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CMDA- The Colorado Society for Post-Acute and Long-Term Care Medicine
(Colorado Medical Directors Association)

Medical Errors and the Law

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Speaker Disclosures

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Alan C. Horowitz, Esq., RN has no relevant financial relationship(s).

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Learning Objectives

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By the end of the presentation, participants will be able to:

- Understand that there are both mandatory and voluntary reporting requirements for disclosing medical errors
- Appreciate that medical errors are generally caused by flawed systems
- Explore how medical errors (and near misses) can promote a culture of safety rather than blame and shame
- Understand how a defendant in a criminally negligent homicide case involving a medication error was found not guilty
- Learn how Colorado's "Apology Law" can reduce litigation for medical errors

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The Definition of Medical Error

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- Commission or omission of an action with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, **independent of whether there were any negative consequences**
- Preventable errors may be more common in older adults
- May be particularly true in nursing homes

Wu AW, Cavanaugh TA, McPhee SJ, Lo B, Micco GP. To tell the truth: ethical and practical issues in disclosing medical mistakes to patients. J Gen Intern Med. 1997;12:770-775.

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How Big is the Problem?

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- 44,000 – 98,000 deaths/yr. IOM *To Err is Human: Building a Safer Health System* (1999)

- 440,000 deaths/yr. Leapfrog Group, *Journal of Pt. Safety* (2013)

- >250,000 deaths/yr. due to medical error in the U.S (*Medical error—the third leading cause of death in the US*) BMJ May 3, 2016

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How Big is the Problem? OIG Report

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- *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, Report OEI-06-11-00370 (February 27, 2014)

- "An estimated 22 percent of Medicare beneficiaries experienced adverse events during their SNF stays.

- Physician reviewers determined that 59 percent of these adverse events and temporary harm events were clearly or likely preventable. They attributed much of the preventable harm to substandard treatment, inadequate resident monitoring, and failure or delay of necessary care. Over half of the residents who experienced harm returned to a hospital for treatment, with an estimated cost to Medicare of $208 million in August 2011. This equates to $2.8 billion spent on hospital treatment for harm caused in SNFs in FY 2011."

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Is There a Disconnect?

- Survey of more than 2,600 physicians from US and Canada revealed:
- 98% of physicians endorsed disclosing serious errors to patients, but…
- Only 58% made full disclosure
- Can we learn from the FAA's ASRS?

- Source: Gallagher TH, Waterman AD, Garbutt JM, et al.*US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. Arch Intern Med 2006;1661605-11.*

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Aviation Safety Reporting System

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- Federal Aviation Safety Reporting System (ASRS)
  - Designed by NASA
  - Voluntary reporting of events/incidents and near misses
  - Confidential
  - Non-punitive
  - Collects and analyzes data
  - Independent (operated by NASA, no enforcement ability)
  - Immunity (limited)
  - Enhances human factors research, makes recommendations
  - Served as model for other industries re: error/near miss reporting

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Mandatory versus Voluntary Disclosure?

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- Federal Law
  42 CFR § 483.10(g)(14)
  PSQIA of 2005
- State Law
- Contractual

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Mandatory versus Voluntary Disclosure?

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- 42 CFR 483.10(g)(14)
- A facility must immediately inform the resident; consult with the resident's physician; and notify, consistent with his or her authority, the resident representative(s), when there is –
- (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
- (B) A significant change in the resident's physical, mental, or psychosocial status (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
- (C) A need to alter treatment significantly (that is, a need to discontinue or change an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

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Medical Errors and Criminally Negligent Homicide: Two Different Outcomes

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Vanderbilt University Medical Center, TN (RN found Guilty)

Rx: Versed; RN administered vecuronium instead of versed.

Centura St. Anthony Hospital, Denver, CO (RN found Not Guilty)

Rx: “Penicillin G benzathine150,000 units IM.”

Jury was shown all the systems problems

No need for Rx (attending physician was on vacation)

Ten-fold increase in dose (1,500,000 units dispensed)

Penicillin was given IV instead of IM

Other mistakes were made

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“Former nurse guilty of homicide in medication error death
A former Tennessee nurse has been found guilty of criminally negligent homicide in the accidental death of a patient because of a medication error.”

ByTRAVIS LOLLER Associated Press
March 25, 2022, 2:14 PM

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A Legal Nightmare: Denver Nurses Indicted in Newborn Death

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ISMP provided a systems analysis and expert testimony at trial. ISMP identified *over 50 different failures in the system* that allowed this error to occur, go undetected,

Rx: “Penicillin G benzathine 150,000 U IM.”

Latent Failures:

Limited knowledge about this nonformulary drug. The pharmacist consulted both the infant’s progress notes and Drug Facts and Comparisons to determine the usual dose of penicillin G benzathine for an infant. However, she misread the dose in both sources as 500,000 units/kg, a typical adult dose, instead of 50,000 units/kg. Consequently, the pharmacist also incorrectly read and prepared the order as 1,500,000 units, a ten-fold increase

A unit dose system was not used in the nursery, the pharmacy dispensed the tenfold overdose in a plastic bag containing two full syringes of Permapen 1.2 million units/2 mL each, with green stickers on the plungers to "note dosage strength."

