Infusion/Vascular Access Lawsuits Trends and Issues

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Disclosures

- Speaker and/or consultant for:
  - AccuVein
  - Atrion
  - B Braun
  - BD Medical
  - Biolife
  - Fresinius Kabi
  - Global Biopharm
  - MedLite
  - Nexus Medical
  - Teleflex

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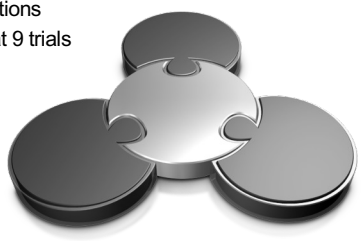
Expert Witness Role

- Putting the pieces of patient care together
- 26 years
  - ~ 700 cases reviewed
  - ~ 70 depositions
  - Testimony at 9 trials



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Learning Objectives

- Describe the most frequent infusion-related complications leading to lawsuits.
- Analyze the role of the expert witness in a lawsuit involving infusion therapy and vascular access.
- Discuss the resources used in lawsuits to measure professional performance.

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Clinical Facts- High Risk

- Infusion therapy is administered to virtually every patient
  - All ages
  - All healthcare settings
    - Acute care
    - Long term care
    - Ambulatory care
    - Home care
  - All service lines and medical specialties

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Clinical Facts High Volume

- Accessing the vascular system is the most invasive procedure performed by clinicians at all levels of practice
  - Includes radiologic technologists, respiratory therapists, unlicensed assistive personnel
- VAD Complexity
  - Intra-arterial
  - Intraosseous
  - Intraspinal
  - Subcutaneous

Annual global sales:

- 1+ Billion peripheral catheters
  - 69% fail before end of therapy
- 17+ million central vascular access devices (CVAD)
  - 25% fail before end of therapy

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Clinical Facts – High Volume

- Dozens of types of fluids
- Electrolytes
- Hundreds of I.V. medications
- Blood and blood components
- Parenteral nutrition


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Clinical Facts – Low Frequency

- Procedures are specific to certain patient population
  - Accessing implanted ports
  - Inserting central vascular access devices
  - Monthly, quarterly, yearly doses for some medications
  - Issues with maintaining competency

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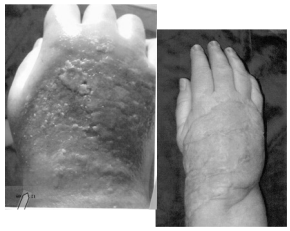
Clinical Facts – Problem Prone

Complications range from mild to severe and life-long

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Clinical Decision-Making

- Vascular Access Device
  - Planning and insertion of appropriate type
  - Routine care and maintenance
  - Complication identification and treatment
  - Removal when no longer necessary
- Infusion Therapy
  - Appropriate prescriptions
  - Administration techniques
  - Adverse events recognition and management

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Outcomes Producing Lawsuits

Infiltration – non-vesicant fluid and medication in tissue outside the vein
- peripheral and central sites

Acute extremity compartment syndrome or serious thoracic injury
- Associated with infusion pump use

Peripheral nerve injury, mediastinal or pulmonary injury

Complex regional pain syndrome

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Outcomes Producing Lawsuits

Extravasation - vesicant medications in tissue outside vein
- peripheral or central

Necrotic ulcer
- Phenergan (promethazine)

Surgical debridement, skin grafting, surgical washout

Nerve injury, CRPS

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Outcomes Producing Lawsuit - Actual Case

- 38-year-old female admitted thru ED with viral syndrome; an OB-GYN surgeon
  - 20 g catheter unknown vein of left antecubital fossa, blood samples taken from catheter, 3 L fluid over 4 hours then KVO rate, lorazapam X 2, promethazine, hydromorphone, ceftriazone
  - 20 hours later, complained of pain in site, warm blanket applied
  - 4 hours later, husband visited (also an MD), requested IV catheter be removed, infusion pump stopped
  - 4 hours later, husband returned, catheter still in place, pain increasing, catheter finally removed
  - Documented ulnar nerve damage so severe that entire surgical career was ended
  - Settled in mediation

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Outcomes Producing Lawsuits

Venous Air Embolism

- Respiratory arrest
- Brain damage

In USA - No payment for treatment as hospital-acquired condition

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Outcomes Producing Lawsuit - Actual Case

- 57-year-old man, admitted with renal stone, sleep apnea, PCA morphine and fluids ordered
- 20-gauge peripheral catheter in hand
- ~ 39 mg morphine used over ~36-hour period
- Intermittent use of CPAP during sleep
- Infusion pump alarm at 1 am indicating bag empty
- Patient found unresponsive, CPR failed, death
- Autopsy found “150 mL air in heart”, family alleged that venous air embolism from peripheral IV catheter
- Trial jury out for 20 minutes and return verdict for defense

