Pain and the Law

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Objectives

- The participant will be able to identify components of pain management that are areas of potential liability
- The participant will be able to define standard of care

Healthcare Providers

Actions and Omissions

Tort law

- A tort is any action or omission that harms somebody
- Intentional- Assault, Battery, False imprisonment, Invasion of Privacy, Slander
- Unintentional- Negligence

Buckley, W.R., Okrent, C.J. *Torts and Personal Injury Law. 2nd Ed. 1997*

Standard of Care

- Sets the minimum criteria for your proficiency on the job to enable you and others to judge the quality of nursing care you provide
- The behavior or care of a reasonably prudent nurse under the same circumstances

Nurses Legal Handbook, 4th edition. Springhouse, 2000. *Nursing Practice and the Law*

Negligence

- Failure to exercise reasonable care which causes a foreseeable injury to another person.
- Elements of negligence
  - Duty (Standard of Care)
  - Breach
  - Causation
  - Harm

Buckley, W.R., Okrent, C.J. *Torts and Personal Injury Law. 2nd Ed. 1997*

Malpractice

- A professional persons wrongful conduct, or failure to meet the standard of care
- Professional Negligence

Buckley, W.R., Okrent, C.J. *Torts and Personal Injury Law. 2nd Ed. 1997*

Pain related nursing liability

- Overmedication/Undermedication
- Failure to assess/reassess
- Failure to monitor and/or document
- Failure to communicate findings
- Error in programming pumps

Case

- Estate of Henry James v. Hillhaven Corp., No. 89 CVS 64 (N.C. Sup. Ct. Jan. 15, 1991)
  - Jury verdict- 15 million
  - 7.5 million was punitive damages
  - Nursing negligence

Case

- *Bergman v. Chin*- No. H205732-1 Alameda County Court. June 13, 2001
  - Elder abuse and reckless negligence
  - 1.5 million dollar jury verdict
  - Superior court reduced to 250,000

Opioid Delivery Systems

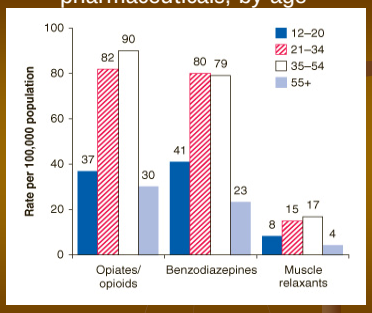
- Immediate and Extended Release Oral/IV
- Patient Controlled Analgesia
- Transdermal/ transmucosal
- Epidural, intrathecal

Gordon, D.B., Pain Management Nursing, Vol. 8, No. 3 Sept. 2007:pp S6-S13

Opioids

Overmedication

Rates of ED visits for selected pharmaceuticals, by age



Source: Office of Applied Studies, SAMHSA, Drug Abuse Warning Network, 2004 (September 2005 update). The DAWN Report; Issue 23, 2006

Nursing duty

- Know appropriate dosing
- Know the medication onset, action and duration
- Know that other meds can cause synergistic effects
- Assess, monitor and reassess
- Document

FDA Name Differentiation Project "TALL MAN" Letters

- oxyCodone
- Morphine
- fentaNYL
- HYDROcodone
- traZODone
- INVanz
- OxyCONTIN
- HYDROmorphone
- SUFentanil
- oxyCODONE
- traMADol
- AVINza

http://www.fda.gov/CDER/Drug/MedErrors/nameDiff.htm Accessed 12/27/08
http://www.ismp.org/ Accessed 12/27/08

Guidelines and Tools

- Controlled substance Act
- Opioid risk assessment tools
- Opioid prescribing guidelines
- Opioid contracts or agreements
- Patient education
- Urine drug testing

Patient safety

- Multimodal analgesia
- Pulse oximeter/End tidal CO2
- Reassess
- Education

Technology

Failure

Operator Error

Patient Controlled Analgesia

Viscusi ER. Reg Anes & Pain Med, Vol. 33; No. 2. 2008: 146-158. Hicks R. et al. Am J Health-Syst Pharm. 2008; Vol.65: 429-440

IV PCA Issues/ Liability

- Pump issues
  - Failure and medication/programming errors
- Over 5 years of observation (2000-2004) PCA error rates remain unchanged in spite of technological improvements

Cohen MR, Smetzer J: J Pain Palliat Care Pharmacother 2005;19:45-50.
Hankin CS, Zhang M: Abstract at: American Society of Health-System Pharmacists Summer Meeting. June 11-15, 2005. Boston, Mass. Institute for Safe Medication Practices. Available at: www.ismp.org. USP Quality Review, No. 81. 2004. Accessed October 30, 2006. Sikirica V et al. presented at The 41st American Society of Health-System Pharmacists Midyear Clinical Meeting. December 3-7, 2006. Anaheim, Calif.

