MARYLAND DEPARTMENT OF HEALTH

FY2018 Patient Safety Update

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Overview of Patient Safety Regulations

- COMAR 10.07.06, Maryland Patient Safety Program
- Enacted in March, 2004
- Requires mandatory hospital reporting of Level 1 adverse events (those that cause death or serious disability, defined as lasting seven days or still present on discharge).
- Requires disclosure to patient/family.
- Also requires submission of RCA within 60 days of reporting.
- Over 3500 adverse events reported since 3/2004.

FY 2018 Events

- 222 Level 1 events affecting 259 patients.
  - 22% increase from FY17's 207 total events
- Forty delays in treatment, with 90% mortality.
  - 38% increase from FY17.
- Thirty-three surgical events including 19 RFBs.
  - More than double FY17 (15/10)
- Nine airway events.
  - More than double the four reported in FY17
- Eight suicides, one serious attempt.
- Forty-eight falls with 8% mortality.
- Forty-seven HAPU reports

In FY18, 1.4 people per week died in Maryland hospitals of preventable adverse events. This number represents a 40% increase from a five-year average.

Surgery Deaths

- Six patients died of unnoticed or undiagnosed hemorrhage after minor surgical procedures; two following liver biopsies, one following hernia repair, and three following lap cholecystectomy.
- Two other surgical patients died during or immediately post-op HD access placement for which they'd had inadequate pre-op clearance.
- Two patients developed unnoticed bowel ischemia following surgery.

Critical Values

- Coumadin patient with INR consistently >15 w/3 rechecks, widely assumed to be an error.
- Pt. told ED she had taken parent's Glipizide to get high. No one asked how much was taken or when. No glucose check.
- K+ >5 on admission. K+ over next 3 days assumed to be hemolyzed because it was high, but no "accurate" specimen obtained. Returned to ED day after d/c in full arrest with K+ >8.
- Free air on head CT not reported to MD because it was not in the critical values policy.

Vascular Access

- Four deaths were caused by discontinuing femoral vascular access and one death from an air embolus from an IV.
- One patient had R/P hemorrhage after cardiac cath. RN ignored c/o back pain and worsening MS overnight, assuming this was patient's baseline.
- One patient pulled out an old groin line and bled out.
- One patient had a femoral line inserted into the artery by mistake. Exsanguinated when the line was pulled.
- One patient exsanguinated during HD.
- ED patient about to be discharged when RN noted an order for a fluid bolus. Gave it with a pressure bag, causing a fatal air embolus.

Head Injuries and Mental Status

- Eight fatalities:
- Two died following falls with no neuro assessments/CTs.
- Three patients died following same cerebral vascular procedure. Done with little clinical justification, multiple violations of P&P and standards of care, and poor real-time QA monitoring.
- Three patients died when mental status deterioration was assumed to be baseline.

Airway Misadventure

- Five patients suffered inadvertent extubations, and died when airways could not be re-established.
- One young patient septic from a throat abscess was on observation status rather than admitted. Was A&O so deteriorating VS were not acted upon. No urgency to care, needed emergency intubation two days later but was too septic to survive multiple intubation attempts.
- One patient with severe OSA had no precautions taken following anterior cervical laminectomy. Had been on OSA protocol in PACU (continuous pulse ox) but not continued on the floor. Assigned RN did not know he had OSA.

Anoxic Injuries

- Five patients suffered permanent anoxic injury. Two by hanging/asphyxiation in suicide attempts and three by airway misadventures.
- One patient with known difficult airway was extubated in the ICU following CABG by an intensivist who wanted to get it done during the 20 minutes before the next patient arrived.
- One young vent-dependent quadriplegic became disconnected from the vent for upwards of 10 minutes without anyone in ED noticing.
- Third patient was on high flow O2 and was assisted to BSC with no leads on and no O2. Found unresponsive 30 minutes later.

