Board of Osteopathic Medicine and Surgery Guideline

Title:	A Collaborative Approach to Reducing Medical Errors and Enhancing Patient Safety	Number: OP 19-01
Reference:	Attached	
Contact:	Becky McElhiney, Program Manager osteopathic@doh.wa.gov	
Effective Date:	May 31, 2019	
Approved	Board	
	Chair, Board of Osteopathic Medicine and Surgery	

"We need to quit blaming and punishing people when they make mistakes and recognize that errors are symptoms of a system that's not working right, and go figure out and change the system so no one will make that error again, hopefully. We have to change the culture, so everyone feels safety is his or her responsibility, and identifies hazards before someone gets hurt."

-Lucian Leape, MD
Adjunct Professor of health policy, Harvard School of Public Health
Co-Founder, National Patient Safety Foundation

Purpose

The Board of Osteopathic Medicine and Surgery (board) adopts this guideline to collaborate with the health care system to reduce medical errors[1] and enhance patient safety.

Background

Medical errors continue to be a leading cause of death in the United States.[2] [3] In its seminal report, *To Err is Human: Building a Safer Health System*, the Institute of Medicine (IOM) studied other high-risk industries that have taken a systems approach to improving safety, and concluded that the most effective way to reduce error and improve patient safety is not to blame individuals, but to create an environment that encourages organizations to identify errors, evaluate causes, and take appropriate actions to prevent future errors from occurring.[2] [4] [5]

Leading national patient safety advocates such as Lucian Leape, MD, have proposed going beyond the IOM's recommendations and building momentum for a "just culture" in medicine—a culture that is open, transparent, supportive and committed to learning; a culture centered on teamwork and mutual respect, where every voice is heard and every worker is empowered to prevent system breakdowns and correct them before they occur; where patients and families are

fully engaged in their care; and where caregivers share information openly about hazards, errors and adverse events.[6] [7] [8] [9] [10] Communication and Resolution Programs have shown great promise in providing a structure to employ these principles to reduce medical error.

Despite the efforts of many organizations across the country to develop initiatives to enhance patient safety, progress has been slow and insufficient.[6] [7] Medical errors remain vastly underreported.[11] [12] [13] Traditional malpractice and disciplinary systems are thought to impede progress by discouraging the reporting of errors, contributing to a culture of blame and a "wall of silence" in health care that inhibits learning and prevents systems change that is critical to reducing error.[13] [14] [15] Dr. Leape calls on regulators to become a force for error reduction rather than a force for error concealment.[14]

The board is committed to its statutory mandate to protect the public through licensing, discipline, rule-making, and education. The board recognizes the limitations of the traditional disciplinary process to reduce error in a rapidly evolving health care delivery system. As health care becomes more patient-centered, team-based, and transparent[16], a new regulatory model is needed, one that focuses less on punishment and more on improving systems and preventing error.[17] The board believes that a more effective regulatory approach is to work directly with entities in the health care system to foster open communication with patients, proactively prevent or reduce medical error and increase patient safety.[18]

The board answers Dr. Leape's call to become a force for error reduction rather than concealment through the following activities:

- Endorsing just culture principles. The board encourages institutions, hospitals, clinics and the health care system to adopt a just culture model to reduce medical error and make systems safer. Likewise, the board will use just culture principles in reviewing cases of medical error.
- Entering into a Patient Safety Collaboration with the Foundation for Health Care Quality to support and develop Communication and Resolution Programs throughout the state of Washington and to develop a process to handle such cases.
- Collaborating with the Foundation for Health Care Quality to develop a state-wide system to disseminate lessons learned from unanticipated outcomes and medical errors, fostering a learning culture in our state and making the entire health care system safer.

By taking these steps, the board collaborates with the health care system to reduce medical error, become a more effective regulator, and better meet its mandate to protect the public.