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A Legal Nightmare: Denver Nurses Indicted in Newborn Death

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The Neofax monograph on penicillin G did not specifically mention penicillin G benzathine; instead, it noted the treatment for congenital syphilis with aqueous crystalline penicillin G IV slow push or penicillin G procaine IM. Nowhere in the two-page monograph was penicillin G benzathine mentioned, and no specific warnings regarding "IM use only" for penicillin G procaine and penicillin G benzathine were present.

Believing that aqueous crystalline penicillin G and penicillin G benzathine were the same drug, the nurse practitioner concluded that the drug could be safely administered IV. The nurses knew that, while taught that only clear liquids can be injected IV, certain milky white substances, such as IV lipids and other lipid-based drug products, can be given IV. Therefore, they did not recognize the problem of giving penicillin G benzathine, a milky white substance, intravenously.

While preparing for drug administration, neither nurse noticed the tenfold overdose, and neither noticed that the syringe was labeled by the manufacturer "IM use only." The manufacturer's warning is very difficult to see because it is not prominently placed, and the syringe must be rotated 180° away from the drug name to view it. The nurses began to administer the first syringe of Permapen slow IV push. After about 1.8 mL was administered, the infant became unresponsive, and resuscitation efforts were unsuccessful.

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Legal Defense: It Was a Flawed System, Not a Flawed Nurse

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Is Honesty the Best Policy?

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A Better Way?

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- Full Disclosure
- Compensation (as appropriate)
- Extreme Honesty
- “I’m Sorry”
- CANDOR
- Apology laws

Currently 39 States and D.C. Have "Apology Laws"

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- ✓Apology laws have increased physician apologies, expedited claim resolution, and decreased the number of claims and payments for malpractice claims.

- ✓Few authoritative studies are available given variables (partial vs. full apology laws, surgical vs. non-surgical, definition of "adverse event" or "error," only errors with adverse outcomes).

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Communication and Optimal Resolution (CANDOR) - MedStar Health

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- ✓Engage patients and families in disclosure following adverse events.
- ✓Implement a Care for the Caregiver program for providers involved in adverse events.
- ✓Investigate and analyze an adverse event to learn from it and prevent future adverse events.
- ✓Review and revise the organization’s current processes to align with the CANDOR process.
- ✓Establish a resolution process for the organization.

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Communication and Optimal Resolution (CANDOR)

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“MedStar saved an estimated $70 million between 2012 and 2017 by reducing costs related to patient safety events, including medical liability payments.”

“The programs have reduced their medical liability because the most important thing about CANDOR besides the open and honest communication is that there’s a requirement for learning,”

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University of Michigan Health System (UMHS) has fully disclosed and offered compensation to patients for medical errors (since 2001)

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Results:

- ✓After full implementation of a disclosure-with-offer program, the average monthly rate of new claims decreased from 7.03 to 4.52 per 100,000 patient encounters
- ✓The average monthly rate of lawsuits decreased from 2.13 to 0.75 per 100,000 patient encounters
- ✓Median time from claim reporting to resolution decreased from 1.36 to 0.95 years.
- ✓Average monthly cost rates decreased for total liability, patient compensation, and non-compensation-related legal costs.
- ✓since implementing the “I’m sorry” strategy, malpractice claims against UMHS fell from 121 in 2001 to 61 in 2006. 50% decrease in claims

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Communication and Resolution Programs (CRP)

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“Anecdotal reports from the University of Michigan Health System and other early adopters of CRPs suggest that these programs can substantially reduce liability costs and improve patient safety.”

Mello MM, Boothman RC, McDonald T, et al. *Communication-and-resolution programs: the challenges and lessons learned from six early adopters*. Health Aff 2014; 33: 20–29.

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How Does Colorado Treat Admissions & Apologies?

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Colorado Revised Statutes Title 13. Courts and Court Procedure § 13-25-135. Evidence of admissions--civil proceedings--unanticipated outcomes--medical care

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- "In any civil action brought by an alleged victim of an unanticipated outcome of medical care, or in any arbitration proceeding related to such civil action, any and all statements, affirmations, gestures, or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence which are made by a health-care provider or an employee of a health-care provider to the alleged victim, a relative of the alleged victim, or a representative of the alleged victim and which relate to the discomfort, pain, suffering, injury, or death of the alleged victim as the result of the unanticipated outcome of medical care shall be inadmissible as evidence of an admission of liability or as evidence of an admission against interest."

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Colorado Candor Act (2019)

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- A brief overview of the process is as follows:

- The process is initiated by the health care provider.
- The written notice must be sent to the patient within 180 days of the incident.
- The notice must include specific details about the patient’s rights and the nature of the communications/discussions under the Colorado Candor Act.
- Under the Colorado Candor Act, health care providers and facilities may investigate and communicate about how the incident occurred and what steps are being taken to prevent a similar outcome in the future.
- As part of their assessment, health care providers and facilities can determine whether an offer of compensation is warranted.
- To facilitate open communication under the Colorado Candor Act, discussions and offers of compensation under the Act are privileged and confidential.

