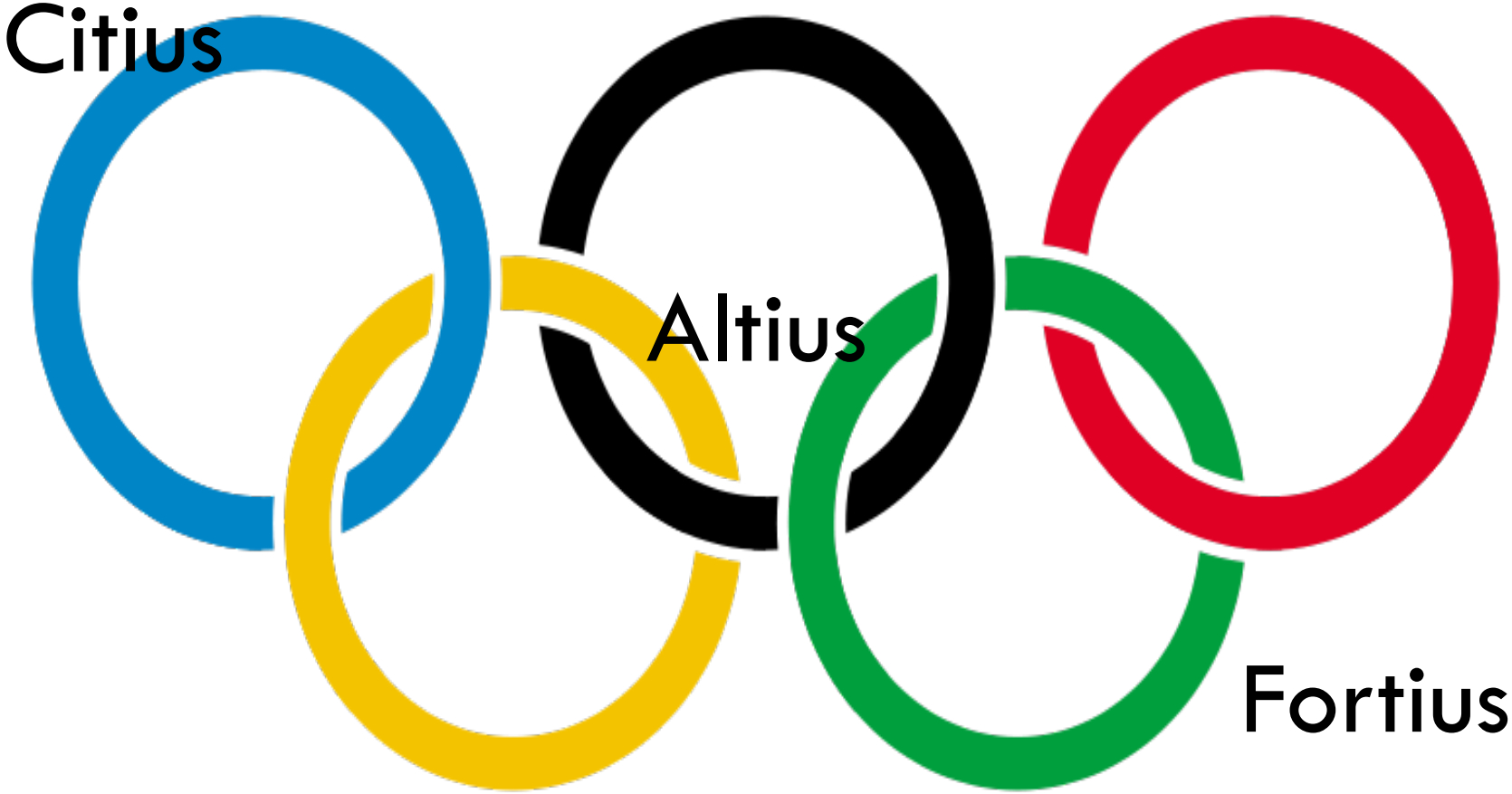
Increased transparency/more consumer friendly

- Disciplinary orders are more clear, consistent and transparent.
  - Include section in orders on sanction guidelines/rules
  - Headings for each section and for paragraph on sanctions
  - Goal to write orders that are understandable to public.
- Listserv for Commission actions
- Revised web site to be more clear and user friendly
- Solicit public comment at Commission meetings
- Implemented the reconsideration process and the complainant impact statement process as mandated by SHB 1493.

Current Projects

- Collecting demographic data on licensees to assist stakeholders in making workforce decisions
- Proposal to Legislature to update licensing requirements to enable the Commission to license qualified physicians from other countries to address shortages
- Budget request to fund state-wide education efforts
- Research disciplinary recidivism among physicians and physician assistants
- Developing guidelines on the use of social media
- Board to Board discussions, ten completed so far

Washington State Medical Commission



Washington State Medical Commission

Faster, Higher, Stronger

Medical.Commission@doh.wa.gov




TEAM MEDICINE℠ VIRGINIA MASON

Seeking Zero Defects: Creating a Patient Safety Culture

Medical Quality Assurance Commission Workshop
August 23, 2012

Gary S. Kaplan, MD, Chairman and CEO
Virginia Mason Medical Center
Seattle, Washington

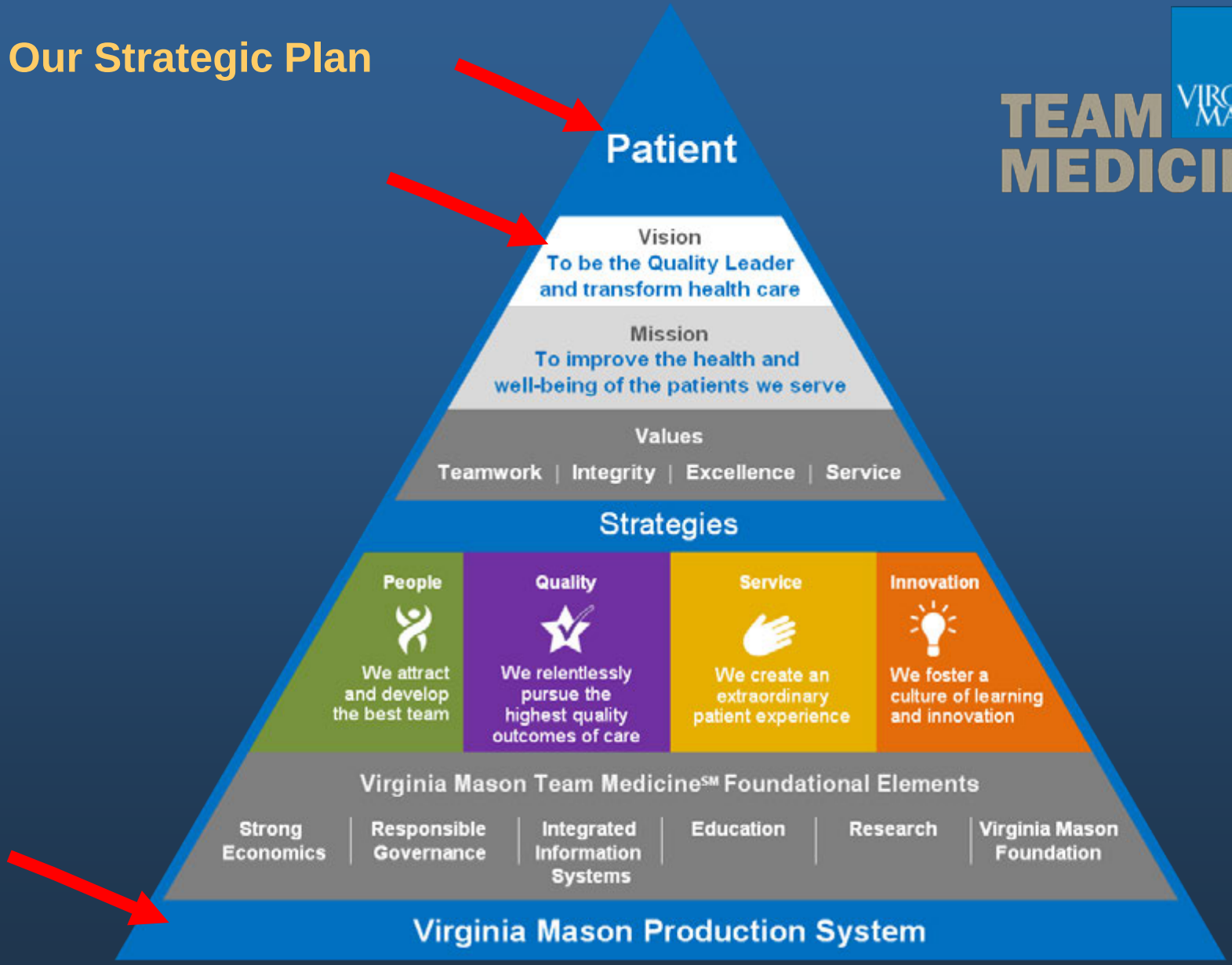
“If you are dreaming about it… you can do it.”

Sensei Chihiro Nakao

Virginia Mason Medical Center

- Integrated health care system
- 501(c)3 not-for-profit
- 336-bed hospital
- Nine locations
- 500 physicians
- 5,000 employees
- Graduate Medical Education
- Research Institute
- Foundation
- Virginia Mason Institute

Our Strategic Plan



Why is Change So Hard?

- Culture
- Lack of Shared Vision
- Misaligned Expectations
- No Urgency
- Ineffective Leadership

"Let's just start cutting and see what happens."

VMMC Physician Compact

Organization's Responsibilities

Foster Excellence
- Recruit and retain superior physicians and staff
- Support career development and professional satisfaction
- Acknowledge contributions to patient care and the organization
- Create opportunities to participate in or support research

Listen and Communicate
- Share information regarding strategic intent, organizational priorities and business decisions
- Offer opportunities for constructive dialogue
- Provide regular, written evaluation and feedback

Educate
- Support and facilitate teaching, GME and CME
- Provide information and tools necessary to improve practice

Reward
- Provide clear compensation with internal and market consistency, aligned with organizational goals
- Create an environment that supports teams and individuals

Lead
- Manage and lead organization with integrity and accountability

Physician's Responsibilities

Focus on Patients
- Practice state of the art, quality medicine
- Encourage patient involvement in care and treatment decisions
- Achieve and maintain optimal patient access
- Insist on seamless service

Collaborate on Care Delivery
- Include staff, physicians, and management on team
- Treat all members with respect
- Demonstrate the highest levels of ethical and professional conduct
- Behave in a manner consistent with group goals
- Participate in or support teaching

Listen and Communicate
- Communicate clinical information in clear, timely manner
- Request information, resources needed to provide care consistent with VM goals
- Provide and accept feedback

Take Ownership
- Implement VM-accepted clinical standards of care
- Participate in and support group decisions
- Focus on the economic aspects of our practice

Change
- Embrace innovation and continuous improvement
- Participate in necessary organizational change

The VMMC Quality Equation

$$Q = A \times \frac{(O + S)}{W}$$

Q: Quality
A: Appropriateness
O: Outcomes
S: Service
W: Waste

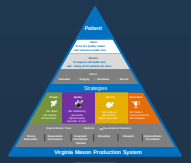
Guiding Vision
Hippocratic Oath

First, do no harm

Priority Zero Defects

First priority, zero defects

Henry Otero MD



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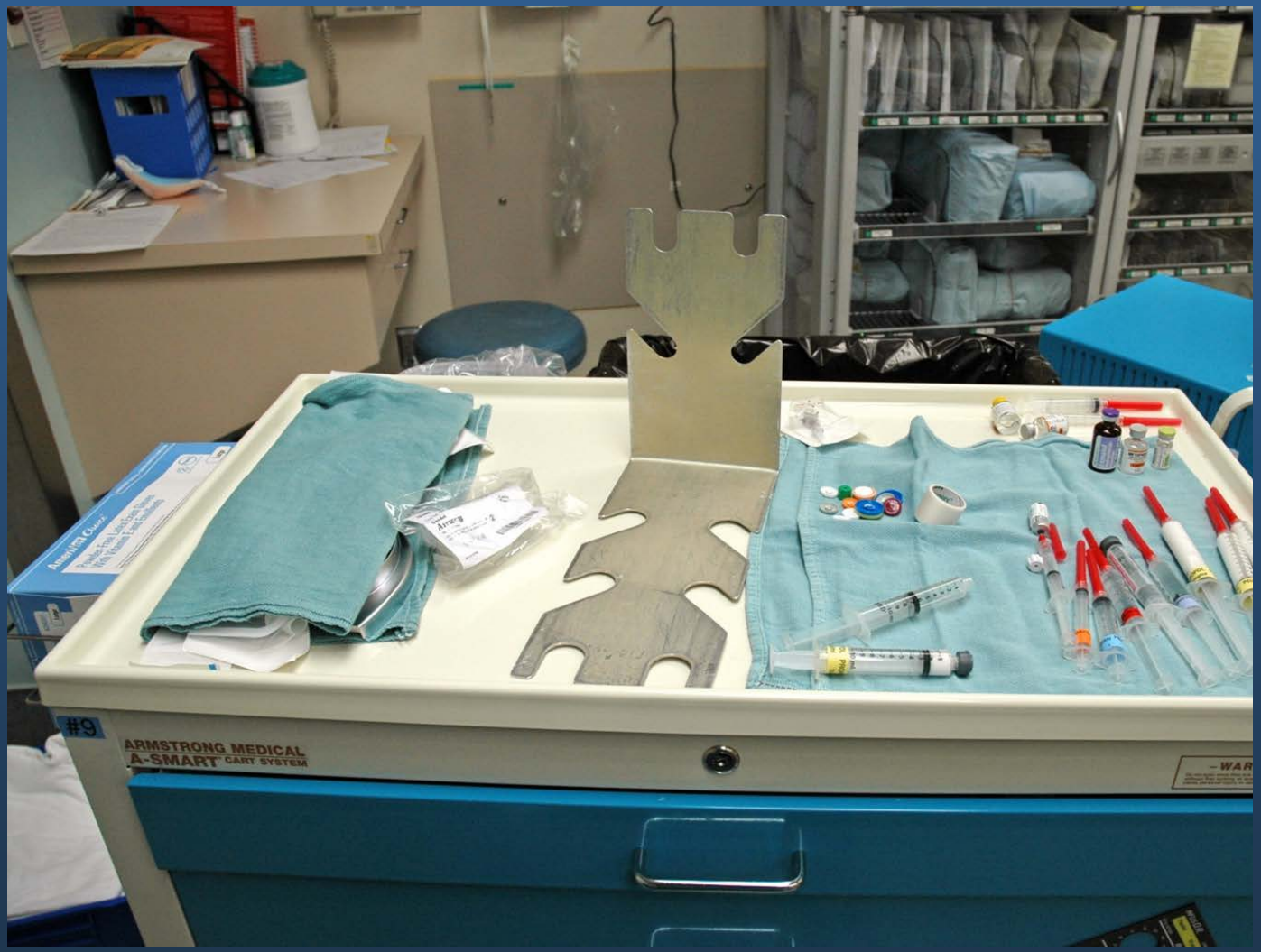
New Management Method: The Virginia Mason Production System

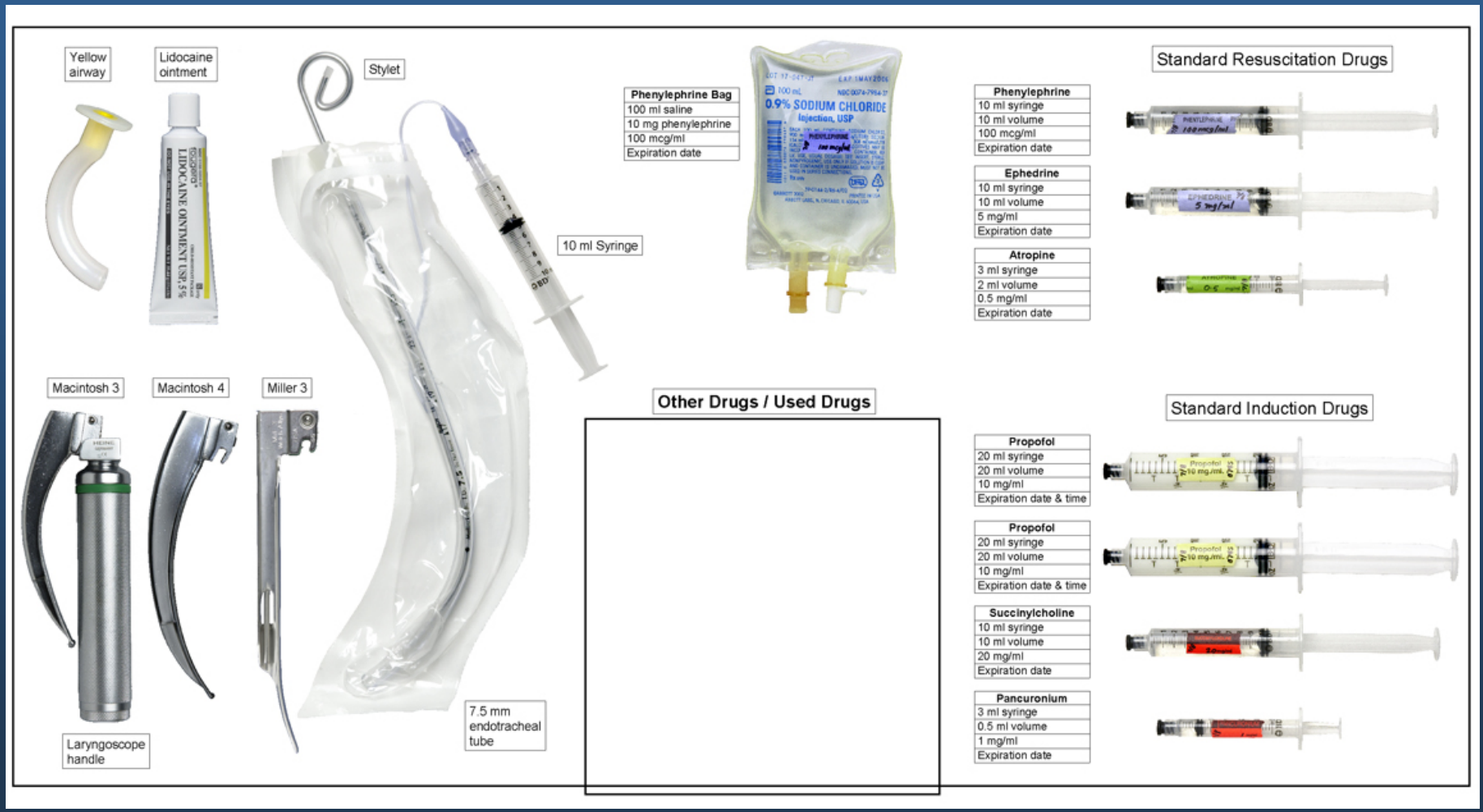
We adopted the Toyota Production System philosophies and practices and applied them to health care because health care lacks an effective management approach that would produce:

- Customer first
- Highest quality
- Obsession with safety
- Highest staff satisfaction
- A successful economic enterprise

Seeing with our Eyes
Japan 2002



5S Anesthesia “Shadow Board” - Before



5S Anesthesia "Shadow Board" - After

Central Line Insertion Standard Work

Before



Dry:
30 sec scrub
30 sec dry
Wet:
2 min scrub
1 min dry

Paws

Maximum Barrier Protection

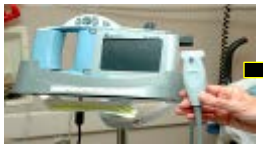

Thyroid

OR


Angio Drapes

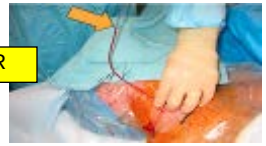
AND

During



Transducer Kit in Top Drawer of Cart


OR


Transducer Method

Manometer Method

After


"Approved to use Date/Initial"


Yellow – top of cart


White – in chart progress notes

Complete Paperwork

Stopping the Line™

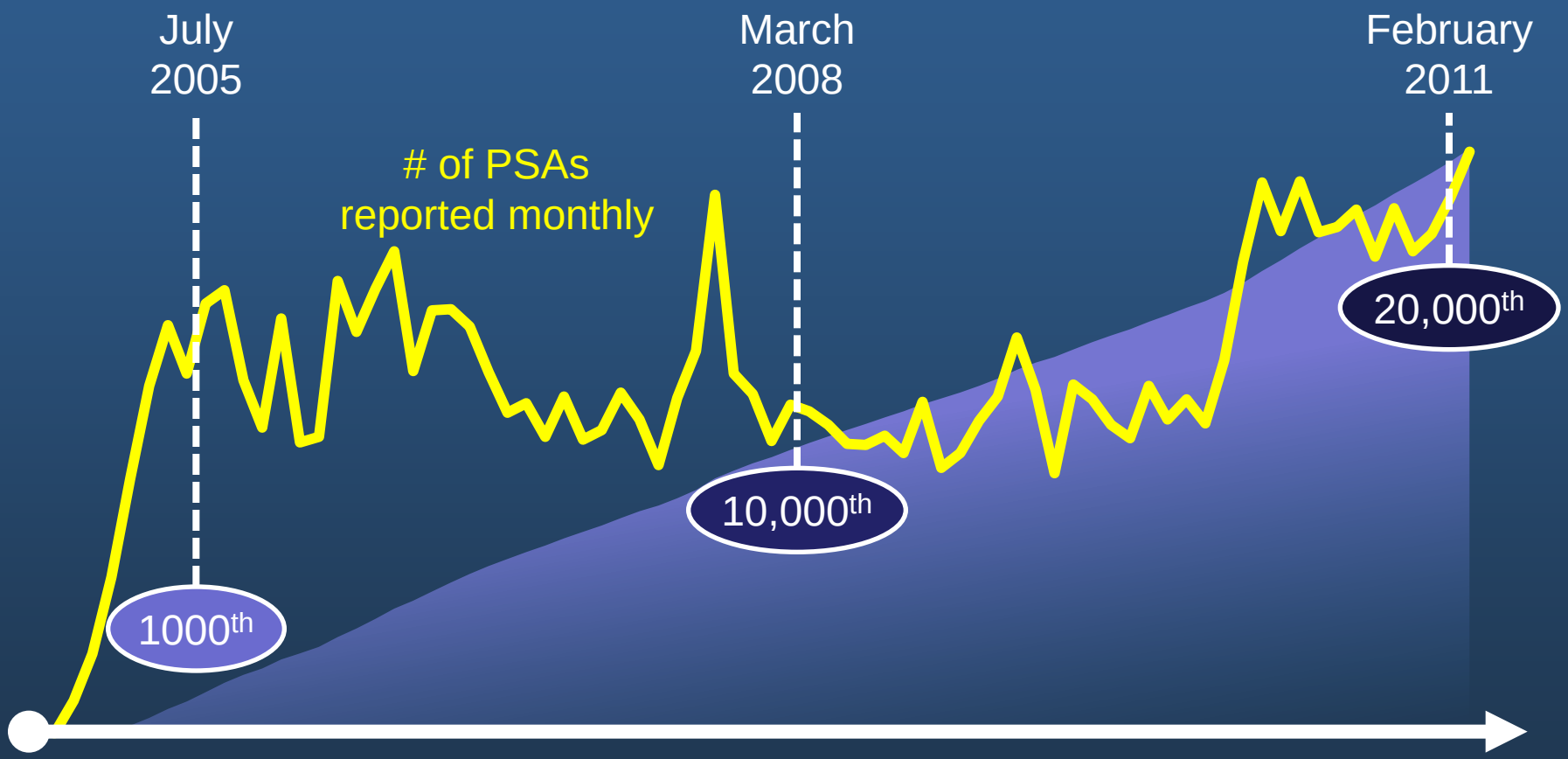
Virginia Mason's Patient Safety Alert System™

Stopping the line

Patient Safety Alert Process ™ Created August 2002

- Leadership from the top
- “Drop and run” commitment
- 24/7 policy, procedure, staffing
- Legal and reporting safeguards

20,000th PSA Reported



Categorizing Patient Safety Risk Events

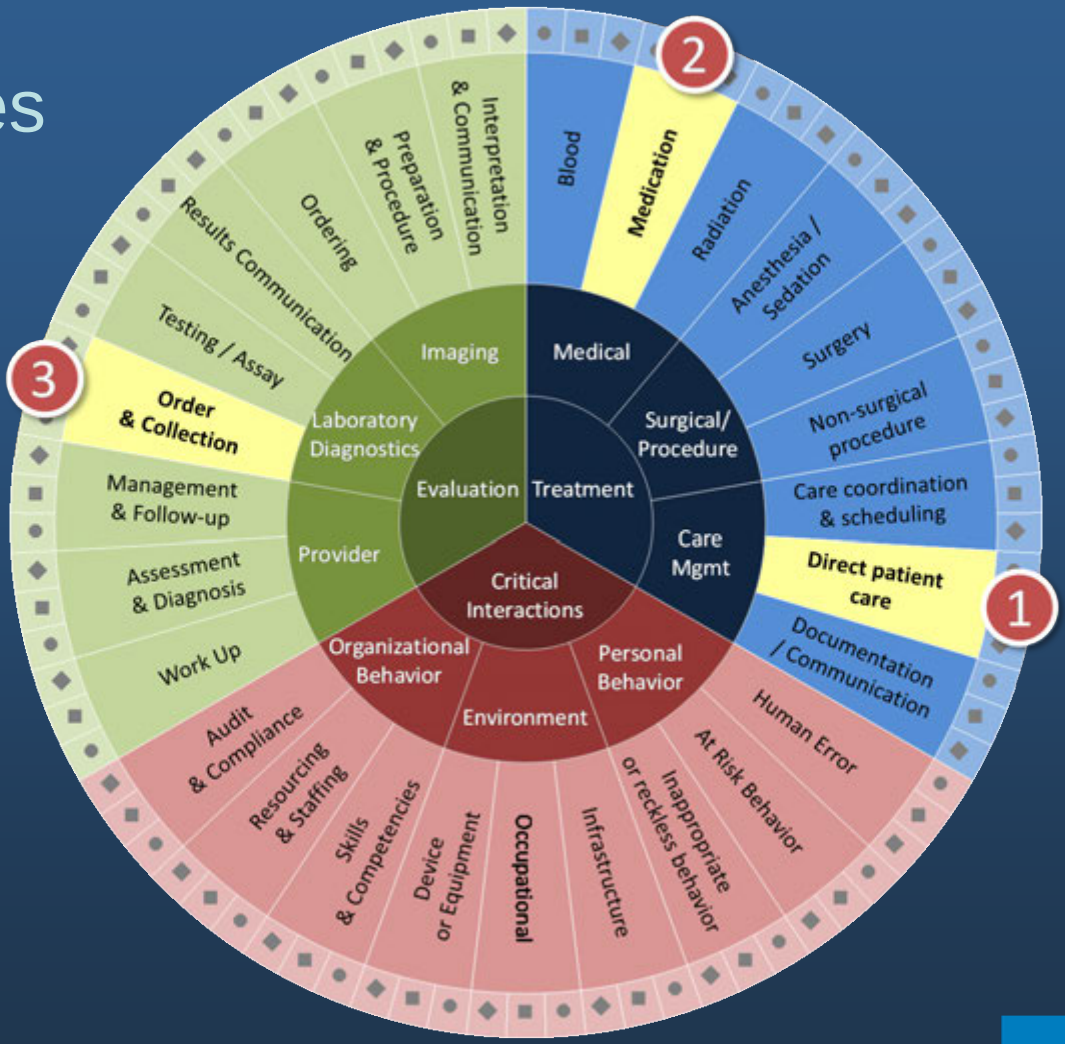
3 Basic Risk Sources

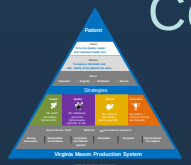
- Evaluation
- Treatment
- Critical interactions

27 Specific Risk Categories

3 of the top 5 risks

- Direct Patient Care
- Medication
- Laboratory Order & Collection





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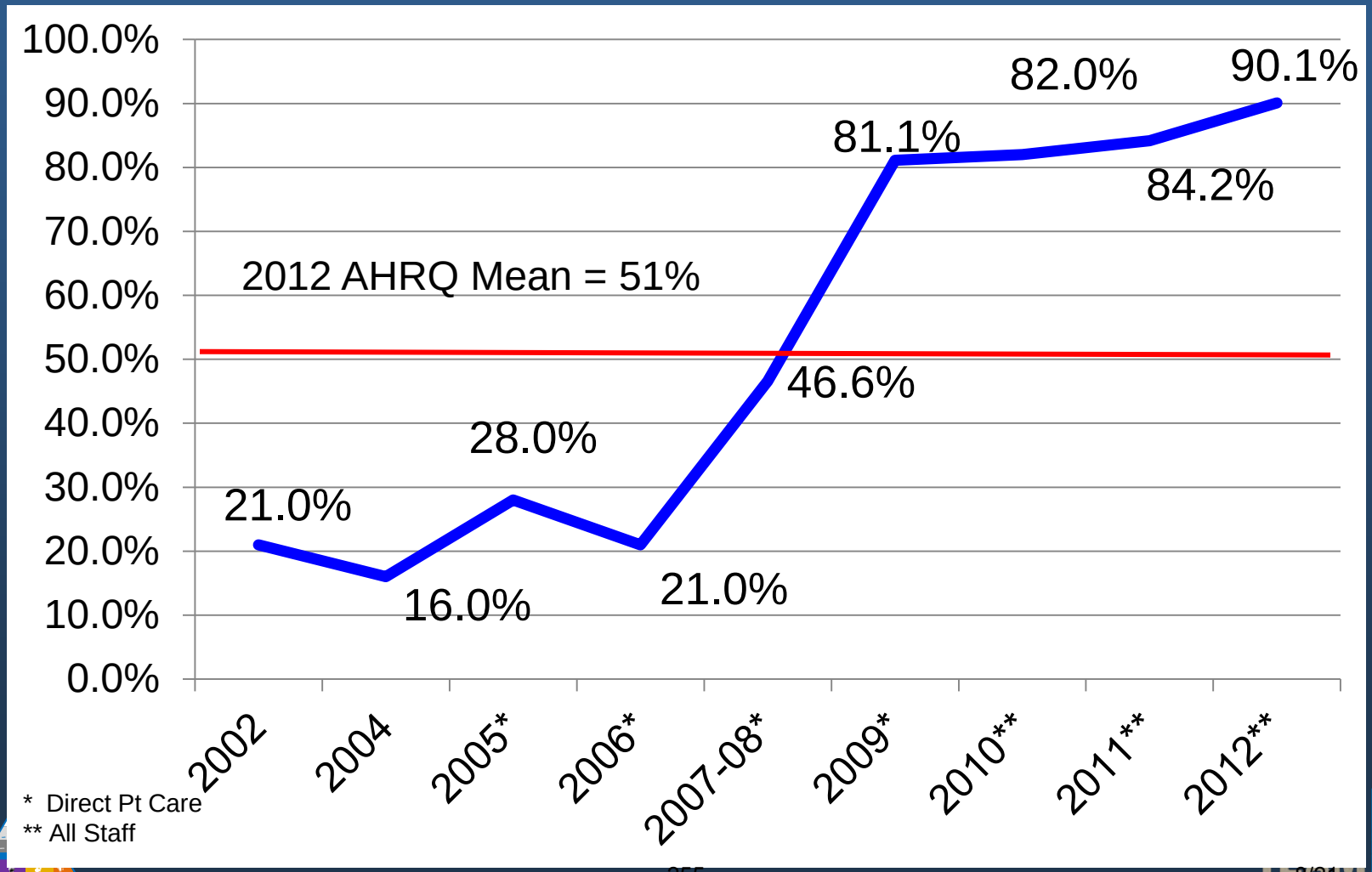
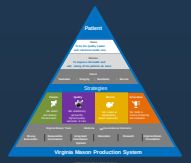
VM Staff Response Rate

Safety Survey

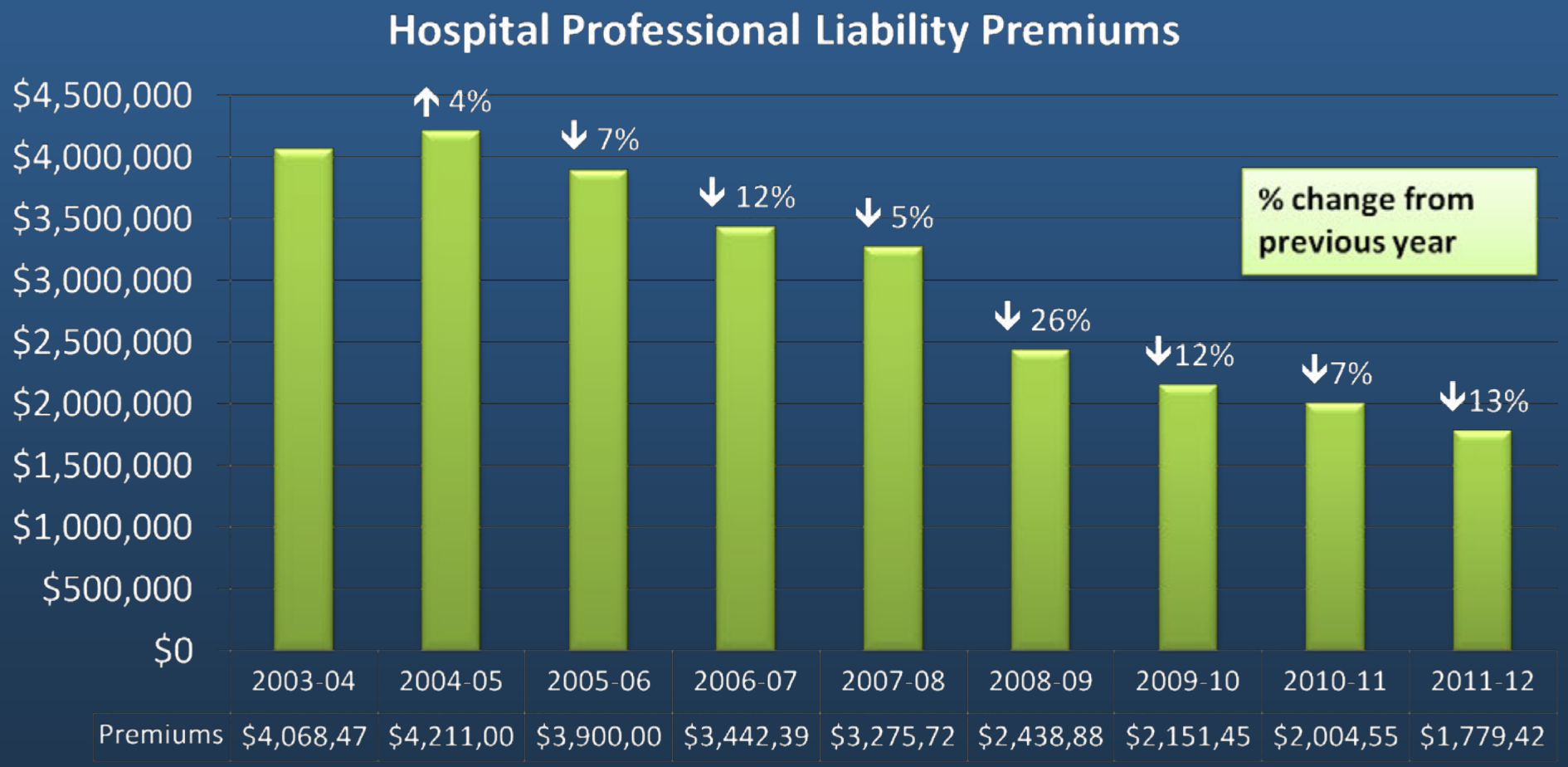


Mistakes vs. Defects

- Mistakes are inevitable…but reversible
- Defects are mistakes that were not fixed soon enough…and are now relatively permanent
- If you fix mistakes soon enough, your work will have zero defects - what the customer wants!
- Mistakes are least harmful and easiest to fix the closer you get to the time and place they arise



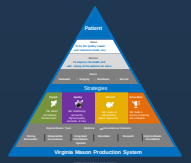
Reduction of Hospital Professional Liability Premiums



Cornerstones of a Safety Culture

- ✓ Create a Learning Culture
- ✓ Create an Open and Fair Culture
- ✓ Design Safe Systems
- ✓ Manage Behavioral Choices

  [Just Culture Algorithm]



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An Embarrassingly Poor Product

The March 16, 2003 edition of The New York Times Magazine front cover reads, “Half of what doctors know is wrong.”

The lead story is titled “The Biggest Mistake of Their Lives” and chronicles four survivors of medical errors.

The article goes on to say that in 2003, as many as 98,000 people in the United States will die as a result of medical errors.

Virginia Mason Medical Center

November 23, 2004

***Investigators*: Medical mistake kills Everett woman**

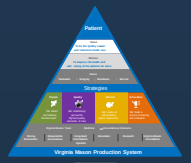
KING5.com
K5 Coverage You Can Count On

Hospital error caused death

The Seattle Times
seattletimes.com

A Defining Moment

- Decision to be transparent
- Emotional toil on staff, leaders and board
- One organizational goal
  - Ensure the Safety of our Patients: Eliminate Avoidable Death and Injury
- All staff meeting: One year anniversary



TEAM MEDICINE VIRGINIA MASON

The Mary L. McClinton Patient Safety Award
For Outstanding Teamwork in Making Patient Care Safer

Hands That Make Dreams Come True

Virginia Mason Medical Center, Seattle, Washington

A tireless volunteer and civic activist, Mary Louise McClinton devoted her life to helping others. She was a steadfast advocate for the disabled, poor and disadvantaged.

She earned adoption by the Tlingit Tribe of Juneau, Alaska, and the name "Jin-Koo-See'e" or in English, "Hands That Make Dreams Come True."

Mrs. McClinton died on November 25, 2004, while she was a patient at Virginia Mason, due to an avoidable medical error.

To honor her life, Virginia Mason has rededicated itself to eliminating avoidable death and injury.

This award is given annually to a team that has shown extraordinary effort and devotion to that goal.

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Mary L. McClinton
1935 - 2004

A tireless volunteer and civic activist, Mary Louise McClinton devoted her life to helping others. In 1969, she moved to Juneau, Alaska where she remained for more than 30 years.

Mary was active in local social and public policy issues where she was widely recognized as a community leader. The governor of Alaska appointed Mary to serve on the Women's Commission, a post she held for several years.

During her years in Juneau, Mary worked for the state of Alaska, in the Alaskan foster care system. She also worked for the Juneau Alliance for the Mentally Ill (JAMI) for many years as a life counselor and job coach. While raising her four sons, she fostered eight children and worked with countless others.

Mary worked with the Tlingit and Haida tribes helping Native Alaskans. Because of her passion and hard work, Mary became one of the few people ever adopted as a member of the Tlingit Tribe of Juneau. Mary was named "Jin-Koo-See'e" or, in English, "Hands that make dreams come true."

The Mary L. McClinton Patient Safety Award

In November 2004, Mary L. McClinton died at Virginia Mason Hospital as a result of a medical error. In response, the medical center apologized and accepted responsibility. Subsequent to that event, the entire staff has refocused and rededicated itself to the organization's patient safety efforts.

To honor her life, Virginia Mason established the Mary L. McClinton Patient Safety Award, which recognizes a team that has made extraordinary effort to improve patient safety at Virginia Mason. The first award was presented in March 2006. The award will be given annually during National Patient Safety Awareness Week.

BACK ROW:
Judy Graham, RN; Julie Gorveatt, RN; Joe Streiff, RRT; Michael Nevins, MD; David Kregenow, MD

FRONT ROW:
Robert Hase, MF, RRT; Michael Westley, MD; Shirley Sherman, RN; Lori Tyler, RN; Rosemary Tempel, RN; Penny Gilliatt, RN

Critical Care Unit Breakthrough Coordinating Group

Virginia Mason's Critical Care Unit (CCU) Breakthrough Coordinating Group (BCG) was awarded the first Mary L. McClinton Patient Safety Award in March 2006. This award will be given annually.