Monitors

- Twelve deaths associated with delayed reaction to monitor alarms.
- Similarities:
  - Poor communication between tele and nursing with unclear communication pathways.
  - Lack of urgency in reacting to alarms.
  - Lack of, or delayed assessments of changes in patient condition despite notification from CNAs.
  - Lack of empowerment of CNAs and tele techs to go up the chain of command.
  - Equipment challenges, some self-induced.

Mother-Baby

- Five reported events involving L&D, resulting in three maternal deaths and three fetal/neonatal deaths.
- L&D unit had upgraded their FHR monitors the week before but monitors no longer alarmed for coincident mother/fetal rhythms and did not show both on screen, leading RN to mistake FHR for maternal. None of the involved RNs had FHR certification.
- Two maternal post-partum deaths, both with lack of f/u of S&S of hemorrhage.
- Pregnant woman had MVA and suffered retroperitoneal bleed. 90 minute delay in getting to the OR after FHR dropped.

Medications

- One BH patient suffered a fatal drug interaction when he took a peer's medication. RCA found that, even though this was a unit with a lot of substance abusers, the RNs were not in the habit of confirming med ingestion so the patients were swapping pills.
- One elderly patient fell and suffered a fatal SDH after being given Ambien to sleep. No additional fall precautions were implemented and patient was newly on Eliquis.
- Patient stopped antiplatelet aggregators for cardiac procedure. Not restarted. Patient had STEMI 3 days later.

The Problem:

- Patient deaths and injuries from staff use of unapproved restraint tactics and weapons such as clubs, handcuffs, and pepper spray.
- Assumption that off-duty law enforcement officers (LEOs) employed by the hospital already know how to safely restrain people.
- Lack of clinical oversight of restraint practices and use of weapons. Slippage of roles.
- Unclear identification of people “presenting for treatment” has led to EMTALA violations when security turns “disruptive” people away from EDs.

Patient 1

- Brought in by police for violent, disruptive behavior. Initially cooperative so police left.
- Patient tried to leave when he found out he was to receive an IM antipsychotic.
- Patient died when he was restrained prone by security for 10 minutes while they waited for the police.
  - ED had no seclusion room but was adjacent to inpt. BHU with a seclusion room.
  - Security personnel had had no training in safe use of restraints, and no CPR. Could not recognize distress.
  - No/ineffective clinical oversight. RNs deferred to security, MD not notified about patient's behavior until code blue called.
- RCA made a point of mentioning that patient was still yelling and saying he couldn't breathe while prone on the floor.

Patient 2

- 350+ lbs man brought in on EP after threatening a family member.
- Refused to have blood drawn. Not violent. Sitting on edge of stretcher in a private room in the psych ED.
- Five security staff pepper-sprayed him, dragged him prone onto the ground, and handcuffed the patient.
- Code team had a very difficult time trying to resuscitate him due to pepper spray and were ultimately unsuccessful.
- Stretcher with patient and code team became trapped between two exit doors because one had to be closed before the other would open.

Other Injuries

- “Annoying” BH patient was hit several times by security person after RN asked security to watch the patient.
- Pt. in ED waiting room, mad and loud about wait times. Punched by security during a take down.
- Three patient suffered fractures and other injuries while intervening in patient to patient assaults when staff failed to intervene.
- Security person fractured a patient’s arm while holding the arm behind the patient’s back while “escorting” the patient to the seclusion room.

Regulatory Language

- **§482.13(e)** Standard: Restraint or seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.
- **§482.13(e)(3)** - The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.
- **§482.13(e)(4)(ii)** - implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.
- All of the training requirements under **§482.13(f)(2)(i to viii)** must be met.