The Board Endorses a Just Culture Model for the Health Care System

"Just culture" is a term describing an approach to reducing error in high-risk and complex industries by recognizing that errors are often the result of flawed systems, and that blaming individuals for human error does not make systems safer. A just culture describes an environment where professionals believe they will be treated fairly and that adverse events will be treated as opportunities for learning. A just culture encourages open communication so that near misses can serve as learning tools to prevent future problems, and adverse events can be used to identify and correct root causes. It holds individuals accountable for the quality of their

choices and for reporting errors and system vulnerabilities, and holds organizations accountable for the systems they design and how they respond to staff behaviors.[19] [20] [21]

In *To Err is Human*, the IOM detailed the efforts of high-risk industries, most notably aviation, in applying these principles with remarkable success.[2] [22]The report called for applying these principles to health care, observing that health care is decades behind other high-risk industries in its attention to ensuring safety and creating safer systems.[2] A just culture in healthcare recognizes that medical errors often involve competent providers in flawed systems, and encourages greater voluntary event reporting, open communication, learning, and improvement of systems.[18] [20] [23]A just culture has no tolerance for reckless or intentional disregard of safe practices. In those instances, discipline is required. Since the IOM report, many healthcare organizations have adopted a just culture model in their systems and have experienced the benefits of increased event reporting and decreased medical error.[24] [25] [26]

The Board of Osteopathic Medicine and Surgery endorses just culture principles and encourages institutions, hospitals, and clinics to adopt these principles to improve the health care system in the state of Washington.[27] As the healthcare delivery system becomes more patient-centered, team-based, and transparent, the employment of a just culture model is critical to making meaningful improvement in patient safety.

The Patient Safety Collaboration to Support Communication and Resolution Programs

In 2019, the board and the Foundation for Health Care Quality (Foundation) signed a Statement of Understanding to form a Patient Safety Collaboration. (Attachment A) The purpose of the collaboration is for the board and the Foundation to work together to help the medical profession reduce medical errors by supporting and promoting communication and resolution programs (CRPs). The collaboration also sets forth a process by which the Board will handle cases that go through a CRP process.

Communication and Resolution Programs

CRPs promote a patient-centered response to unanticipated outcomes: when a patient is harmed by medical care, providers should be able to tell the patient exactly what happened, what steps will be taken to address the event, and how similar outcomes will be prevented. CRPs are a stark departure from the long-standing deny and defend posture following unanticipated outcomes.[12] [28] [29]

CRPs are characterized by open and prompt communication; support for involved patients, families, and care providers; rapid investigation and closure of gaps that contributed to the unanticipated outcome; proactive resolution; and collaboration across all involved stakeholders. CRPs are based on just culture principles, and recognize that most medical errors are caused not by incompetent providers, but rather by the interaction between competent providers who have made a simple human error and faulty healthcare systems, processes, and conditions.

A CRP involves the following steps:

- Immediate reporting of unanticipated outcomes, both to the patient and family, and to the institution;

- Immediate investigation to determine the factors that led to the event;
- Communicating the findings of the investigation to the patient and the patient's family;
- Apology to the patient and, when appropriate, an offer of compensation or non- financial resolution;
- A change to the system to prevent the event from re-occurring; and
- Shared learning.

CRPs emphasize provider accountability. Providers must report unanticipated outcomes as soon as they occur, participate in efforts to understand whether the unanticipated outcome was due to medical error or system failure, and participate in efforts to prevent recurrences. CRPs do not tolerate reckless or intentional disregard of safe practices. CRPs have been used in a number of institutions and systems across the country with early success, and have the support of the Joint Commission and the Agency for Health Care Quality and Research.[13] [28] [29] [30]

The Foundation for Health Care Quality

The Foundation is a non-profit organization that administers quality improvement programs. The Foundation uses clinical performance data as a tool, working with providers and hospitals to adopt evidence-based practices and improve patient safety.[31] The Foundation also houses the Washington Patient Safety Coalition, a collaboration of patient safety leaders who share best practices to improve patient safety and reduce medical errors.

In 2011, the Foundation received a grant from the Agency for Healthcare Research and Quality to form HealthPact. HealthPact is a program designed to improve communication in health care by (1) training healthcare providers to communicate better with each other and with patients, (2) working with stakeholders to create an ongoing learning community and implement best practices in their respective institutions, and (3) developing CRPs.

The CRP Certification Process

Collaboration between the Washington Medical Commission and the Foundation led to the creation of an additional step in the standard CRP process: the formation of a CRP Event Review Board (CRP-ERB). This CRP-ERB serves as a neutral panel to review and certify CRP events. The CRP-ERB is composed of individuals from across the health care spectrum, including patient safety advocates, risk managers, insurers, and physicians.