The CCU BCG is a multidisciplinary team that provides oversight, planning, analysis and support to the CCU staff on quality improvement initiatives. This team has challenged old ways of providing care and has set a goal of zero defects. The team engages the patient and family as a member of the team, and focuses its work to embed evidence-based practices in the daily work processes. The team promotes a culture of safety through use of transparent data and open discussion about how to improve. Numerous safety efforts initiated by the CCU Breakthrough Coordinating Group are benefiting patients throughout the hospital as standard work developed by the team is duplicated in other hospital units.

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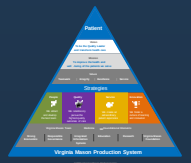
The Three Duties

The duty to avoid causing unjustified risk or harm

The duty to produce an outcome

The duty to follow a procedural rule



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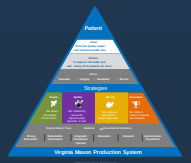
Two Specific Classes of Duty

- Meet me at 7:00 pm at 410 Chestnut Street

The Duty to Produce an Outcome

- Leave the house at 6:45 pm. Go south on Independence Ave, turn right on Parker. At the third light, hang a left, go three blocks, turn right and go to the fourth house on the right.

The Duty to Follow a Procedural Rule



Did the employee breach a duty to follow a procedural rule in a system designed by the employer?

- Rule specifies *how* to perform the job
- System largely controlled by employer

Duty to Follow a Procedural Rule
(system largely controlled by the employer)

Note: This test applies when the employee works within a system and is responsible for being a reliable component within that system.

Was the duty to follow a rule known to the employee? — YES → Was it possible to follow the rule? — YES → Did the employee knowingly violate the rule? — YES → Did the social benefit exceed the risk? — NO → Did the employee have a good faith but mistaken belief that the violation was insignificant or justified? — NO → Consider punitive action (RB)

- Was the duty to follow a rule known to the employee? — NO → Investigate circumstances leading to failure to know of duty
- Was it possible to follow the rule? — NO → Investigate circumstances leading to impossibility
- Did the employee knowingly violate the rule? — NO → Console employee and conduct human error investigation (HE)
- Did the social benefit exceed the risk? — YES → Support employee for decision to violate rule
- Did the employee have a good faith but mistaken belief that the violation was insignificant or justified? — YES → Coach employee and conduct at-risk behavior investigation (ARB)

Where working under a duty to follow a procedural rule within a system, an employee will be subject to disciplinary action when they have acted with reckless disregard toward the risk associated with non-compliance.

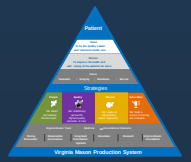
◢ *Burden of production falls on employee*

The Behaviors We Can Expect

- Human error - inadvertent action; inadvertently doing other than what should have been done; slip, lapse, mistake.

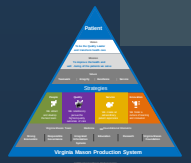
- At-risk behavior – behavioral choice that increases risk where risk is not recognized, or is mistakenly believed to be justified.

- Reckless behavior - behavioral choice to consciously disregard a substantial and unjustifiable risk.



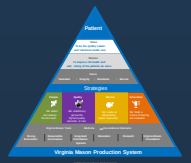
The Three Behaviors

Human Error	At-Risk Behavior	Reckless Behavior
Product of Our Current System Design	*A Choice: Risk Believed Insignificant or Justified*	*Conscious Disregard of Substantial and Unjustifiable Risk*
Manage through changes in: • Processes • Procedures • Training • Design • Environment	Manage through: • Removing incentives for at-risk behaviors • Creating incentives for healthy behaviors • Increasing situational awareness	Manage through: • Remedial action • Disciplinary action
Console	**Coach**	**Punish**



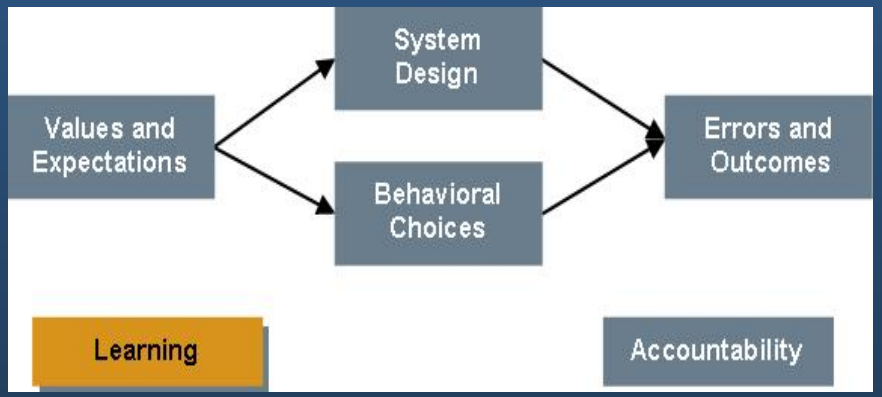
What's In an Investigation?

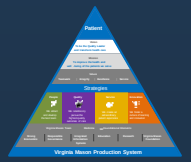
- An explanation for the Human Error – why it occurred
- An explanation for the At-Risk Behavior – why it occurred
- Extrapolation to broader contributing factors – systemic solutions



Internal Transparency

My Manager Openly Discusses Adverse Events and Lessons-Learned Involving Patient Safety With My Group.





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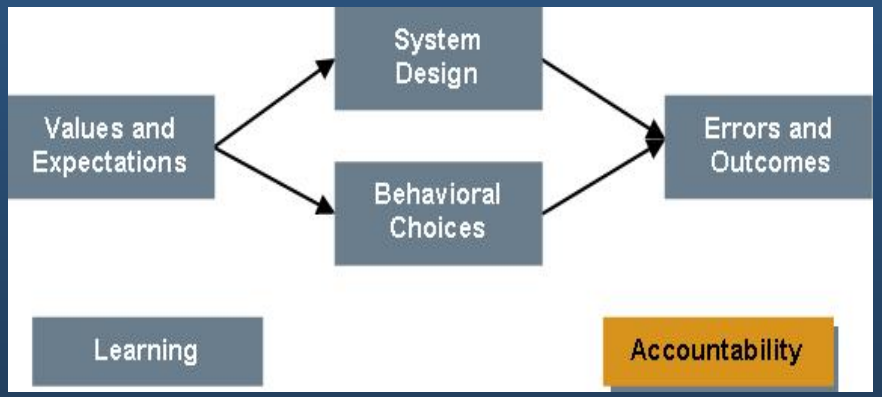
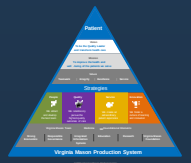
Response to Reckless Behavior

My Manager Disciplines Employees Who Knowingly And Intentionally Endanger Patient Safety.





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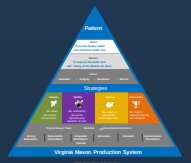
Board's Responsibility

- Aligned with the Strategic Plan
- Quality and Safety
- Patient Experience and Service
- Strong Economics and Growth
- Health Care Environment, Reform
- Positioning VM for the Future



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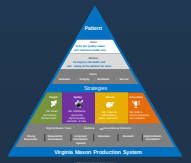
Voice of the Patient

- Each board meeting begins with patient story
- Stories are both good and bad
- Stories and letters shared with leadership
- Drives accountability



TEAM VIRGINIA MASON MEDICINE™

Commitment Of Board

Quality Governance Structure

VMMC

Quality Oversight Committee

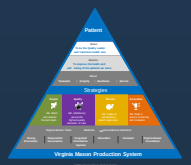
- Chairman of Board
- CEO
- 4 public board members
- Senior Vice President, Quality
- Medical Director, Quality

Quality Assessment Committee

Credentials Committee

Health Information Committee

Core Safety Committee



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QOC Outstanding Red PSA Report
April 23rd, 2012

- 60 Total Open Red PSA's
- 9 Submitted for April QOC closure
- 12 Ready for Closure (2 downgrade requests)
- 5 Ready to post for unanimous consent approval

	RED PSA Update 04/19/12			Bolded PSAs = reportable events Shaded = upcoming case presentation Shaded = upcoming unanimous vote Shaded = Ready for closure		
File #	**Shared PSA Folder Name**	**Date Opened**	**Days Open**	**Description**	**Date of Last Activity**	**Status**
49595 49596 49597 49598 49600 49601 49603 61079	RED_SS_Supply_Issues_OR_100810_DA	10/8/10	559	Multiple PSAs received related to OR staff not having adequate supplies for surgical procedures.	8/26/11	QOC declined closure. Three month QOC update in April 2012.
49823	RED_SP_CT_drug_diversion_process_101810_JL	10/18/10	549	PACU staff diverting controlled substances.	11/22/11	CAP in Progress
49884	RED_KC_OR_Medication_Mislabeling_102010_DA	10/20/10	547	Mislabeling in OR.	11/7/11	CAP in Progress.
53726 54096 54120	RED_AJ_Medication_Management_Errors_031711_LM	3/17/11	399	Multiple cases of transfers and discharges without adequate med reconciliation causing adverse or potential adverse events.	1/6/12	Ready for Closure
54669	RED_CT_Patient_Fall_with_Fracture_040511_DA	4/5/11	380	Patient fall with Ankle fracture	10/17/11	**April QOC Presentation**
54708	RED_MO_CT_Delay_In_Detecting_Infiltrate_040711_DA	4/7/11	378	A Federal Way post surgical patient had an undetected IV line infiltrate causing her IV pain medication to be ineffective. The nurses continued to give IV pain medications unsuccessfully so the patient was transferred via ambulance to the	Follow up meeting scheduled 1/18/12	Ready for Closure

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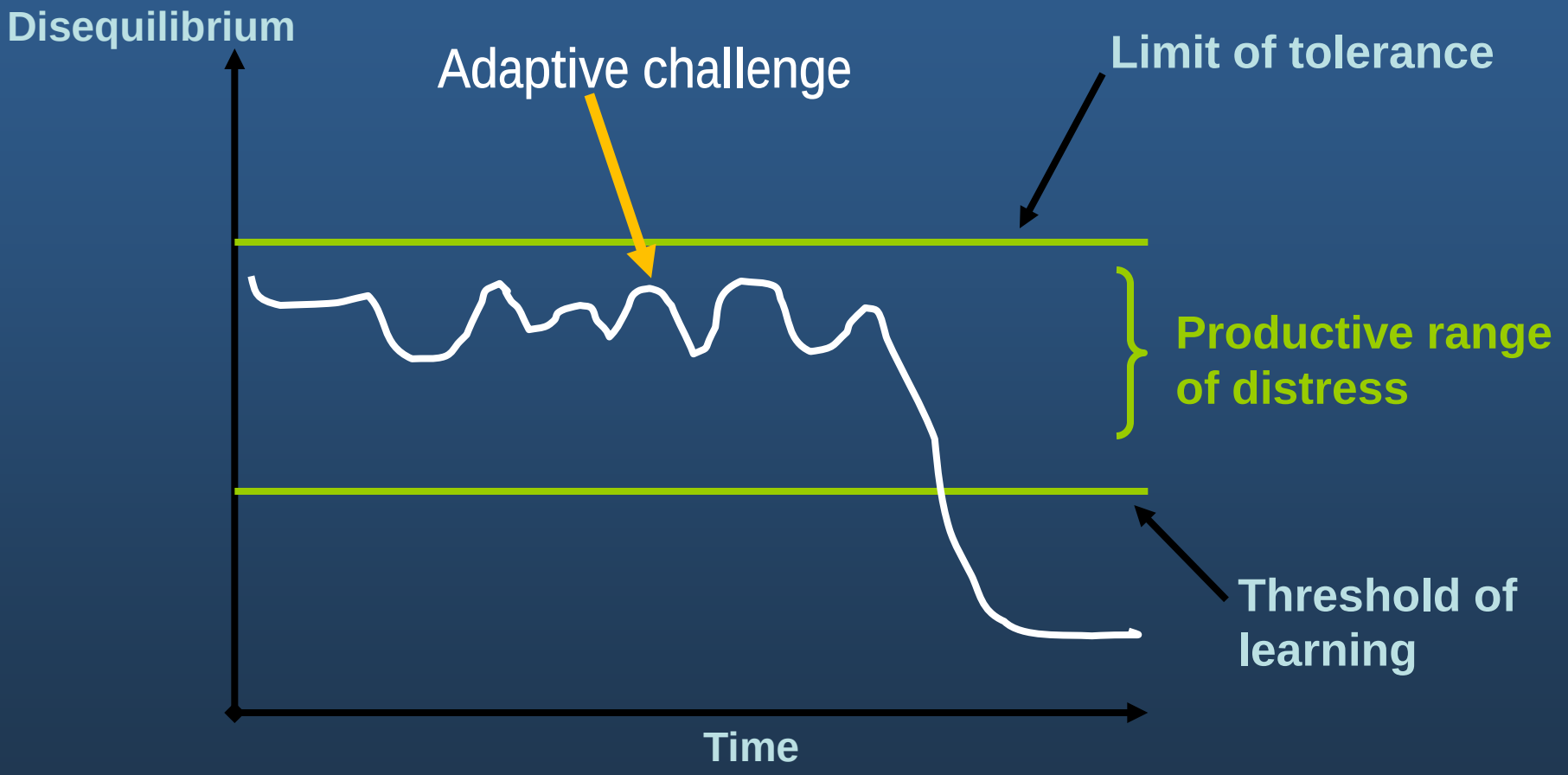
Tuesday “Stand Up”

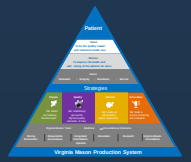
“Distress” and Adaptive Work



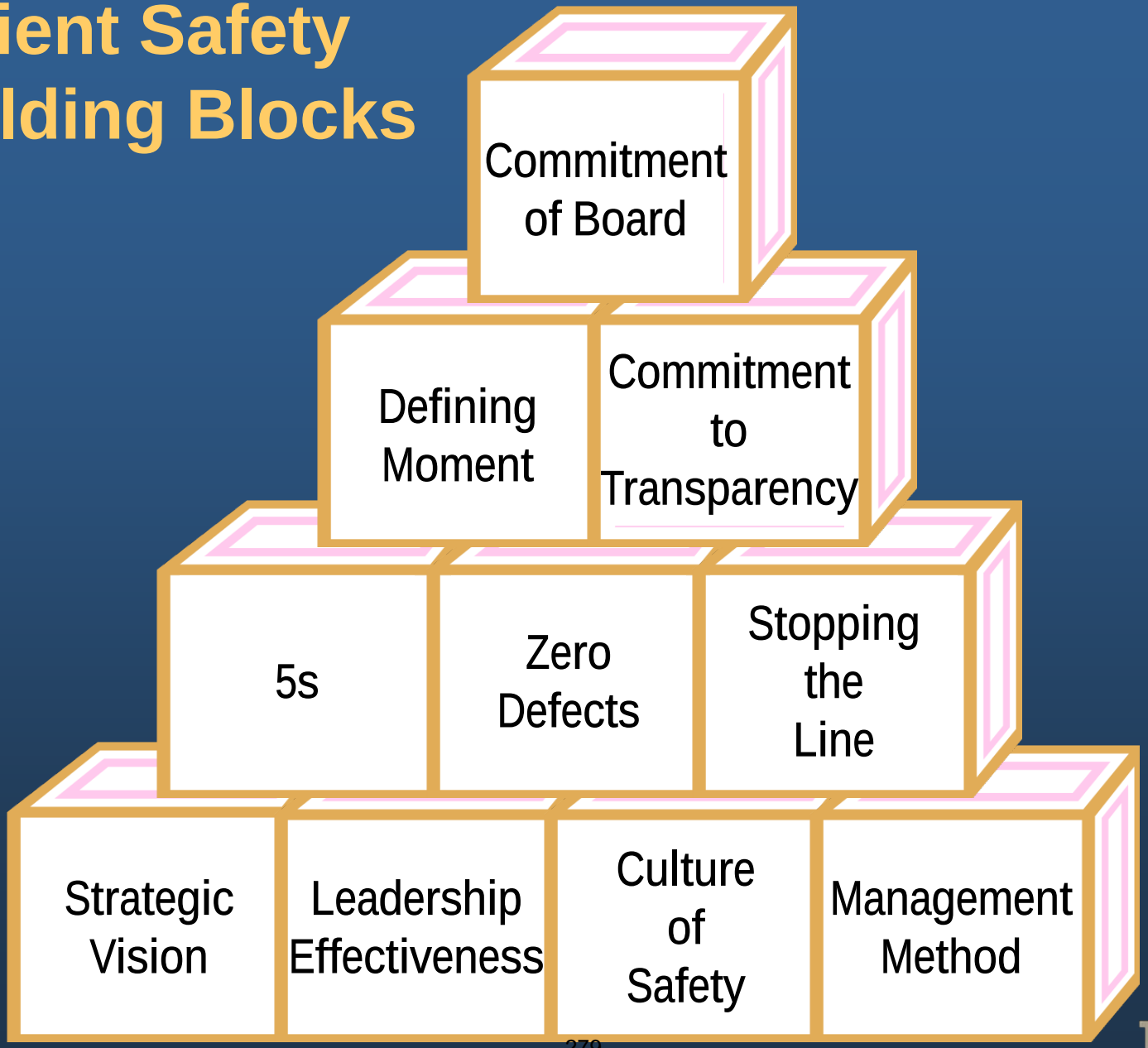
Heifetz, Ronald A. and Marty Linsky. *Leadership on the Line*, Harvard Business School Press, 2002, p 108

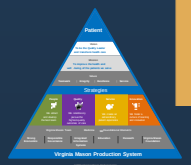
Managerial Courage

- It will be worth it
- Patients and staff depend on it
- Leading change is hard work
- Skeptics can become champions



Patient Safety Building Blocks





TEAM MEDICINE VIRGINIA MASON

Our Quality & Safety Journey

2000

- **1st IOM[1] Report**
- 1st Culture of Safety Work Plan
- **2nd IOM[1] Report**
- **ADEPT[2]** Preprinted Order Sets
- **VM Board:** Business Case for Quality

2001

- **Toyota Production System** Introduced to VMMC
- **Virginia Mason Production System** established
- Executive Walk Rounds

2002

- 1st Safety Culture Survey
- **CEO Mandates PSA System**
- **Strategic Quality Plan**

2003

- PSA Case Studies
- **Patient Safety Alert (PSA)** for clinical events

2004

- **Mary L. McClinton** Fatal medical error
- **CPOE** Go Live
- 2nd Safety Culture Survey
- **PSA** for non-clinical events
- IHI[3] 100,00 Lives

2005

- **Declare One Organizational Goal:** Patient Safety
- Q4Q Site Visit
- MD Disclosure Training

2006

- **Patient/ Family Engagement**
- IHI[3] 5 Million Lives
- Move to yearly AHRQ[4] Safety Culture Survey
- **Standard Quality Goal Reporting Process**

2007

- **Leapfrog Governance Award**
- Cross Pillar Culture of Safety Work Plan

2008

- Staff & Patient Leader Rounds

2009

- AHRQ[4] Safety Culture Survey: 81% Participation
- MDM RPIW[6]
- Time Out ST-PRA[5]
- **Just Culture**

2010

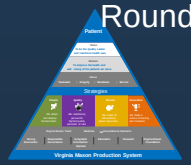
- Falls ST-PRA[5]
- **2010 HealthGrades Patient Safety Award**
- AHRQ[4] Safety Culture Survey: 82% Participation (all staff, all electronic)

2011

- **Leapfrog Top Hospital of the Decade**
- AHRQ[4] Safety Culture Survey: 84% Participation
- PSA 3P
- Patient Safety Risk Registry
- **Quest for Quality Citation of Merit**

2012

- Respect for People Training

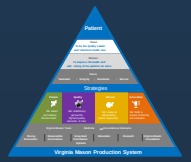


1. Institute of Medicine
2. Adverse Drug Events Prevention Team
3. Institute for Healthcare Improvement
4. Agency for Healthcare Research and Quality
5. Sociotechnical Probabilistic Risk Assessment
6. Must Do Measure Rapid Process Improvement Workshop

TEAM MEDICINE VIRGINIA MASON

"In times of change, learners inherit the earth, while the learned find themselves beautifully equipped to deal with a world that no longer exists."

Eric Hoffer



TEAM MEDICINE VIRGINIA MASON

Federation of
STATE MEDICAL BOARDS
100 YEARS

PROMOTING THE HIGHEST STANDARDS FOR MEDICAL LICENSURE AND PRACTICE



Protecting
Advocating
Serving

Protecting
Advocating
Serving

Challenges to State-based Medical Licensure

Lisa Robin
Chief Advocacy Officer
Federation of State Medical Boards (FSMB)

Washington State Medical Commission Educational Workshop
August 23, 2012

Presentation Overview

1) National Medical Licensure Legislation/Movement
2) Federal Legislation to Expand State Licensure Exceptions
3) FTC Intervention in State-Based Licensure
4) Senate Letter to HHS Inspector General
5) Senator Grassley's Letters to State Medicaid Programs
6) Facilitating Multi-state Practice While Preserving the State-based Licensure System
7) The Role of State Medical Boards in Protecting the Public
8) Federal and State Telemedicine Legislative Update
9) Summary and Conclusion

National Licensure Legislation

- **U.S. Senator Tom Udall (D-NM) is expected to introduce legislation establishing a national tandem medical licensure system**
  - ***Increasing Credentialing and Licensing Access to Telehealth (ICLAST) Act***

- **FSMB remains adamant in opposition to any legislation establishing a national medical licensure system**

National Licensure Movement

- Business community, trade associations, and health coalitions are taking an active role in promoting national licensure

- American Telemedicine Association (ATA) hosted a Capitol Hill briefing entitled, "*Physician Licensure Barriers to 21st Century Healthcare*"

- ATA is also the sponsor of the www.fixlicensure.org movement

- Health IT Now, a broad based coalition of patient groups, provider organizations, employers and payers, have called for "bipartisan legislation that will establish a federal framework for medical licensing as well as remove statutory barriers to using telehealth services in rural and urban areas"

Federal Legislation to Expand State Licensure Exceptions

- *The Servicemember's Telemedicine and E-Health Portability (STEP) Act* (Passed and Signed into Law in DoD Reauthorization)
  - Expansion of state licensure exceptions for DoD health care professionals, including personal services contractors

- *The Veterans E-Health & Telemedicine Support (VETS) Act of 2012* (Introduced in July 2012)
  - Allows for a licensed health care professional (either authorized or contracted with the VA) at any location in the U.S. to provide treatment to a patient using telemedicine, regardless of where the health care professional or the patient is located

Federal Trade Commission

- The Federal Trade Commission (FTC) has recently taken a number of actions against state legislation and state health regulatory boards' decisions and proposed rules regarding who may provide certain services to patients
    - Actions taken in Alabama, Florida, Georgia, Kentucky, Louisiana, Maine, Missouri, North Carolina, Tennessee, and Texas

- The FTC has cited its statutory authority to intervene in these cases by its jurisdiction over antitrust and anticompetition enforcement

Federal Trade Commission (cont.)

- A coalition of health care organizations raised awareness on Capitol Hill regarding the FTC's actions
- A bipartisan Congressional letter was sent to the FTC, urging the agency to cease and desist from further intrusions into state-based health regulation

HHS Inspector General

- On February 15, three U.S. Senators sent a letter to the HHS Inspector General, requesting OIG to conduct a comprehensive evaluation of state medical boards and provide recommendations to improve boards' performance
  - Senators Grassley (R-IA), Hatch (R-UT), and Baucus (D-MT)
- As rationale, the letter references Public Citizen's 2011 report, "*State Medical Boards Fail to Discipline Doctors With Hospital Actions Against Them,* a misleading and inaccurate portrayal of state medical boards
- The letter also references advanced medical technologies, including teleradiology, and its ability to foster multi-state practice
  - May have been drafted with the support of advocates for national licensure

Sen. Grassley and Medicaid

- Sen. Chuck Grassley (R-IA), Ranking Member of the Senate Judiciary Committee, recently sent letters to 46 Medicaid Directors, demanding to know how the agencies oversee physicians suspected of over-prescribing and fraud
- Sen. Grassley requested the following information related to the top ten prescribers of several pain management and mental health drugs in the state:
  - What action, if any, has Medicaid taken with respect to these prescribers?
  - If no action has been taken with respect to these prescribers, please explain why not.
  - Has each prescriber been cross-checked for complaints or misconduct with the state medical board or the National Practitioner Data Bank? If not, do you plan to do so?
  - Have any of these prescribers been referred to your state medical board?
- These letters, in connection with the OIG evaluation request, clearly demonstrate Senator Grassley's interest in investigating the conduct of SMBs.

Facilitating Multi-State Practice

- Recent challenges to state-based licensure have primarily generated from calls to streamline the licensure process in order to expand access to care with emerging delivery modalities, including telemedicine
- State medical boards continue to explore ways to:
  - Standardize licensure requirements
  - Define the physician-patient relationship in this technological age

State medical boards seek to:

- Maintain the highest standards for licensure
- Protect state board jurisdiction over physicians providing services in state (remotely or otherwise)
- Protect state fees
- Facilitate multi-state practice while preserving a state-based licensure system

The Role of State Medical Boards (SMBs)

- The responsibility to regulate the practice of medicine, as well as all the other healing arts, is appropriately delegated to the individual states to protect the health, safety and welfare of the public

- This system of state-based regulation provides a comprehensive network that ensures close monitoring of health care professionals in every region of the country and responds to the diverse circumstances and needs of each state

The Role of SMBs (cont.)

- The state-based licensure system works. It has proven its resilience and ability to adapt to changes in the delivery of health care in the United States

- State-based licensure has evolved over the decades to respond to the changing needs of medicine. We are in such an era now, as telemedicine continues to grow

- Telemedicine is currently one piece of the overall health care equation – like other developments that preceded it in medical history, it will continue to evolve, but it must evolve safely and efficiently

The Role of SMBs (cont.)

- As state boards seek to address factors that allow for multi-state practice, we must consider the best oversight mechanisms to ensure providers have the requisite qualifications to provide health care services in a safe and competent manner

- State boards recognize the potential of new technologies, particularly telemedicine, to increase quality and access to care in rural or underserved communities

Federal Telemedicine Legislative Update

- The Supreme Court recently upheld *The Patient Protection and Affordable Care Act*

- The bill includes provisions for the development of payment models to foster the adoption of innovative care delivery approaches, including telehealth (i.e. grants for telehealth services)

- Telemedicine will play an integral role in the implementation of the *Affordable Care Act*

State Telemedicine Legislative Update

- Reimbursements for Public and Private Telemedicine Services
  - Maryland, Michigan and Vermont become the 13th, 14th and 15th states to require private insurance companies to cover telemedicine services to the same extent as face-to-face consultations.
    - Arizona, the District of Columbia, Massachusetts, South Carolina and Tennessee introduced similar legislative initiatives this session
  - 39 states currently offer reimbursements for at least some Medicaid services.

- 10 state boards issue a special purpose license, telemedicine license or certificate, or license to practice medicine across state lines to allow for the practice of telemedicine.
  - Minnesota allows physicians to practice telemedicine if they are registered to practice across state lines
  - States continue to propose the issuance of licenses specific to the practice of telemedicine

State Legislative Update (cont.)

- States continue to explore ways in which they may expand the use of telemedicine
  - KY HB 294 directs the creation of a Telehealth Board to establish telehealth training centers and develop a telehealth network (passed)
  - TN HJR 58 encourages and advocates the use of telemedicine in the state of Tennessee (passed)
  - MA SB 520 establishes a pilot project program to test telemedicine capacity to provide quality medical services to inmates (pending)
  - VA HJ 171 directs the study of telemedicine to research methods of reducing costs using telemedicine within the Medicaid program (pending)

FSMB License Portability Enablers

- The FSMB has developed tools such as uniform licensing applications and streamlined credentials verification, allowing state boards to bring more standardization to licensing processes across state lines, while maintaining jurisdiction over physicians practicing in their states

- The FSMB aims to expedite licensing process for physicians in multiple states

- The FSMB is also considering new models of state-based rapid licensing, which would address problems of access to health care in rural areas while helping facilitate telemedicine

Summary

- Telemedicine is playing a prevalent role in the delivery of care, and the FSMB seeks to streamline the licensure process and expand access to care via technological means
- However, some individuals and entities are utilizing telemedicine as an argument for national licensure
- Patient safety remains the top priority for the FSMB and SMBs, and we remain steadfast in opposition to national licensure
- FSMB and Member Boards are in the process of developing tools and models to facilitate multi-state practice and telemedicine while preserving a state-based licensure system

Questions/Discussion/Contact Us

Lisa Robin

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Protecting
Advocating
Serving

Thank you!

SEXUAL BOUNDARY VIOLATIONS AND BOARD DIVERSITY

WASHINGTON STATE MEDICAL COMMISSION ANNUAL WORKSHOP

AUGUST 23, 2012

Barbara Schneidman, MD, MPH

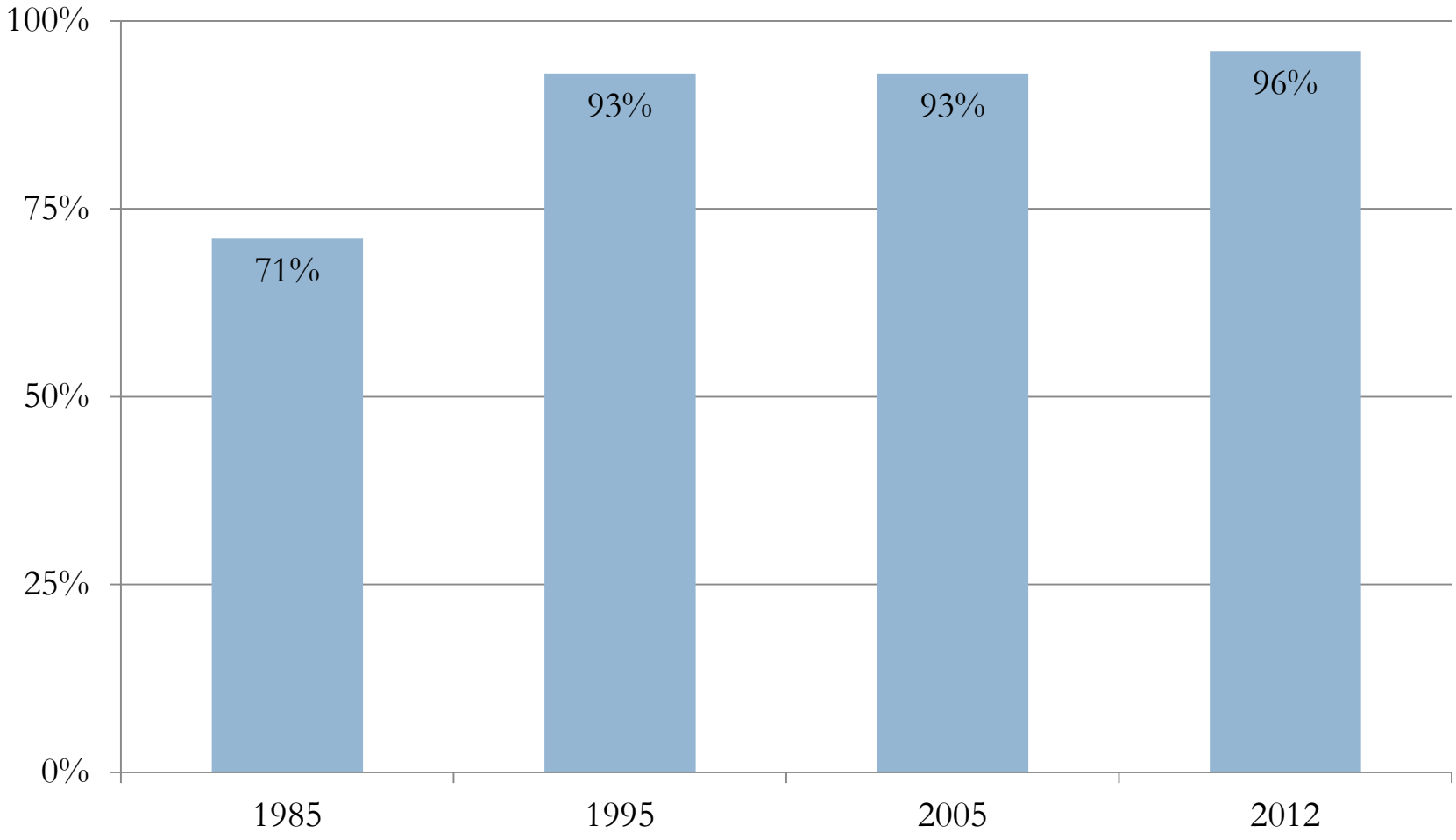
Overview

- Introduction
- Board Composition - FSMB and MQAC
- Disciplinary Data - FSMB and MQAC
- FSMB Policy
- MQAC Policy
- Conclusions
- Questions and Discussion

Introduction - Why and How?

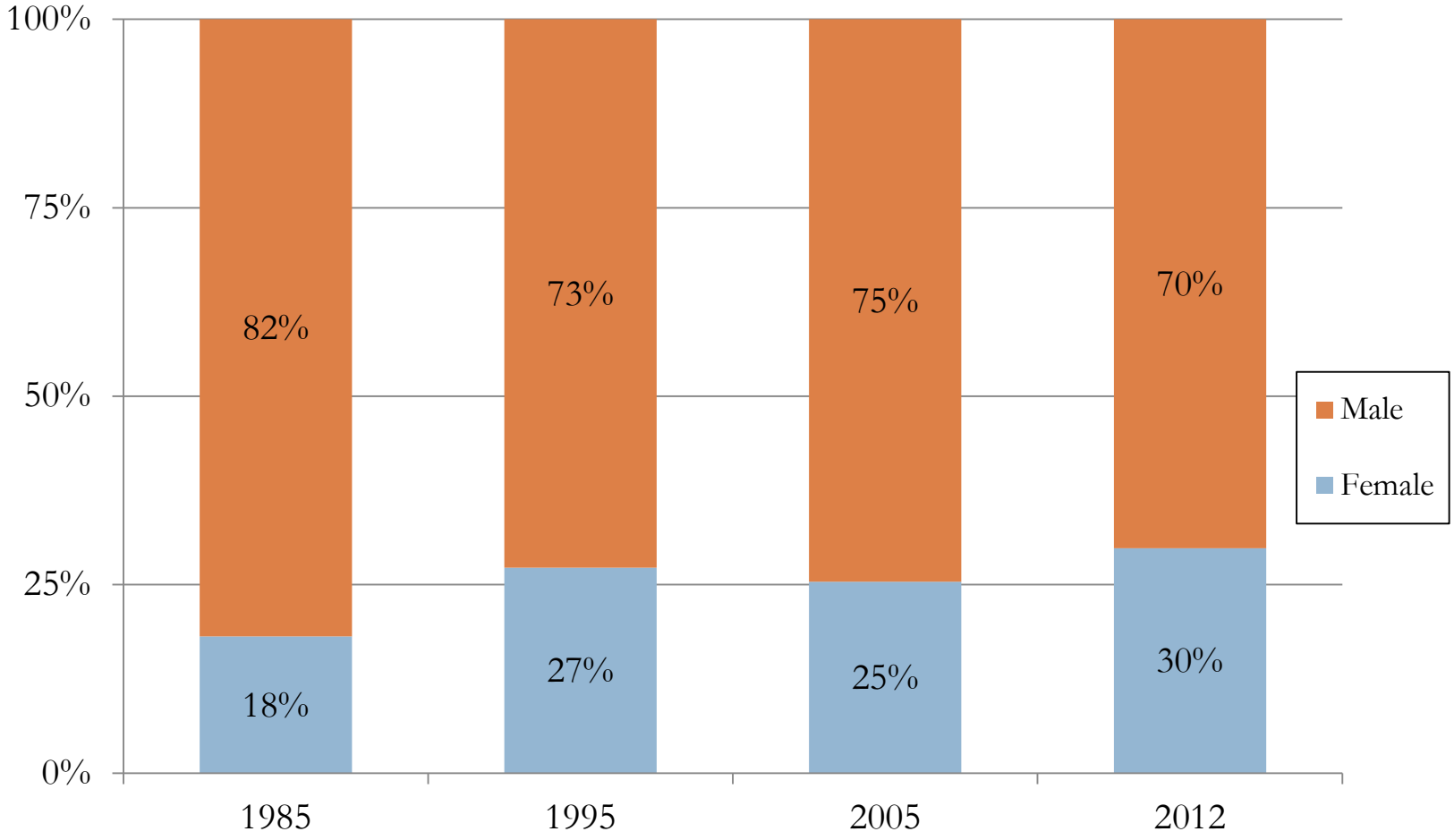
Board Composition –FSMB Data

Percentage of State Medical Boards with a Female Board Member 1985-2012



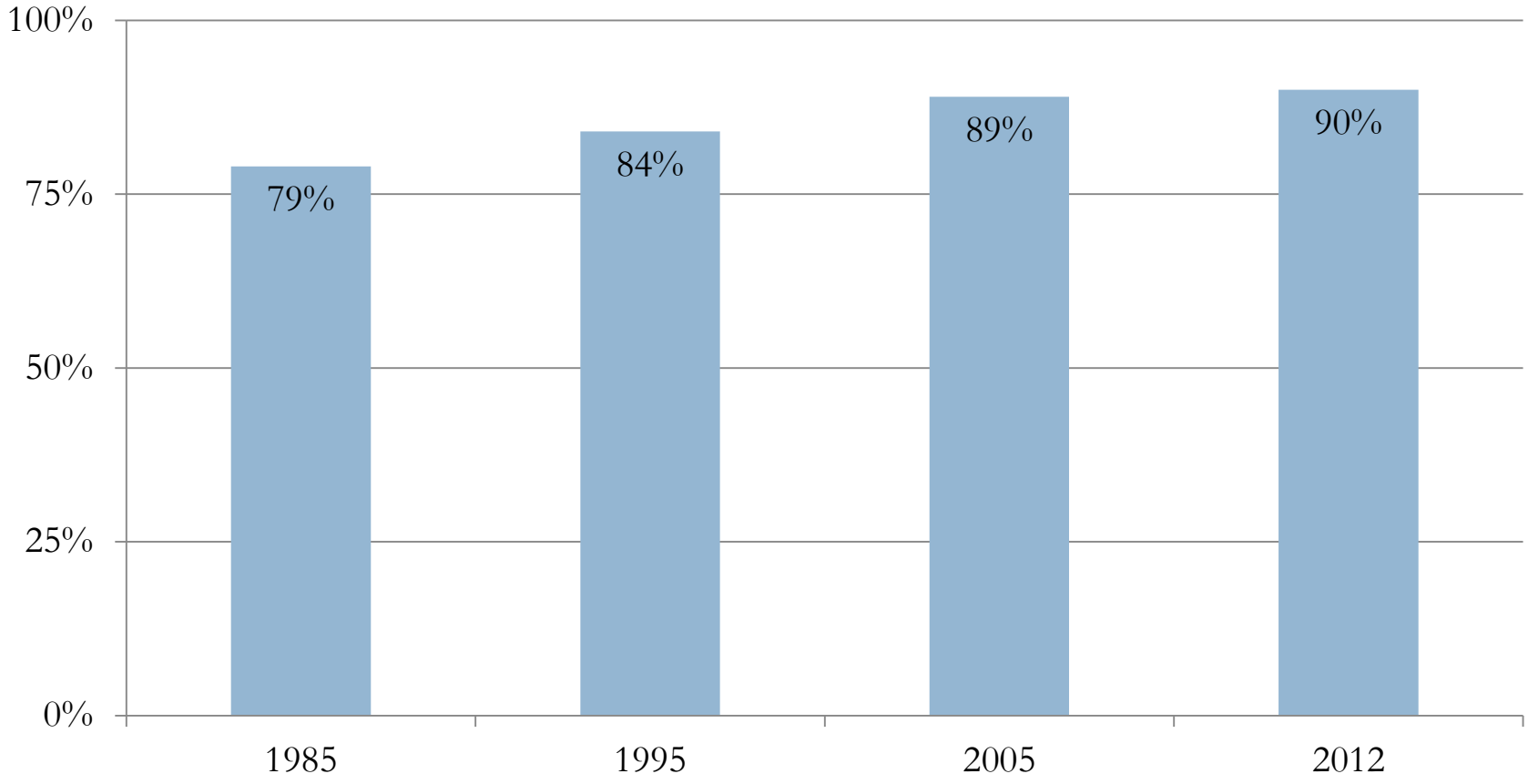
Source: Federation of State Medical Boards