Interpretive Guidance

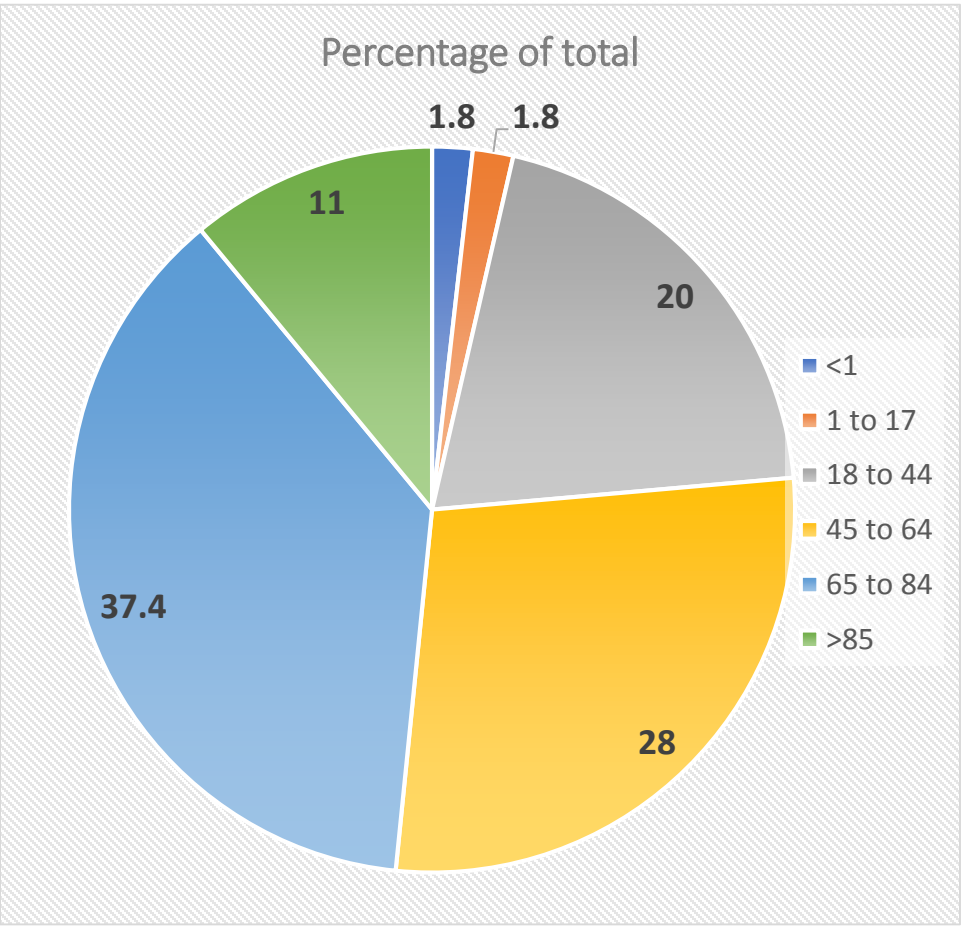
- "CMS does not consider **the use of weapons** in the application of restraint or seclusion as a safe, appropriate health care intervention. For the purposes of this regulation, the term "weapon" includes, but is not limited to, pepper spray, mace, nightsticks, tazers, cattle prods, stun guns, and pistols. Security staff may carry weapons as allowed by hospital policy, and State and Federal law. However, the use of weapons by security staff is considered a law enforcement action, not a health care intervention. CMS does not support the use of weapons by any hospital staff as a means of subduing a patient in order to place that patient in restraint or seclusion. If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, or visitor) to protect people or hospital property from harm, we would expect the situation to be handled as a criminal activity and the perpetrator be placed in the custody of local law enforcement.
- The use of handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices applied by non-hospital employed or contracted law enforcement officials for custody, detention, and public safety reasons are not governed by this rule. **The use of such devices are considered law enforcement restraint devices and would not be considered safe, appropriate health care restraint interventions for use by hospital staff to restrain patients.** The law enforcement officers who maintain custody and direct supervision of their prisoner (the hospital's patient) are responsible for the use, application, and monitoring of these restrictive devices in accordance with Federal and State law. However, the hospital is still responsible for an appropriate patient assessment and the provision of safe, appropriate care to its patient (the law enforcement officer's prisoner)."