When an unanticipated outcome occurs and an institution completes a CRP process, the institution may request an independent review by submitting an application for certification to the CRP-ERB. The CRP-ERB reviews the application and all relevant records and documents, and determines whether all key elements of the CRP process have been satisfied, particularly that the systems changes are appropriate and effective. If all the elements are fully satisfied, and patient safety has improved as a result, the CRP-ERB will send a report back to the institution stating that the event is certified. This step provides an additional level of objective quality review of the CRP process.

The Board's Coordination with the CRP Process

When the Board receives a complaint against a provider, and learns that the provider is participating in a CRP process, the Board will exercise its discretion to decide whether to place

the case on hold pending timely completion of the CRP process. The Board will not place a case on hold if the provider's continued practice presents a risk to patients or if the Board is concerned that patient safety will not be adequately addressed by the CRP. In such a case, the Board will conduct a prompt investigation and take appropriate action to protect the public.

If the Board places a CRP case on hold and then receives a report that the event has been certified, the Board will exercise its discretion to determine whether to investigate the matter or to close the case. If the Board determines that the CRP process has timely and thoroughly enhanced patient safety, including individual and system-level improvements, the Board may close the case as satisfactorily resolved. If not, the Board will promptly investigate the case and take appropriate action, if warranted.

The CRP process is limited to cases of human error. The CRP-ERB will not certify cases involving reckless or intentional conduct, gross negligence, sexual misconduct, boundary violations, patient abuse, drug diversion, criminal activity, and other unethical or unprofessional behavior.

CRPs Benefit Patients and Families, Providers, and the Board

The use of CRPs is a drastically different approach to medical error than the traditional system of secrecy, denial and defensiveness. CRPs provide patients with what they need after an unanticipated outcome: open and honest communication about what occurred, emotional first aid, accountability, an apology, remediation, and compensation. Ultimately, CRPs have the potential to reduce medical errors and improve patient safety.

CRPs benefit providers by reducing the barriers to reporting medical errors. CRPs offer a safe environment for providers to disclose unanticipated outcomes, have an honest discussion with the patient and the patient's family, and work to improve systems, without undue fear of malpractice suits, professional discipline or personal embarrassment.[32] CRPs promote a non-punitive, learning culture to improve patient safety.

For the Board, CRPs remove the limitations inherent in the traditional disciplinary process:

- Reports of medical errors to the Board are often delayed for years by the malpractice system, limiting the effectiveness of the Board's response to complaints.[11] The CRP process requires prompt reporting and patient-centered action allowing for early resolution of medical errors. This expedited process will allow the Board to address errors much sooner than under the current system.
- The Board has no jurisdiction over institutions, such as hospitals or clinics. When a medical error occurs, the Board can discipline the individual provider but is unable to directly influence the institution to make system changes to ensure the error is not repeated. The collaboration requires the individual provider and the institution to change the system to prevent future patient harm.
- The Board has no good mechanism for sharing lessons learned so that licensees and institutions can prevent errors from occurring. The collaboration requires shared learning across and among institutions.

The collaboration allows the Board to have a greater effect on patient safety than the traditional

disciplinary process and thereby improve its ability to protect the public.

Furthermore, medical errors that do not cause harm --"near misses"-- seldom come to the attention of the Board. This collaboration strongly encourages reporting of near misses to help identify potential system problems and implement system fixes before patients are harmed. By promoting early reporting of all unanticipated outcomes, as well as near misses, a wider range of errors will be identified and corrected.[33]

The Board encourages all institutions, clinics, and practices in the state of Washington to develop a CRP program, make it available to all physicians, have events certified by the CRP Event Review Board, and join in the effort to foster open communication, reduce medical error, and improve patient safety in our state.[34]

The Collaboration to Develop a State-Wide System for Dissemination of Lessons Learned from Medical Error

Learning from medical errors is crucial to improving patient safety. To facilitate and enhance learning, the Board and the Foundation have committed to collaborating to develop a state-wide system to disseminate lessons learned from medical error cases to health care providers and institutions.