Gender Composition of FSMB Fellows for State Medical Boards 1985-2012



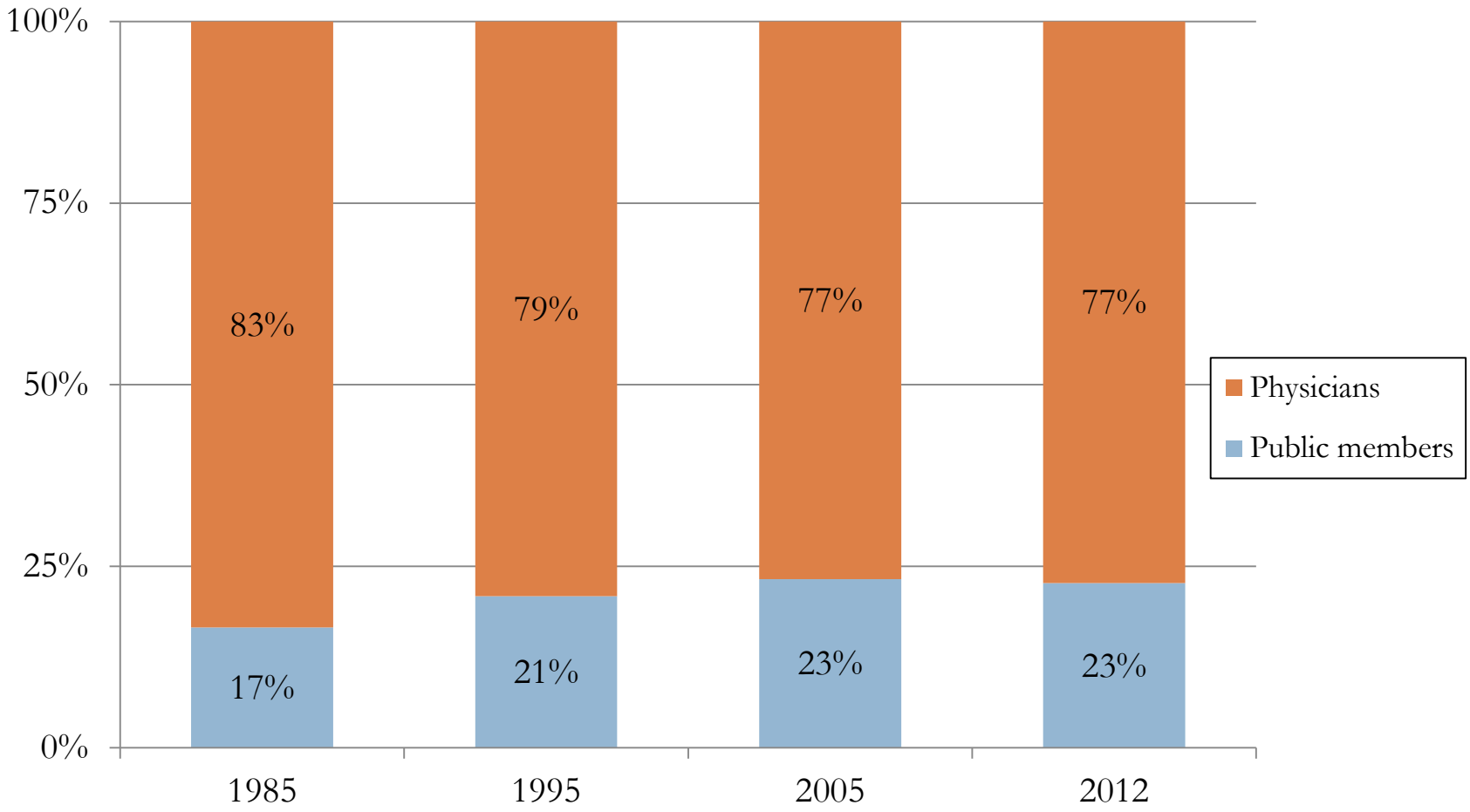
Source: Federation of State Medical Boards

Percentage of State Medical Boards with a Public Board Member 1985-2012



Source: Federation of State Medical Boards

Public Member Composition of FSMB Fellows for State Medical Boards 1985-2012



Source: Federation of State Medical Boards

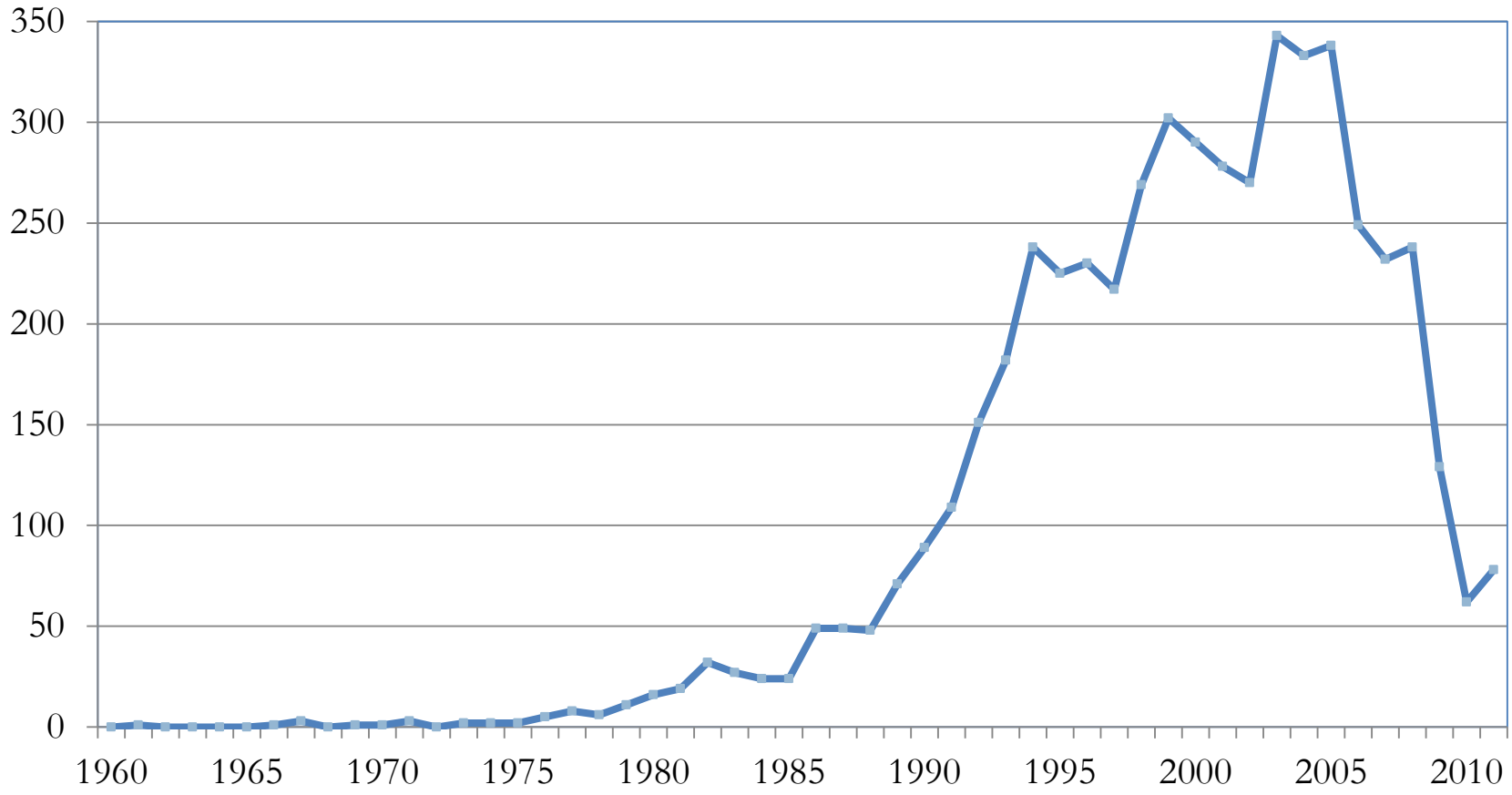
MQAC Composition 1994-2012

- 1994 - 16 MEMBERS
  - 6 Women
  - 4 Public Members

2012 - 21 MEMBERS
- 7 WOMEN
- 6 PUBLIC MEMBERS

Disciplinary Data - FSMB

Physician Discipline by State Medical Boards for Sexual Misconduct 1960-2011

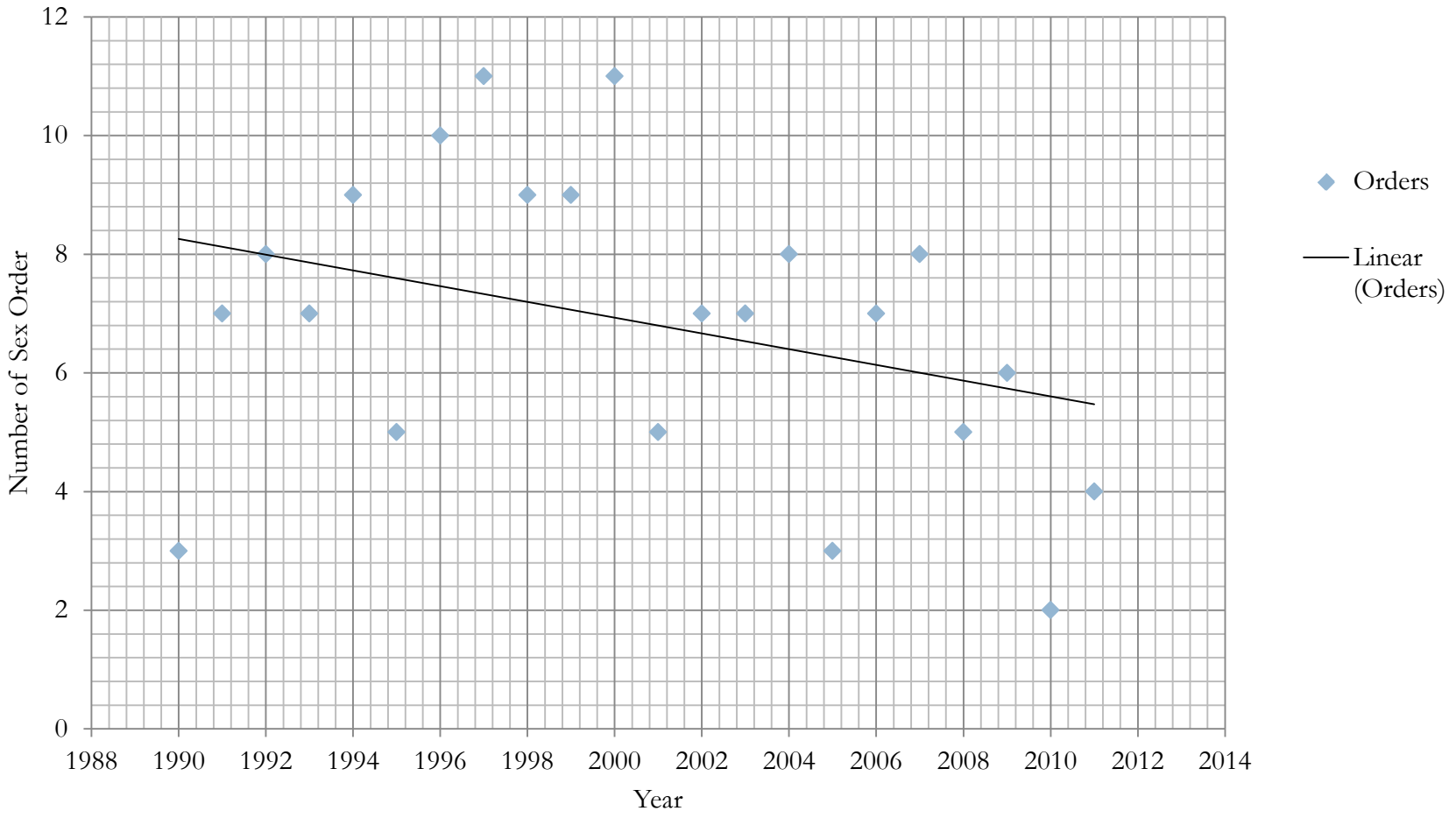


Source: Federation of State Medical Boards

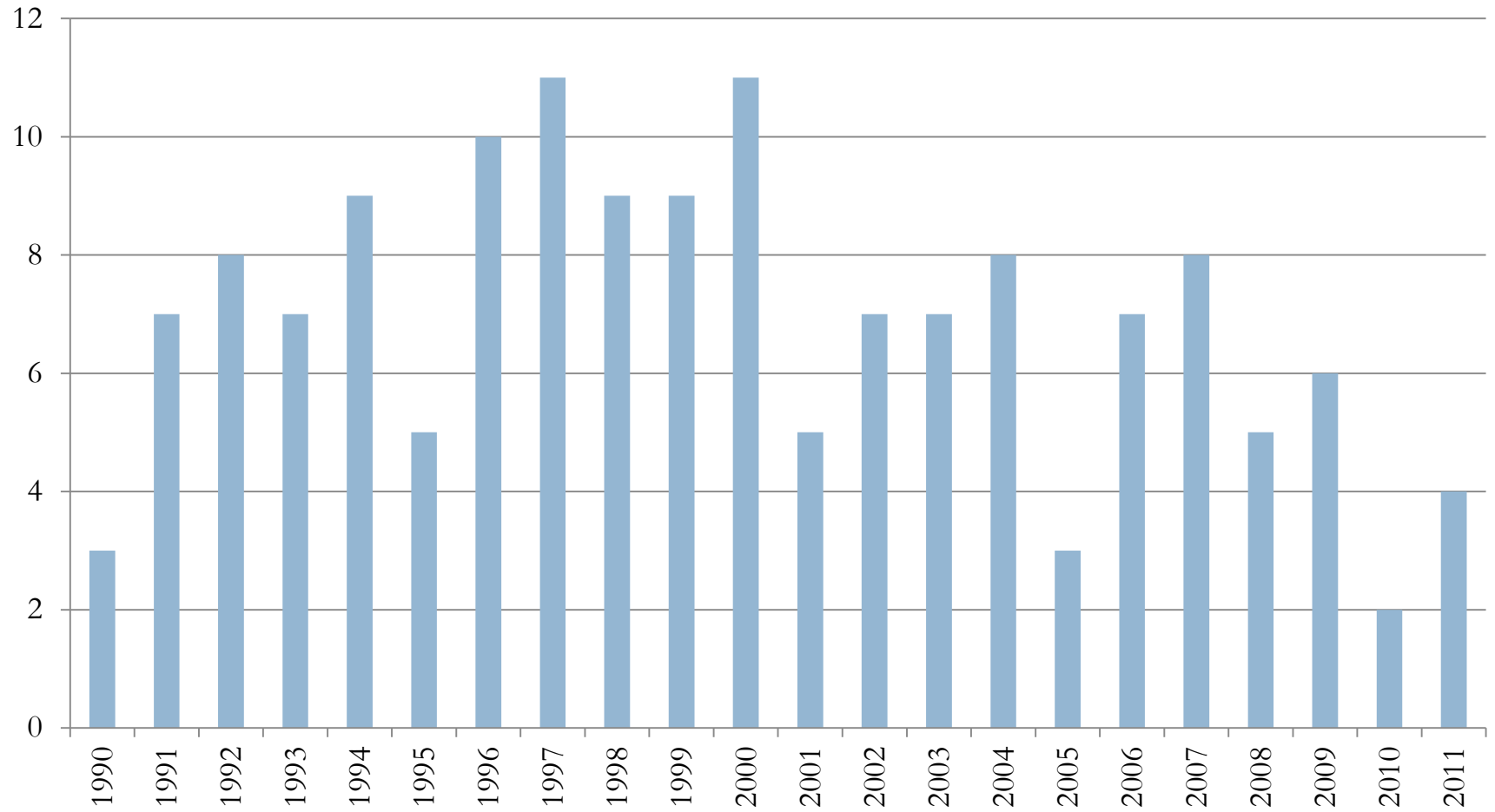
Note: Data represents discipline where the reason for the action taken was sexual misconduct or the medical board referenced sexual misconduct in the board order.

Disciplinary Data - MQAC

Number of Sex Orders by Year



Sex Violation Orders by Year
1990-2011



FSMB Policy

Sexual Misconduct

- Sexual misconduct by physicians and other health care practitioners adversely affects the public welfare and harms patients individually and collectively, and is damaging to the medical profession.
- The FSMB first addressed this issue more than a decade ago in its *Report on Sexual Boundary Issues* (HOD 1996).
- *Addressing Sexual Boundaries: Guidelines for State Medical Boards* (HOD 2006) provides state medical boards with a framework for handling sexual misconduct cases and can be used to educate licensees about sexual boundary issues.

FSMB Guidelines for Addressing Sexual Boundaries

- Applies to all health professions regulated by a state medical board.
- The scope of the policy goes beyond the physician-patient relationship to include surrogates, 3rd parties, or other members of the health care team.
- Recognizes the importance of a cooperative working relationship between the state medical board and the state physician health program.
- Includes elements and goals of a comprehensive evaluation as well as the attributes and qualifications of evaluators.

FSMB Guidelines for Addressing Sexual Boundaries

- Defines physician sexual misconduct as behavior that exploits the physician-patient relationship in a sexual way and is never diagnostic or therapeutic.
- Refers to two types of professional sexual misconduct: sexual impropriety and sexual violation – both of which are the basis for disciplinary action by a state medical board if the board determines that the behavior exploited the physician-patient relationship.
- Provides recommendations to assist state medical boards with the investigation process, preparation for formal hearings, crafting an appropriate disciplinary response, physician monitoring and physician education.

Investigations

- Board Authority
  - It is imperative that state medical boards have sufficient statutory authority to investigate complaints and any reported allegations of sexual misconduct
  - State medical boards should place a high priority on the investigation of complaints of sexual misconduct due to patient vulnerability unique to such cases
- Complainant Sensitivity to Investigation
  - Because of the delicate nature of complaints of sexual misconduct, boards should have special procedures for interviewing and interacting with such complainants, i.e., investigators who are appropriately trained in the area of sexual misconduct

Hearings

- Initiation of Charges
  - In assessing whether sufficient evidence exists to support a finding that sexual misconduct has occurred, corroboration of a patient's testimony should not be required.
- Open vs Closed Hearings
  - Boards should have statutory authority to close the hearing during testimony which may reveal the identity of the patient.
- Patient Confidentiality
  - Boards should have statutory authority to ensure nondisclosure of the patient's identity to the public.

Hearings

- Testimony
  - Boards may consider the use of one or more expert witnesses to fully develop the issues in question and to define professional standards of care for the record.
- Other Issues
  - Rules of evidence applicable in all other administrative hearings should be applied in hearings involving sexual misconduct.
  - Boards should not consider romantic involvement, patient initiation or patient consent a legal defense, although these may be factors for the board's consideration in cases of sexual misconduct.
  - Witness credibility is often an important factor in hearings involving sexual misconduct.[323]

Comprehensive Evaluation

- The use of diagnostic evaluations provides significant information that may not otherwise be revealed during the initial phase of the investigation, and may be valuable to the board's ability to assess future risk to patient safety.
- The FSMB policy provides guidelines for selecting an evaluator(s) to conduct the evaluation, general goals of the evaluation and important elements in the evaluation process.

Discipline

- Upon a finding of sexual misconduct, the board should take appropriate action and impose a sanction(s) reflecting the severity of the conduct and potential risk to patients.
- The guidelines list multiple factors the board should consider in determining an appropriate disciplinary response.
- In the event of license revocation, suspension, or license restriction, any petition for reinstatement or removal of restriction should include the stipulation that a current assessment, and if recommended, successful completion of treatment, be required prior to the board's consideration to assure the physician is competent to practice safely.

Monitoring and Physician Education

- If a license is not revoked or suspended, it is essential that a board establish appropriate monitoring of the physician and his/her continued practice.
- State medical boards should take a proactive stance to educate their licensees about sexual misconduct. Physicians may encounter situations in which they have unknowingly violated the medical practice act through boundary transgressions and violations.
- State medical boards should develop cooperative relationships with state physician health programs, state medical associations, hospital medical staffs, other organized physician groups, and medical schools and training programs to provide physicians and medical students with educational information that promotes awareness of physician sexual misconduct.

Washington State Department of Health MQAC

- Sexual Misconduct Statement and Policy - 2002
- Sexual Misconduct and Abuse Rules – 2005
- Updated - July, 2008

MQAC Statement and Policy

- Sexual misconduct between health care providers and patients or key third parties detracts from the goals of the health care provider-patient relationship, exploits the vulnerability of the patient, obscures the health care provider's objective judgment concerning the patient's health care and is detrimental to the patient's well-being. The Commission wishes to inform health care providers that sexual misconduct , in any form, will not be tolerated.

Sexual Misconduct, con't

- Any sexual or romantic behavior between a health care provider and a patient or key third party is forbidden and constitutes sexual misconduct. It includes any and all sexual and romantic behaviors, physical and verbal, whether inside or outside the professional setting, with persons a particular profession is intended to serve. Sexual misconduct by a health care provider frequently, though not always, involves use of the power, influence, and/or special knowledge inherent in one's profession in order to obtain sexual gratification or romantic partners.

2005 Rule Making Order

- The purpose for the sexual misconduct and abuse rules is to raise the awareness of sexual inappropriate behaviors and prevent physicians and physician assistants from engaging in abusive or sexual contact or sexual activity with current and former patients. The Commission has difficulty taking action on a practitioners license who engages in sexually inappropriate behavior that does not constitute "sexual contact" under RCW 18.130.180 (24).

Rule, con't

- When the Commission evaluates a case involving a sexual boundary issue in which the behavior does not constitute "sexual contact," the Commission either takes action under subsection RCW 18.130.180 (1) on the theory the conduct constitutes "moral turpitude" or simply closes the case. These rules will allow the Commission to better protect the public by taking disciplinary action in a wider range of inappropriate behaviors.

Rule, con't

- Abuse:

- Statements about patient's body, appearance, sexual history or orientation
- Removing clothing without consent
- Respectful treatment of unconscious or deceased patients
- Demeaning, humiliating behaviors

2008 Update - new section 5

- With regard to complaints that only allege that a license holder has committed an act or acts of unprofessional conduct involving sexual misconduct, the secretary shall serve as the sole disciplining authority in every aspect of the disciplinary process, including initiating investigations, investigating, determining the disposition of the complaint, holding hearings, preparing findings of fact, issues orders or dismissals of charges as provided in RCW 18.130.172, or issuing summary suspensions under section 6 of this act.

Update, con't

- The board or commission shall review all cases and only refer to the secretary sexual misconduct cases that do not involve clinical expertise or standard of care issues.

Conclusions

- Was I correct? Could be many other variables
- FSMB reports 1996, 2006
- Subsequent State Medical Board Actions
- Educational sessions and CME programs across the country
- Awareness in newly graduating physicians
- Questions on USMLE and board certification exams
- Terminology becoming more consistent
- State Boards take these violations very seriously

Thanks to Many

- FSMB staff – Linda Jordan, Aaron Young, Pat McCarty
- Commission staff - Micah Matthews

Questions and Discussion

Protecting patients within and without systems

Margaret E. O'Kane, NCQA President

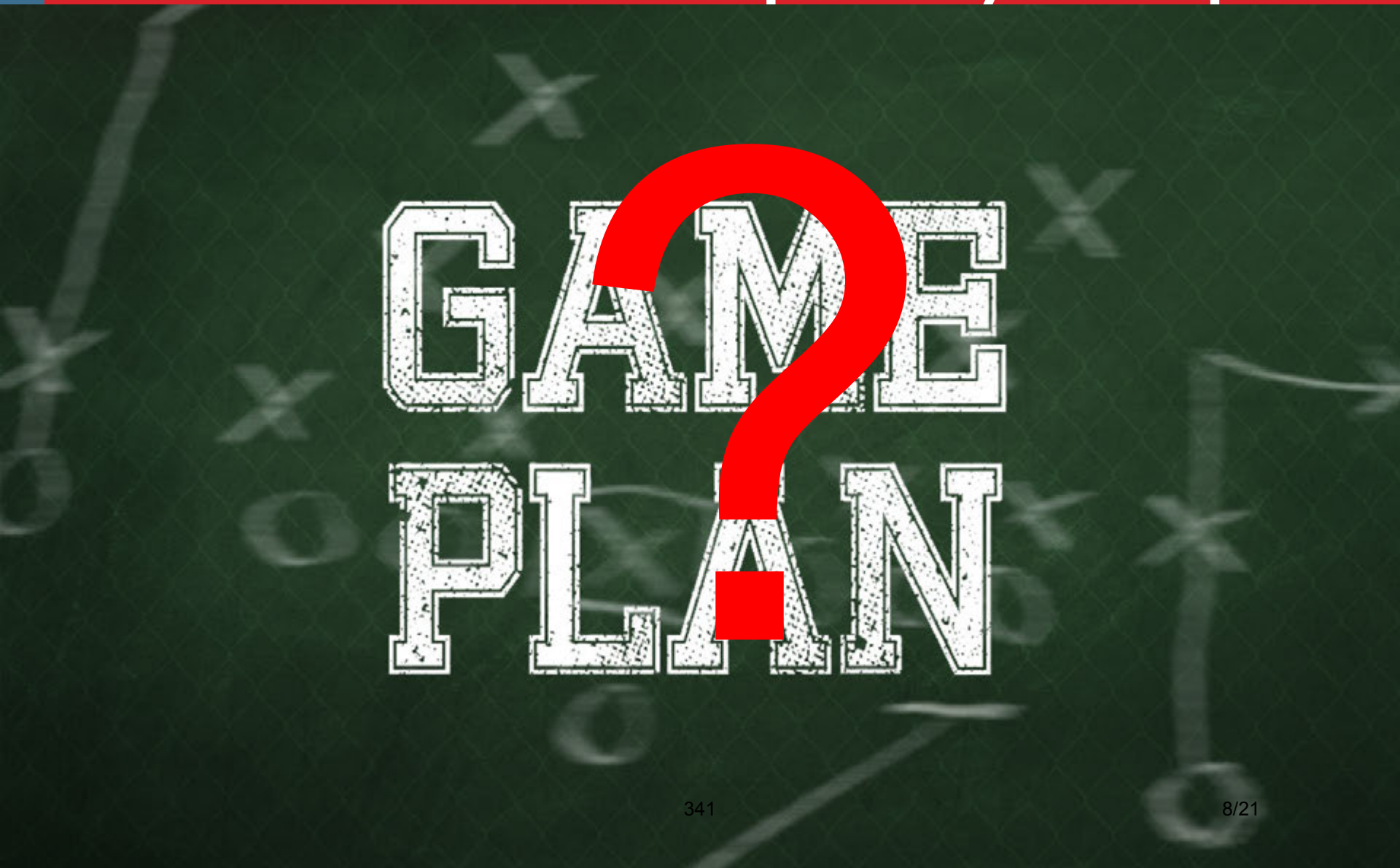
Washington State Medical Commission Educational Workshop

August 23, 2012

Overview

What NCQA has learned

My background:
The frequent lack of a game plan troubled me as a respiratory therapist.



Being clear about who is responsible for which aspects of care is crucial.

What NCQA does

Our mission

- **To improve the quality of health care**

Our method

- **Measurement**

We can't improve what we don't measure

- **Transparency**

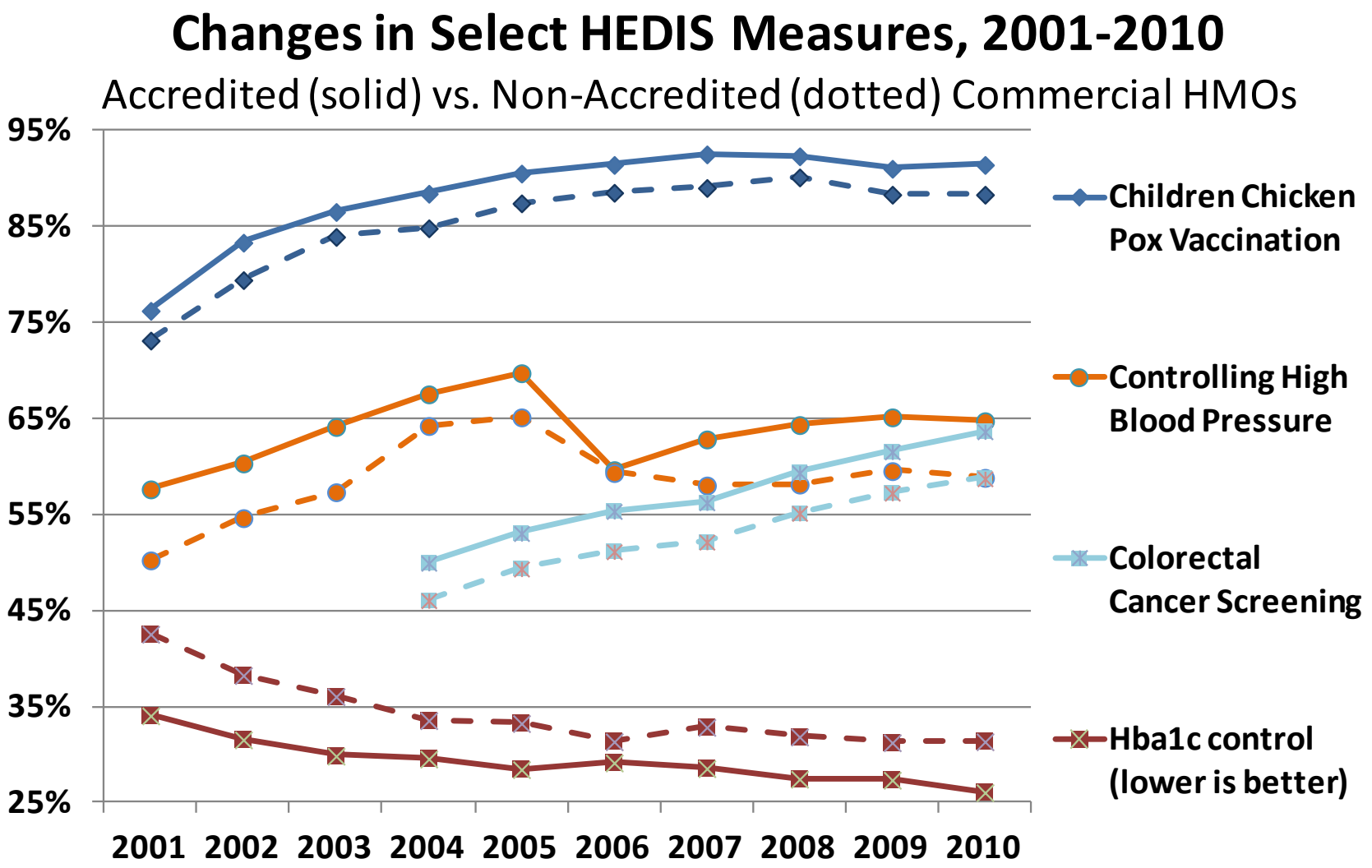
We show how we measure so measurement will be accepted

- **Accountability**

Once we measure, we can expect and track progress

Where NCQA focuses

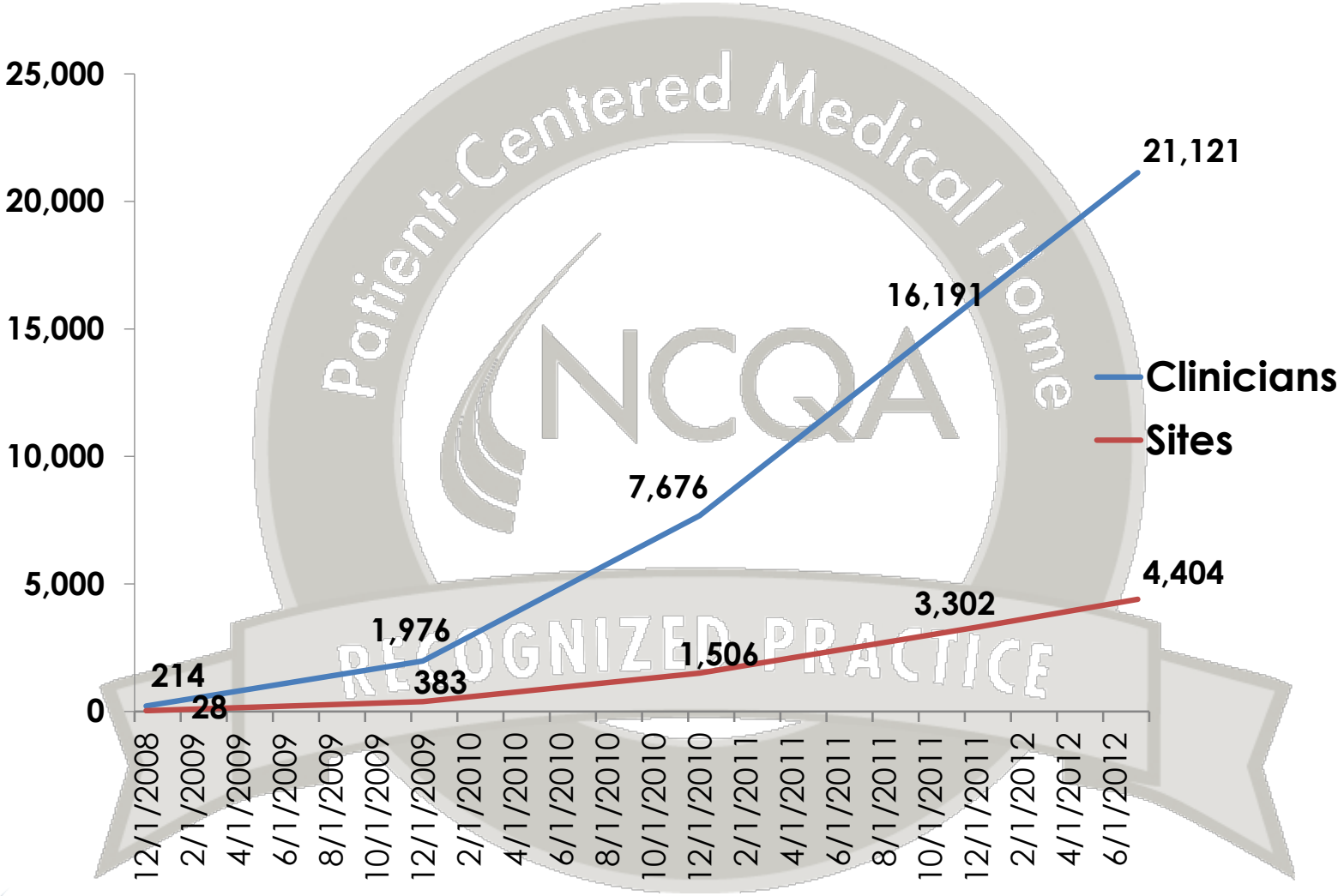
What gets measured gets improved.



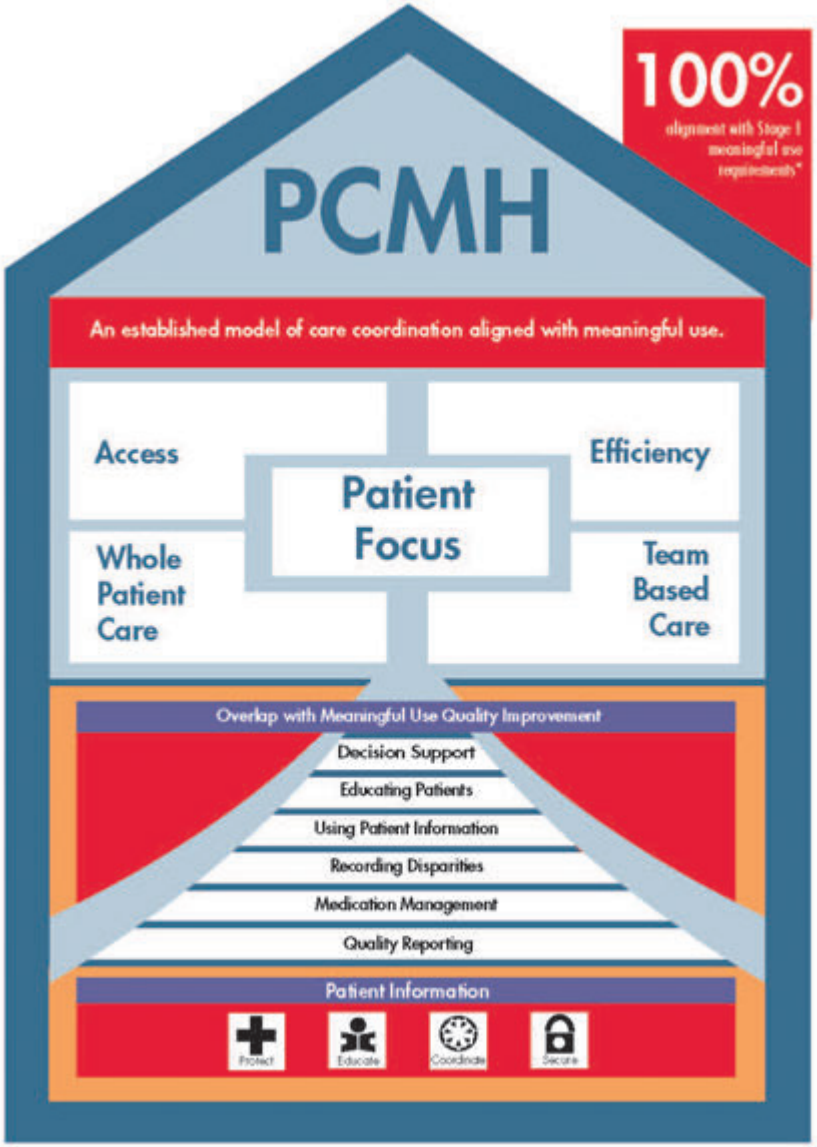
NCQA Recognition programs distinguish practices and people who deliver quality care.

What NCQA has learned: Patient-Centered Medical Homes

PCMH is the nation's most widely adopted medical home program.



PCMH's alignment with Meaningful Use helps patients and providers.



- Maximize protection and use of patient data
- Help patients understand and take an active role in their own care
- Improve coordination of care among patients' many providers
- Ensure that patients get the drugs they need and avoid drugs that can harm them
- Include clinical decision support so patients and providers have information to make good decisions
- Make sure people get culturally appropriate care and disparities are addressed
- Require reporting on clinical performance

Vermont and North Carolina use PCMH to build accountable care systems.

What NCQA has learned: Accountable Care Organizations

Variation in capabilities and readiness make ACOs risky for payers, patients.

Accreditation aligns purchasers with common expectations.

Unites health plans, employers, states and federal purchaser initiatives to prompt providers to change how they provide care

ACOs demonstrate capabilities in seven areas to earn NCQA Accreditation.