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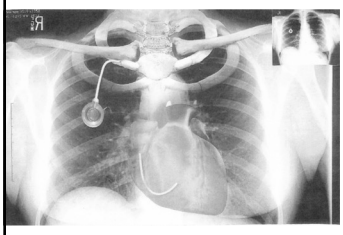
Outcomes Producing Lawsuits

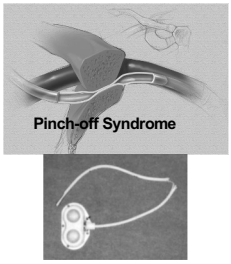
Catheter damage

- Fracture or split

Catheter embolism

Surgical removal from heart





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Outcomes Producing Lawsuits

- Infection
  - Catheter related bloodstream infection
    - Peripheral catheter inserted in emergent conditions, not changed within 24-48 hours
      - CDC and INS
  - Local site infection
  - Port pocket infection
  - Tunnel infection
- Hospital-acquired condition
  - No payment for treatment in USA

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Outcomes Producing Lawsuit - Actual Case

- 57-year-old man, admitted with possible thrombophlebitis, headache
- 4 catheter sites documented in right arm, beginning with antecubital site with subsequent sites distal
- Several notes about redness, swelling at various sites; many sites without any notes of assessment or reason for removal
- Wife reported constant concern about changes in patient over the weekend
- Monday physician visited on consultation, found patient to be septic, treatment began, moved to ICU, died the next day; bloodstream infection and sepsis attributed to IV site
- Settled in mediation

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Outcomes Producing Lawsuits

- Medication adverse events

Red Man Syndrome – idiopathic anaphylaxis, mast cell activation
- Vancomycin

Ototoxicity
- Gentamicin
- Vancomycin

Nephrotoxicity
- Vancomycin
- Gentamicin

Cardiac -QT interval prolongation, ST segment depression
- Ondansetron

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Red Man Syndrome (RMS)

- Anaphylactoid reaction, direct and non-immune release of histamine from mast cells
- Reported in 3.7% to 47% of patients receiving Vancomycin
- Expert in 2 lawsuits involving RMS
  - 1 working for plaintiff, patient's wife
  - 1 working for defense, infusion clinic in a physician's office
- Both patients died from unrecognized and untreated RMS

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Case #1 Red Man syndrome

- 31-year-old man, severe cut on left foot from boat anchor in salt water
- Went immediately to ED, site cleaned, sutured, and placed on Doxycycline PO
- Visit to primary care physician, change of PO antibiotics
- 3 days later – admitted to hospital with diagnosis of cellulitis of left foot and an open wound.
  - Surgical incision and drainage
  - Vancomycin 2000 mg IV every 12 hours –
    - height 6 feet 7 inches, weight 280 lbs, former college and pro athlete

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Case #1 Red Man Syndrome

- 2nd post-op day, 5 Fr dual lumen PICC inserted, CAJ tip position
  - Several hours after procedure, c/o chest pain with hypertension, anxiety, lasting about 15 minutes
  - Cardiology consult- chest pain not cardiac origin, prescribed enalapril, later changed to lisinopril 10 mg daily.
- 2nd post-op day discharge planning to home care with:
  - Lisinopril 10 mg **TWICE** per day PO
  - Cefepime 1 gram every 12 hours IV
  - Vancomycin 2000 mg every 12 h IV
    - pharmacy to adjust dose, hold for trough level greater than 18
- 3rd post-op day discharged to home care with home admission orders of
  - Vancomycin 1.5 gram IV every 12 h X 14 days, trough ~15, hold if greater than 18
  - Cefepime 1 gram every 12 h IV
  - Lisinopril 10 mg **TWICE** per day PO

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Case #1 Red Man Syndrome

- Documented Home Care Plan
- Independence with IV therapy within 4 days
  - Documented independence within 2 days, home care nurses visiting daily for wound care
- Lisinopril 10 mg PO BID
- Cefepime 1 gram in 100 mL over 30 minutes
- Vancomycin 1.5 grams over 90 minutes
- 15 minutes between each infusion
- Elastomeric balloon pump used for both drugs
- 3rd Home Care Day
  - Vancomycin trough level 6.4 mcg/mL

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Case #1 Red Man Syndrome

- 4th Day of Home Care documentation
- Wound care visit, no c/o pain
- 2 antibiotics infused with no wait time between doses
- Vancomycin dose changed to 2 grams every 12 h
- Pharmacists called to discuss dose changes, discarding previous supply
- Delivery ticket confirmed 15 doses of Vancomycin 2 grams in 250 mL 0.9% sodium chloride in elastomeric balloon pump
- Both evening doses of both drugs infused within 75 minutes
- 75 minutes later - c/o chills and hot feeling in leg, no elevated temp, leg not hot to touch