The collaboration will consist of the following: The collaboration will give the Foundation two additional sets of data about medical errors: (1) the CRP Event Review Board will submit information on cases that go through the certification process, and (2) the Board will submit de-identified reports of medical error cases that come from complaints.

The Foundation will analyze the information to determine trends in the root causes of medical errors and lessons learned from these cases, and will combine this information with data from other Foundation programs such as the Clinical Outcomes Assessment Program (COAP), the Surgical Care Outcomes Assessment Program (SCOAP), and the Obstetrics Clinical Outcomes Assessment Program (OB-COAP) to create a comprehensive picture of medical errors, their causes, and lessons learned across the state.

On at least a bi-monthly basis, the Foundation will produce a written briefing on medical errors for distribution to healthcare workers across the state that identify key steps they can take to improve patient safety. The distribution of this briefing will be closely coordinated with the Patient Safety Coalition, another Foundation program, along with the Washington Osteopathic Medical Association and the Washington State Hospital Association. Depending on the nature of the medical errors that are highlighted in the briefing, the distribution of this material may be targeted to specific providers.

The Foundation will produce a written briefing on medical errors on a quarterly basis for distribution to healthcare institutions across the state emphasizing patterns of medical errors and lessons learned. The Foundation will closely coordinate the distribution of this briefing with the Washington State Hospital Association. In the event that a lesson learned has potential immediate impact on patient safety, the Foundation will issue an emergency briefing on the subject to both healthcare providers and institutions using the distribution channels described above.

Conclusion

Medical errors continue to pose a serious threat to patient safety. The Board is firmly committed to its mandate to protect the public, but recognizes the limitations of the disciplinary process in the evolving health care delivery system. The Board believes that a more effective approach is to collaborate with the health care system to develop a more patient-centered response to medical error and improve patient safety.

The Board believes that by endorsing just culture principles, collaborating with the Foundation for Healthcare Quality to support and develop CRPs, and collaborating with the Foundation to develop a system to disseminate lessons learned from medical error statewide, the Board will help to reduce medical errors, become a more effective regulator, and better meet its mandate to protect the public.

[1] Medical Error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Institute of Medicine 2000. Committee on Quality of Health Care in America. *To Err is Human: Building a Safer Health System*. Washington DC: National Academy Press; 2000.
[2] Institute of Medicine 2000. Committee on Quality of Health Care in America. *To Err is Human: Building a Safer Health System*. Washington DC: National Academy Press; 2000.
[3] James, John T., PhD, (2013). A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care, J*ournal of Patient Safety, 9,* 122-128.
[4] Institute of Medicine 2001. Committee on Quality of Health Care in America. *Crossing the Quality Chasm*. Washington DC: National Academy Press; 2001.
[5] Sentinel Event Statistics Released for 2014, the Joint Commission. April 2015: "In 2014 the leading root causes and contributory factors are examples of cognitive failures. Cognitive failure is preventable and safety-critical industries take a systems view. Health care organizations must focus on factors that influence errors and operationalize strong corrective actions aimed at improving working conditions and eliminating all preventable injury, harm and death." Ronald Wyatt, M.D., M.H.A., medical director, The Joint Commission. Accessed at http://www.jointcommission.org/assets/1/23/jconline_April_29_15.pdf
[6] Leape L, Berwick D, et al., Transforming Healthcare: a Safety Imperative, *Qual. Saf. Health Care*, 2009; 18:424-428. Waterson P, *Patient Safety Culture*. Ashgate 2014.
[7] Safe Practices for Better Healthcare—2010 Update, National Quality Forum, page 7. http://www.qualityforum.org/Publications/2010/04/Safe_Practices_for_Better_Healthcare_%E2%80%93_2010_U pdate.aspx accessed 3-9-15.
[8] Marx D.*Whack a Mole: The Price We Pay for Perfection*. By Your Side Studios: 2009.
[9] Marx D. *Patient Safety and the "Just Culture": A Primer for Health Care Executive.* New York, NY: Columbia University: 2001.
[10] Waterson P, *Patient Safety Culture*. Ashgate 2014.
[11] Studies show that disclosure of medical errors occurs in approximately 30% of cases. Wu A, Boyle D, Wallace G, Mazor K, Disclosure of Adverse Events in the United States and Canada: an Update and a Proposed Framework for Improvement, *J. Public Health Research,* 2013; 2:e32:186-193.
[12] James J., A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care. *J. Patient Saf.* 2013;9(3) 122-128.
[13] Bell SK, Smulowitz P, Woodward A, Mello M, Duva A, Boothman R, Sands K, Disclosure, Apology, and Offer Programs: Stakeholders' Views of Barriers to and Strategies for Broad Implementation. *Millbank Quarterly* 2012;90(4): 682-705.
[14] The Commonwealth Fund, Q&A with Lucian Leape, http://www.commonwealthfund.org/publications/newsletters/states-in-action/2010/jan/january-february- 2010/ask-the-expert/ask-the-expert accessed 4-28-15.
[15] Sage WM, Medical Liability and Patient Safety, *Health Law*. 2003;22(4):26-36.