1. Structure & Operations
2. Access to Needed Providers
3. Patient-Centered Primary Care
4. Care Management
5. Care Coordination and Transitions
6. Patient Rights and Responsibilities
7. Performance Reporting and Quality Improvement

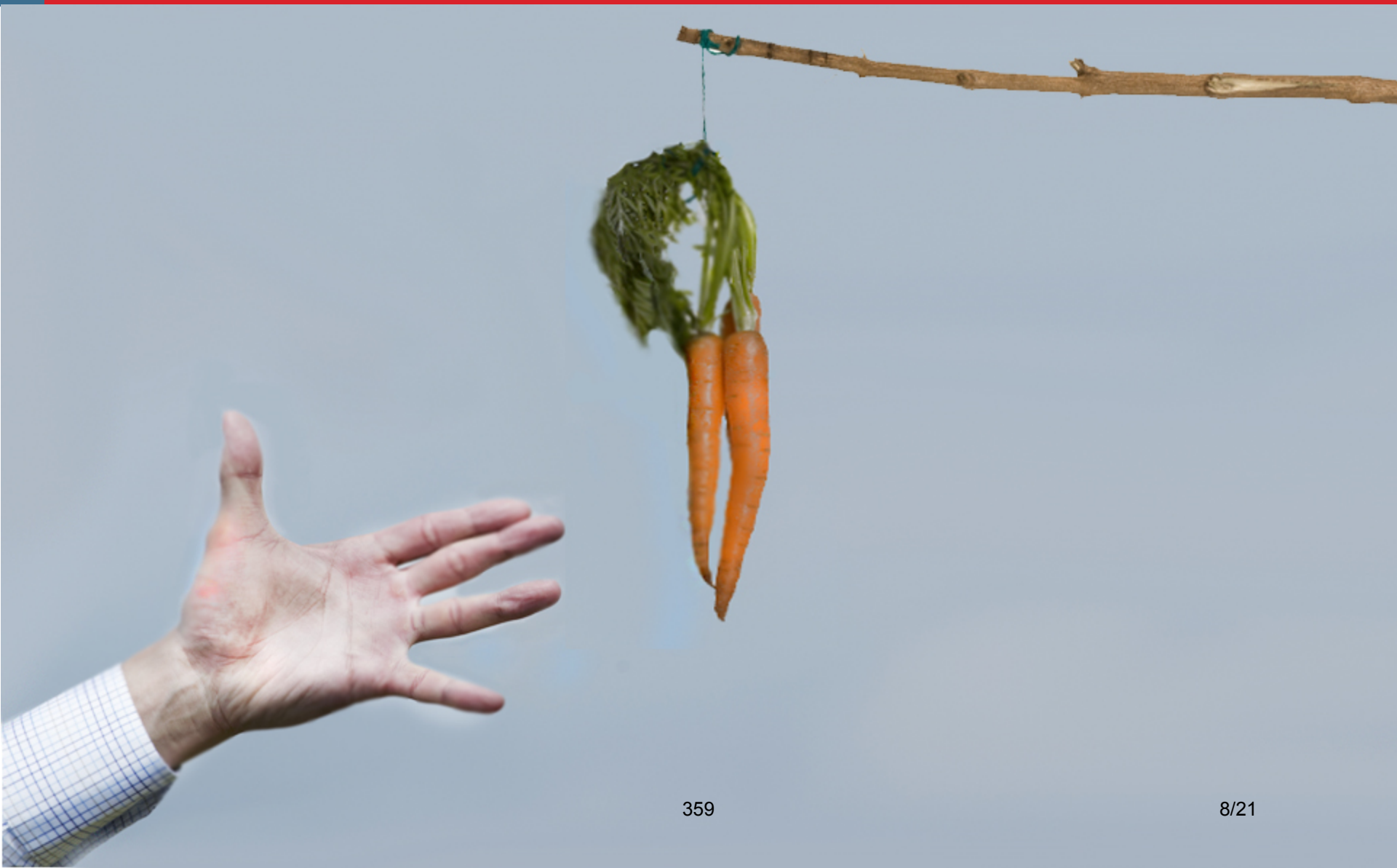
How changes in health care affect physicians

The days of the all-knowing and omnipotent practitioner are gone.

Quality tends to focus on pieces but breakdowns occur at the seams, where accountability is unclear.

The sicker the patient, the more important it is that the pieces fit together.

We need to motivate and reward patients for taking care of their own health.



Activating and engaging patients

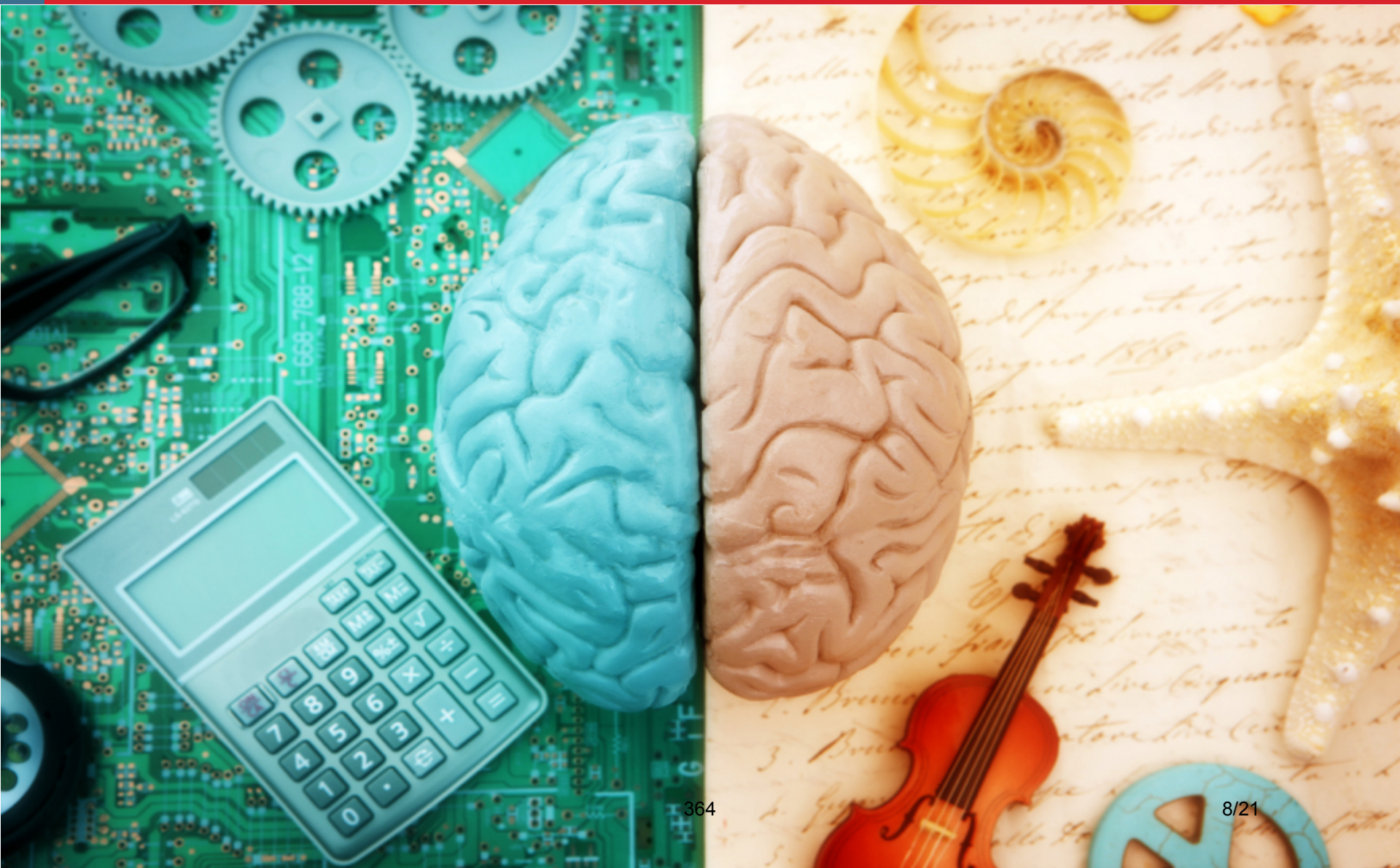
- Central to successful medical homes
- Promotes shared decisions, so patients make informed choices and get better results
- Supports use of decision aids that help patients become informed partners in their care

How should a medical board think about its role?

Medical boards focus on several topics to protect the public.

Should every provider be in a system?

Building good systems is both an art and a science.



Gawande's "pit crews, not cowboys" is a helpful metaphor.

THE NEW YORKER

COWBOYS AND PIT CREWS

May 26, 2011

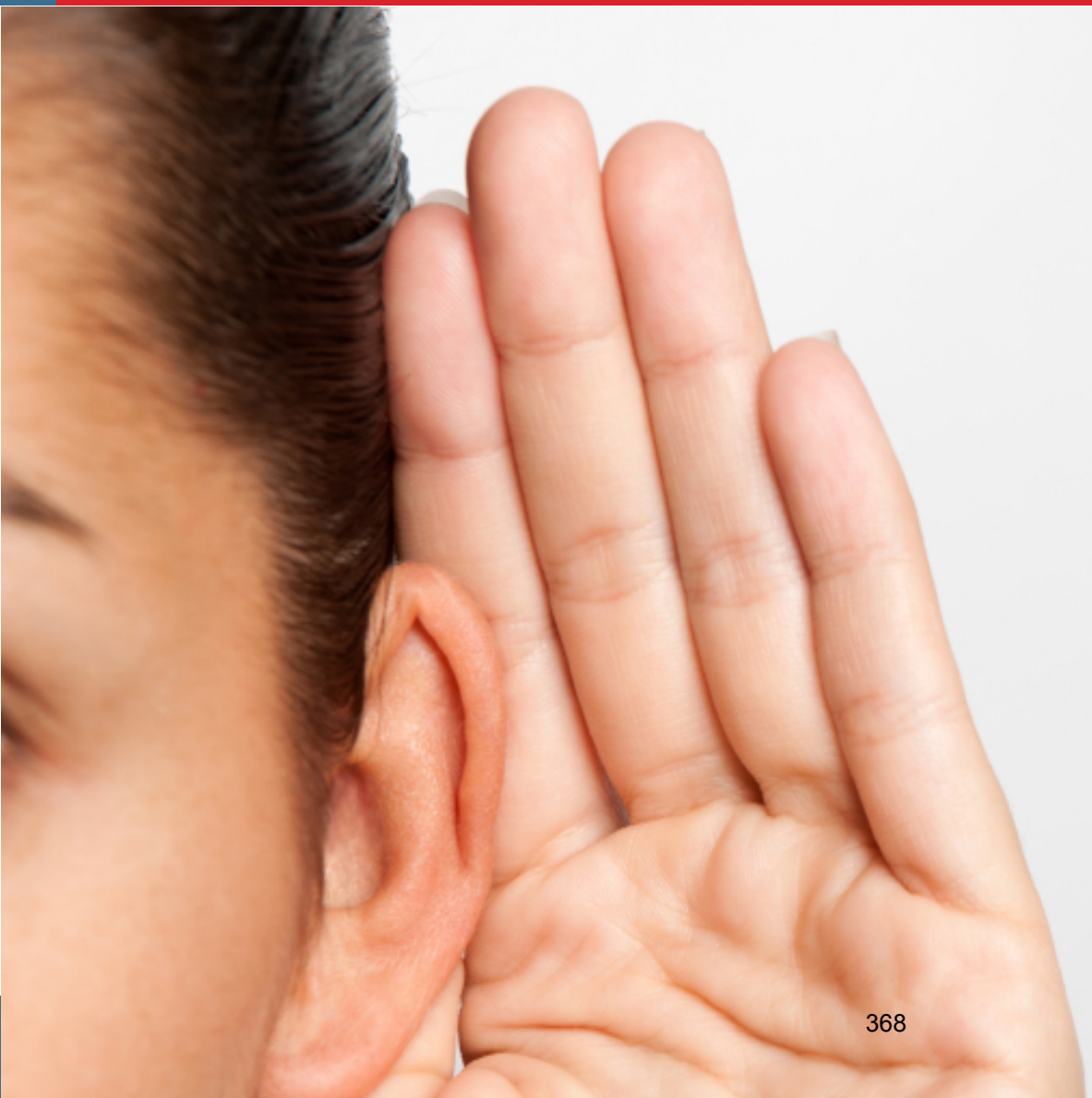
Posted by Atul Gawande

What's the best way to ensure competent care?

- Specialty board certification is best
  - Pay attention to maintenance of certification
- Being part of a PCMH or ACO brings the assurances of a system
- Should there be a systems assessment for physicians who aren't in a PCMH or ACO?

A climate of fear is not conducive to quality improvement.

I'd like to hear what you think.



Applying system control to maintain patient safety in a large multispecialty group.

"First, do no harm"

Management of Chronic Non-Malignant Pain.

Why CNMP?

This may be the "elephant in the room" of patient safety issues for Washington State.

Scope and scale of the problem.

- Accidental overdose on prescribed opiates became the leading cause of death in adults age 35-55 in Washington State in 2010.
  - Rate of unintentional overdose deaths in the US has risen 10 fold from 1970 to 2007.
  - Rate of unintentional death due to prescription opiates is now twice that of illegal drug overdose deaths.
- US has 5% of the worlds population and consumes 85% of the worlds opiates.
- 25% of Washington high school students confirm using prescription opiates to "get high".

"We like our opiates"

- Sales of opiates have "soared" in the US. Only codeine is down.
  - Sales increase from 1997 to 2007
    - Methadone up 1200%
    - Oxycodone up 700%
    - Hydrocodone up 200%
- The annual opioid consumption per person in the US was 73 mg in 1996. It is now 329 mg!
    - That is 55 x 5mg oxycodone for every man, woman and child in the USA per year.

Why do opiates kill people?

- Drug induced apnea.
  - Not always related to a significant change in dosage.
  - 83% of King County deaths investigated in 2009 showed concomitant use of Benzodiazepine.
  - Co-morbidities associated:
    - Sleep apnea
    - COPD
    - Other drugs:
      - Benzos, ETOH, Barbiturates.

Why is this happening?

- Likely contributing factors.
  - Mid 90's Physicians were told that we were not doing an adequate job of controlling pain.
  - Early 2000's JCAHO makes "pain assessment an indicator of good quality.
  - "Pain Score" becomes a hospital vital sign.
    - "manage the pain to the lowest score possible".
  - Oxycontin arrives in 1996.
  - By 2001 Oxycontin becomes the "best selling" narcotic.

So this is a problem worth "tackling".

- How to approach this.
  - Education.
    - Let Physicians, staff and patients know that there is a problem.
  - Communication.
    - Find out how we currently dealing with this and set up lines of communication and expectation.
  - Execution.
    - Create "standard work" to increase reliability around what should be "standard of care".
    - Measure for success and spread.
    - Continue to innovate as you learn more.

Focus group evaluations of Physicians and staff revealed:

- Much of our problem was "too much variability" in the way we treated patients with CNMP.
  - Physicians were "over-treating" and "under-evaluating" patients.
  - The fund of knowledge for most treating Physicians was low on this issue.
  - Access to care for patients with CNMP was poor and worsening.
    - "If I open up to taking these folks, I will get all of them."

Approaching the fix.

- Get educated
  - CME collaboration with the U of W Pain Clinic.
  - Assigned review of the current literature.
  - Assigned development of a "Care Pathway" for use throughout the clinic.
  - Clearly established guidelines and expectations for Physicians and staff.
    - Consistent triage and "intake system".
    - Everyone does their part. (no closed practices)
  - Clear communication to patients.
    - "get everyone on the same page."

What's the system look like?

A review of the "Physician Toolbox" portion on the WVMC Intranet site.

Results so far.

- Roughly 1200 patients treated through the "New System" so far.
  - 30% successfully weaned off of narcotics or to very low levels (under 50 MED), without worsening of pain scores and with an overall improvement in functional capacity.
  - 30% are successfully maintained at 120 MED or less with no worsening of their pain scores or decrement in function.
  - 30% have failed treatment and moved on to other providers or are still struggling to get below 120 MED o

Results so far.

- Strong adoption of the care process.
  - All new CNMP patients are enrolled in this program
  - >90% of patients on chronic narcotics have a diagnosis of CNMP on their problem list and a current Opioid Treatment Informed Consent and Agreement on the chart.

Results so far.

- 80% reduction in patient on more than 120 MED in our system.
- >50% reduction in patients on methadone in our system.

Next steps.

- Community wide approach.
  - Strong collaboration with local Community Health Clinics.
  - Enthusiastic support from local City and County Law Enforcement and Pharmacies.
  - Patient and community education events.
  - Schools are next.
  - Pain specialist hired to lead multidisciplinary team.
    - Starts Feb. 2013.

Chronic Pain

A Primer on Pain – Core strategies for effective care of patients with chronic non-malignant pain

Chronic Pain should be managed by Primary Care Providers (PCPs)

A. Behavioral aspects of care present huge challenges best managed through a strong therapeutic relationship with a PCP-directed multidisciplinary team.

B. Clear boundaries, carefully explained and frequently readdressed, are key to minimizing aberrant behavior.

   i. Substance abuse is best recognized and avoided by limiting access to one prescriber with careful monitoring.

C. Access to specialty consultation is enhanced by PCP insistence on specialist consultation <u>not</u> management.

   ii. Specialist evaluates and recommends treatment
   iii. PCP team institutes recommendations and assesses progress.

D. A <u>Chronic Pain Care Pathway</u> using evidenced-based Guiding Documents ensure high-quality, responsible, compassionate care. Utilization of staff for information gathering via these documents can greatly facilitate care. These Chronic Non-malignant Pain Resources and others are available via our Physician Toolbox stethoscope icon on the Intranet Homepage and will be referred to throughout this Primer. **<u>Documents</u>** are signified by bold, underlined script. **Headings** under which these documents can be found are in bold type.

Function is the focus of treatment

A. Pain is part of life. Therefore, we aim to increase <u>function</u>, not to eliminate pain, but rather make pain manageable.

   i. Help patients *confront their fears* of movement and pain.
   ii. Increased function will increase pain in the short run, and decrease pain in the long run.
   iii. Physical Therapy can provide guidance/coaching.

B. The majority of chronic pain is related to muscle tension.

   i. Pain leads to inactivity
   ii. Inactivity leads to muscle tension and stiffness
   iii. Muscle tension leads to pain
   iv. Increased activity will decrease overall pain.

C. Improved function will improve quality of life and self-esteem

D. Reinforce *wellness* with regular activity and an exercise program. Construct a plan for improvement in function with the patient using the **<u>Personal Care Plan</u>** (under **Guiding Documents**)

E. Document function

   i. Using the **<u>Brief Pain Inventory</u>** (under **Questionnaires**), pg 2: *Pain Disability Index*

ii. Function must be improving to justify ongoing opioid therapy.

Educate the patient

A Let the patient know that you believe their *pain is real.* The patient's self-report is the most reliable indicator of pain. See **Brief Pain Inventory** (under **Questionnaires**) pg.1, *Severity*

B Explain: "Medical studies have shown that chronic pain leads to changes or *rewiring* in the brain that cause ongoing pain even after the cause of the original pain has gone or diminished. These brain changes can result in an over-sensitivity to pain, cause pain to occur under circumstances that previously wouldn't lead to pain and can even spread pain to areas of the body previously not involved. Why these changes take place in one person but not another with the same injury is not yet known."

C Describe this current understanding of the *pathophysiology* of chronic pain, the expected fluctuation in pain levels, the risk of overdoing activities and the need for pacing.

D Many patients have *poor self-esteem* as a result of the impact of chronic pain; reassure that they are a good person with a bad problem that you wish to help them through.

E Explain to the patient that their *pain* rather than the original cause is a problem in and of itself and requires specific therapy. *Understanding* reduces fear. Use the PowerPoint **Chronic Pain Patient Education Tool** (under **Pt Education**) to explain this relationship. Further explain:

i. Their pain has become unlinked from tissue derangement
ii. Must recognize PAIN itself is now a problem
    a Focus on PAIN management
    b Focus on living with PAIN
iii. Core Strategies
iv. Different medicines for different types of pain
v. How to refill medications (never after hours, never early)
vi. Provide the **Patient Handout** (under **Pt Education**) regarding chronic pain

Engage the patient in their care plan

A Describe that successful therapy involves a team in which they are the most important member. This requires a *multidisciplinary approach* and their participation is mandatory if they are to receive care through our clinic.

B It is the patient's pain, not ours

C Establish *clear expectations and responsibilities* via the **Opioid Treatment Informed Consent & Agreement** (under **Guiding Documents**)

D. The patient is ultimately responsible for managing their own pain
   i. We will educate and support their pain management
   ii. We will not enable maladaptive behavior
   iii. We are the coach, but it is their ball-game

E. Demand patient participation
   i. Few things in their life should take precedence
   ii. Missed visits only in exceptional circumstances

F. Document and address comorbid conditions affecting outcomes including obesity, tobacco use, substance abuse, sleep disorders, alcohol/drug abuse (**CAGE**), and depression (**PHQ-9**)—under **Questionnaires**. Listed in **Initiation of Therapy** (under **Guiding Documents**). See **Medication for specific comorbidities** under **Tools**.

Treatment

A. Medicines are only one part of pain management and must be used carefully as part of a comprehensive strategy. They are only one "tool" in the patient's "tool-kit."

B. Use appropriate medications for the specific *pain mechanism,* i.e.:
   i. Neuropathic pain – TCA or neuromodulator first
   ii. Inflammatory pain – NSAID first
   iii. See the 4 **Biologic Mechanisms of Pain** under **Appendices**; **Opioid/Non-Opioid Analgesics**, **Specific Indications for Neuromodulators** under **Tools**)

C. Avoid telling the patient to *"let pain be your guide"*

D. Essential dosing concepts
   i. By mouth,
   ii. By the clock,
   iii. By the ladder (start with NSAIDs, work up to opioids)
   iv. For the individual,
   v. With attention to detail

E. Opioid Management (see **Tools—Opioid Prescribing**, etc)
   i. Screen with the **DIRE Score** (under **Questionnaires**) before initiating to determine patient risk for adverse events/ behavior.
   ii. Establish *informed consent* via the Opioid Treatment Informed Consent and Agreement (under Guiding Documents) which includes limitations of opioids, side-effects, and dependency/addiction risks, dangers including death, destructive-behavior, depression, worsening pain and barriers to improvement that *opioids* can cause requiring close monitoring with a plan to taper and ultimately discontinue these medications if at all possible. The consent must be obtained prior to the use of long-term opioids.
   iii. Caution with conditions that may potentiate opioid adverse effects (COPD, CHF, Renal disease, Liver disease, Sleep apnea, Substance abuse, Elderly)

iv. Dosing: (see **Opioid Prescribing** under **Tools**)
   a Use long acting "controller" medication in fixed dosing and, if needed, short-acting "rescue" medications for specific, limited circumstances.
   b Avoid prn use for chronic pain control. Fixed dosing is preferred.
   c Limit acetaminophen if dosed in combination to 2500mg / 24 hours.
   d Counsel patients extensively around Methadone use. (see **Using Methadone Safely** under **Patient Education** and **Methadone Interactions** under **Tools**)
   e Monitor closely for side effects of nausea, constipation, over sedation, itching. (see **Management of Pain Medication Side Effects** under **Tools**)
   f Opiate rotation may improve effectiveness and decrease side effects
   g Opiates offer limited relief for neuropathic pain (see **Pharmaceutical Interventions for Neuropathic Pain** under **Support**)

v. Avoid concurrent use of sedative hypnotics (benzodiazepines, barbiturates)

vi. Regular follow-up (q 3 months once stabilized) see Review of Therapy under Guiding **Documents**
   a Screen opioid patients with documentation of the "*four* **A**'*s*":
      1 **ADVERSE** drug effects
      2 **ACTIVITY** (function)
      3 **ANALGESIA** (effectiveness) in **Brief Pain Inventory**, pg. 1 under **Guiding Documents**
      4 **ADHERENCE** (UDS, pill counts)
   b Regular and random UDS (see **Retention Times of Drugs in Urine** under **Appendices**)
   c Assure participation in Behavioral Medicine
   d Educate/validate/support

vii. Ceiling opioid dose = 120mg MED
   a Alert the patient as to the current guidelines of government agencies requiring *documentation of ongoing improvement in function and pain* in order to justify continued treatment with opioids and the maximum dose of 120mg MED triggering specialist consultation.
   b May exceed ceiling only with documented improved function.
   c Recommend Pain Specialist consultation above ceiling dose.

viii. Behavioral medicine is a cornerstone of treatment (see **Cognitive Behavioral Interventions** under **Appendices**)
   a Emotional pain masquerades as physical pain whenever possible.
   b Emotional state impacts ability to tolerate/cope with burden of pain.
      1 Pain -> Anxiety -> Tension -> Fatigue -> Pain
   c Assess for and treat behavioral illness aggressively
   d Anger management problems are frequent co-morbidities
   e Sleep dysfunction should be addressed
      1 Pseudo-addiction is real and should be recognized

f. Pain -> Fear -> Desperation -> Aberrant behaviors
g. Enlisting the family and or other personal resources if available is often helpful.

ix. Zero tolerance for untreated substance abuse

h. Every patient should be screened for substance abuse regularly
i. Co-occurring disorders require ongoing substance abuse treatment
j. The clinic's Opioid Oversight Committee (OOC) will make a final and binding decision in cases where a patient wishes care that is not felt to be appropriate by the provider or if conditions of the **Consent** are violated.
k. Refer aberrant behavior to the Opioid Oversight Committee (OOC)

Management

A. Use regular pill counting & random urine drug screening to monitor **ADHERENCE**
   i. If patient not compliant with dosing schedule: reeducate/adjust schedule/consider discharge if repetitive
   ii. If medication not effective or reaction noted: change medication if to another narcotic: 50-70% of equianalgesic dose, (see **Dosing Threshold/ Opioid Conversion**, **Opioid Analgesics** and **Methadone Conversion** under **Tools**)
   iii. If diversion/altering prescriptions noted: inform authorities, refer to Addiction Services and discharge from practice
B. Refer to Pain Specialist if no improvement in function or pain relief in spite of 6-9 mo Tx or > 120 mg **MED**/day (80mg oxycontin/ 50mcg/hr transdermal Fentanyl/ 40 mg methadone)
   i. see (**Chronic Pain Questionnaire: Barriers to Treatment-Patient/ Staff**)
C. Discontinue opioids if ineffective after titration (6-9 mo), produce significant adverse effects or if abused or diverted.
   i. See **Weaning Opioids** and **Considerations for Initiating, Altering or Discontinuing Opioids** under **Tools**)
D. Refer patient to *Drug Abuse Treatment Program* if exhibits drug-seeking behavior or diversion
   i. **Recognizing and Managing Aberrant Behavior** under **Support.**
   ii. Consider *Discharge from Practice* per **Opioid Treatment Informed Consent and Agreement**
E. Trust, validation and support are cornerstones of treatment
   i. Mutual trust is enhanced with:
      a. Pain agreements ("contract")
      b. Random Urine Drug Screens (UDS)
   ii. Support comes best from other pain patients (group visits)
   iii. The Primary Care Provider (PCP) is the patient's advocate within the established care plan
      a. Patient must participate in all aspects of plan
      b. Patient must at all times be honest with their PCP

c. Referral to OOC allows PCP to remain an advocate, not disciplinarian

iv. There is no room for bad behavior within the clinic

F. Work is good for everyone

i. Work enhances self worth and self reliance
ii. Work is the best distraction
iii. Work requires improved function
iv. All efforts will be made to sustain work or assist in a stepwise return to work

Chronic Pain

Initiation of Therapy

Patient Name _____ Date _____

Assessment

Pain Diagnosis "***Biologic Mechanisms of Pain***"

☐ Neuropathic Pain ☐ Muscle Pain

☐ Inflammatory Pain ☐ Mechanical/Compressive Pain

Pain Intensity "***Brief Pain Inventory***"

1----------5----------10

Contributory co-morbid illness

☐ Obesity ☐ Depression ("***PHQ-9***") ☐ Anxiety

☐ Hx of Personal Abuse ☐ Tobacco ☐ Other ____

History

☐ Complete history and physical, including pain history (*PQRST*), are in the chart.

☐ Reviewed current and past pain treatment.

☐ History of substance abuse was asked.
Positive history: YES _____ NO _____

Pain-related disability

☐ Self Care ☐ Family/Social ☐ Mobility ☐ Social

☐ Lifting ☐ Work ☐ Leisure ☐ Mood ☐ Irritability

☐ Sleep Current sleep _____ Hours per night ____

Restless _____ Interrupted _____ Sleep Apnea? _____

Treatment

☐ Medication trial with _____
"***DIRE Score***" for risk stratification if chronic opioid analgesia considered

☐ Detoxification from _____

☐ Taper opioids if possible – goal ≤ 120mg **MED**/day

Pain Rehabilitation

☐ Physical Therapy ☐ Occupational Therapy

☐ Stress Management ☐ Vocational

Reason for selecting therapy

☐ Failure of analgesics ☐ Overuse of analgesics

☐ Therapy of co-morbid illness

☐ Other _____

Goals of therapy

☐ Reduce pain ☐ Improve disability

☐ Minimize Organ toxicity from analgesics

☐ Improve ability to participate in rehabilitation/work

☐ Reduce use of medical system and emergency visits

Risks, benefits and appropriate dosing schedule were reviewed with the patient

☐ Provided written instructions _____

☐ "***Pain Contract***" Signed

Follow-up plans

☐ Office follow-up in _____ weeks ☐ Consult with _____

☐ Telephone follow-up in _____ weeks ☐ Diagnostic tests _____

Pre-visit Questionnaires: ***Chronic Pain, Brief Pain Inventory, PHQ-9, CAGE, DIRE***

MED = morphine equivalent dose: 120mg = 80mg oxycodone = 50mcg/hr transdermal fentanyl = 40mg methadone. see ***Dosing Thresholds for selected Opioids***

Chronic Pain

Review of Therapy

Patient Name _____ Date _____

New contributory comorbid illness: _____

Tolerability

ADVERSE Drug Effects "***Side Effects Management***"

☐ Constipation ☐ Nausea ☐ Sedation ☐ Dizziness

☐ Other _____

☐ Medication is well tolerated.

Efficacy

ACTIVITY: improvements in pain-related disability

☐ Self Care ☐ Family Social ☐ Mobility ☐ Work

☐ Lifting ☐ Irritability ☐ Leisure ☐ Mood

☐ Other _____

☐ Sleep: Hours per night ____ More Restful ____
Less Interrupted ____

ANALGESIA: goal attainment "***Brief Pain Inventory***"

☐ Severity: 1----------5----------10

☐ Reduced Pain _____

☐ Frequency of Flares _____

☐ Duration of flares _____

ADHERENCE: unused meds/drug screen results reviewed

☐ Patient is compliant with dosing schedule:

☐ Continue current medications

☐ Patient is **not** compliant with dosing schedule:

☐ Adjust medication dosing schedule

☐ Reeducation

☐ Patient has **violated the law**-- diversion suspected by negative urine drug screen, unprescribed drugs noted

☐ Drug Abuse Treatment Program Referral

☐ Case referral to Opioid Oversight Committee

Recommendations

Prescribed Additional Therapy

☐ Physical therapy ☐ Psychology/Stress Management

☐ Occupational therapy ☐ Vocational Therapy

☐ Physician consult for: _____

☐ Medication trial with: _____

☐ "***Personal Care Plan***" completed

☐ Written instructions given

Patient not showing improvement

No improvement in function or pain relief in spite of 6-9 mo Tx or >120mg **MED**/day

☐ Referral to pain specialist

☐ Medications tapered/discontinued

☐ Other _____

*Previsit Questionnaires: ***Brief Pain Inventory***, ***PH-Q9*** in depression

MED = morphine equivalent dose: 120mg = 80mg oxycodone = 50mcg/hr transdermal fentanyl = 40mg methadone. see ***Dosing Thresholds for selected Opioids***

Chronic Pain

Opioid Treatment Informed Consent & Agreement

Medical studies have shown that chronic pain leads to changes in the brain that cause ongoing pain even after the cause of the original pain has gone or diminished. These brain changes can result in an over-sensitivity to pain, cause pain to occur under circumstances that previously wouldn't lead to pain and can even spread pain to areas of the body previously not involved. Why these changes take place in one person but not another with the same injury is not yet known.

The management of chronic pain is a challenge that requires a team approach. You are the most important member of this team. Without your understanding and participation in therapy we can't accomplish that *retraining* of the brain recognized as being involved in the true healing process.

The purpose of this Agreement is to prevent misunderstandings and complications in the use of narcotic pain medications (also known as opioids) and to help you and your doctor comply with the laws regarding their use.

The decision was made to use narcotic pain medications because other treatments have not adequately controlled your pain. The goal of this treatment is to improve your pain enough to improve your overall functioning. We will be using various assessment tools to monitor this. If no significant improvement in function is noted, then we may decide to discontinue the medication. New state guidelines are specific about these issues including a safe maximal dose. These guidelines were designed to prevent severe complications, including death, which have been associated with ongoing high-dose narcotic use.

Diagnosis for which pain medicines are being prescribed_____

Doctor who will be prescribing my pain medicines_____

Medication prescribed:_____

I agree to the following terms regarding the narcotic medications prescribed to me (please initial each item)

1._____ I understand that *improvement in my ability to function*, a *decrease in my pain* and *improvement in my quality of life* and *self esteem* are the **goals** of this program.

2._____ I will communicate fully with my doctor about the type and severity of my pain, its effect on my daily life, and how well the medicine is helping to relieve it.

3._____ *I agree to do my part* to improve my health including regular exercise (but avoiding overdoing it with strenuous activities), weight management, working on stopping smoking, and learning stress management techniques. I understand that only through following a healthier life-style can I hope to have the most success from my treatment plan.

4._____ *I agree to participate in* programs deemed appropriate by my doctor such as physical or occupational therapy, vocational rehabilitation programs or specialist referral. *I agree to* any testing, consultations or other treatments that my doctor recommends in order to further assess and manage my pain.

5._____ I realize that these medicines have possible *side effects* which have been fully explained to me (see Appendix). I release my doctor from responsibility for harmful reactions that may result from my improper use of these medicines. I realize that my medicines may cause drowsiness and that alcohol and certain medications may intensify this. I will inform my doctor of all medications and treatments I am receiving (including over the counter

medications, herbs and other alternative treatments). I understand it is my responsibility to keep others and myself from harm, by not engaging in activities such as operating heavy machinery, working in unprotected heights or driving until I am sure of the effects of my medicine has or doesn't have on me. **It is very important in particular to not crush, chew or otherwise open long acting narcotic pain medicine as this may result in serious overdose or even death**. Take medication **only as prescribed** by your doctor.

6._____ I understand that opioid pain medicine may have *unintended psychological effects* such as a false sense of well-being and a feeling of being better able to cope with problems. Sometimes people who experience these effects may use their medication in a way other than prescribed. This can lead to psychological addiction. This is rare among people who've never had an addiction problem with other substances, but may be more common in those who have. The following definitions are important for you to understand. Please read them carefully.

Physical dependence: A property of certain drugs such as caffeine and opioids, that causes changes in the body. Suddenly stopping these drugs results in a "withdrawal" response. Physical dependence occurs in most patients who use opioid medications regularly. Physical dependence should not be confused with psychological addiction.

Addiction: A psychological and behavior problem in which there is a drug-craving and drug-seeking behavior for purposes other than those intended by your doctor. For example, addictive behavior would include increasing your usual dose of opioid (without prior discussion with your doctor) for psychological benefit during a stressful situation.

Tolerance: A property of certain drugs, such as opioids, defined by the need for increasing doses to maintain effect. This doesn't appear to be much of an issue in chronic pain once your dose has been increased to a level to control your pain adequately enough to significantly improve your functional status (contrast this to the person who is psychologically addicted and continues to need more and more of the drug to "get high"

7._____ I will not use illegal controlled substances, including marijuana, cocaine, heroin, amphetamines, etc.

8._____ I will not use alcohol regularly. Limiting intake to one beverage when I do. Never when opioid dose is changed.

9._____ I agree to submit to a blood or urine test if requested to determine my compliance with my pain control program. I understand that if the test shows that I don't have evidence of the prescribed medication in my body , or if I have evidence of unprescribed addictive drugs in my body, that my doctor will no longer be willing to prescribe narcotic pain medication and a drug treatment program may be recommended.

10._____ I will not share, sell or trade my medication with anyone. I will not use medicine that has been prescribed to someone else. I will not try to get medicines using forged prescriptions or under other false pretenses.

11._____ I will not attempt to get any controlled medicines, including opioid pain medicines, controlled stimulants, or anti-anxiety medicines from anyone other than my doctor (or his/her appointed designee). I understand it is against the law to obtain these from a non-medical provider. If I require treatment with opioid pain medicines in an emergency room, I will inform the ER physician of my present medication regimen and agreement and ask him/her to inform my doctor of this visit. **I understand that if I use another doctor office to obtain additional controlled drugs in a non-emergency situation, I risk not being able to get refills from my regular doctor.**

12.____ I will not engage in disruptive, angry, loud or physically threatening behavior in the clinic. This interferes with patient care and will not be tolerated.

13.____ I will safeguard my pain medicine and keep all medications away from children. **Lost, stolen or destroyed medicines will not be replaced or early refills given**.

14.____ I agree that refills of my pain medicine will be made only during an office visit or regular office hours. **No refills will be available during evenings or weekends or from anyone other than my regular provider**.

15.____ I agree to use _____ Pharmacy for filling all of my pain medicine prescriptions.

16.____ I authorize my doctor and my pharmacy to cooperate fully with any city, state or federal law enforcement agency, including this state's Board of Pharmacy, in the investigation of any possible misuse, sale, or other diversion of my pain medicine. I authorize my doctor to provide a copy of this Agreement to my pharmacy or any other medical provider that I am seeing. I agree to waive any applicable privilege or right of privacy or confidentiality with respect to these authorizations.

17.____ **I will not adjust the medication myself**. I agree not to use my medicine up faster than prescribed, and I understand that violation of this may result in me being without it for awhile, and may cause my doctor to be unwilling to continue prescribing these medications. If I feel an adjustment is needed, then I will first discuss this with my doctor. I further agree not to hoard medication and will inform my doctor if I have less need for pain medication.

18 ____ **I will bring all unused pain medicine to every office visit**. I agree that refills of my pain medications will be made during regularly scheduled appointments (unless otherwise arranged) and that I am responsible for scheduling these appointments monthly or as determined by my doctor. I understand that if I cancel or no show my appointment, I may be without my medicine for a period of time. I further agree not to make repeated phone calls regarding needed prescription refills.

19 ____ I agree to follow these guidelines that have been fully explained to me. All of my questions and concerns regarding treatment have been adequately answered. **I understand that if I do not abide by this agreement, my doctor may stop prescribing these medications and a drug abuse treatment program may be recommended**. Repeated non-compliance with recommended therapy or any violation of the law will result in my doctor terminating my care. A copy of this document has been given to me.

Date: ____/____/____

Patient Signature:_____

Physician Signature: _____

Witnessed by:_____

Dates of re-review & Initials _____

2/6/09

Chronic Pain

Personal Care Plan for Chronic Pain

Set Personal Goals

☐ Reduce Brief Pain Inventory Question #9 (interference) score by _____ points by Date_____

☐ Return to specific activities, tasks, hobbies, sports....by Date _____

1 _____ 3 _____

2 _____

☐ Return to limited work /or ☐ normal work by: Date _____

Improve Sleep (Goal _____ hours per night, Current _____ hours per night

☐ Improve ICSI Functional Ability Score by _____ points by Date_____

1 Eliminate caffeine and naps, relaxation before bed, go to bed at target bedtime_____

☐ Take nighttime medications

1 _____ 3 _____

2 _____

Increase Physical Activity

☐ Attend physical Therapy (_____ days per week)

☐ Complete daily stretching (_____ times per day for _____ minutes)

☐ Complete aerobic exercise/endurance exercise

1 Walking(_____ times per day, for _____ minutes) or pedometer (_____ steps per day)

2 Treadmill, bike, rower, elliptical trainer (_____ times per week, for _____ minutes)

3 Target heart rate goal with exercise _____ bpm

☐ Strengthening

1 Elastic, hand weights, weight machines (_____ minutes per day, _____ days per week)

Manage Stress – List main stressors_____

☐ Formal Interventions (counseling or classes, supoprt group or therapy group)

1 _____

Daily practice of relaxation techniques, meditation, yoga, creative / service activity...