Our Stance

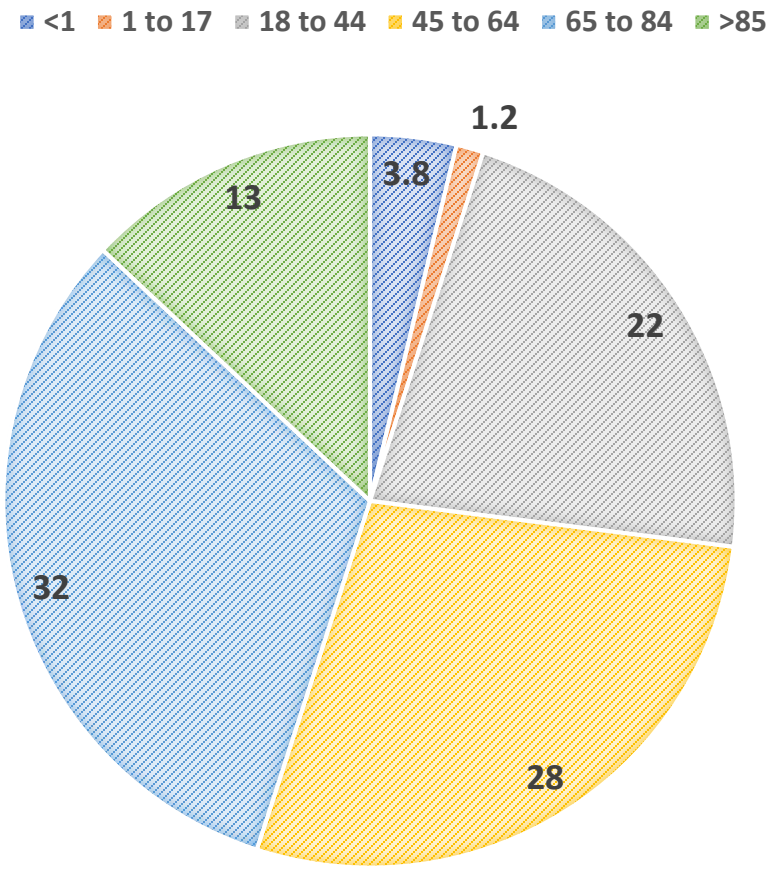
- Since CMS considers the use of weapons to be solely the purview of LEO and considers them inappropriate for employed staff to use, any use of weapons by hospital-employed staff whether clinical or non-clinical is impermissible.
- Additionally, all of the training requirements for restraints must be met for anyone putting hands on a patient, including contracted LEOs.
- Training in EMTALA must be done with anyone who is in a position to turn people away from the hospital.
- All hands-on interventions require continuous clinical oversight.
- Prone restraints are **never** appropriate.