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Case #1 Red Man Syndrome

- 5th Home Care Day
- Patient reported event of previous night to home care nurse
- Wife's deposition reported c/o nausea, headache, lethargy, and "not feeling good" for entire day
- No documented nursing actions

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Case #1 Red Man Syndrome

- 6th Home Care Day
- Wound care by home care nurse
- Both drugs infused over 90 minutes, no wait time
- Afternoon phone call to nurse c/o headache, "face feels like it is on fire"
  - Home care nurse called physician office, spoke with infusion clinic nurse, who spoke with physician
  - Instructions - Benadryl 25 mg PO every 6 h PRN, Tylenol 650 mg PO every 4-6 h PRN, home care nurse gave instructions to patient over phone
  - Infusion clinic nurse called pharmacists, vancomycin to be diluted in 500 mLs 0.9% sodium chloride, change to gravity infusion with a manual flow control device
    - Delivery ticket – 11 doses of Vancomycin, 6 administration sets

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Case #1 Red Man Syndrome

- 6th Home Care Day, continued
- Benadryl & Tylenol obtained from local drug store for "medication side effects"
  - Doses taken around 6 pm
- Both doses of drugs infused over 75 minutes, completion around 9:15 pm
- 11 pm – shaking chills, abdominal cramps
  - Discussed with wife, nurses knew about his problem, concluded he must have flu, returned to bed
- 2 am – wife woke to patient moaning, stiff left hand, eyes "rolled back in his head", nonresponsive, called EMS, started CPR
- 3:08 am – arrived at ED in cardiac arrest, pupils fixed and dilated, depressed gag reflex, no spontaneous pulse.
  - Intubated, ACLS protocol for 40 minutes, pronounced dead

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Case #1 Red Man Syndrome

- 2 autopsies with conflicting results
- County Medical examiner – hypertensive heart disease, with left ventricular hypertrophy and dilatation
- Second look autopsy by another pathologist
  - Death from acute episode of hypotension
  - Highlighted clinical course and terminal events indicated "hypotension such as might have occurred after an allergic reaction"
  - Did not find cardiac hypertrophy
  - Settled for plaintiff in mediation

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Case #2 Red Man syndrome

- 62-year-old female with pain and cellulitis of left lower extremity, Type 2 DM, hypertension, history of melanoma of lower leg
- Hospital admission for cellulitis
  - Vancomycin 25 mg/kg prescribed = dose of 2245.25 mg, no dilution documented
  - With 1st dose – severe itching, "trouble breathing", c/o feeling hot, flushed and itchy
  - Vancomycin stopped, changed to Daptomycin and Clindamycin
  - Discharged home after 4 days, instructed to follow up with PCP in 1-2 weeks

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Case #2 Red Man syndrome

- Self-referral to Infectious Disease within 3 weeks, stating leg still swollen and red
- Reported that she did not have any issues with antibiotics in hospital, except for slight facial redness
  - Resolved with Benadryl
  - Told Vancomycin infused too fast
- Inserted PICC, started Daptomycin and Levaquin daily at infusion clinic
  - Weekly physician visits and labs
  - 5th week of treatment
    - leg improving, plan 3 more weeks of antibiotics
  - 6th week of treatment
    - Patient not satisfied
    - Cefipime 2 grams daily added

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Case #2 Red Man syndrome

- 10th week of treatment
  - 75% improvement, still some edema and redness
  - Patient not satisfied, wants to continue antibiotics
  - Discussion about past history with Vancomycin between MD and patient, Risks explained to patient
  - Discontinued Levaquin, changed cefipime to Rocephin, continued daptomycin
    - Added "Vancomycin 1 gram at a very slow rate, along with Benadryl if needed"

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Case #2 Red Man syndrome

- Returned to infusion clinic the next day
  - Vancomycin to be infused at 20 mL/hr but documentation is unclear about rate
  - Infusion administered by LPN
  - Respiratory distress within 7 minutes of beginning infusion, awake, alert, elevated BP, EMS activated
    - Benadryl 50 mg IV given
    - Increasing respiratory distress, cyanosis of lips, non-verbal
    - No documentation of lung sounds or oxygen saturation
  - EMS transferred to ED in cardiac arrest, died 4 days later in hospital
    - Son gave more details of previous vancomycin reaction, new information for physician
  - Autopsy listed causes of death as anoxic encephalopathy, cardiopulmonary arrests, allergic reaction to vancomycin
  - Settled for plaintiff in mediation

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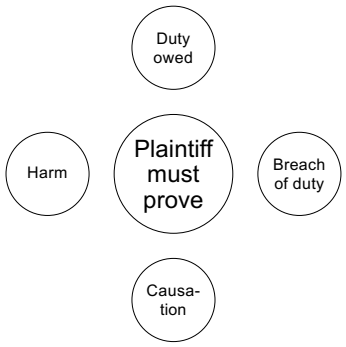
Successful Malpractice Lawsuit