Stats from FDA MAUDE* Database

2004 PCA Deaths

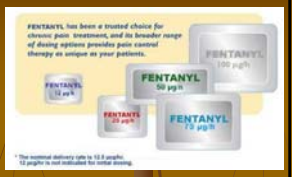
- 22 Deaths
  - 4 programming errors
  - 5 not related to device
  - 10 unknown if devise related
  - 3 devise malfunction

2004 ADE's

- 106 ADE's
  - 4 PCA by proxy
  - 2 user error
  - 21 programming errors
  - 24 unknown if devise related
  - 55 devise malfunction

*Manufacturer and User facility Device Experience Database
FDA MAUDE Database from January 2004-December 2004

Transdermal



- Prescribing errors
- Lack of education
- Product defect
- Publication of prescribing problems

Institute For Safe Medication Practices: June 28, 2007 Issue.
www.ismp.org/ Accessed 12/27/08

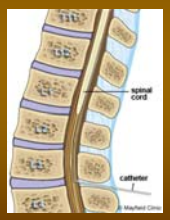
Transmucosal

Buccal

Liability Issues

- Inappropriate prescribing
- Failure to educate patient/family
- Discharge instructions are extremely important
- Document that pt. or family understand

Epidural and Intrathecal Delivery



Practice Guidelines for the Prevention, Detection and Management of Respiratory Depression Associated with Neuraxial Opioid Administration: DRAFT by ASA Task Force on Neuraxial Opioids. 8/3/2007

Liability Issues

- Cauda Equina
- Neuro deficits- i.e. foot drop
- Hematoma
- Abscess
- Programmer error
- Mix up in medication
- Failure to monitor

Liability Issues

- Failure to appropriately monitor
- Failure to educate staff
- Overmedication
- Failure to communicate findings

Case Example

- Estate of John Doe vs. Lame Healthcare System
- 51 y.o. male with h/o high cholesterol, gout, depression, anxiety, esophagitis, diverticulitis, bowl resection, and sleep apnea
- Admitted to E.R. with N/V diarrhea and abd. pain
- Expired approx. 24 hours later

Process of Expert Review

- Review complaint, medical records, depositions, expert reports
- Decide if you will take the case
- Formulation of opinion
- Discussion with attorney
- Write expert report (Pennsylvania)
- Trial/ Settlement

Initial review

- Review facts around incident
- Read defendant nurse deposition
- I reviewed over 50 documents
  - Medical records from admission
  - 14 Depositions
  - Pharmacy and outpatient records
  - Hospital Policies and Procedures

Timeline

October 25, 2001

- 1430 – Admitted to ER
- 1500 – Hydromorphone 1mg IV
- 1900 – Hydromorphone 1mg IV
- 1930 – Admitted to Medical Unit for intractable pain/gastroenteritis
- 2300 – Hydromorphone 2mg IV

Timeline

October 26, 2001

- 0500 – Hydromorphone 2mg IV For abd pain
- 0900 – Hydromorphone 2mg IV- abd. pain
- 1200 – Pain escalating- 5/10, refuses to go home
- 1300 – Pain 7/10- MD notified,hydromorph 4mg IV administ
- Approx 1400 – Pt found unresponsive, CPR performed, Pt. expired

Interesting facts

- Plaintiff only suing hospital and nurse
- Patient stopped breathing with 4mg IV hydromorphone 2 years prior/resuscitated
- Physician didn't recall
- Nurse was never informed
- Family and friend depositions state patient told everyone he died and came back after getting hydromorphone

Plaintiff allegations

- Nurse did not approp care for and monitor pt.
- 2 plaintiff experts misinterpreted hospital Policy and Procedure- reassess every 10min. Applied to ICU, not Med/Surg 30min.
- "shouldn't have delivered such a large dose based on lack of proper reassessment of pt. She should have called her supervisor for resolution of the issue"

Allegations cont.

- Expert implied hydromorphone escalated from 1mg to 4mg
- Stated nurse didn't see pt. for 35 minutes after administering

My expert report

- Describe my nursing experience, credentials
- List all documents reviewed
- Restate the events
- Respond to each allegation directed to the nurse
- State an opinion based on a reasonable degree of nursing certainty

My expert conclusion

- Nurse's care was in compliance with hospital's policies and procedures.
- She did not deviate from the standard of care

Nursing implications

- Know the drugs and side effects/pt. co-morbidities
- Know pumps and modalities/ If you don't know; ask!
- Appropriately monitor
- Assess and reassess
- Document, document, document
- Be sure of ancillary documentation
- Discharge instructions

Emerging Pain Care Standards

- All patients entitled to effective pain relief
- Multi-modal approach for all types of pain
- Assessment and Reassessment
- Diligent monitoring of patients receiving opioids

Legislation

- National Pain Care Policy Act 2009
- NPCPA included in Healthcare reform bill of 2010
  - Aimed at better training for physicians, increased research, and improved access
- Controlled Substances Act

Standards of care & reference links

- http://www.asahq.org/
- http://www.jointcommission.org/
- http://www.ampainsoc.org/
- http://www.aspmn.org/
- http://www.ismp.org/
- http://www.fda.gov/
- http://www.usdoj.gov/dea/index.htm

Reference links cont.

- http://www.guideline.gov/
- http://www.painandthelaw.org/
- http://legalsideofpain.com/index.cfm
- http://www.ahrq.gov/
- http://apsf.org/

Questions?

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