Fatalities per Age

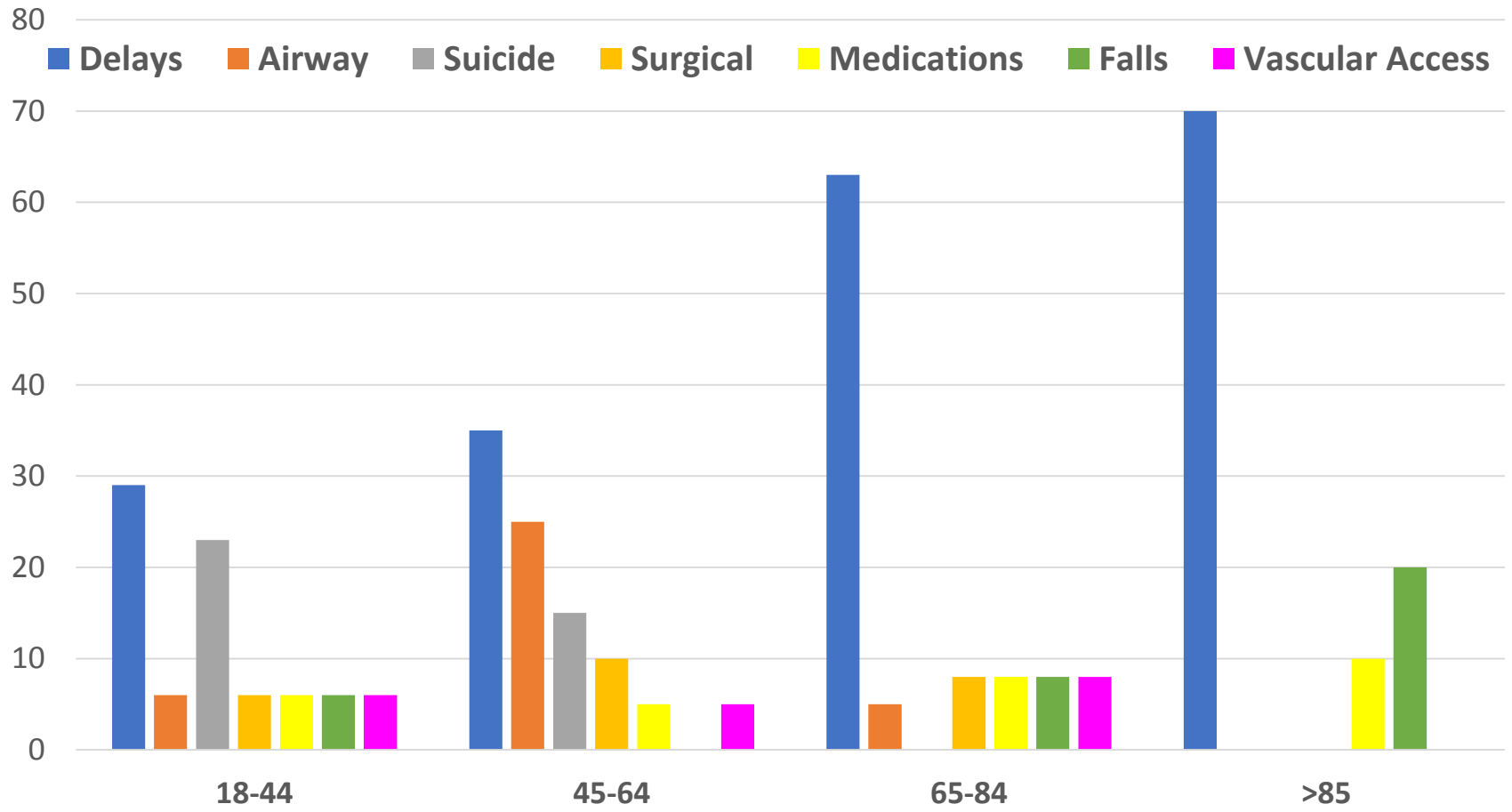
Percentage of Total Events



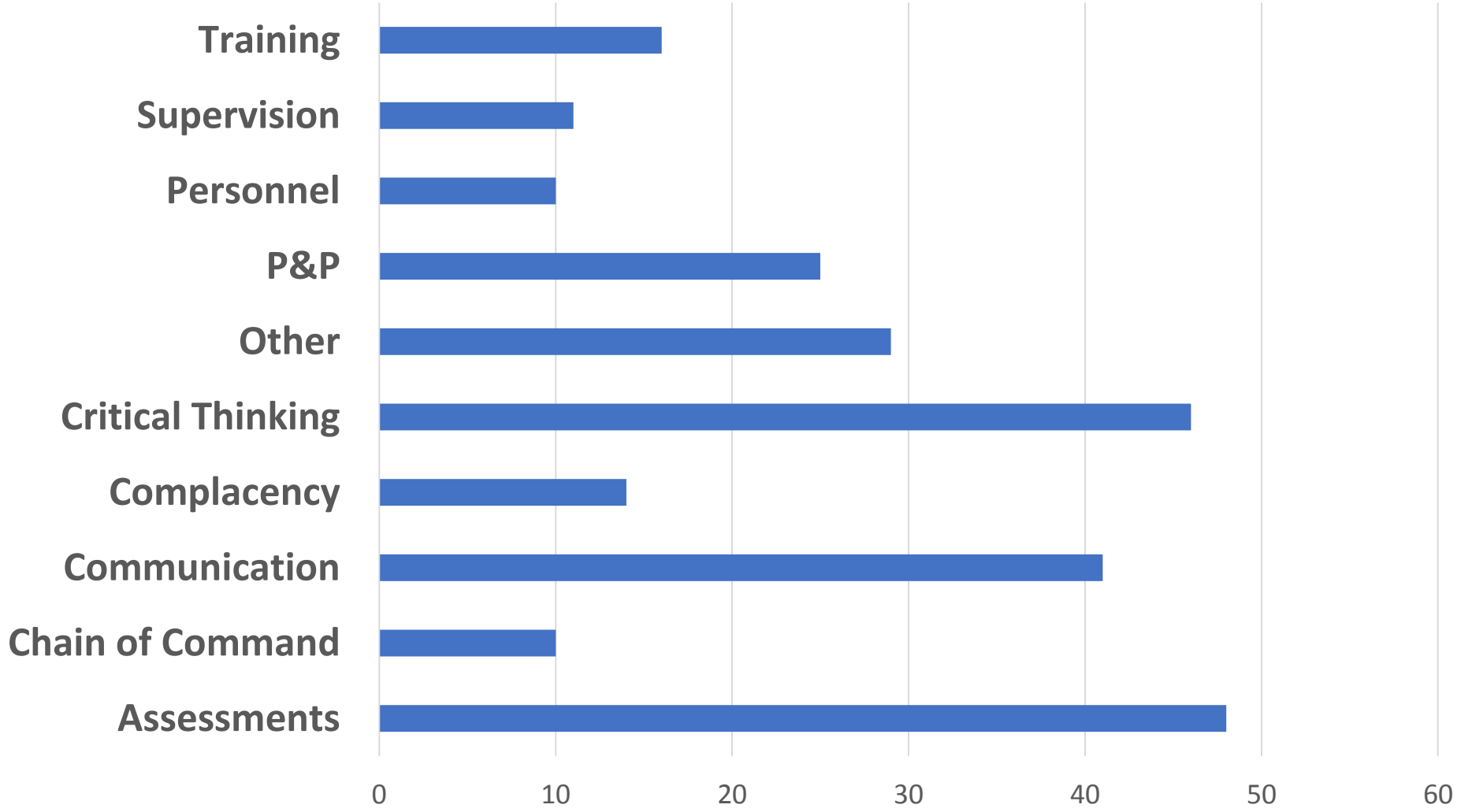
Percentage of Total Fatalities



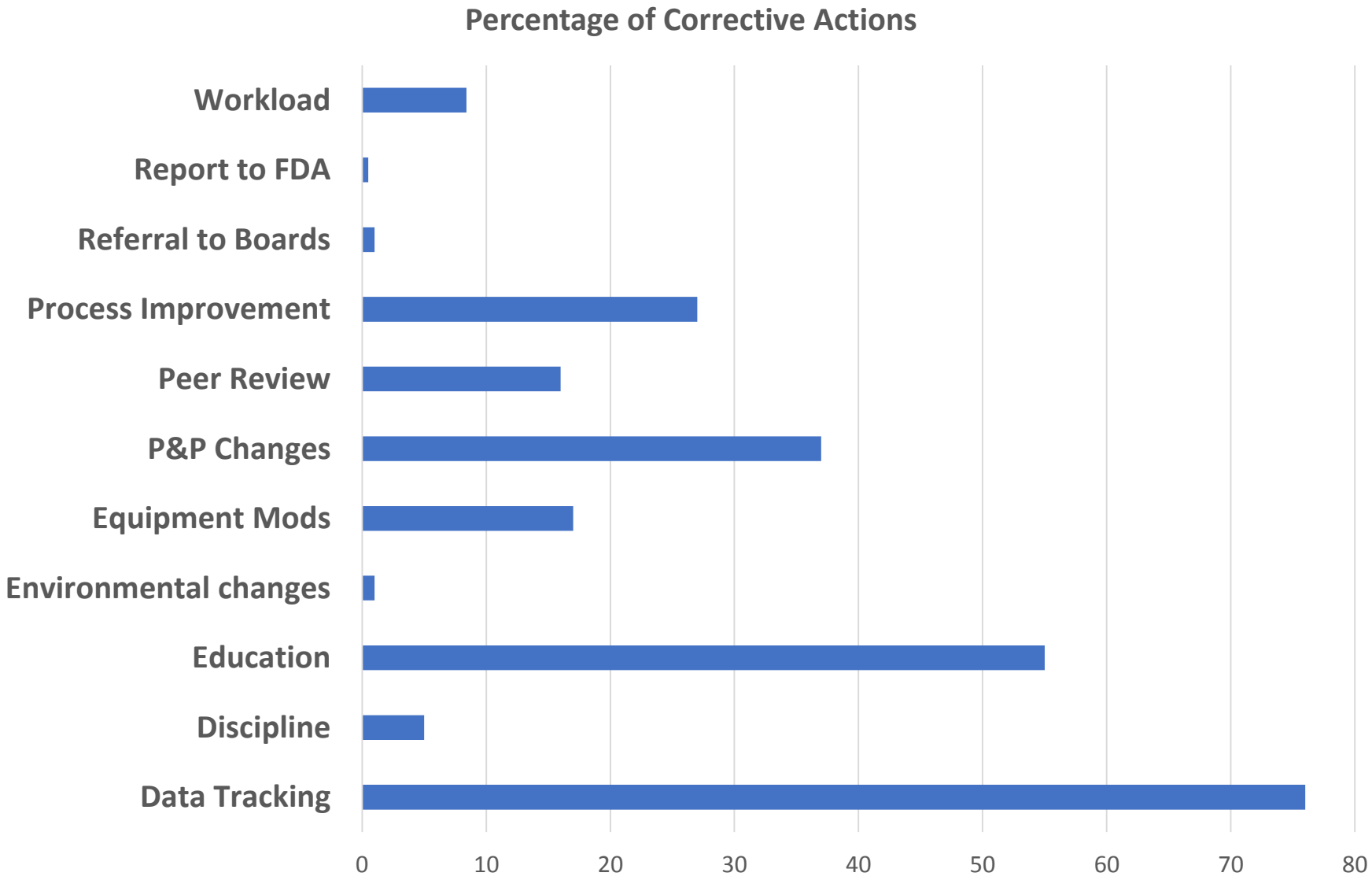
FY18 Causes of Death per Age Bracket



Root Causes for FY18 Events



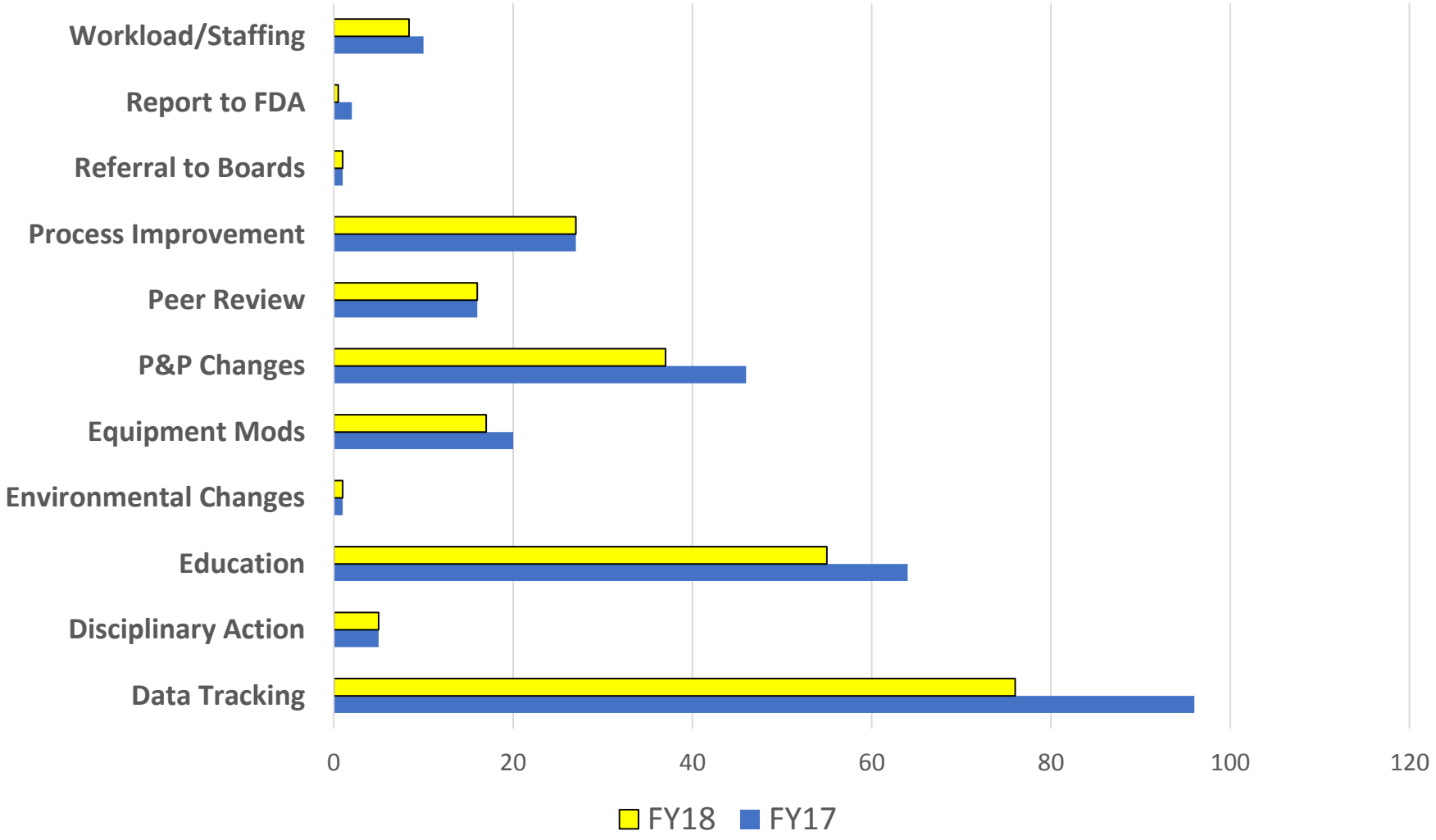
FY18 Corrective Actions



OHCQ Office of Health Care Quality

MARYLAND Department of Health

FY17/FY18 Corrective Actions



FY19 To-date Update