[16] In March 2015, the Robert Wood Johnson Foundation issued a report on the importance of implementing a team-based model: Lessons from the Field: Promising Interprofessional Collaboration Practices, Robert Wood Johnson Foundation report 2015, available at http://www.rwjf.org/content/dam/farm/reports/reports/2015/rwjf418568 .
[17] In January 2015, the National Patient Safety Foundation's Lucian Leape Institute issued a report on the importance of transparency: Shining a Light: Safe Health Care Through Transparency, available at http://c.ymcdn.com/sites/www.npsf.org/resource/resmgr/LLI/Shining-a-Light_Transparency.pdf .
[18] This approach is consistent with the Commonwealth Fund scorecard: "Aiming Higher: Results from a Scorecard on State Health System Performance, 2014: "The Scorecard also reminds us, however, that improvement is possible with determined, coordinated efforts. The most pervasive gains in health system performance between 2007 and 2012 occurred when policymakers and health system leaders created programs, incentives, and
collaborations to raise rates of children's immunization, improve hospital quality, and lower hospital readmissions. These gains illustrate that state health system performance reflects a confluence of national policy and state and local initiatives that together can make a difference for state residents."
http://www.commonwealthfund.org/publications/fund-reports/2014/apr/2014-state-scorecard
[19] Marx D. Patient Safety and the "Just Culture": A Primer for Health Care Executives New York, NY: Columbia University; 2001. Available at http://www.safer.healthcare.ucla.edu/safer/archive/ahrq/FinalPrimerDoc.pdf
[20] Latter C, And Justice For All, *Prevention Strategist,* Winter 47-53.
[21] Griffith K, Column: The Growth of a Just Culture, *The Joint Commission Perspectives on Patient Safety,* 9(12), 8-9.
[22] The success of the Aviation Safety Reporting System is attributed to three factors: reporting is safe (pilots are not disciplined if they report promptly), simple (a one-page report is made), and worthwhile (experts analyze the reports and disseminate recommendations to the pilots and the FAA). Leape L, , Reporting of Adverse Events, *N Eng J Med.* 2002;347:1633.
[23] Boysen PG, Just Culture: A Foundation for Balanced Accountability and Patient Safety, *The Ochsner J.* 2013;13:400-406.
[24] Petschonek S, Burlison J, Development of the Just Culture Assessment Tool: Measuring the Perceptions of Health-Care Professionals in Hospitals, *J Patient Safety* 9(4): 190-197.
[25] Wachter RM, Pronovost PJ Balancing "no blame" with accountability in patient safety. *N Eng J Med.* 2009;361:1401-1406.
[26] The National Quality Forum endorsed a just culture approach as part of a patient safety program. See Safe Practices for Better Healthcare—2010 Update.
https://www.qualityforum.org/Publications/2010/04/Safe_Practices_for_Better_Healthcare_%E2%80%93_2010_Update.aspx
[27] The Board of Osteopathic Medicine and Surgery encourages health care systems to implement a Just Culture into their organizations by integrating the following key elements:

1. Create working health care teams with open communication among team members, recognizing that patients and their family members are active members of the health care team.
2. Encourage each member of the healthcare team to immediately internally report unanticipated outcomes, near misses, and hazardous conditions.
3. Promptly inform the patient and family of unanticipated outcomes, and keep patient and family fully apprised of the process.
4. Apply thorough analysis within facilities to identify factors that contribute to adverse events.
5. Inform the patient and family of the findings of the analysis. If the analysis reveals a medical error, notify the family of the remedial action to be taken, including apologizing for the medical error.
6. Take prompt action with adequate resources to fix system flaws and ensure individual remediation to prevent future patient harm.
7. Share improvements and learning between facilities and with pertinent specialty organizations so that other facilities can improve their systems and prevent future harm.
8. Maintain ongoing staff training to support implementation of all Just Culture elements.