1 _____ 2 _____

Medications

1 _____ 2 _____

Decrease Pain – Best pain level in past week _____ / 10, worst pain level in past week _____ / 10

☐ Non-medication treatments

1 Ice / Heat _____ 2 _____

☐ Medication

1 _____ 3 _____

2 _____ 4 _____

☐ Other treatments_____

Physician Name _____ Date _____

Created by Peter Marshall, MD as a member of the ICSI Chronic Pain guideline work group.
ICSI – Assessment and Management of Chronic Pain – Second Edition/March 2007

CDC

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Morbidity and Mortality Weekly Report

www.cdc.gov/mmwr

Weekly October 30, 2009 / Vol. 58 / No. 42

Overdose Deaths Involving Prescription Opioids Among Medicaid Enrollees — Washington, 2004–2007

During 1999–2006, the number of poisoning deaths in the United States nearly doubled, from approximately 20,000 to 37,000, largely because of overdose deaths involving prescription opioid painkillers (*1*). This increase coincided with a nearly fourfold increase in the use of prescription opioids nationally (*2*). In Washington, in 2006, the rate of poisoning involving opioid painkillers was significantly higher than the national rate (*1*). To better characterize the prescription opioids associated with these deaths and to reexamine previously published results indicating higher drug overdose rates in lower-income populations (*3*), health and human services agencies in Washington analyzed overdose deaths involving prescription opioids during 2004–2007. This report describes the results of that analysis, which found that 1,668 persons died from prescription opioid-related overdoses during the period (6.4 deaths per 100,000 per year); 58.9% of decedents were male, the highest percentage of deaths (34.4%) was among persons aged 45–54 years, and 45.4% of deaths were among persons enrolled in Medicaid. The age-adjusted rate of death was 30.8 per 100,000 in the Medicaid-enrolled population, compared with 4.0 per 100,000 in the non-Medicaid population, an age-adjusted relative risk of 5.7. Methadone, oxycodone, and hydrocodone were involved in 64.0%, 22.9%, and 13.9% of deaths, respectively. These findings highlight the prominence of methadone in prescription opioid–related overdose deaths and indicate that the Medicaid population is at high risk. Efforts to minimize this risk should focus on assessing the patterns of opioid prescribing to Medicaid enrollees and intervening with Medicaid enrollees who appear to be misusing these drugs.

For this analysis, the Washington State Department of Health defined an overdose death involving prescription opioids as a death in Washington during 2004–2007 of a state resident whose death certificate had 1) a manner of death of "accidental" or "natural"; 2) one or more contributing causes coded to "poisoning by narcotics" or a "mental and behavioral disorder due to use of opioids" (based on *International Classification of Diseases, 10th Revision* codes T40.0–T40.6 and F11*); 3) specific words compatible with an acute drug intoxication recorded in any of the cause of death fields (e.g., "overdose"); and 4) a prescription opioid term in any of the cause of death fields. Examples of prescription opioid terms sought on manual review of the certificates were "oxycodone," "methadone," and "hydrocodone." Although morphine is a prescription opioid painkiller, it is also a metabolite of heroin. Therefore, mention of morphine on a death certificate was only accepted as evidence that a death was prescription opioid–related when the certificate specified that the morphine was a prescription drug. As a result, 82 deaths involving morphine and no other opioids (36.6% of all deaths in which morphine was mentioned) were excluded from this analysis.

The Washington State Health and Recovery Services Administration (WSHRSA), which operates Medicaid and several associated medical-assistance programs, determined which deaths occurred among persons who were enrolled in

* Available at http://apps.who.int/classifications/apps/icd/icd10online.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

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Medicaid at some time during the year of their death. During 2004–2007, the Medicaid-enrolled population (5,109,363 person-years) represented 20.2% of the Washington population (25,287,800 person-years). WSHRSA also linked the deaths from prescription opioids to records of clients in the Medicaid Patient Review and Coordination (PRC) program, a special state program for clients who overuse or inappropriately use medical services.† PRC program members (5,858 person-years) represented 0.1% of the Medicaid population during 2004–2007. Rates were age adjusted because the Medicaid population was younger than the non-Medicaid population.

During 2004–2007, a total of 2,282 deaths in Washington met the manner and cause of death case definition criteria. Of these, 2,194 (96.1%) had a death certificate that included a term indicating acute drug intoxication. Of these 2,194, a total of 1,668 (76.0%) had a death certificate that included a prescription opioid term and were included in this analysis. The age-adjusted prescription opioid overdose rate was 6.4 per 100,000 per year (Table 1). The male mortality rate was 1.4 times the female rate. Rates increased with age to a peak of 15.0 per 100,000 in the 45–54 years age group and then declined.

Among all decedents, 758 (45.4%) were enrolled in Medicaid at some point during the year of their death. Medicaid-enrolled decedents had an age distribution comparable with that of decedents statewide. However, the percentage of females was greater among Medicaid-enrolled decedents (52.2%) than among decedents statewide (41.1%). A total of 34 Medicaid-enrolled decedents were in the PRC program, representing 4.5% of all Medicaid-enrolled decedents.

The risk for prescription opioid overdose death varied substantially by Medicaid status (Table 2). The crude annual risk for prescription opioid overdose death was approximately one in 6,757 in the Medicaid-enrolled population and one in 172 in the Medicaid-enrolled PRC program population.

Medical examiners and coroners recorded methadone on death certificates nearly three times more often than the next most common opioid, oxycodone (Table 3). At least one nonopioid prescription drug was reported in 54.6% of the deaths. A benzodiazepine was listed on the death certificate in 20.9% of the deaths, and an antidepressant in 31.7%. An illegal drug was reported in 21.8% of the deaths. Cocaine was involved in 15.7%, methamphetamine in 5.5%, heroin

† During 2004–2007, approximately 90% of clients in the Washington PRC program misused prescription opioids by doctor shopping, frequent cycling through emergency departments, and prescription forgery. WSHRSA attempted to limit such misuse by restricting PRC clients to one primary-care provider, one narcotics prescriber, one pharmacy, and one hospital for nonemergency care. In addition, WSHRSA could require prior authorization for all opioid prescriptions.

TABLE 1. Number, percentage, and rate of deaths attributed to overdoses of prescription opioid drugs among the total and Medicaid-enrolled populations, by selected characteristics — Washington, 2004–2007

Characteristic	Total population			Medicaid-enrolled population		
	No.	(%)	Rate*	No.	(%)	Rate
Sex						
Male	977	(58.9)	7.4	362	(47.8)	41.2
Female	691	(41.1)	5.3	396	(52.2)	24.8
Age group (yrs)						
<18	16	(1.0)	0.3	10	(1.3)	0.4
18–24	117	(7.0)	4.6	32	(4.2)	4.4
25–34	285	(17.1)	8.4	133	(17.5)	22.6
35–44	425	(25.5)	11.3	200	(26.4)	53.2
45–54	573	(34.4)	15.0	284	(37.5)	101.9
55–64	211	(12.6)	7.7	89	(11.7)	50.4
≥65	41	(2.5)	1.4	10	(1.3)	2.9
Year						
2004	351	(21.0)	5.5	114	(15.0)	19.9
2005	399	(23.9)	6.1	190	(25.1)	32.2
2006	464	(27.8)	7.0	213	(28.1)	33.4
2007	454	(27.2)	6.7	241	(31.8)	37.2
Total	**1,668**	**(100.0)**	**6.4**	**758**	**(100.0)**	**30.8**

* Per 100,000, age-adjusted to the 2000 U.S. standard population for all but the age-specific rates. Total rates are based on 25,287,800 person-years for the total population and 5,109,363 person-years for the Medicaid-enrolled population.

TABLE 2. Number and rate of deaths attributed to overdoses of prescription opioid drugs, by Medicaid status — Washington, 2004–2007

Status	No.	Crude rate*	Age-adjusted rate†	Age-adjusted RR§ (95% CI¶)
Medicaid	758	14.8	30.8	5.7 (5.3–6.1)
Medicaid PRC** program	34	580.4	381.4	92.6 (64.1–129.5)
Non-Medicaid	910	4.5	4.0	Referent

* Per 100,000. Rates are based on 5,109,363 person-years for the Medicaid population, 5,858 person-years for the Medicaid PRC program, and 20,178,437 person-years for the non-Medicaid population.
† Per 100,000, adjusted to the 2000 U.S. standard population.
§ Relative risk, adjusted to the age distribution of the non-Medicaid population.
¶ Confidence interval.
** Patient Review and Coordination.

TABLE 3. Number and percentage of deaths attributed to overdoses of prescription opioid drugs, by specific drug involved — Washington, 2004–2007

Drug	No.	(%)*
Methadone	1,068	(64.0)
Oxycodone	382	(22.9)
Hydrocodone	232	(13.9)
Fentanyl	76	(4.6)
Propoxyphene	61	(3.7)
Hydromorphone	60	(3.6)
Codeine	53	(3.2)
Morphine†	40	(2.4)
Meperidine	11	(0.7)
Sufentanil	1	(0.1)

* Percentages are based on 1,668 deaths. Percentages add to more than 100% because some deaths involved more than one opioid drug.
† Includes only morphine attributed to prescription drugs.

in 2.4%, and alcohol in 17.1% of the deaths. More than one drug was listed for 72.3% of decedents. The mean and median numbers of drugs per death were 2.7 and 2.0, respectively.

Reported by: *P Coolen, MN, S Best, Patient Review and Coordination Program, Washington State Health and Recovery Svcs Admin; A Lima, Center for Health Statistics, J Sabel, PhD, Injury and Violence Prevention Program, Washington State Dept of Health. L Paulozzi, MD, Div of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC.*

Editorial Note: The number of deaths attributed to poisoning, more than 90% of which involve drugs, has risen steadily in the United States for the past decade (*1*). Poisoning became second only to motor-vehicle crashes among leading causes of injury death in the United States in 2004 (*4*). By 2006, poisoning had become the leading cause of unintentional injury death in Washington, five other states,§ and the District of Columbia. Overdoses associated with prescription opioid painkillers are driving increases in poisoning death rates nationally (*1*), which parallel increases in opioid prescribing in the United States (*2*). Opioids are subject to abuse and are frequently used recreationally in combination with other drugs, including alcohol. In 2006, Washington's opioid overdose death rate was 8.2 per 100,000 population, compared with a national rate of 4.6 per 100,000 (*1*). Some of this might be attributable to Washington's high rate of self-reported nonmedical use of prescription opioid painkillers, which was the fourth highest in the United States during 2006–2007 (*5*). The findings of

§ Connecticut, Massachusetts, New Jersey, Ohio, and Rhode Island.

What is already known on this topic?

Since 1999, deaths from overdoses of prescription opioid painkillers have been increasing in the United States, but no study has determined whether the rate of such deaths is higher in the Medicaid population.

What is added by this report?

The rate of prescription opioid–related overdose death during 2004–2007 in Washington state was 30.8 in the Medicaid population and 4.0 per 100,000 in the non-Medicaid population (a relative risk of 5.7), and methadone was involved more frequently than any other prescription opioid.

What are the implications for public health practice?

Health authorities (e.g., state and local health departments, coroner and medical examiner offices, and substance abuse programs) in other states should examine trends in and risks for prescription opioid–related overdose death in their jurisdictions, especially among Medicaid clients.

this analysis indicate that deaths from prescription opioid drug overdose in Washington occurred disproportionately among males and persons aged 45–54 years. This analysis also is the first to show an increased risk among persons enrolled in Medicaid. The age-adjusted risk of such a death for a Medicaid enrollee was 5.7 times the risk for a person not enrolled in Medicaid. These findings are similar to previous research showing a higher risk for such deaths in lower-income populations (*3*) and can be used to better focus preventive interventions.

The cause of the higher death rate in Washington's Medicaid enrolled population might be related, in part, to differences in opioid prescribing in the Medicaid population. Although comparable prescribing data for Medicaid and non-Medicaid populations are not available for Washington, studies indicate that opioid prescribing rates among Medicaid enrollees are at least twofold higher than rates for persons with private insurance (*6,7*). In one of these studies, both the percentage of patients with pain being treated with opioids and the opioid dose per prescription were higher in Medicaid patients than in non-Medicaid patients (*6*). The higher death rate among Medicaid enrollees in Washington also might be related to a higher prevalence of substance abuse and other mental health problems, which has been found in other Medicaid populations (*8*). In this analysis, medical examiners and coroners reported the presence of an illegal drug (e.g., cocaine, methamphetamine, and heroin) in nearly a fifth of deaths, and psychotherapeutic drugs such as benzodiazepines and antidepressants were reported in a high proportion of deaths.

Methadone, a drug used both for treatment of heroin addiction and as a long-acting, inexpensive painkiller, has become increasingly prominent among drugs involved in overdoses, both nationally and in state studies (*1,9,10*). Methadone's use as a painkiller increased more than twelvefold in the United States and Washington during 1997–2006 (*2*), driven in part by its low cost. Washington ranked fourth among states in the per-capita consumption of methadone in 2005 and 2006 (*2*).

The findings in this report are subject to at least two limitations. First, the number of overdoses involving prescription opioids might be underestimated because 1) such drugs might not have been specified on the death certificates even though they contributed to death and 2) some deaths involving morphine and no other opioids were not included because the morphine detected might have been a metabolite of heroin. Second, some deaths labeled unintentional might have been suicides by poison or vice-versa, but the net effect of such errors likely is minimal.

Surveillance for prescription drug overdose deaths should be improved. Drugs listed on death certificates for overdoses are coded into broad categories, making identification of specific drugs difficult. Use of uncoded text in the cause-of-death fields on death certificates, as was done in this study, might be a promising strategy at the state or national level. Health authorities (e.g., state and local health departments, coroner and medical examiner offices, and substance abuse programs) in other states should examine trends in and risks for prescription opioid-related overdose death in their jurisdictions, especially among Medicaid clients.

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Unintentional Drug Poisoning in the United States

July 2010

Background

A poisoning occurs when a person's exposure to a natural or manmade substance has an undesirable effect. A drug poisoning occurs when that substance is an illegal, prescription, or over-the-counter drug. Most fatal poisonings in the United States result from drug poisoning.

Poisoning can be classified as:

- self-harm or suicide when the person wants to harm himself;
- assault or homicide when the person wants to harm another; and
- unintentional, also known as "accidental," when no harm is intended. Unintentional drug poisoning includes drug overdoses resulting from drug misuse, drug abuse, and taking too much of a drug for medical reasons.

This document summarizes the most recent information about deaths and emergency department (ED) visits resulting from drug poisoning. Information about deaths comes from death certificates for deaths in 2007. Information about emergency department visits comes from a national surveillance system, the Drug Abuse Warning Network (DAWN), operated by the Substance Abuse and Mental Health Services Administration (SAMHSA).

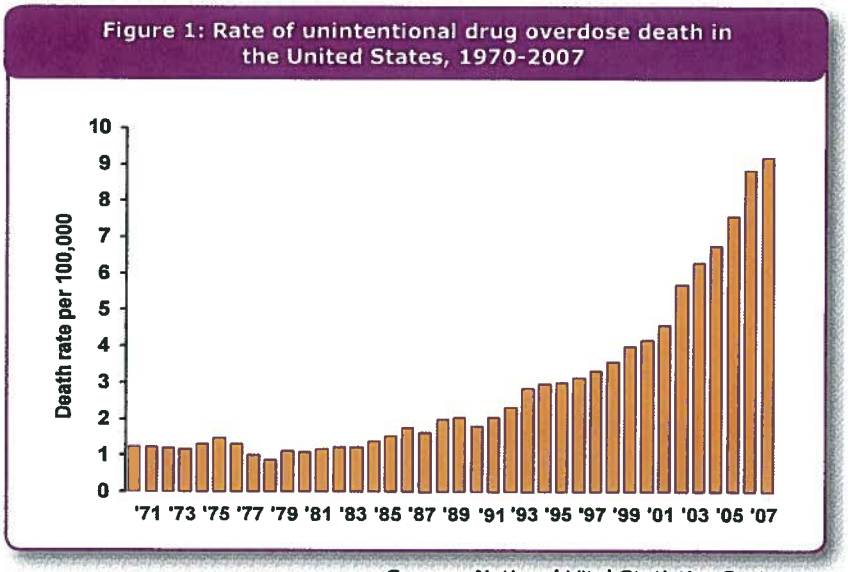
Drug overdose death rates in the United States have never been higher

- Drug overdose death rates have risen steadily in the United States since 1970. (See Figure 1)
- In 2007, 27,658 unintentional drug overdose deaths occurred in the United States.
- Drug overdose deaths were second only to motor vehicle crash deaths among leading causes of unintentional injury death in 2007 in the United States.

Rates have increased roughly five-fold since 1990.

- Age-adjusted rates of drug overdose death for whites have exceeded those among African Americans since 2003.

Figure 1: Rate of unintentional drug overdose death in the United States, 1970-2007



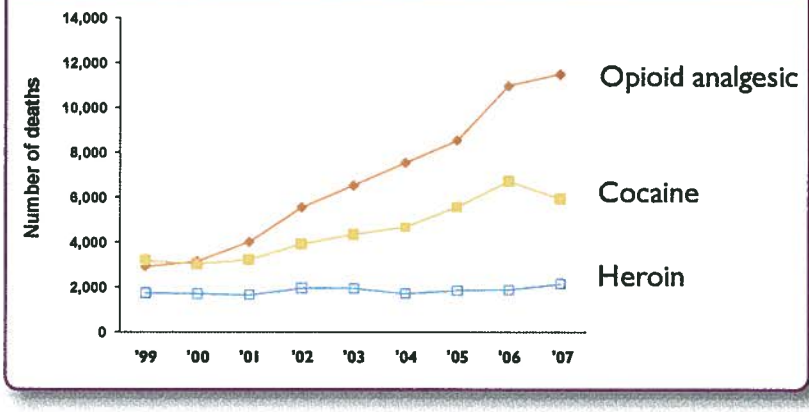
Source: National Vital Statistics System

The increase in drug overdose death rates is largely because of prescription opioid painkillers

- Among deaths attributed to drugs, the most common drug categories are cocaine, heroin, and a type of prescription drug called opioid painkillers.
- "Opioids" are synthetic versions of opium. They have the ability to reduce pain but can also suppress breathing to a fatal degree when taken in excess. Examples of opioids are oxycodone (OxyContin®), hydrocodone (Vicodin®), and methadone.
- There has been at least a 10-fold increase in the medical use of opioid painkillers during the last 20 years because of a movement toward more aggressive management of pain.
- Because opioids cause euphoria, they have been associated increasingly with misuse and abuse. Opioids are now widely available in illicit markets in the United States.

In 2007, the number of deaths involving opioid analgesics was 1.93 times the number involving cocaine and 5.38 times the number involving heroin.

Figure 2: Unintentional drug overdose deaths by major type of drug, United States, 1999-2007



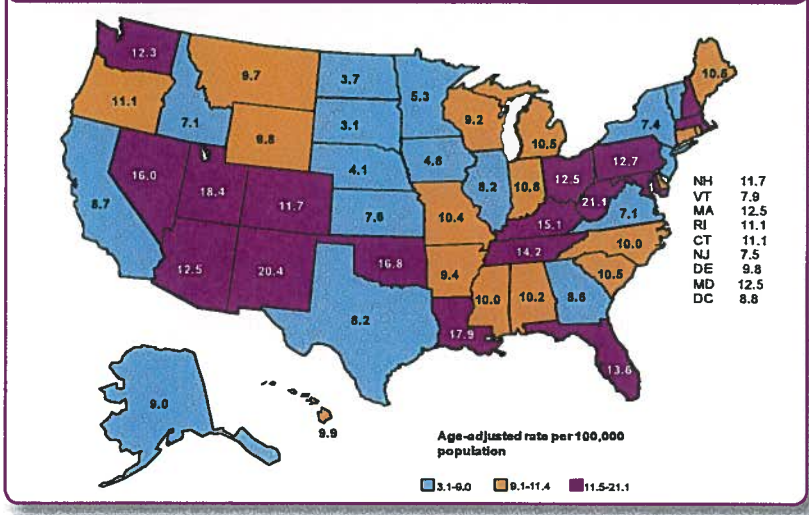
Source: National Vital Statistics System

In 2007, opioids were involved in more overdose deaths than heroin and cocaine combined. (See Figure 2)

Overall drug overdose death rates in the United States vary by state and region

- States in the Appalachian region and the Southwest have the highest death rates. (See Figure 3)
- The highest drug overdose death rate was found in West Virginia, which was nearly 7 times that of the state with the lowest drug overdose death rate, South Dakota.
- In 2007, states such as California and New York had some of the lowest overall death rates among all states because of low opioid overdose rates. In contrast, in the early 1990s these states had some of the highest overall rates, largely because of high heroin and cocaine overdose rates.

Figure 3: Drug Overdose Death Rates by State, 2007

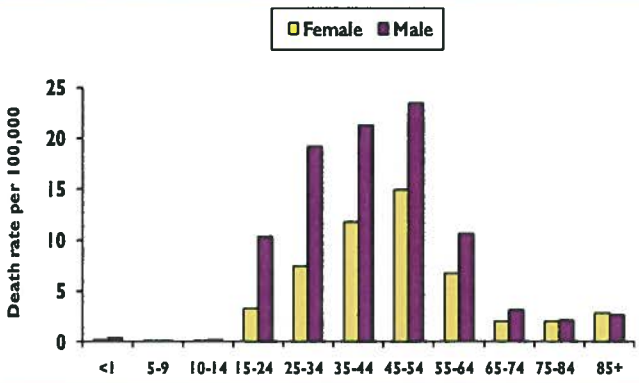


Source: National Vital Statistics System

Men and middle-aged people are more likely to die from drug overdose

- In 2007, 18,029 drug overdose deaths occurred among males and 9,626 among females. Male rates exceeded female rates in almost every age group. Men have historically had higher rates of substance abuse than women. (See Figure 4)
- Male rates have doubled and female rates have tripled since 1999.
- For both sexes, the highest rates were in the 45-54 years old age group. Rates declined dramatically after the age of 54.
- After age 64, the male and female rates become comparable, probably as a result of the reduction in rates of substance abuse with age.

Figure 4: Unintentional drug overdose death rates by sex and age group, United States, 2007



Source: National Vital Statistics System

Among emergency department visits for the misuse or abuse of drugs, legal drugs have caught up with illegal drugs

- The Drug Abuse Warning Network (DAWN) estimates ED visits caused by illicit drugs or the nonmedical use of legal drugs, which includes taking more than the prescribed amount, taking drugs prescribed for someone else, or substance abuse. Nonmedical use by this definition does not include use of drugs to harm oneself, e.g., suicide attempts, or unintentional ingestions.

ED visits for the nonmedical use of prescription and over-the-counter drugs are now comparable to ED visits for use of illicit drugs like heroin and cocaine.

Figure 5: Estimated numbers of ED visits involving legal drugs used nonmedically and illegal drugs, United States, 2008

Source: Drug Abuse Warning Network

- In 2008, DAWN estimates show that prescription or over-the-counter drugs used nonmedically were involved in 1.0 million ED visits, and illicit drugs were involved in 1.0 million visits (See Figure 5). Among the legal drugs, the most common drug categories involved were drugs acting on the central nervous system, especially opioid painkillers, and psychotherapeutic drugs, especially sedatives and antidepressants. Opioid painkillers were associated with approximately 306,000 visits and benzodiazepines (a type of sedative) with 272,000 visits.
- Among illicit drugs, cocaine was involved in 482,000 visits, and heroin was involved in 201,000 visits.
- People who abuse opioids have direct health care costs more than eight times those of nonabusers. A conservative estimate of the costs to society of prescription opioid abuse in the United States was $8.6 billion in 2001 ($9.5 billion in 2005 dollars).

Recommendations

The following recommendations are not founded in evidence-based research but are based on promising interventions and expert opinion. Additional research is needed to understand the impact of these interventions on decreasing unintentional drug poisoning and on health care costs. All of the following recommendations should be implemented in concert and collaboration with public health entities and other relevant stakeholders.

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 ≥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.

Private Insurance Providers and Pharmacy Benefit Managers (PBMs)

- Identify patients using opioids for noncancer pain who 1) receive a total of 120 or more morphine milligram equivalents of opioids per day from two or more sources; 2) show inappropriate patterns of usage such as multiple prescriptions for the same medication from different providers; or 3) also use a sedative-hypnotic. Notify the prescribing providers about such patients.
- For patients whose use of multiple providers cannot be justified on medical grounds, insurers and PBMs should only reimburse opioid prescription claims from a single designated physician and a single designated pharmacy.

State and Federal Agencies

- To the extent permitted by applicable law, state prescription drug monitoring programs should routinely send reports to providers on patients less than 65 years old if they are being treated with opioids for more than 6 weeks by two or more providers or if there are signs of inappropriate use of controlled substances. (If legal authority to do so does not exist, work toward obtaining that authority.)
- To the extent permitted by applicable law, state and federal benefits programs should consider monitoring prescription claims information for signs of inappropriate use of controlled substances by patients. For patients whose use of multiple providers cannot be justified on medical grounds, such programs should consider reimbursing opioid prescription claims from a single designated physician and a single designated pharmacy.
- State and federal agencies should work to improve the availability of substance abuse treatment services.

For More Information on Unintentional Drug Poisonings in the United States, go to:

Centers for Disease Control and Prevention *www.cdc.gov*

National Center for Injury Prevention and Control
www.cdc.gov/HomeandRecreationalSafety/Poisoning

Call: *1-800-CDC-INFO (232-4636) | TTY:1-888-232-6348*

CS 208893

Wenatchee Valley Medical Center
Chronic Pain Program
Information for New Patients

Description of the Program

1. We have established a program that looks at all of your health care needs, not just your medication needs. This may or may not include:
   A. Routine health care to help you stay healthy.
   B. Routine health care to address other health problems.
   C. Referrals for specialty care to evaluate and/or treat pain issues as well as other medical issues.
   D. Referrals for emotional help, which may include counseling at Okanogan Behavioral Health or with our mental health counselor.
   E. Other referrals such as:
      a. Physical Therapy
      b. Other alternative treatments

2. Some important things you should know about our Pain Management Program:

A. Chronic pain is a difficult and challenging problem. Often we must use several different action plans to help you. Medical studies have clearly shown that patients' improve when more than one approach is used focusing on increasing function. Dramatic improvement in pain management occurs when patients can be more active. Pain relievers are often part of your care plan but there may be situations where narcotic pain relievers may not be considered an appropriate treatment plan. This is determined on an individual basis, based upon your diagnosis as well as your health history.

B. Narcotics can be dangerous drugs. More people die from prescribed narcotics than from illegally obtained narcotics. The Washington State Medical Directors Group has noted that the likelihood of complications from narcotic use increases significantly above a certain dose threshold. We make every effort to help keep our patients safe by being aware of that threshold in our care.

Narcotics can cause physical dependence and psychological addiction. **If you take them with certain other drugs, including street drugs and alcohol or if you do not take them as prescribed, they can put you at risk for an overdose or even death.**

C. If you use illegal street drugs or drink large amounts of alcohol; you will not be considered a good candidate for narcotic pain medications.

D. We may request a urine drug screen and/or pill counts at any time.

Your health and safety is our primary concern and we take this responsibility seriously.

STEPS TO TAKE TO GET INTO THE PROGRAM

There are steps you must take to be accepted into our program. ***This will take time.*** We do not refill narcotic prescriptions before certain steps are completed. If you will run out, we urge you to contact your previous provider for refills until you can establish as a patient here.

STEP ONE:
1. Meet with our Patient Access Nurse. Discuss your reasons for transferring care. Please be open and honest about any past problems.
2. Sign record-release forms.
3. Give a Health History for your Patient Profile.
4. Do a pain assessment questionnaire.

STEP TWO:
1. Records are reviewed and meeting is set up with Dr. Justus, our Medical Director or your new provider.
2. A provider is selected for you and a tentative appointment is made for you.

STEP THREE:
1. Meet with Dr. Justus or your new provider to sign the CARE COMPLIANCE AGREEMENT.
The care compliance agreement is NOT the same as a pain contract. You will be agreeing to follow certain rules such as showing up for appointments and working with your provider to address your health care needs.

2. If you **do not come** to this appointment **and you do not call ahead** to cancel the appointment, you will not be accepted into the program. This is important because the Omak Clinic as well as the North Valley Family Medicine Clinics in Tonasket and Oroville will not see you for primary care. You **may** receive care here if you need to see a specialist.

3. We will, of course, help you reschedule this appointment if you call ahead. We understand that situations may arise where this is necessary.

STEP FOUR:
1. Receive your appointment date and time to establish care with your new provider. You will get this information at the meeting.

STEP FIVE:

1. See your new provider.
2. **If you miss this appointment and you do not call ahead to reschedule, you may also be dismissed from the clinic.**

Patient Name:_____**Hx Number:**_____

DOB:_____

This is to certify that I have received the Chronic Pain Program Handout. The program has been explained to me by:_____**. I have had an opportunity to ask questions and these have been addressed to my satisfaction.**

Signed:_____ **Date:**_____

Printed Name:_____

Witness:_____

A checklist for health CEOs seeking to improve care, cut costs

June 9, 2012 | By LocalHealthGuide | Reply

Virginia Mason President and CEO **Dr. Gary Kaplan** is one of eleven health system executives who helped draw up a checklist for health-care CEOs seeking to control costs and improve the quality of care that was published this week by the **Institute of Medicine** .

All the executives come from health systems that have established national reputations for their quality improvement initiatives, including executives from the Cleveland Clinic, Kaiser Permanente, and the Department of Veterans Affairs (see full list below).

The 10-item "**Checklist for High-value Health Care**" identifies strategies that these health-care executives have found to be "effective and essential" in their efforts to reform their health systems.

"Taken together, the Checklist provides a blueprint for improving quality and reducing cost," the contributors write.

The items are grouped under four headings:

- Foundational elements
- Infrastructure fundamentals
- Care delivery priorities.

To learn more: read the the full document "**Checklist for High-value Health Care**" available for free on the Instute of Medicine's website.

Contributors to the CEO Checklist

- Delos Cosgrove, MD, President and CEO, Cleveland Clinic
- Michael Fisher, President and CEO, Cincinnati Children's Hospital Medical Center
- Patricia Gabow, MD, CEO, Denver Health and Hospital Authority
- Gary Gottlieb, MD, MBA, President and CEO, Partners HealthCare System, Inc.
- George Halvorson, Chairman and CEO, Kaiser Permanente
- Brent James, MD, MStat, Executive Director Intermountain Institute for Care Delivery Research
- Gary Kaplan, MD, Chairman and CEO, Virginia Mason Health System
- Jonathan Perlin, MD, PhD, President, Clinical and Physician Services HCA, Inc.
- Robert Petzel, MD, Undersecretary for Health Department of Veterans Affairs
- Glenn Steele, MD, PhD, President and CEO Geisinger Health System
- John Toussaint, MD, CEO, ThedaCare Center for Healthcare Value

Tags: CEOs, Checklist, Cleveland Clinic, Doctors, Gary Kaplan, Institute of Medicine, IOM, Kaiser Permanente, Medical Errors, Patient Safety, Quality Improvement, Seattle Clinics, Seattle Doctors, Seattle Health, Seattle Hospitals, Seattle Medicine, United States Department of Veterans Affairs, Virginia Mason, VM

Category: Doctors, Health-care Policy, Healthcare Reform, News, Virginia Mason

Making Just Culture a Reality: One Organization's Approach

Perspective

by Alison H. Page, MS, MHA

We've all been there...something goes wrong, a patient is harmed, and we, as medical directors, managers, and administrators, are forced to judge the behavioral choices of another human being. Most of the time, we conduct this complex leadership function guided by little more than vague policies, personal beliefs, and intuition. Frequently, we are frustrated by the fact that many other providers have made the same mistake or behavioral choice, with no adverse outcome to the patient, and the behavior was overlooked. Quite understandably, the staff is frustrated by what appears to be inconsistent, irrational decision-making by leadership. The "just culture" concept teaches us to shift our attention from retrospective judgment of others, focused on the severity of the outcome, to real-time evaluation of behavioral choices in a rational and organized manner.

At Fairview Health Services, a large integrated delivery system in Minnesota, we identified addressing our culture as the primary opportunity to improve patient safety in 2001. We focused on two key areas of cultural concern: the leadership culture that sets the tone and judges the behavior of others, and the culture at the point of care, or team culture. In 2003, we worked with the Minnesota Alliance for Patient Safety (MAPS), a multi-stakeholder group founded by the Minnesota Hospital Association, the Minnesota Department of Health, and the Minnesota Medical Association, to establish a state-wide initiative to create a culture of justice and accountability. This effort includes hospitals, the professional boards, and the department of health.

Establishing a just culture within an organization requires action on three fronts: building awareness, implementing policies that support just culture, and building just culture principles into the practices and processes of daily work. Based on our experience over the past 6 years, let me give you examples of how you might do this.

Raising Awareness

Building awareness is the first step in any movement. To raise awareness we did two things.

First, with the assistance of David Marx, JD, president of Outcome Engineering, we conducted a survey of staff, medical leaders, managers, and administrators asking them various questions about how they thought the organization would respond to a given behavior by a clinician (e.g., bringing unauthorized equipment into the operating room [OR] for use in a surgery) if that behavior resulted in harm. We then asked the same question, except this time the behavior resulted in no harm. The survey results were clear. Members of the organization had no clear sense of how people would be judged, or how they should be judged when their behavioral choice was the wrong choice. And respondents consistently judged people more harshly if the behavior resulted in harm (Figure). The survey results were a wake-up call for the organization's leaders.

Our second step to raise awareness was education. First, a small group of 10 key clinical and operational leaders attended a day-long session with David Marx to evaluate the just culture concepts and learn how we should proceed inside our organization and as a state. Following this, 60 Minnesota health care leaders attended a 2-day summit sponsored by MAPS, which included the professional boards and the department of health, to deepen understanding of just culture and to better understand the perspective of the professional boards and public agencies. The leaders who attended enthusiastically embraced the just culture concept, finding that it provides practical and useful principles and tools anyone can use.

We then conducted a "big bang" educational session for all operational and clinical leaders across the system. Our message: "anyone who finds himself/herself in the position of judging the behavioral choices of other human beings" should attend the session. Three hundred and fifty people were educated in an 8-hour training session with David Marx. The education included an overview of the concepts, education on the use of a set of algorithms that guide people through the process of classifying behavioral choices as "error," "at-risk behavior," or "reckless behavior." Participants also practiced applying the algorithms to real-life scenarios. In hindsight, conducting this mass education was very effective. It caused the organizational perspective on justice and accountability to shift almost overnight. We did not conduct education sessions for front-line staff on just culture, but instead we have woven the expectations for staff behavior, along with the concepts of error, at-risk behavior, and reckless behavior, into orientation and unit education sessions.

The behaviors we can expect:

- **Human error**—inadvertent action; inadvertently doing other than what should have been done; slip, lapse, mistake.
- **At-risk behavior**—behavior that increases risk where risk is not recognized, or is mistakenly believed to be justified.

- **Reckless behavior**—behavioral choice to consciously disregard a substantial and unjustifiable risk.

Implementing Policies that Support Just Culture

This might better be termed, "eliminate the policies that don't allow you to incorporate just culture." Policies that require punishment for errors, for example, won't work. Sentinel event investigation policies that say, "We will only look at systems and not human behavior" won't work. Ideally, the organizational policies related to employee behavior expectations, consequences for behavior, and event investigation would incorporate the language of just culture. Job descriptions, medical staff bylaws, and codes of conduct should incorporate the principles. This will take time, so start by removing the policies that are barriers to just culture and work incrementally to build the philosophy in as you go. Our organization is still in the process of incorporating just culture principles into policies, but we have eliminated the policy barriers to using the principles. For example, if you have policies that authorize punishment (e.g., written reprimand or dismissal) after a certain number of errors, or that predicate punishment on the severity of the outcome, get rid of them.

Building Just Culture into Organizational Practices and Processes

Once the leadership group of the organization has grasped the concept and leaders buy in to the philosophy, you can begin to incorporate it into the work you do every day. I recommend not introducing just culture as a new initiative or it could become the "flavor of the month." Instead, leaders should look at the challenges they face and ask, "How would I apply just culture principles to this situation?"

If your organization's priority is reducing harm related to misidentification of patients, for example, how would you work with the staff to understand and categorize behavioral choices as "error," "at-risk," or "reckless"? How would you clarify what the organizational response will be to each type of behavior? If a person makes an *error*, he/she knew the right thing to do, intended to do the right thing, and followed the right process, but made a mistake (e.g., misreads a label); he/she should be consoled and we should figure out a system that will prevent future errors. If a person engages in *at-risk* behavior, he/she knows the right thing to do, but does otherwise because he/she does not see the risk or feels that the benefit of the chosen behavior outweighs the risk (e.g., does not wake a patient to check a name band), management must understand why people are engaging in this risky behavior. Leaders must ask hard questions like, "How prevalent is this behavior? Why are people doing this? How can we put systems in place that will encourage or force the correct behavior? How can we help people perceive the risk that exists so they will make the right behavioral choice?" Lastly, the organization and clinical leadership should identify which behaviors will be considered *reckless* and are, therefore, punishable. Reckless behavior is punishable regardless of the outcome of the behavior. Leaders must establish processes to know when someone is engaging in reckless behavior and be willing to punish those who engage in it. A given behavior may be considered "at risk" in one situation or organization and be considered "reckless" in another.

Consider this scenario. In hospital "A," a nurse, not wanting to disturb a sleeping patient, does not check a patient's name band and administers an IV antibiotic to the wrong patient, who was allergic to that drug. The patient has an anaphylactic reaction and ends up in the ICU on a respirator. How do we judge this nurse's behavioral choice not to check the name band before administering the medication? Do we punish her? Some organizations would punish the nurse (i.e., retrain, reprimand, or dismiss) because she violated the patient identification policy. A just culture would want to know:

- Was the nurse aware of the policy to check name bands?
- Was it possible to check the name band?
- Do all the nurses on the unit check name bands prior to administering medications?
- Why didn't the nurse check the name band? Did she mistakenly believe it was better not to? Why?

The error in this scenario is administering the medication to the wrong patient. We determined the nurse's behavior to be "at-risk" (and not "reckless") because the nurse violated the policy for what she believed to be a good reason—allowing the patient to sleep. It turns out that customer satisfaction scores had recently been reviewed at a staff meeting, and sleep interruption was identified as the number one concern of patients. In addition, the other nurses on the unit agreed that they have not awakened patients to check name bands many times.

Now consider another scenario. In hospital "B," a patient checks in. A name band is applied, and the patient is told that all staff will be asking patients to spell their names and give birth dates before providing care or treatment. The patient notes that all care providers and transport personnel follow the procedure. Now, let's say a nurse does exactly the same thing as the nurse in the first scenario. She enters the room, observes the patient sleeping, and decides not to wake the patient to check the name band. A just culture would classify the nurse's behavior as "reckless." The policy was known, the policy was doable, and others were following the policy.

Within Fairview, we have incorporated just culture into our performance improvement initiatives, such as hand washing and patient identification. We identify what types of errors are made, what types of at-risk

behaviors we see, and whether or not anyone is engaging in reckless behavior. As we make improvements in the process, we make sure we design it to prevent error, make risk apparent, and discourage at-risk behavior. We also clarify what behavior will be considered reckless. Currently, we are incorporating just culture principles into team training.

Just culture principles will help you change your organizational culture. In 2001, an accident occurred in our interventional MRI room when a piece of equipment flew across the room and attached to the outside of the MRI while a patient was in the tunnel. The event investigation that followed focused on system solutions and staff behavior. The department established safe processes and expectations for staff training and behavior. All staff are screened for MRI safety themselves, participate in MRI safety training, follow check-in procedures, and wear pocketless scrubs to minimize the opportunity to forget something in a pocket. Six years later, in 2007, a physician entered the room wearing scrubs with pockets, disregarding the prompt from colleagues to stop. Administration was notified. The conversation that ensued among operational and medical leaders focused on categorizing the behavior as error, at-risk, or reckless and, from that, determining whether the physician should be consoled, coached, or punished. Since Fairview has implemented clear policies and behavior expectations, and others are able to follow the policies, the behavior was found to be reckless. The physician apologized for her behavior and was warned that future behavior of this type would impact her clinical privileges. Just culture principles and tools provide a useful and necessary construct to aid organizations in dealing with difficult cultural issues, particularly to determine when the generally appropriate focus on systems needs to give way to a focus on individual accountability.