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Stages of a Lawsuit

- State 1 - Consultation with Attorney
  - Injured parties (or family) presents their information about the events and outcomes
- Stage 2 - Investigation by Attorney
  - Review medical records about the event
  - Was negligence found? By which personnel? What injury directly results from this negligent care? Does the case have merit?
    - May involve a legal nurse consultant
    - Attorney calculates financial aspects of case
      - Degree of liability vs costs of pursuing case vs financial reward to recover
  - Could have expert review at this point

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Stages of a Lawsuit

- Stage 3 - Filing a Complaint with the Court
  - Within the statutory time limit or Statue of Limitations
  - Describes actions that led to negligent conduct, names all parties (people and organizations)
    - Some states require Tribunal to review at this point
- Stage 4 - Discovery Stage
  - Time to obtain relevant information from each side
    - Interrogatories – written questions submitted to defense, written answers from defendants
    - Additional medical records
    - Organizational policies and procedures
    - Personnel files
    - Depositions
  - May take years to complete this stage

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Stages of a Lawsuit

- Stage 5 - Settlement
  - Agreement reached by both parties for a payment
  - Preferred method
  - Settlement amount is always private
- State 6 - Trial
  - Facts presented to judge and jury
    - Judge decides application of the law(s)
    - Jury examines facts of the event
  - Testimony of experts
  - Jury decides outcome
  - Trial is public information

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The Expert Witness

- Involvement during
  - Original investigation
  - Discovery
    - Writing and signing affidavit
    - Witness of opinions, based on evidence
    - Giving deposition
  - Trial testimony
- Experts paid for time, not opinions

- Qualifications
- Same or similar specialty as defendant(s)
- Clearly communicate verbally and in writing
- Careful listener
- Remain unbiased
- Detail oriented
- Very thorough
- Ability to defend your opinions in adversarial proceedings

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Role of Testifying Expert

- Identify deviations from the Standard of Care (SOC)
  - SOC = What a reasonable and prudent professional would do in the same or similar situation
  - Proof of what SOC is
  - Proof that nurse did not follow SOC
- Criteria to establish the SOC
  - A reasonable expectation of care
  - Measurable
  - Valid for the location of the care provided
  - Based on the state of knowledge at the time of event

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Review Process - 3 basic questions

- What actions or interventions were or were not taken to prevent the outcome?
  - Peripheral catheter site selection
    - Hand, wrist, antecubital fossa site of most complications AND most lawsuits
    - Catheter stabilization
      - Tape and transparent dressing alone are NOT sufficient
    - Joint stabilization IF a joint must be used
    - Site assessment before, during, and after medication administration
  - BLOOD RETURN!!

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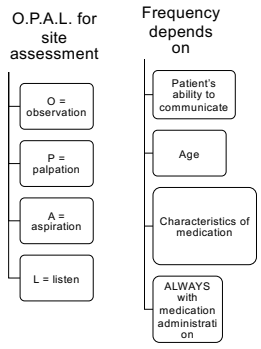
Review Process - 3 basic questions

- When and how was the outcome identified?
  - Documentation of redness, edema, pain WITHOUT removing peripheral catheter
  - Complications are progressive
    - Complete site assessment is critical



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Review Process - 3 basic questions

- Was the clinical management appropriate as identified in published evidence?
  - Immediate peripheral catheter removal
  - For CVAD, identify complication and plan before removal
  - Correct thermal treatment
    - Cold and heat have specific indications
      - Specific complication
      - Medication characteristics – osmolarity, vesicant nature
    - Antidote injection for infiltration/extravasation
    - Rapid surgical intervention for compartment syndrome
    - High index of suspicion for venous air embolism
      - Appropriate diagnostic test

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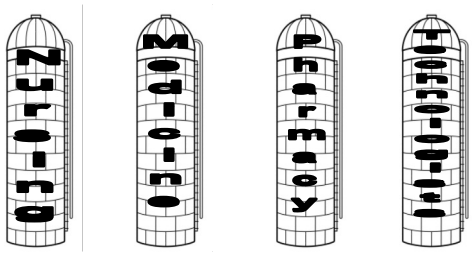
Major Problem – Silo Practices

"Interprofessional collaboration" – a common phrase in Infusion Therapy Standards of Practice, INS



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Evidence-Based Resources

- Regulatory organizations
  - Centers for Medicare and Medicaid
    - Hospital-acquired conditions
  - FDA
    - Regulations for drug and device manufacturers
  - Joint Commission
    - Manual on accreditation for each type of organization
    - Sentinel events
  - OSHA

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Evidence-Based Resources

- Boards governing practice
  - Nursing
    - Rules and regulations regarding infusion therapy
      - LPN/LVN
      - RN
  - Paramedics
  - