



# FIRST

Do No Harm

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**Spring 2019**

Quality and Patient Safety Division, Massachusetts Board of Registration in Medicine

## Quality & Patient Safety Division

The Quality and Patient Safety Division (QPSD) of the Massachusetts Board of Registration in Medicine (Board) uses a collegial approach to help health care facilities (HCF) maintain the highest levels of health care quality.

The QPSD oversees institutional systems of quality assurance, risk management, peer review, and credentialing. These activities are known collectively as the Patient Care Assessment (PCA) Program.

PCA information submitted to the QPSD is confidential and not subject to subpoena, discovery or introduction into evidence. The QPSD does not share its information with any of the Board’s other functions or divisions.

While its ultimate responsibility is public protection, the QPSD operates to be collaborative and educational when working with health care facilities. The QPSD’s purpose is to work with each health care facility to ensure high standards of quality.

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## Introduction

**By Julian N. Robinson, MD**


**Chair, Quality & Patient Safety Committee**

I am happy to have the opportunity to give an update on the Division of Quality and Patient Safety at the Massachusetts Board of Registration in Medicine. There is a lot happening! In the last year we have increased our nurse analyst staffing with the addition of leadership our new director, Dr. Deborah Farina-Mulloy. Deb brings many years of experience in Quality and Safety to our organization and she has many innovative ideas and potential improvements. Dr. Michael Henry will continue in the QPSC member role as vice chair so we can take advantage of his experience as the most recent past chair. There has been some turnover in our committee's membership with the addition of Radiology representative, Dr. Jonathan Kruskal; Chief Medical Officer and Otolaryngologist representative, Dr. Arthur Lauretano; Hospice, Palliative Medicine, and Internal Medicine representative, Dr. Ziad Alfarah; pharmacy representative, Ms. Michelle Chan, and a perspective of patients with our new patient representative, Ms. Zoe Burns.

Change is often an opportunity for both reflection and re-energization and we hope to capitalize on both with these changes. We continue to do our monitoring work and follow-up on healthcare facility Semi-Annual Reports (SARs) and Safety Quality Reviews (SQRs), as well as producing newsletters and advisories. We also want to continue to promote the collegial and consultant-type nature of our organization and our ability to work with healthcare facilities in a productive and innovative fashion. It has been gratifying to have a number of hospitals have reached out to us for support and educational opportunities; we have carried out a number of healthcare facility visits with presentation in this capacity with specialty specific presentation in this role.

We would like to continue to build and expand our quality and safety initiatives with the Betsy Lehman Center, The Massachusetts Coalition for the Prevention of Medical Errors, and the Department of Public Health. We hope our collaboration with these agencies expands statewide initiatives.

We are excited about our spring conference coming up on March 29<sup>th</sup> where we can demonstrate our ability to take a lead in being a Quality Improvement Agency. We are a regulatory, peer-review protected, proactive organization that was established to work with healthcare facilities to improve patient care across the Commonwealth. We will work hard to deliver our agency's message across the state by our future actions in a manner that is both respectful and collaborative.



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## **QPSD Leadership**

### **Julian N. Robinson, MD**

#### **Chair, Quality & Patient Safety Committee**



Dr. Julian N. Robinson trained at Guy's Hospital Medical School in London. His post-graduate training, carried out in the United Kingdom and the United States, was in Obstetrics and Gynecology with further specialty training in Maternal Fetal Medicine. His clinical training was at Guy's Hospital, John Radcliffe Hospital, Oxford, Eastern Virginia Medical School, and Harvard Medical School. He integrated three years of combined clinical and basic science research into his training at the Nuffield Department of Obstetrics and Gynaecology in Oxford. Dr. Robinson is Board Certified in Obstetrics and Gynecology and Maternal Fetal Medicine. He is a fellow of both the American College of Obstetrics and Gynecology and the Royal Society of Obstetrics and Gynaecology. He is actively involved in clinical practice and academic activities with his clinical interests being clinical obstetrics and multiple pregnancy. Julian is Chief of Obstetrics at Brigham and Women's Hospital, is on the Editorial Board of the British Journal of Obstetrics and Gynecology, and is a member of the Massachusetts Board of Registration in Medicine (where he is the Chair of the Division of Quality and Safety). Julian's main professional focus is medical quality and safety: starting from his first attending appointment at Columbia Presbyterian Medical Center in 2000 where he was a member of the Obstetric Quality Assurance Improvement Committee, to his next professional appointment at Newton Wellesley Hospital where he was a member of the Obstetric Quality and Safety Committee, the Peer Review Committee, and the Perinatal Care Committee, to his current appointment at Brigham and Women's Hospital where he chairs the Obstetric Quality Control and Rapid Review Committee, is a member of the Directors of Quality and Safety Committee, and is a member of the Care Improvement Council. He also serves outside the hospital as the chair of the Partner's OBGYN Leaders Committee and on the Case Review Advisory Committee for the Harvard Risk Management Foundation, the CRICO Obstetric Leaders Committee, and the Obstetric Clinical Guideline Committee for the Harvard Risk Management Foundation. Julian is active in Safety and Quality research with manuscripts published on quality improvement, clinical outcomes, and safety benchmarks in journals such as the American Journal of Perinatology, Obstetrics and Gynecology, the British Medical Journal, and the Journal of the American Medical Association.