Alison H. Page, MS, MHA
Chief Safety Officer
Fairview Health Services

Figure

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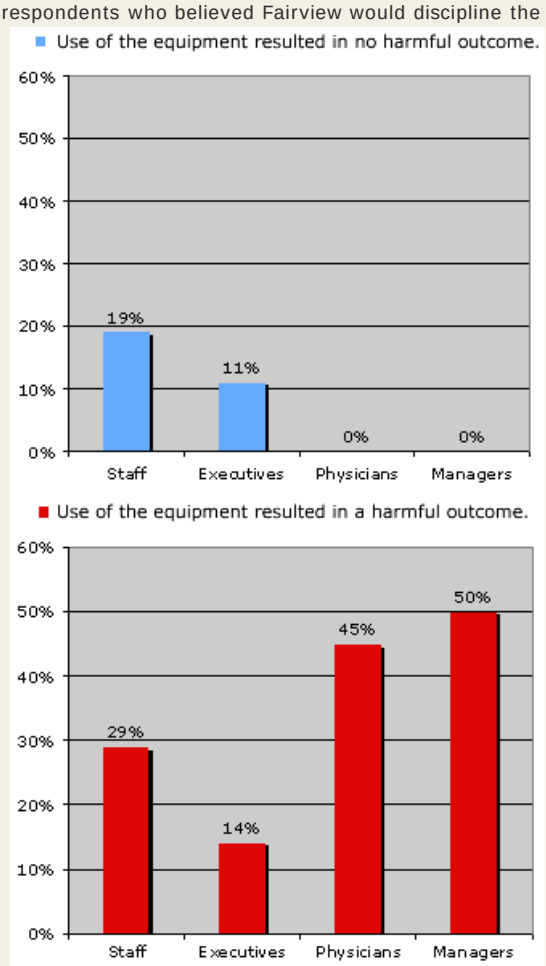
Figure. Survey question: How would our organization respond to a surgeon who uses an unauthorized piece of equipment in the operating room?

(Go to figure citation in perspective)



Position Statement

Just Culture

Effective Date: January 28, 2010

Status: New Position Statement

Originated By: Congress on Nursing Practice and Economics

Adopted By: ANA Board of Directors

Related Past Action:

1. ANA Position Statement (2007): *Safety Issues Related to Tubing and Catheter Misconnections*
2. ANA Position Statement (2006): *Assuring Patient Safety: The Employers' Role in Promoting Healthy Nursing Work Hours for Registered Nurses in All Roles and Settings*
3. ANA Position Statement (2006): *Assuring Patient Safety: Registered Nurses' Responsibility in All Roles and Settings to Guard Against Working When Fatigued*
4. 2000 ANA House of Delegates Report Adopted: *Building Safe Health Care Systems for Informed Patients*

Purpose: The purpose of this position paper is to interpret the *Just Culture* concept and its application for nursing and health care in a variety of settings.

Statement of ANA Position: The American Nurses Association (ANA) supports the *Just Culture* concept and its use in health care to improve patient safety. The ANA supports the collaboration of state boards of nursing, professional nursing associations, hospital associations, patient safety centers and individual health care organizations in developing regional and state-wide *Just Culture* initiatives.

History/Previous Position Statements: This is the first ANA position on the *Just Culture* concept. In regard to patient safety, ANA has published the positions *Safety Issues Related to Tubing and Catheter Misconnections (2007), Assuring Patient Safety: The Employers' Role In Promoting Healthy Nursing Work Hours for Registered Nurses in All Roles and Settings (2006)*, and *Assuring Patient Safety: Registered Nurses' Responsibility in All Roles and Settings to Guard Against Working When Fatigued (2006).* ANA through its National Center for Nursing Quality has long been working with patient safety initiatives, including the National Database for Nursing Quality Indicators, Handle With Care Campaign, Safe Staffing Saves Lives Campaign, and its work with the National Quality Forum, the Joint Commission, and the National Priorities Partnership. The 2000 ANA House of Delegates adopted the report "Building Safe Health Care Systems for Informed Patients".

Supportive Material: In testimony before congress, Lucian Leape, MD, member of the Quality of Health Care in America Committee at the Institute of Medicine and adjunct professor of the Harvard School of Public Health, noted that "Approaches that focus on punishing individuals instead of changing systems provide strong incentives for people to report only those errors they cannot hide. Thus, a punitive approach shuts off the information that is needed to identify faulty systems and create safer ones. In a punitive system, no one learns from their mistakes" (Leape, 2000).

As an alternative to a punitive system, application of the *Just Culture* model, which has been widely used in the aviation industry, seeks to create an environment that encourages individuals to report mistakes so that the precursors to errors can be better understood in order to fix the system issues. The term "*Just Culture*" was first used in a 2001 report by David Marx (Marx, 2001), a report which popularized the term in the patient safety lexicon (Agency for Healthcare Research and Quality, n.d.).

Traditionally, healthcare's culture has held individuals accountable for all errors or mishaps that befall patients under their care. By contrast, a *Just Culture* recognizes that individual practitioners should not be held accountable for system failings over which

they have no control. A *Just Culture* also recognizes many individual or "active" errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that touts "no blame" as its governing principle, a *Just Culture* does not tolerate conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated).

Development of the *Just Culture* Concept

In 1997, John Reason wrote that a *Just Culture* creates an atmosphere of trust, encouraging and rewarding people for providing essential safety-related information. A *Just Culture* is also explicit about what constitutes acceptable and unacceptable behavior. Therefore a *Just Culture* is the middle component between patient safety and a safety culture (Reason, 1997). Marx argues that discipline needs to be tied to the behavior of individuals and the potential risks their behavior presents more than the actual outcome of their actions (Marx, 2001).

The *Just Culture* model addresses two questions: 1) What is the role of punitive sanction in the safety of our health care system and 2) Does the threat and/or application of punitive sanction as a remedy for human error help or hurt our system safety efforts? The model acknowledges that humans are destined to make mistakes and because of this no system can be designed to produce perfect results. Given that premise, human error and adverse events should be considered outcomes to be measured and monitored with the goal being error reduction (rather than error concealment) and improved system design (Marx, 2001).

In addition, the model describes three classes of human behavior that create predictability in error occurrence. The first is simple human error - inadvertently doing other than what should have been done. The second, at-risk behavior occurs when a behavioral choice is made that increases risk where risk is not recognized or is mistakenly believed to be justified. Finally, reckless behavior is action taken with

conscious disregard for a substantial and unjustifiable risk.

Under the *Just Culture* model, creating an open, fair and *Just Culture* relies on developing managerial competencies that appropriately hold individuals accountable for their behaviors, and investigates the behavior that led to the error. With regard to human error, managers console the individual, then consider changes in processes, procedures, training and design. At-risk behavior suggests the need for coaching and managing through removing incentives for at-risk behavior; creating incentives for healthy behaviors; and increasing situational awareness. With reckless behavior, it is necessary to manage through remedial action and/or punitive action (Marx, 2001).

Ultimately, the *Just Culture* model is about creating an open, fair and *Just Culture*, creating a learning culture, designing safe systems, and managing behavioral choices. The model sees events not as things to be fixed, but as opportunities to improve understanding of both system risk and behavioral risk. It is also about changing staff expectations and behaviors to ones such as looking for the risks in the environment; reporting errors and hazards; helping to design safe systems; and making safe choices, including following procedure; making choices that align with organizational values; and never signing for something that was not done.

To mitigate errors, Marx created the *Just Culture* Algorithm, a methodology for considering what a manager should do when a breach occurs and suggests actions to address the breach from both the system and employee perspective (Marx, 2008).

Application to Nursing

The American Nurses Credentialing Center (ANCC) has developed the *Five Model Components* for the Magnet Recognition Program® that reflect the focus of the healthcare organization on achieving superior performance as evidenced by outcomes. The components stress that outcomes of an infrastructure developed for excellence are essential to a culture of excellence and innovation, of which safety is a prime component. The components include Transformational Leadership; Structural

Empowerment; Exemplary Professional Practice; New Knowledge, Innovations and Improvements; and Empirical Outcomes (ANCC, 2008). Although not referred to as such, *Just Culture* is congruent with this model. Transformational Leadership conveys a strong sense of advocacy and support on behalf of staff and patients by all nursing leaders. Professional Engagement, one of the Sources of Evidence for this component, promotes structure and processes that enable nurses to actively participate in organizational decision making groups. This would allow staff to be integral in promoting a *Just Culture* environment. Exemplary Professional Practice promotes nurse control over staffing and scheduling processes and encourages that the nursing staff work in collaboration with their interdisciplinary partners to achieve high quality patient outcomes. The New Knowledge, Innovations and Improvements component establishes and implements effective, efficient care, which would include a culture of safety. A Magnet ® organization continually assesses and monitors the empirical measurements relative to nursing leadership and clinical practice.

The *Just Culture* concept correlates with nurses' critical thinking skills and the nursing process in determining the root cause of an error. Since nursing relies heavily on assessing a situation, diagnosing a problem, and creating a plan to improve or avoid that problem, the *Just Culture* concept is a natural fit for any environment where nursing care is delivered.

For staff nurses and students, the concept gives the opportunity to feel more at ease reporting problems, and a sense of accountability for system improvement. For nurse administrators and educators, the *Just Culture* concept represents an opportunity to improve care delivery systems for patients/individuals, and to improve the environment for those that work in that system, including nurses but extending to all others that work within it.

Intimidation and disruptive behaviors can foster medical errors, contribute to poor patient satisfaction and to preventable adverse outcomes, increase the cost of care, and cause qualified clinicians, administrators and managers to seek new positions in more

professional environments. Safety and quality of patient care is dependent on teamwork, communication and a collaborative work environment. To ensure quality and promote a culture of safety, healthcare organizations must address the problem of behaviors that threaten the performance of the health care team. (Joint Commission, 2008).

All healthcare organizations should implement a zero tolerance policy related to disruptive behavior, including a professional code of conduct and educational and behavioral interventions to assist nurses in addressing disruptive behavior (Center for American Nurses, 2008).

The *Just Culture* concept establishes an organization-wide mindset that positively impacts the work environment and work outcomes in several ways. The concept promotes a process where mistakes or errors do not result in automatic punishment, but rather a process to uncover the source of the error. Errors that are not deliberate or malicious result in coaching, counseling, and education around the error, ultimately decreasing likelihood of a repeated error. Increased error reporting can lead to revisions in care delivery systems, creating safer environments for patients and individuals to receive services, and giving the nurses and other workers a sense of ownership in the process. The work environment improves as nurses and workers deliver services in safer, better functioning systems, and that the culture of the workplace is one that encourages quality and safety over immediate punishment and blame.

Recommendations:

1. That the ANA officially endorse the *Just Culture* concept as a strategy to reduce errors and promote patient safety in health care.
2. That the ANA promote and disseminate information about the *Just Culture* concept in ANA publications, through constituent member associations, and ANA affiliated organizations.

3. That the ANA promote the collaboration of state government, boards of nursing, all healthcare professional associations, and hospital and long term care associations in the development and implementation of *Just Culture* initiatives in each state.
4. That the ANA encourage continued research into the effectiveness of the *Just Culture* concept in improving patient safety and employee performance outcomes.
5. That nurse administrators in any level of oversight act on their dual role as representatives of nursing and stewards of the organization to promote safe systems in the spirit of *Just Culture* to promote safe patient outcomes and protect employees from failure.
6. That direct-care registered nurses advocate for the use of the *Just Culture* concept in their practice settings.
7. That educators incorporate *Just Culture* concepts into nursing curricula at every level, and adhere to the *Just Culture* concepts in the academic setting.
8. That ANA collaborate with other health care professionals to develop *Just Culture* joint statements.
9. That the ANA encourage all healthcare organizations to implement a zero tolerance policy related to disruptive behavior, including a professional code of conduct and educational and behavioral interventions to assist nurses in addressing disruptive behavior

Summary: For many years, the *Just Culture* concept has proved effective in error reduction and improvement in safety in aviation and other industries where errors have dire and sometimes catastrophic repercussions. The *Just Culture* concept is an ideal fit for health care systems, where errors have just as serious consequences. By promoting system improvements over individual punishment, a *Just Culture* in healthcare does much to improve patient safety, reduce errors, and give nurses and other health care workers a major stake in the improvement process.

Examples of *Just Culture* Initiatives in Health Care

Federal and state initiatives

The following are examples of efforts to incorporate and promote the *Just Culture* concepts into healthcare at the federal and state levels.

Veterans Affairs

The National Center for Patient Safety (NCPS) exists to improve the safe delivery of healthcare to America's veterans. The Department of Veterans Affairs National Center for Patient Safety was established to lead Veteran's Affairs (VA) patient safety efforts and to develop and nurture a culture of safety throughout the Veterans Health Administration. Its multi-disciplinary team is located in Washington, DC, Ann Arbor, MI, and White River Junction, VT. It offers expertise on an array of patient safety and related health care issues. Patient safety managers in all 154 VA hospitals actively participate in the program, as well as do patient safety officers in all 23 network headquarters. Internally, the NCPS provides employees with agency guidelines, directives, education, training, tools, products, initiatives, studies, publications, dialogue and conferences.

Minnesota

The Minnesota Alliance for Patient Safety (MAPS) provides a comprehensive active partnership among the Minnesota Hospital Association, the Minnesota Medical Association, the Minnesota Department of Health and more than 50 public-private health care organizations working together to improve patient safety. MAPS is governed by an executive committee, a steering committee, and subcommittees/task forces operating under a set of governing principles. MAPS published a statement of guidance and toolkit for health care organizations under the banner of *Just Culture*. It has also developed a statewide informed consent form and policy envisioning this form as Minnesota's universal documentation of informed consent, and that health care organizations statewide will use the informed consent form with no variation. MAPS

produced a My Medicine List wallet card, published in six languages, to enable consumers/individuals to carry clear notes on the medications they take (Minnesota Alliance for Patient Safety, n.d.).

North Carolina

The North Carolina Center for Hospital Quality and Patient Safety facilitates a collaborative of several state hospitals implementing the *Just Culture* in their facilities. The North Carolina Board of Nursing supports the "*Just Culture*" collaborative, and has a pilot project to partner with participating hospitals to promote consultation and discussion of events in a positive manner. The pilot will serve to assist employers in identifying events that can be addressed in the practice setting versus those that would benefit from board consultation. The purpose of the pilot project is to provide a mechanism for employers of nurses and the regulatory board to come together to promote a culture that promotes learning from practice errors while properly assigning accountability for behaviors, consistently evaluating events, and complying with mandatory reporting requirements (George, Chastain, & Burhans, 2008).

Missouri

A grant from the National Council of State Nursing Boards brought together Missouri regulators and health care providers to improve patient safety in September, 2007. The grant funds the *Just Culture* Collaborative, an effort led by the Missouri Center for Patient Safety (MOCPS) to establish an understanding of why medical errors happen and establish a common understanding of aspects of culture to improve methods for preventing them. Statewide, the following health care leaders have signed statements of support for the project: Healthcare Services Group, Missouri Hospital Association, Missouri Nurses Association, Missouri Organization of Nurse Leaders, Missouri State Board of Healing Arts, Missouri State Board of Nursing, Missouri State Medical Association, Missouri Association for Healthcare Quality, Missouri Department of Health & Senior Services and 33 hospitals, agencies, and health care systems in the state as participating organizations (MOCPS, n.d.).

California

In a state where strict laws mandate medical error reporting, the California Patient Safety Action Coalition (CAPSAC) is attempting to ensure errors are dealt with using the *Just Culture* concepts. CAPSAC conducts trainings and promotions striving to influence healthcare leaders to incorporate a concept called "Fair and *Just Culture*" as part of the environment of patient safety, and to create a system where prevention and learning are stressed, regardless of the severity of the incident (CAPSAC, 2008). At the local level, the Los Angeles County Department of Health Services, which serves more than 10 million people and is the second largest health department in the U.S., adopted and abides by the *Just Culture*, and was one of the earliest health care entities in California to do so (CAPSAC, 2008).

Professional Associations

The following are examples of attempts by professional associations to promote and incorporate the *Just Culture* concepts.

American Organization of Nurse Executives

The American Organization of Nurse Executives (AONE) states in the document *Guiding Principles: The Role of the Nurse Executive in Patient Safety* that "the role of the nurse executive in patient safety is to help lead best practices and establish the right culture across multiple disciplines within the organization" (AONE, 2006a). AONE goes on to state that one of the principles for the nurse executive is to lead cultural change (AONE, 2006b). A major part of this role is to transform the culture from one of a silent, hierarchical structure of blame to an open team-oriented culture to improve patient safety. Reason argues that an informed culture requires a reporting culture, *Just Culture*, flexible culture, and learning culture. Together these subcultures form a blameless culture that encourages and rewards reporting (Reason, 1997).

Another role of the nurse executive is to develop leadership competencies which include culture of safety competencies. The competencies most related to *Just Culture*

are: “Timely, fair, appropriate actions that are carried out equitably when blameworthy behaviors have occurred”; and “Assign accountability, determine goals, avoid blame, thank those that share concerns and perceived patient safety risks” (AONE, 2007).

Association of periOperative Registered Nurses

The Association of periOperative Registered Nurses (AORN) issued a position statement which stated that “all health care organizations must strive to create a culture of safety. Such a culture will provide an atmosphere where the perioperative team members can openly discuss errors, process improvements, or systems issues without fear of reprisals.” (AORN, 2006). Further, AORN recommends that health care organizations adopt a disciplinary system theory approach in promoting a *Just Culture* that freely reports errors. These disciplinary policies must balance the benefits of a learning culture with the need to retain personal accountability and discipline (AORN, 2007).

Illinois Nurses Association

The Illinois Nurses Association (INA) has recommended that “professional nursing organizations and the State Board of Nursing investigate the adoption of the *Just Culture* Algorithm” in a recent position paper on patient safety (INA, 2008).

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Fair and Just Culture, Team Behavior, and Leadership Engagement: The Tools to Achieve High Reliability

Allan S. Frankel, Michael W. Leonard, and Charles R. Denham

Background. Disparate health care provider attitudes about autonomy, teamwork, and administrative operations have added to the complexity of health care delivery and are a central factor in medicine's unacceptably high rate of errors. Other industries have improved their reliability by applying innovative concepts to interpersonal relationships and administrative hierarchical structures (Chandler 1962). In the last 10 years the science of patient safety has become more sophisticated, with practical concepts identified and tested to improve the safety and reliability of care.

Objective. Three initiatives stand out as worthy regarding interpersonal relationships and the application of provider concerns to shape operational change: The development and implementation of Fair and Just Culture principles, the broad use of Teamwork Training and Communication, and tools like WalkRounds that promote the alignment of leadership and frontline provider perspectives through effective use of adverse event data and provider comments.

Methods. Fair and Just Culture, Teamwork Training, and WalkRounds are described, and implementation examples provided. The argument is made that they must be systematically and consistently implemented in an integrated fashion.

Conclusions. There are excellent examples of institutions applying Just Culture principles, Teamwork Training, and Leadership WalkRounds—but to date, they have not been comprehensively instituted in health care organizations in a cohesive and interdependent manner. To achieve reliability, organizations need to begin thinking about the relationship between these efforts and linking them conceptually.

Key Words. Safety, teamwork, leadership, walkrounds, reliability, culture

In health care we excel in defining projects and tackling them with zeal, yet the end result, particularly in the safety-based ones, is that most do not achieve the desired outcomes. Instead, projects suffer from inadequate design, and we harvest, at best, modest results. Five years after the IOM report "To Err Is Human" there is general consensus that we have not accomplished our goal to

appreciably decrease harm, and have little solid evidence that the delivery of health care is safer and more reliable (Kohn, Corrigan, and Donaldson 2000; Leape and Berwick 2005). Other industries, those labeled "highly reliable," have a more systematic approach to achieve greater success.

Highly reliable industries foster "mindfulness" in their workers. Mindfulness is defined by Roberts, Weick, and Sutcliffe as being comprised of five components: A constant concern about the possibility of failure even in the most successful endeavors, deference to expertise regardless of rank or status, an ability to adapt when the unexpected occurs (commitment to resilience), an ability to both concentrate on a specific task while having a sense of the bigger picture (sensitivity to operations), and an ability to alter and flatten hierarchy as best fits the situation (Weick and Sutcliffe 2001). These common characteristics together appear to generate reliably dependable processes with minimal and manageable errors. Health care aspires to high reliability but has not, to date, clearly framed the steps necessary to achieve such. Our historical approach mimics early steps in other industries as evidenced by a preoccupation with fancy technology and outcome-based initiatives, but without the systematic effort to build the mindfulness necessary to make all other initiatives successful. As the science of patient safety deepens, health care's path to mindfulness and high reliability is becoming clearer. This article's goal is to fully relate three initiatives that are underway in many hospitals and health care systems, and to argue that the three together comprise a cornerstone necessary for any comprehensive patient safety plan. These three initiatives are critical and must be pursued with and integrated into all other operations. They are (1) the development of a Fair and Just Culture (Marx 2001), (2) leadership intelligently engaged in WalkRounds safety by using frontline provider insights to directly influence operational decisions (Frankel et al. 2003), and (3) systematic and reinforced training in teamwork and effective communication (Helmreich and Musson 2000; Gaba 2001; Cooper and Gaba 2002; Leonard, Graham, and Bonacum 2004; Baker et al. 2005). The success of these pursuits is interdependent, and hospitals interested in transforming care must spend equal effort on them. That effort must be substantial and equal to what is currently spent on information technology and outcome-based initiatives (see Figure 1), such as IHI's 100,000 lives campaign (Davis 2005),

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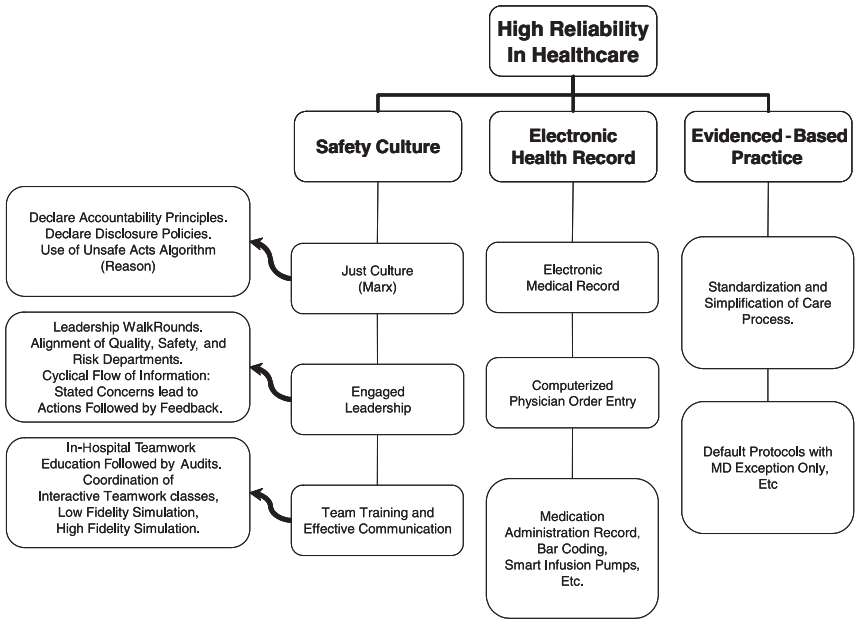
Figure 1: Determinants of high reliability in health care



NQF's Patient Safety Practices (Kizer 2001), and the Leapfrog initiatives (Milstein 2002). If pursued in this manner, the likelihood is that outcome-based initiatives will reach their goals more frequently and faster, failure to do so is likely to ensure that safe and effective care remains an elusive goal. The tools work synergistically, are reasonably simple in concept but less easily implemented, and are difficult to measure. Ultimately they are essential for all other efforts. This article relates the components of Just Culture, Engaged Leadership, and Teamwork and Communication and suggests a framework for action in each, including specific tools.

Fair and Just Culture: Appropriate Accountability

Define Fair and Just Culture

A Fair and Just Culture is one that learns and improves by openly identifying and examining its own weaknesses. Organizations with a Just Culture are as willing to expose areas of weakness as they are to display areas of excellence. Of critical importance is that caregivers feel that they are supported and

safe when voicing concerns (Marx 2001). Individuals know, and are able to articulate, that they may speak safely on issues regarding their own actions or those in the environment around them. They feel safe and emotionally comfortable while busily occupied in a work environment, able and expected to perform at peak capacity, but able at any moment to admit weakness, concern, or inability, and able to seek assistance when concerned that the quality and safety of the care being delivered is threatened. These workers are comfortable monitoring others working with them, detecting excessive workload and redistributing the work when appropriate to maintain safety and reliability.

Each individual feels as accountable for maintaining this environment as they do for delivering outstanding care. They know that they are accountable for their actions, but will not be blamed for system faults in their work environment beyond their control. They are accountable for developing and maintaining an environment that feels psychologically safe. They will not be penalized for underreporting when it feels unsafe to voice concerns.

This is not utopian; it boils down to the comment, "I feel respected by everyone in each work interaction I have." This state is achievable when outstanding leadership ensures that every employee clearly understands his own accountability and models such.

Defining Accountability

Accountability—being held to account—is based on a relationship between two or more parties in which the product of one party—individual or group—is evaluated by another party. This process can be contractually formalized or molded over time by social pressures and historical norms.

The components of accountability include the individual's understanding that they are to perform an action, a clear expectation what that action is, and the means by which they will be evaluated. Consider a surgeon performing an operation. She is accountable to other members of the "team," to the hospital as a whole, to state licensing and accrediting bodies, to the patient. She may have to account for the number of surgeries performed, or perhaps only account for those surgeries that are problematic, or only those that go awry so badly that a patient is hurt. What becomes immediately apparent in this simple description of an operation is that accountability in health care encompasses multiple expectations about actions and the reporting of them; each group's expectations differ based on social mores, regulation, law, and historical precedent. The tenets of a Fair and Just Culture should help organizations develop a framework for consistent accountability, and begin to repair

the current environment, where accountability is poorly defined and individuals are unclear what the rules are or whether the rules are constantly changing.

Today, adding up the surgeon's various accountabilities, she is accountable for increased risk, regardless whether knowingly or not; for not following rules, regardless whether to increase or decrease risk; and for outcomes based on the outcome severity, not the causative activity. In a Fair and Just Culture, the surgeon will be held accountable for knowingly unnecessarily increasing risk. The severity of the outcome and the breaking of rules will be subject to that principle. To be absolutely clear, health care organizations, and occasionally individual providers, are ethically responsible, through insurance mechanisms and otherwise, for aiding and possibly compensating a harmed patient. However, from the perspective of systems improvement, learning and positive change are more likely to occur when compensation is uncoupled from the evaluation of an adverse event. A Fair and Just Culture can be cultivated in health care organizations regardless whether this aspect of adverse events is fully reconciled; in fact a Fair and Just environment is likely a viable mechanism for diminishing the sting of the current malpractice tort process. Open discussion and transparency are characteristics that lead to mediation and resolution, not litigation.

Industries Outside of Health Care

The environment described, while rare in health care, is embedded and evident in other industries we perceive as reliable and safe. In aviation, for example, insights about human behavior 45 years ago led to the science of human factors, which helped shape the industry through the adoption of standardization and simplification rules to produce greater reliability and safety. The importance of acknowledging employee concerns and hazards is evident. For over a quarter century an error reporting system paid for by the federal government through the Federal Aviation Administration and managed by NASA has been extensively used (McGreevy and Ames Research Center 2001). It has evolved to open reporting systems administered within specific airlines. Pilots have been trained for the past 30 years to understand and admit their fallibility, and the industry they work in promotes a discussion, on a regular basis, of individual failing. Pilots are regularly evaluated for both their technical skill and their ability to promote effective teamwork. The application of human factors is uniformly manifest (GABA 2001). The result is an extraordinary safety record.

Relationship to Teamwork and Leadership Involvement

In contrast, as surgeons and anesthesiologists walk into hospital operating theatres, they do so with the underlying expectation, based on training and habit, that everyone in the room is "expertly" trained and will manage their specific job without error. No real briefing of the team consistently occurs before each procedure between surgeon, anesthesiologist, nurse, and technician (albeit per JCAHO requirements they may now stop to insure the correct side of the procedure—an act that is a fraction of the full briefing that should occur). The operating room team's optimal functionality depends on the open discussion of teamwork and team expectation, and that is greatly dependent on how the hospital culture promotes such discussions. It is quite possible to envision strategically, and then produce structurally, an environment where each individual's personal concerns can be voiced about that particular surgical case, and to voice concerns when they arise, in real time, to the best advantage of the patient. How our hospitals strategically approach accountability, followed by the structures put into place to make the strategy manifest, will greatly affect whether the care providers will speak up in that operating room. This will in great part determine the speed and efficacy in surfacing a problem, which affects the reliability of operating room care. The opportunities for improved care are endless, through improved communication and other systematic improvements directed by the knowledge gained from voiced concerns. What would this look like in real life? A perinatal unit provides a good example.

Clinical Example: Brigham and Women's Hospital (BWH) Perinatal Unit

BWH in Boston delivers about 8,600 babies each year, and a significant percentage of those patients are delivered by private practice obstetricians, individuals with excellent reputations. A pregnant woman chooses an obstetrician to care for her (presuming she has the insurance to do so), and over the course of the pregnancy develops a bond with that physician. The obstetrician is duty bound—and accountable—to deliver the best care possible to the couple, and shepherds the pregnant woman over 9 months with the one goal of a healthy child and mother. The obstetrician may be part of a group, but if the patient is asked, she is likely to identify whom she thinks of as "her" obstetrician.

When the expectant mother enters the hospital, she expects expert decisions to be made about her labor by her skilled obstetrician, and because many of the obstetricians at the BWH deliver hundreds of babies each year in

an environment where excellence is the norm, she is quite likely to achieve her desired outcome. But obstetricians are human and fallible. What happens when obstetricians mis-step, when they become fixated on a particular diagnosis they have made and/or ignore new information that is clinically relevant? When they become fatigued, preoccupied, or are slightly less than expert in a given situation? The unique bond between physician and patient actually undermines the ability of other physicians or providers to even know that a poor decision has been made and to intervene. In the current environment on most obstetrical units today, only some percentage of the nurses would feel comfortable speaking up with their concerns if they perceived a problem with the patient's care.

The BWH has instituted twice daily "board" rounds where each patient is discussed jointly with the group of physicians and nurses covering the obstetric service at that point in time. There are always a fair number of providers present, with physicians representing both the teaching service and private staff. Through the board rounds, these clinicians have an opportunity to hear from their equals about the care being delivered—in real time. While it is quite likely the majority of their thinking will be precisely on target, there is now an opportunity for input and reconsideration of the care plan from additional experts. This added perspective is perceived as valuable, not meddling, and is now accepted as the norm. Teamwork, team coordination, and collaboration have been artfully developed by Dr. David Acker, BWH's Chief of Obstetrics and Margaret Hickey, R.N., Nurse Manager for Labor and Delivery, through these twice daily board rounds. Nurses can speak their minds without fear of repercussions and actively advocate for the patients. So can residents-in-training and the more experienced senior staff. The rounds are not just an opportunity for teaching; they are, following the example of their two designers, manifest teamwork in action, based on the concepts of transparency engendered by a Fair and Just Culture; secondarily, and of equal import, they promote cross-professional and cross specialty teaching.

How Do We Get There?

Develop a Just Culture Strategic Vision Document

Ultimately, a Just Culture is about fair, enlightened, and reasonable assessment of behavior and produces a work environment that supports high reliability. Health care organizations are now writing and promoting Just Culture documents. Partners HealthCare and the Dana Farber Cancer

Institute have similar Commitment to Patient Safety (Frankel, Gandhi, and Bates 2003) statements, developed by the organizations' Patient Safety Leaders, signed by the Boards of Trustees of each component organization. While a Just Culture is not derived from the documents alone, a critical step is the clear articulation of the principles to be followed. The commitments state, in essence that:

Figure 2:

FIRST AND FOREMOST WE STRIVE TO DELIVER EVER SAFER AND MORE EFFECTIVE CARE.

WE SUPPORT THE EFFORTS OF EVERY MEMBER OF THE HEALTHCARE TEAM TO DELIVER THE BEST CARE POSSIBLE.

- We view accountability for patient harm or potential harm in the context of individual and system influences.
- We commit to supporting simplification, standardization, effective teamwork and open communication in order to foster an environment to minimize error.
- We believe that individuals are accountable for their own performance but should not carry the burden for system flaws.

WE PROMOTE OPEN DISCUSSION WITHIN OUR ORGANIZATIONS TO LEARN ABOUT ADVERSE EVENTS AND POTENTIAL CAUSES OF PATIENT HARM.

- We commit to developing and maintaining easily accessible and constructive ways for healthcare workers and patients to discuss adverse events and concerns about the safety of care delivery.
- We encourage sharing what we learn within the Partners organizations because this information helps lead us to actions that improve the healthcare environment.

WE PROMOTE INTERDISCIPLINARY DISCUSSION AND THE ANALYSIS OF ADVERSE EVENTS AND POTENTIAL PATIENT HARM.

- We commit to eliciting different points-of-view to identify sources of patient harm and to use the information to improve safe delivery of care.
- We believe that patient input is indispensable to the delivery of safe care and we commit to promoting patient participation on our care delivery teams.
- We commit to analyzing episodes of patient harm or potential harm in an unbiased fashion to determine the contribution of system and individual factors.
- We commit to fostering a team approach to the analysis of adverse events and potential patient harm and the actions taken to address them.

WE WILL ACT TO IMPROVE SAFETY BY IMPLEMENTING CHANGES BASED ON OUR ANALYSIS OF ADVERSE EVENTS AND POTENTIAL PATIENT HARM.

- We commit to identifying actions designed to address the causes of adverse events.
- We commit to assigning responsibility for implementing actions to specific individuals or groups.

WE WILL INFORM PATIENTS AND FAMILY MEMBERS, HEALTHCARE PROVIDERS, LEADERSHIP AND TRUSTEES ABOUT ACTIONS THAT HAVE BEEN TAKEN TO IMPROVE PATIENT SAFETY.

- We commit to fostering an environment that is concerned with safety through continuous education, reminders and leadership.
- We commit to ensuring that our leaders and all healthcare workers are cognizant of the complexities of delivering safe patient care and support the efforts to address those complexities.

WE WILL MEASURE OUR SUCCESS IN PROMOTING AN ENVIRONMENT OF PATIENT SAFETY.

What are the components of an organization that will make these principles come alive?

Use the Unsafe Acts Algorithm

A mechanism to assess individual versus system accountability has been developed by James Reason in his "Unsafe Acts" algorithm (Reason 1997), and is a practical method of ensuring a just assessments of individual acts. (The full algorithm may be viewed on the National Health Systems NPSA website.) Kaiser Permanente has adapted this algorithm into practical use for hospital managers by streamlining the process to four simple questions:

Did the employee intend to cause harm?

Did the employee come to work drunk or equally impaired?

Did the employee knowingly and unreasonably increase risk?

Would another similarly trained and skilled employee in the same situation act in a similar manner (Reason's substitution test)?

If the first three answers are "No" and the last "Yes" the origin of the unsafe act lies in the organization, not the individual. This algorithm is currently actively used in three hospitals in Boston (North Shore Medical Center, Dana Farber Cancer Institute, and Brigham and Women's Hospital), has been adopted by many other U.S. hospitals, and is available in the United Kingdom nationally through the National Patient Safety Agency website.

Open Commitments to "Good Citizenship"

Another structural component being used by hospitals to support the development of Just Culture is open commitment to good citizenship. Employees and all care providers should understand that they have a responsibility to support transparency and open communication. OSF Saint Francis Medical Center in Peoria, Illinois has a limited number of "red rules," which if broken will result in censure and potentially dismissal. One "red rule" is not participating in briefings before invasive procedures. Strategy, structure and design for transformation to reliable care are elegantly evident in this practice (Whittington 2006).

Educate in Safety Concepts

The basic concepts underlying patient safety and reliability are human factors, system complexity, high reliability, and effective communication and teamwork. Each has teachable core components, which should be an integral part of physician credentialing, nursing competencies and new employee orientation. Education efforts in these three areas should be integrated to produce consistent thematic content.

ENGAGED LEADERSHIP

Coordinating Organizational Departments

As noted in the Just Culture section, every individual involved in the organization—patient, employee, physician, unit secretary—should feel safe to voice their concerns, know how to do so, and be able to do so easily. With leadership oversight, the departments of quality, safety, risk management and

patient advocacy should jointly receive and evaluate such concerns and comments. Each of these departments has particular expertise and areas of unique responsibility. In the evaluation process emphasizing these distinctions can undermine the potential organizational benefit. Their common interests with reported information are essentially the same—what are the contributing factors leading to a voiced concern, adverse event or comment, and how can the organization learn and improve itself? Engaged leaders manage these relationships and deftly guide the process of identifying addressing factors that contribute to risk and suboptimal care.

Use Data Wisely: VA Administration Patient Safety Center

A useful example of how the lessons from contributing factors may be used comes from the Veterans Administration Patient Safety Center in Detroit. Here Jim Bagian and John Gosbee oversee the collection of root cause analyses from their 144 hospitals, analyze the findings and develop algorithms and protocols that are then disseminated back to the hospitals for evaluation or required implementation (Bagian et al. 2002). While this is an example from the largest U.S. health care system, it is equally applicable in a single small hospital. The VA hospitals have effective mechanisms for performing root cause analyses on real cases and near misses, and the fruits of those efforts are sent to the VA Patient Safety Center. Frontline providers must be able to comfortably express their concerns in those RCA sessions, and what makes them feel that these sessions are worthwhile is the assurance that their information will be acted upon. The structure to actualize this is quite straightforward: common sense combined with rigorous attention to detail.

This common sense use of information requires a committee or relational structure within the organization that ensures any learning gathered from the frontline will be turned into action that makes a difference. A paradigm for this process is the Executive or Leadership WalkRounds (Frankel et al. 2003).

The Cyclical Flow of Information: WalkRounds

The WalkRounds concept has now been widely applied in hospitals, but many organizations mistakenly think the key component is leadership walking around, and that WalkRounds is an informal conversation between leadership and providers. In fact, the real power is that these conversations elicit useful information within a formal structure, the information is then documented and analyzed, combined with relevant information from root cause analyses and

other reporting systems, and regularly discussed in meetings involving the Clinical chairs, chiefs, and senior leaders. These leaders of the organization accept and have clear responsibility for actions to resolve identified problems. Learning around these issues and the actions to be taken then become part of the operations-committee agenda. Patient safety personnel are responsible for tracking the intervention and no issue is considered closed until it has been fully explored *and* the information sent back to the provider(s) or employee(s) who voiced the concern that began the process. Cyclical flow of information, leading to action that can be tracked over time—this is the power of Walk-Rounds—and the structural component that matches the articulated vision of transparency and openness.

WalkRounds should not stand alone in manifesting this cyclical process. All elicited information should have a cyclical component to it, so that the providers from whom we ask for transparency, from whom we expect the courage to speak their concerns, constantly receive affirmation that their efforts to promote open communication are rewarded by changes in their work environment for which they can feel they played a role.

Effective Teamwork and Communication

Critical Components

It is increasingly clear that future improvements in health care will depend progressively more on our ability to promote excellent teamwork and effective communication across the spectrum of clinical care. Our technology infrastructure, now on a fast track deployment of electronic medical records and the spread of computerized physician order entry, is ultimately an enabler to the "peopleware," the clinicians who must translate such information into clinical practice, and comprise the teams effectively applying protocols and guidelines in the care of patients. Currently, we can assure our patients that their care is always provided by a team of experts, but we cannot assure our patients that their care is always provided by expert teams. There are two components required to successfully train and implement effective teamwork and communication in clinical practice. First, there are critical tools and behaviors that support effective collaborative work. At a minimum, structured language, effective assertion/critical language, psychological safety, and effective leadership are required components. The second aspect is the use of medical simulation to embed and practice such skills. The current question is how to most practically teach and practice such skills so they become

embedded in the delivery of patient care systematically and in a manner that provides value to patients, clinicians and institutions. Teamwork requires learned skills in leadership, group participation, and communication—but such skills cannot be fully implemented by those who have them unless co-workers have been afforded similar new insights and language. The time has come to evaluate the efforts underway in our numerous simulation centers and educational departments, and to strategically define how to bring excellent teamwork and communication consistently into our hospitals. We can reasonably expect that an investment in teamwork and communication strategies will do more than improve quality and safety. The efforts are also likely to decrease patient harm, potential malpractice suits, and increase patient satisfaction. There is extensive experience in other high reliability industries, like commercial aviation, the military, etc., that we can draw on.

We have at our disposal today three main mechanisms to teach teamwork and effective communication skills (Figure 3), and as a result of extensive teamwork training in other industries we can define the most useful components.