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Extreme Honesty Policy – Veterans Administration Medical Center (VAMC), Lexington, KY

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In 1987, the Veterans Affairs Medical Center (VAMC) in Lexington, Kentucky instituted a then-controversial program of disclosing medical errors and apologizing and compensating patients for them. Apart from the ethical and moral rationale for transparency and full disclosure, the VAMC believed that a policy of extreme honesty or full disclosure might reduce malpractice claims.

Twelve years after the VAMC instituted its policy, it reported that hospital administration and staff supported it and, counterintuitively, it yielded unanticipated financial results.

Source: *Extreme honesty: Medical errors and full disclosure,* Alan C. Horowitz, iAdvanceSenior Care, May 31, 2016.

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Veterans Health Administration: Directive 1004.08.

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- ✓Revised policy to ensure consistent practice in disclosing adverse events related to a patient's clinical care (replaced earlier versions 2005-2012)

- ✓The Directive provides direction for disclosing medical mistakes to patients and their families. The policy addresses actions that specific VHA staff members should take during the disclosure process. (October 31, 2018)

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Patient Safety and Quality Improvement Act of 2005 (PSQIA)

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The PSQIA established a voluntary reporting system designed to enhance the data available to assess and improve patient safety and health care quality issues.

To incentivize the reporting and analysis of medical errors, the PSQIA provides a Federal privilege and confidentiality protections for patient safety information, called patient safety work product (PSWP).

Patient Safety Organization (PSO)

Patient Safety Work Product (PSWP)

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Patient Safety Network Website

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AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

AHRQ.gov

WebM&M Spotlight Cases and CE/MOC Courses Now Available!

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Expert analysis of medical errors.

Latest Perspective

Expert viewpoints on current themes in patient safety.

STUDY

Emotionally evocative patients in the emergency department: a mixed methods investigation of providers' reported emotions and implications for patient safety

"This is the wrong patient's blood!": Evaluating a Near-Miss Wrong Transfusion Event

SPOTLIGHT CASE CE/MOC

Sarah Barnhard, MD, January 2020

INTERVIEW

In Conversation With... David Gruen, MD

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Ethics

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The American College of Physicians ethics manual states that “Physicians should disclose to patients information about procedural or judgment errors made during care, as long as such information is material to the patient's well-being. Errors do not necessarily imply negligent or unethical behavior, but failure to disclose them may”

The AMA Code of Ethics: “Situations occasionally occur in which a patient experiences significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred”

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Sorry Works! Coalition

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- The Sorry Works! Coalition is comprised of doctors, lawyers, insurers, and patient advocates.
- Dedicated to promoting full disclosure and apologies for medical errors
- If a standard of care was not met (and there is a negative outcome) providers and their insurer should :
- Apologize, admit fault, provide an explanation of what happened and how the hospital will ensure that the error is not repeated, and offer compensation.
- The Sorry Works! protocol is based on the landmark disclosure program developed at the Department of Veterans Affairs Hospital in Lexington, Kentucky.

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Resources

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- *To Err is Human: Building a Safer Health System* IOM
- *Medical errors – the third leading cause of death in the U.S.* BMJ 2016;353:i2139
- *Communication and Optimal Resolution (CANDOR) Toolkit, AHRQ available at: https://www.ahrq.gov/patient-safety/settings/hospital/candor/modules.html*
- Kraman SS, Hamm G. *Risk management: extreme honesty may be the best policy.* Ann Intern Med, 1999 Dec 21;131(12):963-7.
- Available at: https://pubmed.ncbi.nlm.nih.gov/10610649/
- *Liability claims and costs before and after implementation of a medical error disclosure program,* Ann Intern Med 2010 Aug 17;153(4):213-21.
- *Apologies and legal liability. Saying sorry is not the same as admitting legal liability, BMJ 2009 Feb 10;338:b520.*
- *The Role of Apology Laws in Medical Malpractice,* May 2021 JAAPL.200107-20;

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Resources

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- The Patient Safety and Quality Improvement Act of 2005 (PSQIA) amends the Public Health Service Act (42 U.S.C. 299 et. seq.; P.L. 109-41)
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- Kachalia A, Kaufman S, Boothman RC, et. al. *Liability claims and costs before and after implementation of a medical error disclosure program*. Ann Intern Med 2010 Aug 17;153(4):213-21.
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Additional Recommended Resources

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9. American Nurses Association. *Code of Ethics for Nurses with Interpretive Statements*. Available at: http://www.nursingworld.org/codeofethics. Accessed May 16, 2013.
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11. Kraman SS, Hamm G. Risk management: extreme honesty may be the best policy. *Ann Intern Med*. 1999;131:963-967.

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Thank you!

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