(July 1, 2018 through February 28, 2019)

- 148 Level 1 events with 34 fatalities (overall 23%)
  - 27 surgical events with 5 fatalities
  - 3 suicide attempts with 1 fatality
  - 4 maternal or fetal deaths associated with the birth process.
  - 8 airway events with 5 fatal and 3 anoxic injuries
  - 34 falls, 2 fatal head injuries
  - 15 delays in treatment with 11 fatalities (73%)

Guardian Program

- Started by Sepsis Committee at UM BWMC with goal to intervene early to reduce morbidity and mortality associated with sepsis. Went live in June 2017.
- Experienced ICU RNs monitor 15 parameters for all adult patients real-time.

Parameters

- EWS
- 6 Vital Signs
- Oxygen level-SpO2
- WBC
- CO2
- Bands
- Anion Gap
- Lactate
- ETCO2
- Code Status

Outcomes

- 30% reduction in sepsis deaths. This is over a time frame where the number of diagnosed cases almost doubled.
- This reduction in mortality made the case that these nurses should be permanently assigned to this work.
- Huge satisfier for staff, both in M/S and the ICU.

Resources

- http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html?DLPage=1&DLSort=0&DLSortDir=ascending Go to the Appendices (pdf) and click on Appendix A for the Hospital A-Tags.
- http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html for the S&C memos.

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