Visible Leadership Involvement

To successfully apply and sustain effective teamwork and communication requires three components: visible and consistent senior leadership involvement, clinical physician leadership, and embedding the tools and behaviors in clinical work that people do every day. The key and consistent message by senior leaders must be that these efforts are important, and appropriate resources will be available to support them. In the culture of medicine, with physicians being de facto leaders, respected physicians as champions is critical. This requires physicians who are willing to publicly commit their support among their peers and express the importance of such efforts. They must also be willing to openly deal with resistance from their colleagues in an open, constructive manner. When clear physician support is lacking, and it is left to nurses and others to deal with physician resistance, the results will be suboptimal.

Practically applying the tools and behaviors needed for effective teamwork and communication is challenging because clinicians are busy and not terribly interested in more work to do. Framing the adoption of such techniques as practical tools to make one's day simpler, safer and easier is a good approach. Being seen as practical and relevant to the clinical work makes it far easier to embed the changes so they become the way care is routinely delivered.

Teaching Tools and Behaviors of Effective Teamwork and Communication

The basic core skills are structured language (SBAR, which stands for situation, background, assessment, and recommendation), effective assertion, critical language, psychological safety, and effective leadership. Situational awareness and debriefing are also valuable.

Structured language increases predictability and provides a common template for communication. Communication styles are personality dependent, and effective communication is affected by factors such as the confidence and skill of a nurse and how receptive a physician is to the communication. SBAR is a situational briefing model adopted from the U.S. Nuclear Navy that helps providers organize their thoughts and communications to increase the likelihood of a mutually understood and agreed upon conclusion.

Assertion/critical language is a core element of effective teamwork, as it provides a mechanism that allows any team member to voice a concern relative to patient care and trigger active communication among the team about the expressed concern. Having structure to this process is quite important, as we know from risk management data that often people speak up softly, indirectly, or not at all.

Psychological safety means that one can voice a concern or ask for help and know that the response will always be respectful. Unless this environment of respect is consistently present, and a basic property of the organizational culture, people will hesitate to express concern and avoidable harm will occur.

Effective physician leaders actively work to flatten the existing hierarchy, share the plan of care with other team members, actively and repeatedly invite others into the conversation, and create familiarity by knowing the names of individual team members. Some doctors naturally have these skills. Many do not, and we have not systematically taught leadership skill in medical education.

The Spectrum of Teamwork Education

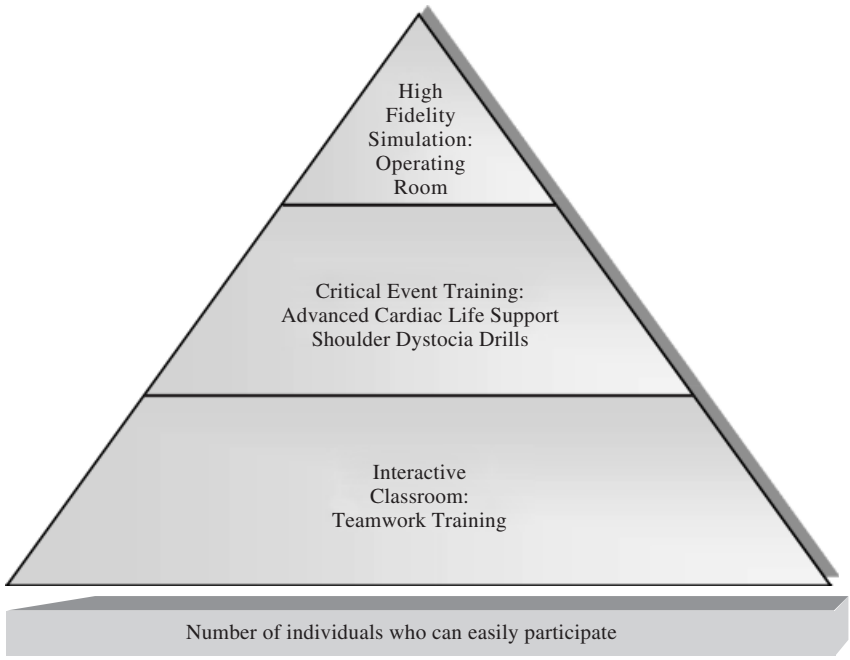
Teamwork training falls along a spectrum from interactive classroom training to full-bore simulation where skills can be practiced in realistic scenarios, evaluated, and debriefed. Low fidelity simulation models include table-top simulations or simply walking through the steps of a process. Although there is a tradeoff with regard to realism and complexity, the advantage is low cost and flexibility. Mid-range simulation is done with computerized mannequins that allow multiple protocols and provide a dynamic response depending on the effectiveness of the team in responding to the situation. Another advantage of

this mode of simulation is that training can be done in the clinical units where people regularly deliver care, so it is quite realistic and often system weakness is readily uncovered. High fidelity simulators provide a great degree of realism and are very effective. The potential limiting factor is they are resource intensive by their very nature. They are also generally removed from the clinical care units. Historically, these devices originated medically in the domain of anesthesia and operating rooms. They have become quite sophisticated and are now applied in cardiac catheterization techniques, surgical skills, and other domains.

As the pyramid in Figure 3 suggests, the number of individuals an organization is likely to be able to teach using interactive classroom training is significantly higher than in the high fidelity simulators, which are much more costly, and are not as easy or simple to access.

Interactive classroom training requires a curriculum, as noted above, and a skilled facilitator who is able to combine didactic material with audience engagement and role playing. Multidisciplinary classes are essential but no

Figure 3: The spectrum of teamwork training



specific technology is required. This teaching should incorporate an explanation of each of the components of teamwork, how human factors knowledge identifies why they are critical to delivering safe care, and how they may be implemented. Fully robust interactive classroom trainings would likely be taught by a clinician known to, and respected by, the group being trained, repeated on a regular basis, and required of all the disciplines in a unit who work together. For example, on an obstetric floor, the group attending a session would include an anesthesiologist, obstetrician, neonatologist, nurse, nurse midwife, secretary, and cleaning staff—and all would be required to, together, attend these sessions.

Each simulation modality has a valuable role to play in a robust teamwork and effective communication development plan, but to understand their roles, it is useful to examine the history of high fidelity training, specifically to appreciate that high fidelity simulators have been available to health care for many years and have had, at best, limited impact. Why? High fidelity simulators, beginning with anesthesia simulation, have played a major role in improving the safety of surgical procedures. Participants come away with awareness that a different set of skills is required to manage available resources than is required to manage the concomitant clinical problems. An anesthesiologist or surgeon may have the clinical knowledge necessary to stop massive blood loss or control an intraoperative cardiac arrhythmia, but to actually do so also requires an ability to maintain oversight of the emergency, and direct others to work collaboratively and effectively with regard to specific task and communication. Jeff Cooper and David Gaba's sentinel efforts in the development and implementation of these simulators into health care has been a significant factor in saving untold lives in our operating rooms and elsewhere (Cooper and Gaba 2002; Lighthall et al. 2003; Gaba 2004). However, for all its positive benefit, the acceptance of simulation into health care training has been slow at best, and in the initial evaluations of patient safety, beginning in 1999 with the IOM report, the role of simulation was not highlighted, nor suggestions made at that point to extensively incorporate simulation. There are a few plausible answers as to why.

Simulation: Strengths and Weaknesses

Simulators have been expensive to buy and maintain, and the need for actors, technicians, and facilitators to run them meant with each training ongoing expense were upwards of a few thousands dollars for a day's training of 10 or 12 individuals. Second, while almost every clinician who has trained in a

simulator appreciates the new insights they gain, they do not necessarily enjoy the experience. Physicians do not usually comfortably or willingly "suspend disbelief" when acting out a simulated scenario, and often find the experience inherently uncomfortable even before the scenario exposes their knowledge limitations and forces them, as a teaching process, to fail. More problematic, and an essential drawback that is less a fault of simulation than of the health care profession as a whole, is that the select group that is trained often go back to work in hospital environments with other providers who neither understand or appreciate the lessons learned. This can make the training difficult to use, and until very recently hospital leaders have not fully appreciated how better teamwork lessens error and improves the reliability of care. Hospital leaders often have not felt capable of influencing their providers, specifically physicians, to participate. None of these qualities endear simulation to its participants. Lastly, a single day's simulation training, as powerful as the experience might be, still has limitations, encapsulated by one observer who stated, "It was like watching a religious conversion because the experience was powerful enough to generate in a single day whole new insights in each person about the importance of Team Behavior and how to manage resources in a crisis, but the problem was that the conversion was solely of each individual, not the group. Very few left the sessions with enough understanding of the concrete behaviors to utilize in the clinical care setting, nor did they really understand the concepts or theories that would make sense of the behaviors. Each individual knew, and most importantly believed, that when they went back to work they needed to do something differently, but not necessarily exactly what, with whom, or how" (Maynard 2005). A great credit to these simulations is that they create the environment to generate wholesale conversion of skeptics into believers in less than a full day, but then there is not enough time to also expand the new belief into usable knowledge. This comment leads back to the overall issues of strategy, structure, and implementation.

Teamwork: Strategy, Structure, and Implementation

The high fidelity simulators are a component of the structure and implementation of teamwork—but their power to effect change is thwarted if they are not part of a health care-wide organizational teamwork and communication educational strategy. That is, a strategy with thematic content taught through physician credentialing, nursing competency, and new-hire orientation that is repeated appropriately and evaluated periodically with surveillance and audit. The evolution of thinking about patient safety is leading organizations to think

more globally about this issue, and to consider how the extraordinary teachings promulgated by Gaba, Cooper, Salas, Simon (Salas and Cannon-Bowers 2001), Helmreich (Helmreich 2000; Helmreich and Musson 2000), and others may be more widely disseminated into the health care environment. This will require an organization wide coordinated effort of interactive classroom training coupled with periodic low fidelity skill drills, managed cohesively by clinical chairs and hospital administrators, and supported by facilitators who will likely be trained in the high fidelity simulated environment. In conjunction with and linked to this organizational effort, specific high fidelity skills training will need to be available in the student period of training (i.e., medical and nursing school environments), the specialty period of training (residency programs) and, afterwards, as a part of specialty recredentailing. There are so many nascent efforts in these areas; the time to develop this strategy is now—before the small projects become better formed and less malleable.

Conclusion

Leadership by our trustees, CEOs, and physician leaders is the single most important success factor to turning the barriers of diminished awareness, accountability, ability, and action into accelerators of performance improvement and transformation (Denham 2005). Awareness is the first critical dimension of innovation adoption. Leaders must be aware of performance gaps before they can commit to adoption of any innovation. Few leaders are fully aware of the magnitude of the problem common to organizations like their own. Fewer still are aware of the performance gaps at their own organization that can only be defined by direct measurement and communication to leadership teams.

Accountability of leaders for closing performance gaps is critical. For innovation adoption to occur, leaders need to be directly and personally accountable to close the performance gaps. Although initiatives like pay for performance are re-calibrating many to focus on quality as a strategic priority, few leaders are directly accountable for specific patient safety performance gaps, especially in the difficult to measure arena of "culture." Organizations must also be accountable to their patients, their communities, and the national community through public reporting.

Leaders can be aware of performance gaps and accountable for those gaps; however, they will fail to close them if their organizations do not have the ability to adopt new practices and technologies. The dimension of ability may be measured as capacity. It includes investment in knowledge, skills, com-

pensated staff time, and the "dark green dollars" of line item budget allocations. Finally, to accelerate innovation adoption, organizations need to take explicit actions toward line of sight targets that close performance gaps that can be easily scored. Miscommunication, for example, is a component of almost every adverse event, but difficult to measure. Barriers exist along each of these dimensions. Such barriers can often be converted into accelerators by specific performance improvement interventions (Denham 2005, 2006).

It is clear that leaders drive values, values drive behaviors, and behaviors drive performance of an organization. The collective behaviors of an organization define its culture (Rhoades 2005). Without the right values supported by robust structures and systems established and sustained by the governance boards, senior administrative leaders, and clinical leaders it will be impossible to become a high reliability organization that embodies a true culture of patient safety.

A Just Culture, the engagement of leadership in safety, and good teamwork and communication training, are critical and related requirements for safe and reliable care. Developed and applied concurrently they weave a supporting framework for the effective implementation of new technologies and evidence-based practices. The mechanisms and tools now exist to do this work. We are late in development and implementation because we have relied too heavily on technology-based solutions and the broad expectation that every clinical project, even those based on social science, must have numerically measurable results. Numerical results for these endeavors are indirectly attainable (through outcome-based projects) if appropriate effort is apportioned to developing mindfulness through the tools described.

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May 7, 2012
An Open Letter from Patient Safety Advocates
RE: "Sorry Works!" Proposal "Reforming the National Practitioner Data Bank and State Medical Boards"

As patient safety advocates working to prevent medical harm and to ensure that consumers have the information they need to obtain the safest health care possible, we oppose a proposal by "Sorry Works!" purported to "reform" the National Practitioner Data Bank (NPDB) and state medical licensing boards.

The proposal would promote apologies by physicians to the victims of their malpractice in exchange for keeping their malpractice record with the NPDB secret. Further, in most cases, the proposal would prohibit state licensing boards from imposing disciplinary action based on a physician making the apology.

The "Sorry Works!" campaign appears to be designed primarily to serve the interests of physicians rather than patients who have been harmed. Although it would likely lead to more apologies to injured patients, it would leave the public even less well protected from medical malpractice than is the case today. It would hide the records of malpractice settlements from entities charged with a responsibility to review physicians' backgrounds for the purpose of licensing, employment or hospital privileges.

Estimates of malpractice deaths in the U.S. range from 100,000 to over 200,000 per year. Three recent studies found that at least one in four hospital patients are harmed – almost nine million Americans each year. Yet in 2011 only 9,762 malpractice payments were made for physicians. The real problem is not how to protect physicians from any legal and professional consequences of their malpractice, as the "Sorry Works!" proposal would do; the real problem is how to better protect the public from the current epidemic of malpractice injuries and deaths.

Attached is our full analysis of this proposal. For further information, please contact Bob Oshel at robert.oshel@gmail.com or Lisa McGiffert at lmcgiffert@consumer.org

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"Sorry Works!" Proposal for "Reforming the National Practitioner Data Bank and State Medical Boards" Fails to Protect Patients from Harm
Critique by Patient Safety Advocates

May 7, 2012

Introduction

"Sorry Works!," a commercial consulting firm with advocacy organization roots, promotes "disclosure and apology" for physicians who have made an error which potentially could lead to a malpractice suit. Indeed, many injured patients or their families take legal action precisely because physicians have traditionally been reluctant to admit their errors or apologize for them. In many cases filing suit has been the only way for patients and their families to find out what happened. "Sorry Works!" recognized this and built its advocacy program around it. As the "Sorry Works!" website puts it, "If hospitals and practices want to avoid lawsuits and reduce the number of claims, do the right thing post-event we pleaded."

Patient safety advocates applaud the call for greater transparency and disclosure of errors but are concerned that the "Sorry Works!" disclosure program is promoted as a method to avoid lawsuits rather than as a tool to reduce errors, which is the real and underlying problem facing both physicians and patients. The position of patient safety advocates has always been that it is better to prevent errors in the first place than disclose and compensate for them after the fact, although that also is necessary.

Now "Sorry Works!," which five years ago was changed from an advocacy organization to a commercial consulting group with physician and hospital clients, has launched a campaign to promote apologies by physicians to the victims of their malpractice by "reforming" the National Practitioner Data Bank (NPDB) and state medical licensing boards. If a physician apologizes, the proposal would have the NPDB keep their malpractice secret and prohibit licensing boards from imposing disciplinary action based on making the apology in most cases. The proposal appears to be designed primarily to serve the interests of physicians and hospitals rather than patients who have been harmed. Although it would lead to more apologies to injured patients, it would leave the public even less well protected from medical malpractice than is the case today because it would hide the providers' records.

As patient safety advocates, we believe the most important problem facing us is reducing medical errors. Authoritative estimates of the number of malpractice deaths in the U.S. range from 100,000 to over 200,000 per year – the rough equivalent of a commercial airliner crashing *every day*. And the number of malpractice deaths is dwarfed by the number of people who are merely injured but not killed. Three respected studies in the past two years found that at least one in four hospital patients are harmed – that is almost nine million Americans each year. Yet in 2011 there were only 9,762 malpractice payments made for physicians. The real problem is not how to protect physicians from the results of their malpractice, as the "Sorry Works!" proposal would do; the real problem is how to better protect the public from the current epidemic of malpractice injuries and deaths.

Background: The National Practitioner Data Bank

By way of background, the National Practitioner Data Bank (NPDB) receives reports of all malpractice payments (not claims) made for physicians, peer reviewed adverse actions based on professional conduct or competence which affect for more than 30 days the clinical privileges of physicians at hospitals or managed care organizations (MCOs), and all adverse state licensure actions based on conduct or competence. Hospitals, MCOs, and state licensing boards (but not malpractice insurers) with a specific need to know about a particular physician's record pay a fee and query the NPDB to receive copies of the NPDB's reports on the physician of interest. NPDB reports contain no information that physicians are not required by hospitals, MCOs, and licensing boards to provide in their applications for licensure or clinical privileges. In fact, privileges and licensing applications typically require more information than the NPDB provides, such as a malpractice claims history in addition to the NPDB's malpractice payments history, and pending licensure or clinical privileges investigations in addition to the NPDB's record of final actions. Thus the NPDB serves as a flagging system to ensure that hospitals, MCOs, and licensing boards are informed of all previous payments and actions even if physicians fail to mention them on their applications. Indeed Congress established the NPDB because it found that many physicians were moving from state to state and getting licenses and privileges after failing to disclose their past record of malpractice or medical discipline.

It is important to emphasize that the NPDB takes no disciplinary actions; it merely reports on actions and payments that physicians are already required to disclose in their applications. If a physician with a bad record has problems securing a license or clinical privileges, it is because of the underlying malpractice, privileges, or licensing actions, not because of the NPDB. The NPDB is only a messenger – and it is a messenger who provides new information only when a physician fails to make a required disclosure. In practice this has been shown to be both necessary and very valuable to queriers, who, in one study, told university-based surveyors that nine percent of the time NPDB reports provided new decision-affecting information not disclosed as required in physicians' applications.

It is also widely known – and even acknowledged by the founder of "Sorry Works!" – that simply having an NPDB report is not a barrier to licensing or gaining privileges. Licensing boards and peer reviewers are known to consider a physician's entire record and the context of actions or payments. In fact, the only time an NPDB report is in itself seen as a negative is when physicians fail to disclose the underlying action or payment on their applications.

"Sorry Works!" Proposal to "Reform" the NPDB

"Sorry Works!" proposes to "reform" the NPDB by preventing the NPDB from disclosing malpractice payments to queriers if a physician apologizes to the malpractice victim any time prior to actual settlement payment – and 97 percent of payments are made by settlements – or prior to a court judgment. Obviously under this scenario, almost every physician would apologize as soon as his insurer has decided to make a settlement payment. This would keep almost all payments from being disclosed by the NPDB.

"Sorry Works!" goes on to propose that if a physician had more than two non-disclosed payments in a ten-year period, or even a third malpractice claim filed within the period, the physician would have all

his previously non-disclosed payments disclosed to queriers by NPDB. The two payments in a ten-year period threshold would have little actual impact on most physicians since the typical practicing physician has no malpractice payments in his/her history at all, and the relatively few physicians who have had any payments over the last twenty years have typically had fewer than two payments. Physicians with two payments are outliers, and many of them also have clinical privileges actions, licensure actions, and even exclusions from Medicare in their records, but the "Sorry Works!" proposal would hide all or a significant part of their record from decision makers. Even a physician who is an outlier because of his/her extremely poor record could rack up six malpractice payments over a thirty-plus year career without NPDB disclosure if the payments came more than five years apart.

The proposal to allow the NPDB to disclose past payments if a physician had a new claim after having two payments in a ten-year period is impractical. It would create a huge and very expensive new reporting burden for filed claims – perhaps requiring as many as ten times more reports to be submitted than are currently submitted for payments – since, by law, the NPDB does not now receive reports of filed claims.

The "Sorry Works!" proposal also says that malpractice payments resulting from "reckless" behavior as determined by some unspecified person or group using the "Just Culture Algorithm" would be disclosed by the NPDB. The "Just Culture Algorithm" sounds scientific, but actually it is based on human judgment, just as is the work of peer review and licensing boards that receive NPDB data. The "reckless" concept in the "Just Culture Algorithm" adds to the problem with its vagueness. According to an article cited on the Just Culture Community's website, "Reckless behavior is action that carries substantial and unjustifiable risk for an adverse event. The person who acts recklessly fully recognizes the risk, but does not actually intend the adverse consequence." It is unclear how it is an improvement to have some new unspecified person or group with unknown loyalties make a decision as to whether a physician's behavior meets this vague standard while denying information to our current experienced peer review and licensure authorities, who are used to weighing questionable medical behavior in the context of complete information and making precisely this kind of decision. This is the kind of judgment peer reviewers and licensing authorities make all the time and should continue to make, assuming we don't keep essential information secret from them as "Sorry Works!" proposes.

The result of the ill-advised "Sorry Works!" proposal would be that the NPDB would disclose very few malpractice payments, but more importantly, hospitals, MCOs, and licensing boards could no longer rely on the NPDB to ensure that the information they received on physicians' applications for privileges or licensure is complete and accurate when it comes to malpractice payments. The greatly increased secrecy in physicians' malpractice history would lead to a lack of trust in the NPDB's reliability. The usefulness of the NPDB would be largely gutted. The extremely detrimental impact of the proposal would far outweigh any benefit from disclosure of malpractice solely to injured patients and their families.

Under the "Sorry Works!" proposal, we would get more apologies for patients and their families, but we would get less disclosure for the decision-makers who are charged with protecting the public's health and safety. That would not be in the public interest.

"Sorry Works!" Proposal to "Reform" State Medical Licensing

The "Sorry Works!" proposal for state licensing is equally troubling, if not more so. If the physician apologizes any time before actual payment – as they would be sure to do once the insurer decides to settle – the state licensing board could not take any action unless the malpractice involved "reckless behavior," again as determined by some individual or group using the vague "Just Culture Algorithm." It is unclear how taking away the authority of the licensing boards to make these kinds of decisions is an improvement.

Also, more than two payments in a ten-year period could lead to licensure action based on all the physician's previous malpractice incidents. But, in effect, since a licensee can only be disciplined once at a time, this would amount to a free pass for at least two malpractice incidents unless somebody decided they were "reckless." And since malpractice incidents are rare in the first place, as a practical matter it would make it impossible for licensing boards to take any action based on malpractice that was not somehow judged to be "reckless" by somebody beholden to whom we do not know and not identified in the proposal.

Patient safety advocates highly value disclosure – disclosure to patients and families and even more importantly, disclosure to the decision makers charged with protecting the public through peer review and licensure. These crucial decision makers should not be hobbled by allowing dishonest physicians with bad records to hide their records without the possiblity of disclosure by the NPDB. Neither should these crucial protectors of patient safety be prevented from taking licensure actions, even licensure actions requiring a physician to be retrained in areas in which he has made errors. The proposal guts the ability of state licensing boards to protect the public.

Conclusion

While the "Sorry Works!" proposal may well foster more apologies to injured patients and their families, it does so from self-serving motives and not simply because it is the right thing to do. It ill-serves the public by keeping information from those charged with protecting the public and thereby making it more difficult if not impossible for them to do their job adequately. The proposal also ill-serves the interests of the vast majority of physicians who rely on peer reviewers and licensing boards to do their job in the best possible way with the most complete information.

The "Sorry Works!" proposal for "reform" of the NPDB and state licensure is a proposal that will reduce patient safety. It does nothing to reduce errors and malpractice. Instead, it would hide errors from hospital and MCO peer reviewers and licensing authorities, making it more difficult if not impossible for them to take the actions needed to reduce errors and malpractice.

We need solutions that that go to the root of the real problem and seek to reduce errors in the first place, not this ill-advised "Sorry Works!" proposal that would only make things worse.

For more information about this critique, contact Bob Oshel at robert.oshel@gmail.com or Lisa McGiffert at lmcgiffert@consumer.org

THE PERCEPTION OF JUST CULTURE ACROSS DISCIPLINES IN HEALTHCARE

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Recently, leading healthcare providers have adopted the principles of just culture to guide their organizations in learning from mistakes to ultimately improve patient safety. To do this, they have adopted an approach to foster active learning wherein members of an organization are encouraged to openly discuss errors without the fear of reprisals. This paper reports results from a just culture survey that was developed at the University of Illinois as part of a patient safety fellowship project. As part of a team, participating hospitals agreed to take part in the study and creation of a "just" culture of shared accountability. Overall results from the survey indicate a slightly positive perception of just culture, but detailed analysis revealed significant differences in the perception of a just culture across professions and departments.

INTRODUCTION

Patient Safety

The subject of human error has garnered wide attention in healthcare over much of the past two decades. Investigators in the Harvard Medical Practice Study studied the incidence of injuries caused by medical mismanagement or substandard care (Brennan, et al., 1991; Leape, et al., 1991). The authors found that these adverse events were reported in nearly 4% of all hospitalized patients in New York State in 1984, with approximately 14% of these injuries reported as fatal (Leape, et al., 1991). Leape extrapolated these figures to the United States population, estimating nearly 180,000 people die each year as a result of iatrogenic injury to some extent (Leape, et al., 1998).

Following this study, the Institute of Medicine report *To Err is Human* (Corrigon, et al., 2000) estimated the number of adverse medical events caused by human error as between 44,000 and 98,000 annually. Estimates also suggest that within the healthcare industry as a whole, medical errors reside among the ten major sources of fatalities (Rall, et al., 2001). The concern for improving patient safety and minimizing human error in medicine cannot be overstated.

Improvement through Culture

The healthcare industry has examined various approaches to quality improvements to current practice. Corrigon, et al., (2000) have suggested healthcare facilities adopt the quality improvement successes in other complex, high-tech industries such as aviation. One such effort is the focus on organizational safety, or *safety culture*. Safety culture has been defined as "The enduring value and priority placed on worker and public safety by everyone in every group at every level of an organization" (Wiegmann, et al., 2002).

Reason (1997), notes the workings of a safety culture are made up of cultures that are just; they report, learn, inform and are flexible. Reason notes that a *just culture* creates an atmosphere of trust, encouraging and rewarding people for providing essential safety-related information. A just culture is also explicit about what constitutes acceptable and unacceptable behavior. Thus, a just culture resides within an organization's overall safety culture (Figure 1).

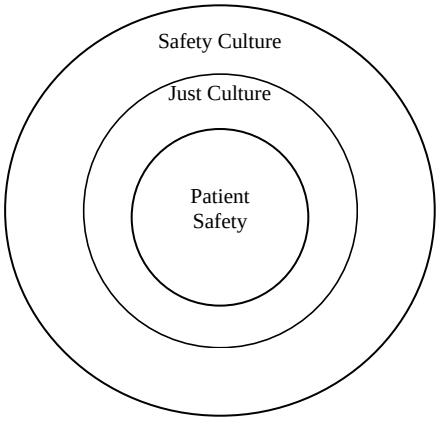

Figure 1. Representation of a just culture as the middle component between patient safety and a safety culture. From Hoppes, M. et al. (2005).

To understand the scope of medical error requires a climate that fosters trust, in which healthcare professionals are encouraged and willing to report errors and incidents; their own, and those of others. These reports provide key information about safety problems and aid in the development of potential solutions. To be effective, just culture must promote an atmosphere wherein the organization and its workers learn from mistakes, rather than focusing on blame and punishment of individuals (however, this does not apply to cases of criminal neglect, abuse, or violations). In a just culture, organizational response to unsafe acts or errors considers the origin of the error and the circumstances under which it was committed. Comprehensively punishing all errors, regardless of their origins and circumstances, along with punishing the acts of the individuals contributing to the errors is unacceptable (Reason, 1997; Reason, 1998). Discerning the underlying behavior that precedes mistakes and

errors allows investigators to determine whether the motivation was deliberately in violation of safe and standard practice (and was this violation system or individually induced), or whether the motivation was the result of inadequate training, tools, staffing or information.

However, there may be perceived barriers to trust in an organization based on the length of employment or an individual's position in the organization. In their discussion of *procedural justice*, Thibaut and Walker (1975), advance the concepts of personal control over the process of justice as the ability to voice opinion and influence the outcome of a process. Leventhal (Leventhal, 1980; Leventhal, et al., 1980) tested the perception of justice through generally applying these concepts, comparing a person's experience of a process to the rules of the process. Such rules include that the: procedures are based on accurate information; decision makers are free from bias; decision makers assure all subgroups affected by a decision are allowed to voice their concerns; rules are applied consistently across people and time; bad outcomes are correctible through appeal procedures; processes are ethical and moral.

However, rules and processes that stagnate do not serve to actively promote the perception of a just culture. Errors and their lessons identified but not put into practice aid in creating a passive organizational atmosphere wherein improvements and system corrections fall into a procedural black hole and do not resurface. In a just culture the organization must be willing to take the time to draw the right conclusions from its errors and the will to implement reforms based on this information (Reason, 1997 & 1998). An active learning approach to identifying errors and their lessons learned enables an organization to embed beneficial system and behavioral changes into the organization's culture (Hoppes, et al., 2005).

Evolution of the Just Culture Team

A Just Culture Team was formed as part of a Patient Safety Fellowship project. The fellowship project was aimed at first understanding a just culture, and secondly creating a just culture. The task force was to identify ways to understand and create a just culture for healthcare organizations. The Team consisted of patient safety specialists, risk managers, nursing officers, physicians, research and statistical experts and quality managers. The team members' facilities ranged in size from 100 employees to 11,000 employees. The project focused on the education and dissemination of information regarding a just culture along with the implementation of the principles of a just culture in the participating healthcare organizations. To accomplish this, each organization recognized its unique challenges and set about to inform the population via newsletters, bulletin boards, meetings, executive patient safety rounds, and training. Multiple participants from each organization were brought in to assist the staff to understand what is a just culture. This was carried out by defining the principles of a just culture and shared accountability, outlining the steps and procedures to achieve a just culture, and demonstrating patience as cultural change was introduced.

Throughout this endeavor, team members noted that there were possible barriers to the acceptance of a just culture. Examples of these barriers include: multiple unions, lack of discipline policies, and getting "buy in" for accountability. As each barrier was recognized the method for deconstructing it was also developed. For instance, with multiple union encounters, the unions should be involved from the beginning; contracts should be reviewed to determine if discipline is a management prerogative; union representatives and human resources should meet to review the concept of accountability as distinguished from blame; and a clear channel for how information will be disseminated to the staff defined (Hoppes, et al., 2005). Following this the team developed a self-evaluation tool to utilize as a staff survey to measure patient safety in healthcare organizations.

METHOD

This study represents an exploration into the perception of just culture across diverse healthcare settings using tools previously developed and validated in other settings and adapted to this survey. The just culture for patient safety survey was initially drafted by the team as part of the Patient Safety Fellowship Project. Originally consisting of 30 items the team merged these with constructs previously developed and validated at the University of Illinois (Wiegmann et al. 2002, 2003; Gibbons, et al., 2004).

Wiegmann et al. (2002; 2004) reviewed the organizational safety culture literature across a number of industries and originally identified five core indicators of an organization's safety culture to include: *organizational commitment*; *managerial involvement, employee empowerment, accountability,* and *reporting system.* The initial validation of the five indicators met acceptable standards with alpha coefficients indicating adequate reliability for each scale: *Organizational Commitment* (27 items) 0.94, *Management Involvement* (18-items) 0.90, *Reward System* (9 items) 0.71, *Employee Empowerment* (14 items) 0.81, and *Reporting System* (13 items) 0.86. However, high correlations between two of the five dimensions indicated the scales might measure the same construct (Wiegmann et al., 2003). After further testing, Gibbons, von Thaden and Wiegmann (2004) validated the correlation structure of the safety survey resulting in an improved version (see Gibbons, et al., 2006).

Combining the previous research, the team developed the items and placed them into four indicators of the constructs specifically related to just culture, which were identified as:

- *Reporting System (R):* Does the organization have one, is it used, do people feel safe using it?
- *Response and Feedback(R&F)*: What happens to reports once they are filed? Does the organization act on the information provided? Does the organization share information and provide feedback?
- *Accountability (A):* Are employees held equally accountable for their actions? Is there blame or favoritism? Does the organization recognize honest mistakes?
- *Basic Safety (BS)***:** What is the organization's

commitment to basic safety? Is it reinforced throughout? Do workers have training, tools, etc. to perform work?

These items were arranged in a seven point Lickert scale, where "1" represented strong disagreement with the construct, "7" strong agreement, and "4" neutrality. The survey was pilot tested on medical professionals. From their comments the survey was reduced to 20 items. Each participating organization distributed the voluntary survey to their employees internally, with a cover letter assuring each participant's anonymity.

RESULTS

For the 12 healthcare facilities, 6200 surveys were distributed with a total of 1984 surveys returned for an overall response rate of approximately 32% (see von Thaden and Hoppes, 2005 for an initial analysis of respondent's demographics). Reliability tests for each item revealed a minimum Alpha coefficient of 0.825, and a maximum Alpha coefficient of 0.850. Cronbach's Alpha based on the items=0.847.

Overall, the initial report indicated respondents were experienced in their professions (31% indicate between 3-7 years experience in their position, slightly over 50% indicate over 8 years experience). The majority of respondents indicated familiarity working at their organization (29.4% indicate working between 3-7 years at the organization, while 51% indicated over 8 years with their organization). Performance scores for each of the four dimensions were calculated by taking the mean of the participants' responses on each item in the dimension scale. Negatively worded items were reverse coded so that higher scores on all items reflected a positive view of the organization's just culture. Overall, respondents had moderately positive views on their organization's just culture in all four dimensions (Figure 2). Response and Feedback has the strongest positive score (4.99), while Accountability has the weakest (4.34). Further detailed analysis is provided in von Thaden, et al., 2006.

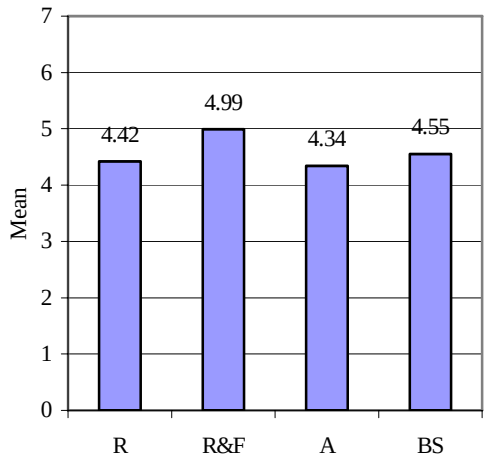

Figure 2. Mean scores of the 4 dimensions of just culture.

The results of the analysis highlight areas to address including perceptions of negative repercussions for reporting errors and perceptions of the assignment of blame for errors committed. Other areas appear to reflect that while intentions may be positive, lack of time prevents disclosure of many mistakes and errors, and an existing perception that human error is aided by problematic technology and time pressure. To the credit of healthcare professionals, patient safety is seen as top priority and training is taken seriously.

A breakdown of respondents' ratings on the four dimensions by occupation within the healthcare organizations is presented in Figure 3. From the figure it is clear that different employee groups tend to rate their organization's culture differently. Physicians tended to have the highest ratings, followed by management, then nurses and clinical staff. Non-clinical staff had ratings less positive than physicians' but tended to vary when compared to management and nurse ratings

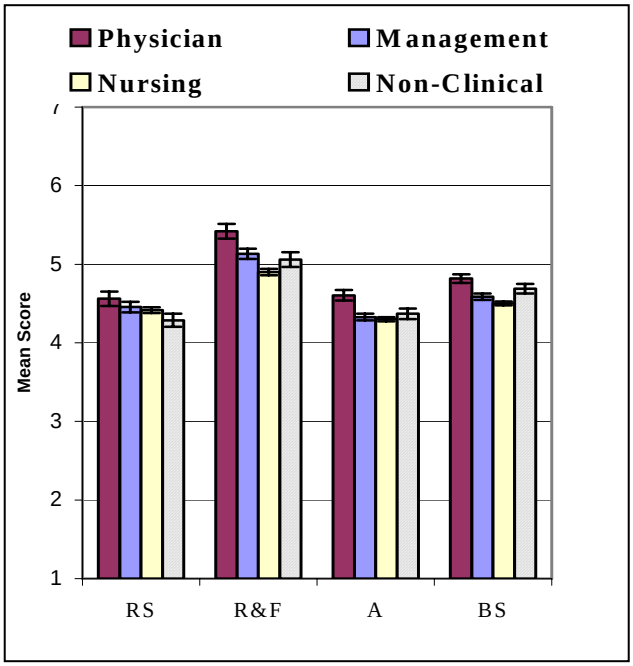

Figure 3. Just culture survey results by dimension and occupation (+/- 1 standard error).

One-way ANOVAs revealed significant differences in mean dimension score between employee groups for response and feedback ($F(3,1536)=9.53$, $p<0.001$), accountability ($F(3,1543)=6.06$, $p<0.001$) and basic safety ($F(3,1548)=9.53$, $p<0.001$). There was no statistically significant difference between mean scores for the reporting system dimension.

Post hoc comparisons (Tukey HSD) on response and feedback ratings showed physicians' ratings to be significantly more positive than managements' ($p<0.001$) and management's to be significantly more positive than nurses' ($p=0.01$). On the accountability and basic safety dimensions, physicians have a more positive view than both management and nurses ($p<0.01$). Across all four dimensions then, a trend emerges where physicians tend to have the most positive view of the culture as just.

In addition to the dimension scores, data was also broken down by responses to individual items. Of particular

note was that respondents indicated concerns to the item regarding *when an incident occurs that impacts patient safety, someone will be blamed* (Figure 4). Looking specifically at responses by each professional group, we see that while physicians have a slightly positive view, all other groups have a negative view of how their organization appropriates *blame* after an incident.

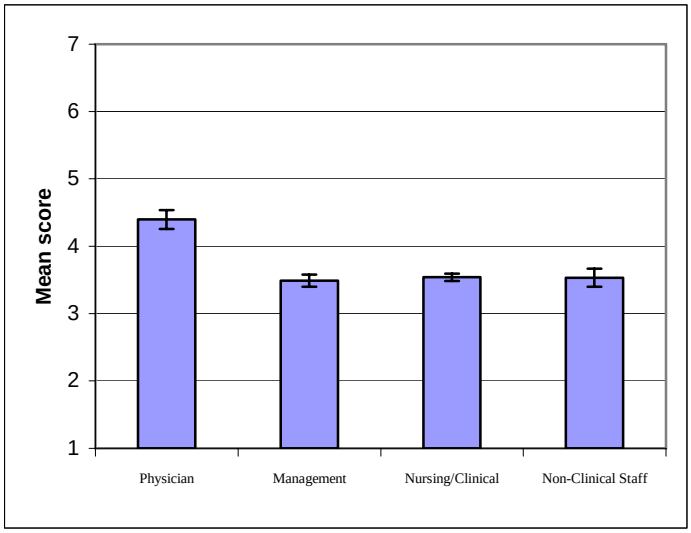

Figure 4. Responses to accountability item: If there is an incident that impacts patient safety, someone will be blamed.

Furthermore, comments gathered from the survey suggest employees perceive that disciplinary action is adjusted according to who makes the error. When comparing *when an incident occurs that impacts patient safety, someone will be blamed* (*M* = 3.58, *SD* = 1.56, min =1, max = 7) with *this organization has a just culture* (*M* =4.67, *SD* = 1.66, min = 1, max = 7), the item mean score appears contradictory to the moderately positive perception of the specific just culture item.

Cross tabulating this item by not only occupation, but also department, we discover the disparity between the physicians and the other healthcare professionals. The shaded areas in Table 1 reveal the negative responses.

Table 1. Cross tabulated responses to accountability item.