### **Deborah Farina Mulloy, PhD, RN, CNOR**

#### **Director of Quality and Patient Safety**



Deborah Farina Mulloy joined BORiM Quality and Patient Division in February of 2018. Dr. Mulloy's focus of research is in quality and patient safety. She has over 15 years working in quality and risk, and over 25 years of experience as a perioperative Registered Nurse.

She is the former Associate Chief Nurse of Quality and the Center for Nursing Excellence (CNE) at the Brigham and Women's Hospital (BWH). As the Associate Chief Nurse she had the opportunity to impact patient safety and advance research agenda across the BWH community.

Dr. Mulloy's work on correct site surgery was supported by grant funding from the AORN, ASHRM Foundations, CRICO and the American College of Surgeons. She has been the recipient of recent grants

from the Commonwealth Corporation and BWH BCRIP, where she implemented a continuous virtual monitoring program for patient safety.

Dr. Mulloy's recently published article, *Effect of peripheral IV based blood collection on catheter dwell time, blood collection, and patient response* can be found in the April 2018 journal of Applied Nursing Research.

Dr. Mulloy earned her diploma in nursing from the Peter Bent Brigham Hospital, her BSN from Boston College, and her MSN from the UMass Lowell and holds a PhD degree from the University of Massachusetts Boston.

## **The Quality and Patient Safety Committee (QPSC)**

The Quality and Patient Safety Committee (QPSC) supports the work of the QPSD by working to ensure that health care facilities provide evidence-based quality care and that physicians practicing within the facility are active participants.

The QPS Committee is made up of practicing physicians in various specialties, a member of the Board of Registration in Nursing, a member of the Board of Registration in Pharmacy, a hospital PCA Coordinator, and a patient representative.

## **QPSC Membership**

Julian Robinson, MD, Chair, QPSC, Brigham and Women's Hospital

Michael E. Henry, MD, Vice-Chair, QPSC, Massachusetts General Hospital

Ziad Alfarah, MD, Lawrence General Hospital

James Bono, MD, New England Baptist Hospital

Zoe Burns, Patient Representative

Michelle Chan, RPh, Massachusetts Board of Registration in Pharmacy

Diane Hanley, MS, RN-BC, EJD, Massachusetts Board of Registration in Nursing

Mark D. Hershey, MD, South Shore Hospital

Karen Johnson, BSN, RN, Baystate Medical Center

Pardon R. Kenney, MD, MMSc, FACS, B&W Faulkner Hospital

Jonathan B. Kruskal, MD, Beth Israel Deaconess Medical Center

Arthur Lauretano, MD, Lowell General Hospital

Marc S. Rubin, MD, North Shore Medical Center

Melissa Sundberg, MD, Boston Children's Hospital

## **QPSD Staff**

Deborah Farina Mulloy, PhD, RN, CNOR, Director

Loretta J. Cooke, BSN, RN, LNC, CMBI, Quality Nurse Analyst

Daniela Brown, MSN, RN, CIC, Quality Nurse Analyst

Mali Gunaratne, Administrative Assistant

## QPSD Spring Conference

### The Board of Registration in Medicine's Quality & Patient Safety Spring Program

Collaborating to Promote Safe Practices ...expedite the learnings

**March 29, 2019**

Physicians: Category I CME- 4.0 hours

Nurses: Contact Hours: 4.0 hours

**LOCATION:** UMASS Medical Center, Worcester, Albert Sherman Center, ASC Auditorium

**DATE & TIME:** Friday March 29<sup>th</sup>, 2019 8:00 a.m. -12:30 p.m. (Registration 7:30-8:00 a.m.)

#### PCA Program Overview

Treating Sepsis: A Team Effort	Paul C. Chen, MD, MBA, FACEP B&W Faulkner Hospital
Converting a "Near Miss" into Systems Improvement in Obstetrics	Julian Robinson, MD Brigham & Women's Hospital
A Case of Delay in Treatment and Postoperative Mortality	Marc Rubin, MD North Shore Medical Center
Maximizing Patient Safety while Minimizing Provider Risk	Ellen Epstein Cohen, Esq Partner, Adler, Cohen, Harvey, Wakeman & Guekguezian LLP
Psychiatric Patients in The Emergency Room: A Case Presentation	Michael Henry, MD Massachusetts General Hospital