[28] Mello M, Senecal S, Kuznetsov Y, Cohn J, Implementing Hospital-Based Communication-and-Resolution Programs: Lessons Learned in New York City. Health Affairs 2014; 33(1): 30-38.
[29] Mello M, Boothman R, McDonald T, Driver J, Lembriz A, Bouwmeester D, et al., Communication-and-Resolution Programs: the Challenges and Lessons Learned from Early Adopters. Health Affairs. 2014; 33(1): 20-29.

[30] Mello M, Gallagher T, Malpractice Reform—Opportunities for Leadership by Health Care Institutions and Liability Insurers. *N. Eng. J. Med.* 2010;362(15):1353-1356.

[31] The Foundation has the following programs:

1. Clinical Outcomes Assessment Program (COAP), which collects data submitted by all 35 hospitals in the state where cardiac interventions are performed, then producing a quarterly report to the hospitals, and documenting statistically significant improvements in quality, as well as establishing standards by peer consensus and holds institutions accountable for performing to those standards.
2. Surgical Care and Outcomes Assessment program (SCOAP), which involves the surgical community working with stakeholders to create a framework which defines metrics, tracks hospital performance, and reduces variability and errors in surgical care.
3. Obstetrics Clinical Outcomes Assessment Program (OB COAP), the obstetrics version of COAP.
4. The Washington Patient Safety Coalition, which consists of diverse groups working together to improve patient safety through the sharing of best practices related to patient safety.
5. HealthPact, which seeks to transform communication in healthcare, recognizing that poor communication is a fundamental cause of most preventable injuries.
6. The Bree Collaborative, established by the Washington State Legislature, consist of stakeholders appointed by the Governor and is tasked with annually identifying three health care services with high variation in the way care is delivered, that are frequently used, and do not lead to better care or patient health, or have patient safety issues. The group then develops evidence-based recommendations to send to the Health Care Authority to guide the care provided to Medicaid enrollees, state employees and other groups. http://www.qualityhealth.org/

[32] Statement on Medical Liability Reform, Bulletin of the American College of Surgeons, March 1, 2015 (CRPs "show the most promise for promoting a culture of safety, quality and accountability; restoring financial stability to the liability system; and requiring the least political capital for implementation.") Available at http://bulletin.facs.org/2015/03/statement-on-medical-liability-reform/

[33] Krause Ph.D., Thomas R and Hidley, M.D., John, *Taking the Lead in Patient Safety,* John Wiley & Sons, Inc. , 2009 Near-miss reporting is recognized as one of several leading indicators for healthcare safety (p. 42) "Virtually every patient injury is preceded by lower-level decisions and outcomes that increase the likelihood of a safety failure. The catastrophic outcome – a sentinel event, serious injury, or death—can be seen as the tip of an iceberg embedded in a larger architecture of behaviors, practices, and outcomes that made the greater loss predictable." (p. 189) ". . . the companies setting the benchmark for industry safety often have the highest rates of reported near misses because they do not penalize the reporting of near misses and do not directly reward the reduction of incident rates. Instead, they welcome the information stemming from near misses, quickly digest its implications, and act immediately to reduce the likelihood of repeated exposures to hazard." (p. 221) "When a single serious event occurs, it can be inferred with high probability that many related but less severe events have occurred previously. To prevent medical errors and adverse events, small events and their precursors must be taken as seriously as large ones." P. 38

[34] The AHRQ has provided grants to other sites around the country to implement CRPs. The Collaborative for Accountability After Patient Injury consists of leading experts on medical error to exchange ideas and support the growth and spread of CRPs.