		Mean				
	Depatment*	Ancillary Support	Acute Care Services	Women's and Children's Care	Long Term or Rehab Care	Outpatient Care
Job	Physician	4	4	4	4	4
	Management	**3**	**3**	4	4	**3**
	Nursing/Clinical	**3**	**3**	**3**	4	4
	Non-Clinical Staff	4	**3**	6	4	**3**

**note: average mean scores may not agree with average mean scores in Figure 4 due to loss of data in cross tabulation.*

Note that while the physician's responses are consistently neutral across all departments, those in management, nursing/clinical, and non-clinical positions reflect varied responses, with the exception of long term or rehabilitation care. This suggests a disparity in the perception of justness in the culture by department and profession (see variance table, Table 2). This is most troubling in acute care, representing intensive care units, surgery units and emergency departments, wherein all but the physicians hold a negative view. There were no significant effects for age or experience level.

Table 2. Variance among responses to just culture item.

Variance	Ancillary Support	Acute Care	Women's/ Children's Care	Long Term/ Rehab Care	Outptnt Care
Physician	2	1	.	1	1
Management	3	4	.	2	1
Nursing/ Clinical	2	3	2	2	3
Non-Clinical Staff	1	2	.	4	1

Examining the rating's distribution among position and department reveals that divergence in responses by position and department is consistently represented in the ancillary and acute services when distinctly responding to the just culture item (see Table 3). The distribution of responses among managers and nursing/clinical staff and managers as compared with the distribution of physician responses upholds the notion of personal control (Thibaut & Walker, 1975). The data illustrate how perceived bias and lack of voice reveals differing experiences among professions and departments both within peer groups and among co-workers.

CONCLUSION

The overall results from the survey indicate healthcare professionals generally have a positive view of organizational just culture yet when considered by sub units and professions, a slightly different sub-cultural view is afforded researchers. The survey revealed differences in perceptions of just culture between physicians, management, nurses/clinical staff and non-clinical staff. Physicians tended to have more positive views than the other professions. Differences in perceptions of evaluation among departments also highlight areas where improvements to the experience of just culture may provide a better encounter for professional and patient safety alike. While on the surface it may appear positive, clearly, the concept of a just culture suffers ostensible differences when compared among the disciplines in healthcare. A just culture necessarily resides within an organization's overall safety culture and addresses the shared understanding of how behavior is determined acceptable and how accountability/culpability is evaluated. Ultimately it represents a shared accountability. Additional research is needed to determine the extent of just culture inconsistency proliferation among the healthcare disciplines.

ACKNOWLEDGMENTS

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Table 3. Within job breakdown of item ranking for *this organization has a just culture*

Department Category	Profession	1	2	3	4	5	6	7
Ancillary Support								
	Physician	4.3%			17.4%	17.4%	39.1%	21.7%
	Management	3.3%	13.0%	7.6%	21.7%	12.0%	34.8%	7.6%
	Nursing/Clinical	1.0%	8.2%	9.3%	23.7%	17.5%	36.1%	4.1%
	Non-Clinical Staff		3.0%	3.0%	36.4%	15.2%	39.4%	3.0%
Acute Care Services								
	Physician			4.0%	16.0%	28.0%	52.0%	
	Management	10.5%	10.5%	15.8%	15.8%	10.5%	21.1%	15.8%
	Nursing/Clinical	6.3%	11.0%	10.1%	23.7%	10.1%	33.8%	5.0%
	Non-Clinical Staff		14.3%	14.3%	28.6%	14.3%	21.4%	7.1%
Women's and Children's Care*								
	Nursing/Clinical	4.3%	8.7%	8.7%	23.9%	17.4%	37.0%	
Long Term or Rehab Care								
	Physician			20.0%	40.0%	10.0%	30.0%	
	Management	5.3%			15.8%	10.5%	52.6%	15.8%
	Nursing/Clinical	3.4%	9.3%	7.6%	18.6%	13.6%	41.5%	5.9%
	Non-Clinical Staff		25.0%		25.0%	25.0%		25.0%
Outpatient Care								
	Physician				33.3%	33.3%	33.3%	
	Management		5.9%		29.4%	11.8%	52.9%	
	Nursing/Clinical	3.7%	7.4%	11.1%	18.5%	11.1%	44.4%	3.7%
	Non-Clinical Staff			16.7%	50.0%	16.7%	16.7%	

*All other ratings in Women's and Children's Care = 6 (100%) for the other professions (deleted for space)

PROFESSION

Defensive medicine seeping into physician training, study says

Most students and residents at one medical school witness the practice in clinical training. They are taught to factor medical liability into patient-care decisions.

By CAROLYNE KRUPA, amednews staff. *Posted Feb. 15, 2012.*

Practicing defensive medicine to avoid medical liability lawsuits may not be a formal part of medical school curriculum, but it's still being taught to medical students and residents, a study shows.

A survey of 202 fourth-year medical students and third-year residents at Northwestern University Feinberg School of Medicine in Chicago found that 94% of students and 96% of residents have seen examples of defensive medicine in their clinical training.

Nearly two-thirds of students and three-quarters of residents said their attending physician implied that they take medical liability concerns into consideration when making clinical decisions. Nearly half of respondents said their attending directly instructed them to do so, says the study in the February *Academic Medicine* (www.ncbi.nlm.nih.gov/pubmed/22189882/).

Educators should reframe such conversations to focus on reducing liability risk by improving patient safety and communication, said Kevin O'Leary, MD, lead study author and associate professor and associate chief of Northwestern's Division of Hospital Medicine.

"At its core, medical malpractice is about preventable injury to patients," he said. "I think we lose track of that and focus on the potential risk to ourselves when we should focus on the potential risk to our patients. We can help trainees with clinical decision-making without having to rely on [medical liability] as the motivation."

The nationwide costs of defensive medicine have been conservatively estimated at $45.6 billion per year, according to a September 2010 *Health Affairs* study (content.healthaffairs.org/content/29/9/1569/).

The *Academic Medicine* study found that assurance behaviors -- when physicians provide additional services that are of little clinical value to the patient -- are particularly common. Ninety-two percent of students and 96% of residents witnessed such behaviors, while only 34% of students and 43% of residents saw physicians avoid providing services to patients for fear of medical liability risk.

Half of medical students and 67% of residents said they witnessed a medical error that resulted in harm to a patient. About 70% of these respondents said the errors were disclosed to patients or their families.

Dr. O'Leary said it was discouraging that about 30% of respondents who witnessed harmful medical errors said the mistakes were not disclosed. Disclosing errors is difficult, but it is a professional obligation, and most hospitals have supporting staff to help physicians through the process.

"It is really a difficult conversation that most medical providers haven't had much training in," he said.

A limitation of the study is that it focuses on a single institution. But Dr. O'Leary said he is confident defensive medicine is prevalent at most academic medical centers. More emphasis should be placed on aligning clinical training with medical school curricula.

"Our goal is that while the formal curriculum is being expanded to include patient safety, that we also take into account the clinical training," he said.

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Defensive medicine in medical education

A 2010 survey of more than 200 medical students and residents found that the majority had witnessed different types of defensive medicine practiced as part of their clinical training.

	Medical students			Residents		
Assurance behavior	**Often**	**Sometimes**	**Rarely/ Never**	**Often**	**Sometimes**	**Rarely/ Never**
Order more tests than medically indicated	45%	42%	13%	43%	50%	7%
Prescribe more medications than medically indicated	15%	48%	37%	17%	41%	42%
Refer patients to specialists more often than medically indicated	26%	41%	33%	28%	49%	24%
Suggest invasive procedures to confirm diagnoses more than medically indicated	7%	40%	53%	5%	34%	61%
Avoidance behavior	**Often**	**Sometimes**	**Rarely/ Never**	**Often**	**Sometimes**	**Rarely/ Never**
Avoid certain procedures or interventions	6%	24%	70%	5%	33%	62%
Avoid caring for high-risk patients	3%	15%	82%	0%	16%	84%

Source: "Medical Students' and Residents' Clinical and Educational Experiences with Defensive Medicine," *Academic Medicine*, February (www.ncbi.nlm.nih.gov/pubmed/22189882/)

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Growing number of 'concierge' doctors offer personalized care, access

Concierge medical care got its start in Seattle in the late 1990s and has been adopted by an estimated 1,000 to 2,000 doctors.

By Nara Schoenberg
Chicago Tribune

CHICAGO — Mary Lou Rothman has her doctor's email and cellphone number, with permission to call day or night.

When she recently came down with a stomachache, she called the office and got an appointment within three hours.

When the stomachache turned out to be appendicitis, her doctor, Marcy Zwelling, went to the hospital with her and stayed by her side through two surgeries, the second brought on by excessive bleeding. Only after 2 a.m., when it was clear the second surgery had been successful, did Dr. Zwelling go home.

"She was practically sitting on my shoulder the whole time, her in conjunction with (the surgeon)," says Rothman, 69, who is expected to make a full recovery.

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"I'm sure everyone thought, who is this person in ICU that she's got doctors on either side of her? But that's what we pay for. Our concierge (medical) service provides us with 24/7 care."

Rothman, a figure skating judge from Cypress, Calif., does pay for the VIP treatment, but it's less than you might expect. She's one of more than 200,000 Americans, from members of Congress to teachers to bus drivers, who pay their doctors up front for more personalized and attentive medical care.

While some concierge practices charge patients as much as $15,000 a year, the typical charge appears to be about $1,500 to $2,000, according to a 2010 report from the University of Chicago and Georgetown University. The fee often covers a comprehensive physical lasting more than an hour, as well as doctor's visits and an array of extras from cellphone access and wellness programs to direct involvement in specialist referrals and hospitalizations.

The fee typically does not cover hospital or specialist fees and may not include all care by the concierge doctor, so patients still need medical insurance.

Concierge medical care, which got its start in Seattle in the late 1990s and has been adopted by an

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estimated 1,000 to 2,000 doctors, is controversial. Some critics say these relatively small practices (doctors often see a few hundred patients, rather than 2,000 to 4,000) are elitist and could contribute to a shortage of primary care physicians.

In an email exchange, Michael Stillman, an internist at the Boston University School of Medicine and a critic of concierge medicine, called the practice a "blatant money grab" and raised the specter of reduced access to care.

"Imagine a country in which every physician took on only a few hundred retainer fee-paying patients," Stillman wrote.

"Where would people of modest and even average incomes receive their care"

Supporters of concierge medicine say that it may encourage more medical students to pursue primary care, easing access problems in the long term, and that concierge doctors can provide free or reduced-cost service for the poor.

"Ten percent of my patients are scholarship patients," says Zwelling.

"I'm able to do scholarship patients because I'm otherwise paid. The patient I saved last week in the hospital — she doesn't pay a dime. ... As (immediate past) president of the (American Academy of Private Physicians), I keep track of my friends: Everyone has scholarship programs, and everyone's proud to do it. It's part of what we do."

Patients choose concierge care for a wide range of reasons; some want a doctor who will actively manage a serious illness or serve as an advocate within the medical system. Some are drawn to the convenience of concierge care, and some like the emphasis on prevention and wellness.

"I felt like if I joined a practice like that it would force me to pay more attention to my health," says Jackson Despres, 63, a real estate developer from Smithfield, R.I., who joined the concierge practice of Lewis Weiner about five years ago and has since referred six people to him.

Rothman, a longtime patient of Zwelling's, wasn't happy when her doctor made the switch to concierge care, reducing her patient load from about 4,000 to about 400 and charging an extra fee, which now amounts to about $2,000 per year for Rothman.

But Rothman is a big fan of Zwelling, whom she describes as extremely determined — "like a dog with a bone" — when it comes to pursuing health care solutions for her patients. So Rothman signed on for concierge care, as, eventually, did her husband, Dave.

"Each year that we re-enroll in our concierge service we go, 'Ohhh, that's a lot of money,'" Rothman says.

— — —

WHAT CAN YOU EXPECT?

Concierge medical care hasn't been widely studied, so generalizations are difficult to make. But a good starting point is a 2010 study from the University of Chicago and Georgetown University for the Medicare Payment Advisory Commission. Drawing on previous studies and 28 interviews with experts, advocates and doctors, the authors reported:

The typical upfront fee appears to be about $1,500 to $2,000 a year, but fees can range from $60 to $15,000.

The upfront fee may cover all office visits with the concierge doctor, but that varies.

Concierge doctors typically offer a physical exam lasting an hour or longer with an emphasis on preventive care. That might include breathing, hearing and vision tests, electrocardiogram, blood tests, and screenings for Alzheimer's, depression and sleep problems.

Many concierge doctors offer longer-than-average office visits, same-day or next-day office visits and access to their cellphone number. They may also visit patients in the hospital or at home.

More Health
White House attacks contraception bills

Wash. father-son killed on Interstate 5 *From Seattle Times Local News*

Which thermometer is best? *From Seattle Times Living*

2 Alaska boys missing since June found in Wash. *From Seattle Times Local News*

Whitney Houston reportedly acted erratically before she died *From Seattle Times Nation & World*

and Hotel Rooms *From Away.com*

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Why You Should Cover Your Gray Hair at Home *From HaircolorForWomen.com*

15 Things Your Walk Says About Your Health *From Caring.com*

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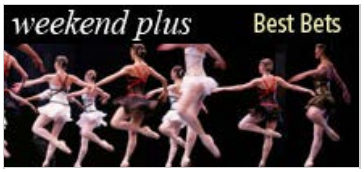

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The Seattle Times

Patient Safety

and the

"Just Culture"

David Marx, JD
President, Outcome Engineering, LLC
2007

Agenda

- What is Just Culture?
- The Safety Task
- The Just Culture Model
- Statewide Initiatives

What is a “Just Culture?”

An Introduction to Just Culture

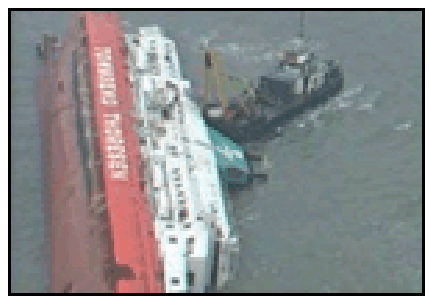
The single greatest impediment to error prevention in the medical industry is "that we punish people for making mistakes."

Dr. Lucian Leape
Professor, Harvard School of Public Health
Testimony before Congress on
Health Care Quality Improvement

An Introduction to Just Culture

"There are activities in which the degree of professional skill which must be required is so high, and the potential consequences of the smallest departure from that high standard are so serious, that one failure to perform in accordance with those standards is enough to justify dismissal."

Lord Denning
English Judge



An Introduction to Just Culture

"People make errors, which lead to accidents. Accidents lead to deaths. The standard solution is to blame the people involved. If we find out who made the errors and punish them, we solve the problem, right? Wrong. The problem is seldom the fault of an individual; it is the fault of the system. Change the people without changing the system and the problems will continue."

Don Norman
Author, the Design of Everyday Things

An Introduction to Just Culture

"…No person may operate an aircraft
in a careless or reckless manner
so as to endanger
the life or property of another."

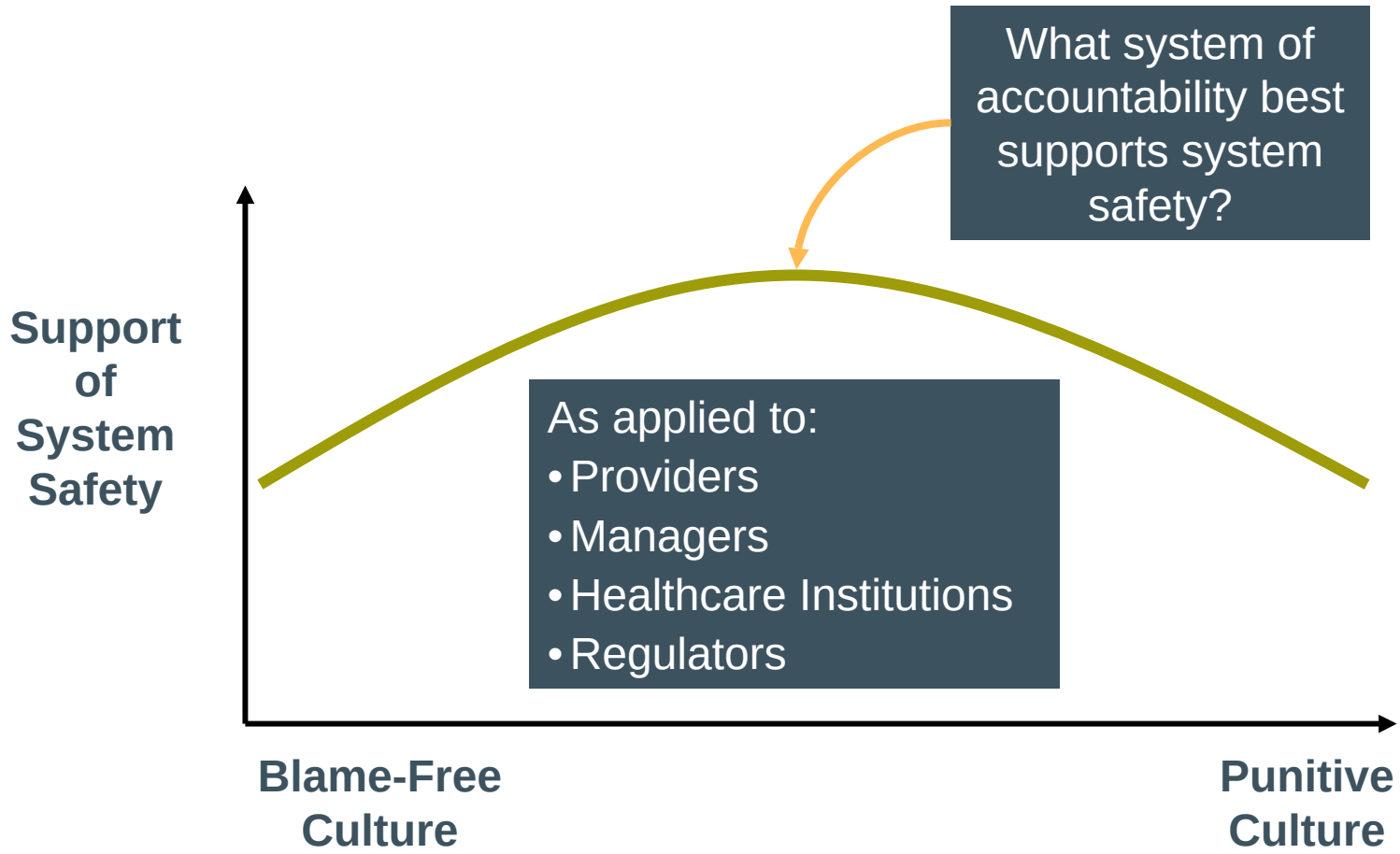
Federal Aviation Regulations
§ 91.13 Careless or Reckless Operation

An Introduction to Just Culture

"As far as I am concerned, when I say "careless" I am not talking about any kind of "reckless" operation of an aircraft, but simply the most basic form of simple human error or omission that the Board has used in these cases in its definition of "carelessness." In other words, a simple absence of the due care required under the circumstances, that is, a simple act of omission, or simply "ordinary negligence," a human mistake."

National Transportation Safety Board
Administrative Law Judge
Engen v. Chambers and Langford

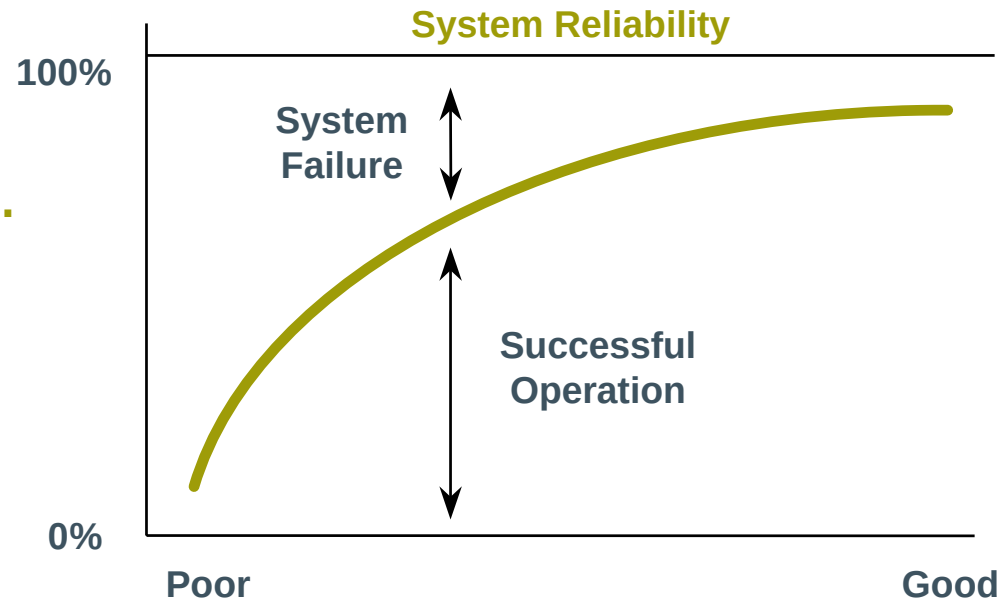
The Problem Statement



The Safety Task

Managing System Reliability

Design for System Reliability…



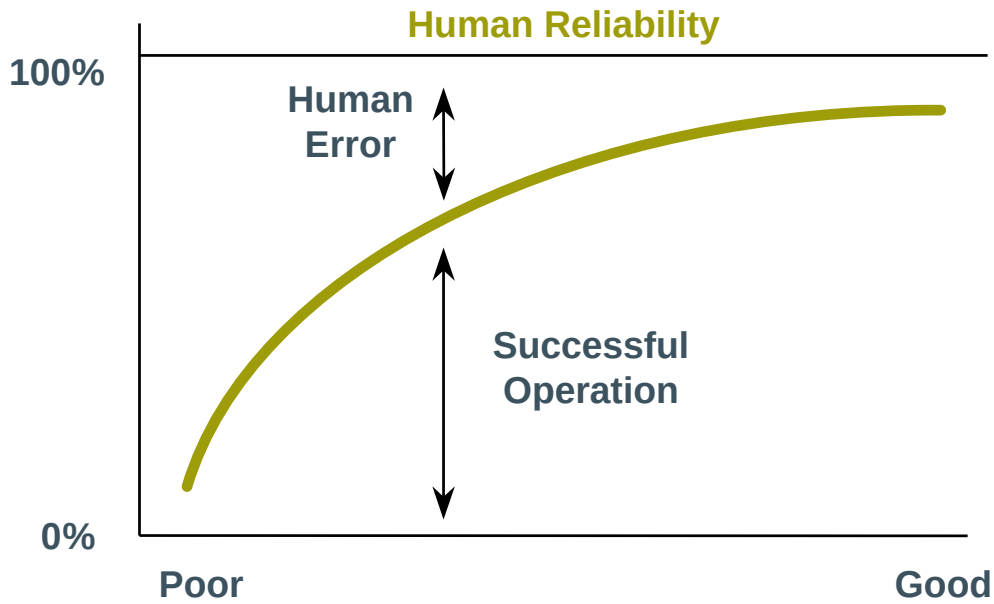
- Human factors design to reduce the rate of error
- Barriers to prevent failure
- Recovery to capture failures before they become critical
- Redundancy to limit the effects of failure

… knowing that systems will never be perfect

Managing Human Reliability

Design for Human Reliability…

- Information
- Equipment/Tools
- Design/Configuration
- Job/Task
- Qualifications/Skills
- Perception of Risk
- Individual Factors
- Environment/Facilities
- Organizational Environment
- Supervision
- Communication



… knowing humans will never be perfect

The Just Culture Model

A Model that Focuses on Three Duties balanced against Organizational and Individual Values

- The Three Duties
  - The duty to avoid causing unjustified risk or harm
  - The duty to produce an outcome
  - The duty to follow a procedural rule
- Organizational and Individual Values
  - Safety
  - Cost
  - Effectiveness
  - Equity
  - Dignity
  - etc

The Behaviors We Can Expect

- Human error - inadvertent action; inadvertently doing other that what should have been done; slip, lapse, mistake.
- At-risk behavior – behavioral choice that increases risk where risk is not recognized or is mistakenly believed to be justified.
- Reckless behavior - behavioral choice to consciously disregard a substantial and unjustifiable risk.

Example

A nurse is going to administer a medication to a baby in the neonatal ICU. The ICU has an automated dispensing system. The automated dispensing system opens a drawer with four bins. As he has always done, he reached into the second bin where the vial of medication is, confirms the blue cap on the vial, grabs the medication and takes it to deliver the medication. At no time in the process did the nurse actually confirm the medication label, instead relying on the medication's location in the dispensing system and color of the cap to confirm the correct medication. In this case, pharmacy had dispensed the wrong dose in the dispensing system.

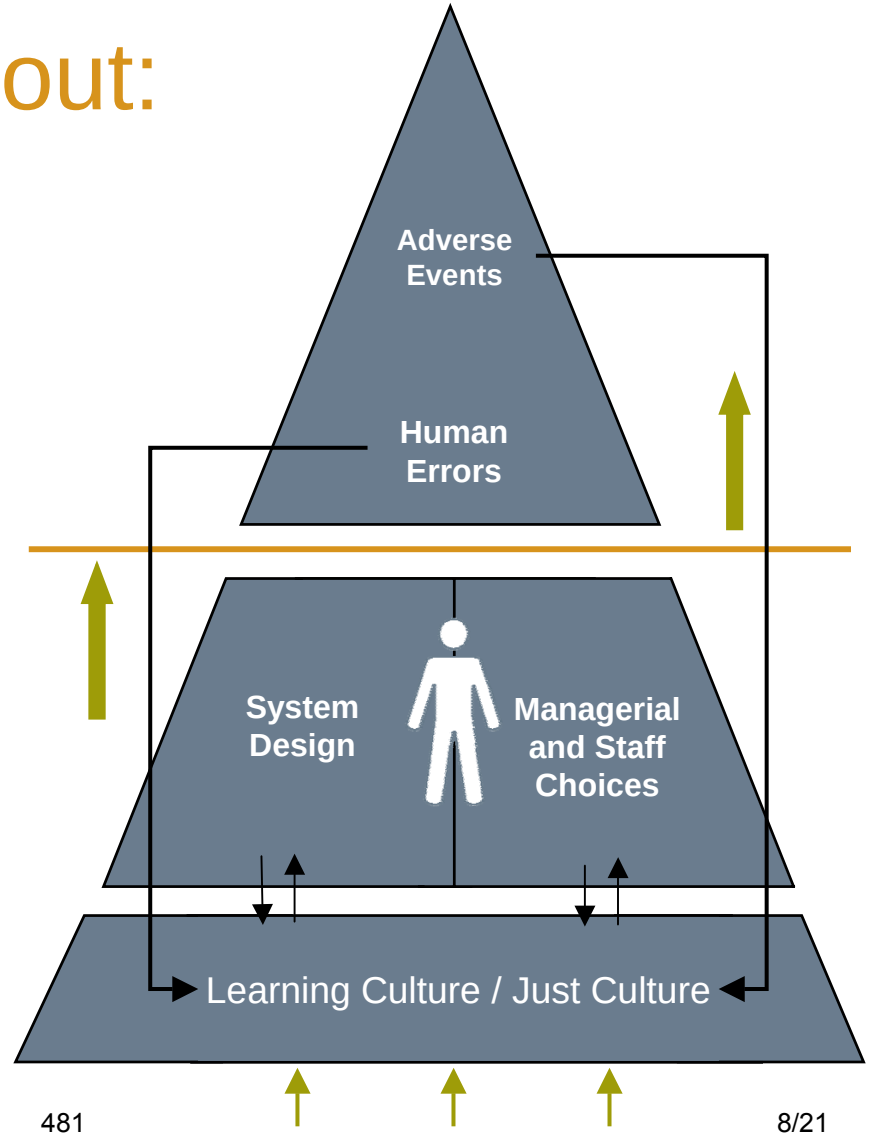
Accountability for Our Behaviors

Human Error	At-Risk Behavior	Reckless Behavior
Inadvertent action: slip, lapse, mistake	*A choice: risk not recognized or believed justified*	*Conscious disregard of unreasonable risk*
Manage through changes in:	Manage through:	Manage through:
Processes Procedures Training Design	emoving incentives for At-Risk Behaviors reating incentives for healthy behaviors ncreasing situational awareness	Remedial action Punitive action
Console	**Coach**	**Punish**

Just Culture is about:

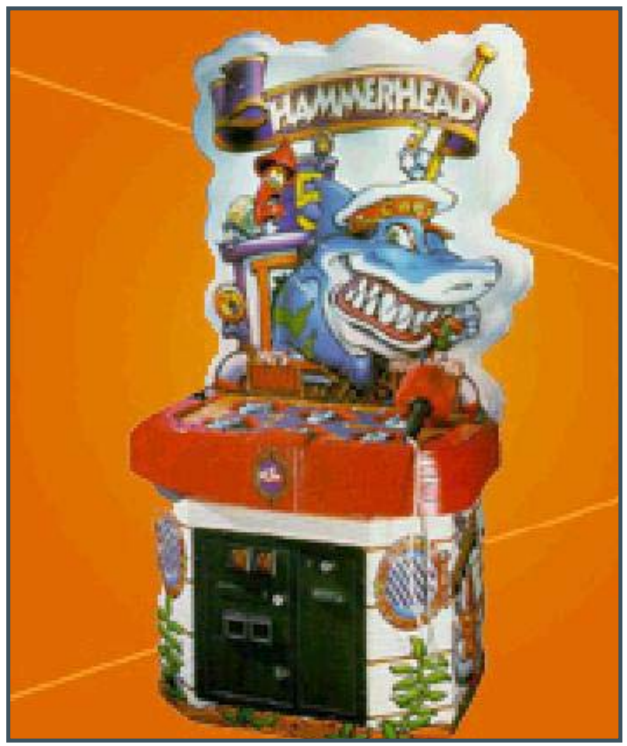
- Creating an open, fair, and just culture
- Creating a learning culture

- Designing safe systems
- Managing behavioral choices



It's About a Proactive Learning Culture

- It's not seeing events as things to be fixed



- It's seeing events as opportunities to improve our understanding of risk
  - System risk, and
  - Behavioral risk

Where management decisions are based upon where our limited resources can be applied to minimize the risk of harm, knowing our system is comprised of sometimes faulty equipment, imperfect processes, and fallible human beings

It's About Reinforcing the Roles of Risk, Quality, and HR

- Risk/Quality
  - Helping improve the effectiveness of the learning process
  - Providing tools to line managers
  - Helping to redesign systems
- HR
  - Protecting the learning culture
  - Helping with managerial competencies
    - Consoling
    - Coaching
    - Punishing

It's About Changing Managerial Expectations

- Knowing my risks
  - Investigating the source of errors and at-risk behaviors
  - Turning events into an understanding of risk
- Designing safe systems
- Facilitating safe choices
  - Consoling
  - Coaching
  - Punishing

It's About Changing Staff Expectations

- Looking for the risks around me
- Reporting errors and hazards
- Helping to design safe systems
- Making safe choices
  - Following procedure
  - Making choices that align with organizational values
  - Never signing for something that was not done

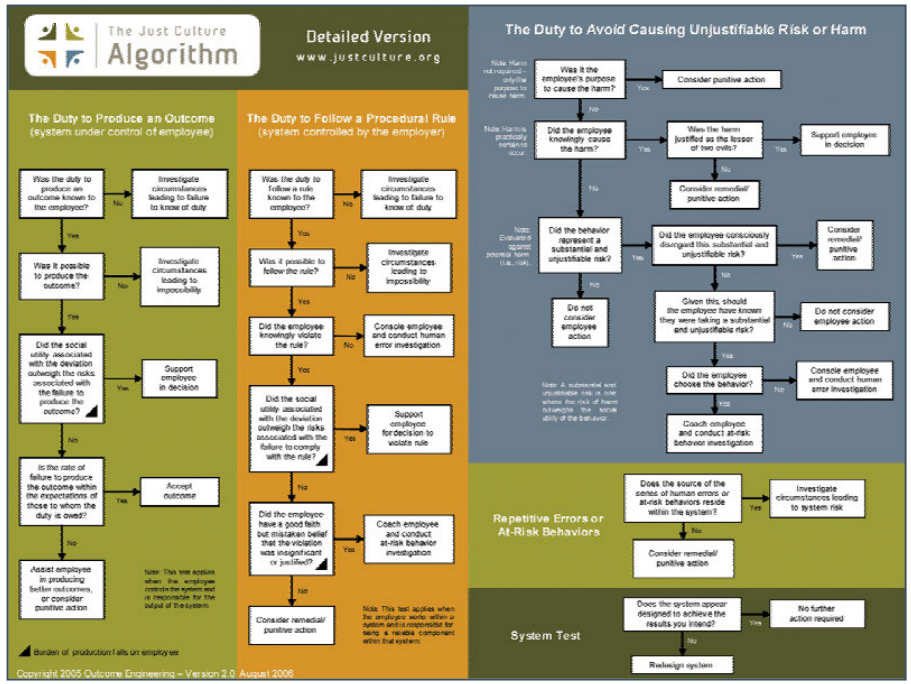
Statewide Initiatives

Statewide Initiatives

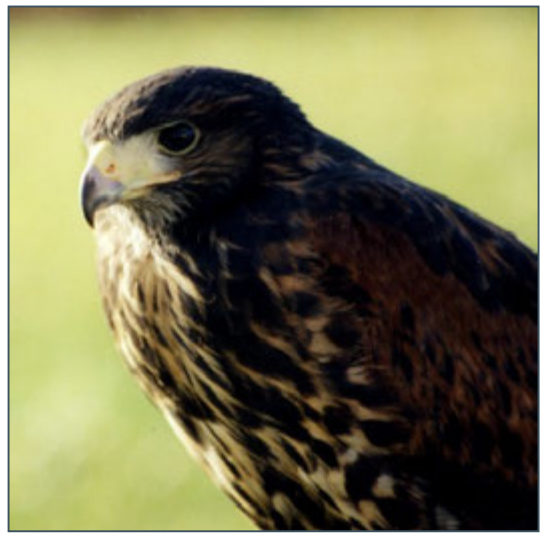
- A willingness of stakeholders to work together
  - Individual providers
  - Healthcare organizations
  - Professional boards
  - Departments of health
- One model of shared accountability
  - Protecting the learning culture
  - Safety-supportive accountability

An Algorithm to Follow

- One method that works across all values
- One method that works both pre and post event



Doves and Hawks – Who are we?



Thank You

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Truthful Doctors May Prevent Malpractice Suits

***Joe Cantlupe, for HealthLeaders Media* , February 16, 2012**

When it comes to malpractice, it seems physicians have developed their own case of "white-coat syndrome."

Their worries about malpractice litigation might actually be making it worse, and hurting healthcare in the process. That's because doctors are keeping their mistakes under wraps, or performing too many tests or costly procedures to avoid a trip to the courthouse.

Instead, physicians should be opening lines of communication with patients, admitting when something goes wrong, and curtailing excessive treatments. They can fight the tort war one step at a time from the moment they pick up that stethoscope.

Two recent reports express urgency about the need to change.

A recent HealthLeaders Media Industry 2012 survey (PDF) shows that a whopping 58% of physician leaders said they ordered a test or procedure for primarily defensive medicine reasons in the past year.

That figure is all the more stunning because only 2% reported ordering a test or procedure for primarily revenue-related reasons.

"We order too much, (practice) too much defensive medicine, keep patients in hospitals too long," Douglas Garland, MD told HealthLeaders Media. He is medical director of the MemorialCare Joint Replacement Center, part of the 1,006-bed MemorialCare Health System in Long Beach, CA.

Results of a recent survey published in *Health Affairs* revealed that as many as 20% of physicians won't tell patients about errors because of doctors' fear of malpractice litigation. As many as 55% exaggerated or failed to tell patients something about their health because, in part, the physicians didn't want to upset their patients. At least 1 in 10 physicians told patients something untrue in the past year.

"When we noted that 20% of physicians said in the last year they had not fully disclosed an error or a mistake to a patient because they were afraid of a lawsuit, it certainly could have been any error they were referring to," Lisa I. Iezzoni, MD, M.Sc, a professor of medicine at Harvard University and director of the Mongan Institute for Health Policy at Massachusetts General Hospital told HealthLeaders Media.

"We don't know from the survey results; we didn't ask that. But you can imagine the errors span a continuum of severity. Some errors may have caused minor discomfort or no discomfort whatsoever. Other errors can be life-threatening. It's hard to know exactly what that 20% remembered; they weren't asked that question," she says.

While physicians' statements are not always linked to malpractice concerns, doctors are aware that the **possibility of litigation** is always a factor. Indeed, more than 60% of physicians aged 55 and older have been sued at least once, according to the American Medical Association.

Physicians also know how costly—financially and emotionally—la malpractice suit can be. In a policy report issued at the end of 2011, the American Medical Association stated that the average cost of defending a physician against a medical liability claim was $47,158 in 2010. That's an increase of 62.7% since 2001. Still, 63.7% of all closed claims against physicians were dropped, withdrawn, or dismissed.

For physicians, the local malpractice environment sometimes influences their "attitudes and behaviors," including how honest they are about errors, according to Iezzoni.

Her study showed that cardiologists and general surgeons were most likely to report never having told patients an untruth in the previous year, while pediatricians and psychiatrists were least likely to report never having told untruths.

More physicians practicing in universities or medical centers, (78.1%) completely agreed with the need to report all serious medical errors than physicians in solo or two-person practices

(60.5%).

The reason appears simple: small practices don't have as much legal leverage, so physicians from these practices with less clout are also less likely to be as forthcoming.

But many experts agree that concealing medical errors, being dishonest, or practicing overly defensive medicine isn't the way to thwart malpractice litigation.

Research shows that the more likely physicians are to discuss errors with patients, the less likely they will be sued, Iezzoni says. Perhaps it makes the doctors seem less god-like and more human, so patients can relate to them.

"Some physicians may wonder about revealing errors to certain patients if no serious harm resulted from them. I know a lot of physicians are reluctant to talk about medical errors. But the more open you are in talking about errors, the less likely patients are going to pursue litigation, and the more likely you are going to gain the trust of patients, and be able to move forward in a therapeutic way," Iezzoni said.

Among other things, informing patients about the errors can "reduce anger," she adds. "If you talk openly to patients in situations where errors happened, it makes patients understand better what happened, why it happened and makes them less likely to pursue litigation as a solution to it."

Iezzoni notes that academic literature stretching back to the 1990s has shown that "openness" in communication between physicians and patients has potentially positive impacts on avoiding malpractice suits.

As for Iezzoni and her colleagues, their biggest concern wasn't simply the malpractice issue. It was the totality of honesty in communications between physicians and patients, for whatever the reason.

Why aren't doctors always upfront with patients? "I think there are probably as many reasons as there are doctors and patients," she says.

In our conversation, she listed some possibilities. "Maybe doctors don't want to upset patients. Maybe doctors feel if they tell patients the truth about their prognosis, it's going to cause the patient undue amount of stress. Maybe doctors aren't trained to talk to patients about different truths," Iezzoni says. "Maybe doctors don't feel they have enough time in 10 to 15 minutes to have a complete conversation about a patient's prognosis."

"Patients themselves are going to have different preferences for how open they want doctors to be," she adds. "There are certain patients who may say, ' I don't want to know everything, just tell me what to do, give me the highlights. Then there are those who want to be frank and open and have a complete discussion about what their prognosis is. They want to know everything."

Iezzoni noted the ABIM (American Board of Internal Medicine) Foundation's Charter on Medical Professionalism, published in 2002, urged doctors to be "open and honest" with patients and to disclose medical errors promptly. With this latest survey, it doesn't appear physicians are following the guidelines or standards of communication laid out by the foundation, she conceded.

With the high percentage of defensive medicine practiced, as well as physicians trying to hide potential errors to offset potential malpractice litigation, Iezzoni notes, "We need to do a lot more work from the patient and physician side to get to the point there is more openness and frank discussion about the patient's health and patient's prognosis."

"Patients need to feel comfortable going into the doctor's office, and saying, 'Look I want to have a conversation about how I want you to talk to me about my health.'"

Engaging in that conversation with complete honesty could be a first step toward avoiding a malpractice suit.

Joe Cantlupe is a senior editor with HealthLeaders Media Online. He can be reached at jcantlupe@healthleadersmedia.com.

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