- **Registration is free of charge.** Registration will close when event reaches capacity.
- To register send email to [QPSD.Conference@state.ma.us](mailto:QPSD.Conference@state.ma.us). Please include your name and credentials, organization, and preferred telephone number
- Breakfast /coffee will be on your own.

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- ✓ Dr. Mulloy presented at the Massachusetts Society for Healthcare Risk Management (MSHRM) Fall Conference. An overview of QPSD regulations, data trends and current work on sepsis was presented.
  - ✓ QPSD is a participating member of the Massachusetts Sepsis Consortium. This public-private partnership of over 30 organizations represent government, health care, and advocacy to develop guidance for the early identification and treatment of sepsis and to raise public awareness of the signs and symptoms of sepsis. <https://www.betsylehmancenterma.gov/initiatives/sepsis>

## SQR Learnings Related to Self-Harm Events

QPSD has received several SQRs involving patient self-harm. Trends that have been identified include:

- Employees unaware of institutional policies and procedures regarding one-to-one observation, patient searches, patient belongings, and visitors, particularly in Emergency Department and Behavioral Health setting. This is despite employees signing annual attestation that policies were reviewed.
- One-to-one observations being performed by untrained staff.
- Face and hands not in view of observer at all times leading to self-injury.
- Visitors being allowed to bring belongings into unit/room to visit patient.
- Patients not searched after expressing suicidal ideation with subsequent self-harm by ingestion of foreign object/medication and/or laceration with sharp object (sometimes hidden in body cavity).
- Increase in ligature-related self-harm (canvas and leather belts, bedsheets, intravenous tubing, shoe laces, window blinds).
- Patient left unobserved in bathroom by one-to-one observer to allow for privacy despite policy.

QPSD recommends leadership engages with staff in the development of policies. All policy updates, revisions, or new must have a process in place to review with staff on an annual and ongoing basis.

Healthcare facilities should ensure that policies have been updated to reflect the Joint Commission's recommendations noted in the November 2017 Perspectives Preview: Special Report: *Suicide Prevention in Health Care Settings* and in the January 2018 *Suicide prevention recommendations for non-hospital behavioral health care settings* update.

### Links:

Suicide Prevention in Health Care Settings:

<https://www.jointcommission.org/issues/article.aspx?Article=GtNpk0ErgGF%2b7J9WOTTkXANZSEPXa1%2bKH0%2f4kGHCiio%3d>

Suicide prevention recommendations for non-hospital behavioral health care settings:

<https://www.jointcommission.org/issues/article.aspx?Article=22c4BduTsGa0F2SF8SiB29cF6oJ0wJvvGn9lr1saABk%3D>

## Type IV SQR Reporting Guidance

The Quality and Patient Safety Division (QPSD) has received feedback from health care facilities (HCF) regarding Type IV events. This information is intended to provide guidance to PCA Program Coordinators in the interpretation of events that require reporting to QPSD, specifically Type IV events.

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HCFs are required to report Major Incidents as defined in 243 CMR 3.08(2)(a) through (d) to the Board of Registration in Medicine (BORiM). The following events must be reported on a quarterly basis to the BORiM's Quality and Patient Safety Division (QPSD):

1. Maternal deaths that are related to delivery
2. Death in the course of, or resulting from, elective ambulatory procedures
3. Any invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity or body part
4. All deaths **or** major **or** permanent impairments of bodily functions (other than those reported above) that are not ordinarily expected as a result of the patient's condition on presentation.

Preventability of an event is determined after an internal review is conducted. The determination should not impact reporting of the event to QPSD if the event meets the criteria for a major incident as defined by the four types of major incidents listed above. Identification of an event as any one of the four types of major incidents does not indicate that the outcome was preventable or that it resulted from substandard medical practice. Whether an event is determined to be preventable or non-preventable, opportunities for improvement may be identified and a corrective action plan may be indicated.

### Type IV Event Reporting

The question of reporting of Type IV events can be challenging. Safety and Quality Review (SQR) reports provide BORiM with reassurance of a HCF's quality-assurance processes. QPSD may request clarification of the event in order to determine if the internal review and subsequent action plan was comprehensive; however QPSD is primarily focused on a HCF's review and response to the event rather than the event itself. In determining whether an event meets reporting criteria, it is recommended that the following questions be considered:

#### **What was the admission plan for this patient? Did it change and why?**

*Unexpected events that caused a deviation in the admission and/or discharge plan for the patient likely require reporting if temporary patient harm **or** permanent patient harm **or** death occurred.*



**Are there system changes being redesigned and implemented?**

*If the event resulted in a change in systems or identified process issues with standard systems, credentialed providers, or employees; it likely requires reporting.*

**Is the event likely to be reported upon by the news media?**

*Events that are or will likely be reported upon by the news media will likely require reporting. If an event is reported upon by the news media, BORiM will verify that a SQR regarding the event has been submitted, or it will contact the HCF for additional information. BORiM recommends HCFs be proactive and report events on a timely basis (within 30 days of the calendar quarter that the event occurred). The HCF may also contact QPSD to inform them of the event, and that a SQR is pending.*

**Did the event involve clinicians who did not adhere to process, protocol, or evidence-based practice that result in temporary or permanent patient injury or death?**

- *If peer-review and /or internal review indicate that the standard of care was not met by credentialed or non-credentialed providers or there is a concern regarding the judgement or practice of the clinician, it likely requires reporting.*
- *Do not provide identifiable clinician information or identified provider-metrics data in the SQR.*
- *For events that involve a credentialed provider, please include de-identified quality-metrics data and/or a statement indicating that the provider is in good standing, has met all Ongoing Professional Practice Evaluation (OPPE) standards as set by their Department, and compares as expected to peers in the SQR. If this is not the case, a brief statement regarding plan of correction (for example, additional education and/or mentoring, collegial intervention, or Focused Professional Practice Evaluation if applicable) should be included in the SQR.*
- *QPSD does not share any of this information with other divisions of BORiM.*

**Did the event involve multi-disciplinary providers where there was a gap in process, communication, and/or coordination of care that may have led to a delay in diagnosis/treatment or a missed finding?**

*Communication or process gaps that contribute to delays in diagnosis and/or treatment and cause temporary or permanent patient harm or death require reporting.*

**Did the event meet the criteria for a Serious Reportable Event (SRE) as defined by the National Quality Forum?**

*If yes, the event should be reported to BORiM as an SQR.*



## Near-Miss Events

Near-miss events are not required to report, however, if the near-miss events resulted in a significant process improvement or initiative, QPSD recommends reporting of the event as a near-miss event. Near-miss events which result in system-wide performance-improvement initiatives are excellent examples to report to the BORiM. Reporting of near-miss events is encouraged but not required.

## Examples of Types of Events Reported in Safety and Quality Reviews

### Acute-Care and Non-Acute Care Hospitals

- Sepsis-delay in early recognition/treatment in ED and inpatient settings
- Lack of pediatric sepsis protocols leading to delay in recognition/treatment
- Electronic Medical Record (EMR) related events during and after transitions in medical record implementation
- Inpatient self-harm
- Focused history and physical in emergency department contributing to unidentified diagnosis (differential diagnosis list not comprehensive)
- Management of emergent events in Labor and Delivery including post-partum hemorrhage, pregnancy-induced hypertension (PIH), maternal-cardiopulmonary events, shoulder dystocia
- Unexpected neonatal injury at delivery
- Events occurring on weekend/off shifts with staffing/coverage contributing to event
- Missed diagnoses in patients with substance abuse history
- Radiology/ Virtual Radiology misinterpretation or late confirmation
- Percutaneous Gastrostomy Tubes malposition, often leading to sepsis
- EMR Cut and Paste functionality leading to lack of re-assessing and editing plan of care
- Falls in Geriatric-Psychiatric Units

### Ambulatory/Clinics

- Wrong-site, wrong-patient, wrong-procedure surgery specifically dermatology, ophthalmology, and radiation oncology
- Insufficient pre-admission testing and work-up, inconsistent with evidenced-based practice
- Not following institutional policies

QPSD welcomes questions regarding events and criteria for reporting. A HCF will not be penalized for reporting a case, but in fact, will be acknowledged for their transparency in reporting. SQR reporting provides BORiM with information regarding a facility's quality assurance and peer-review process. Please contact the Nurse Analysts at BORiM with any questions.

To be added to the QPSD Newsletter and advisory mailing list, update hospital contact information, submit an article, request an SQR form, or obtain additional information, contact QPSD: [mali.gunaratne@massmail.state.ma.us](mailto:mali.gunaratne@massmail.state.ma.us) or (781) 876-8243.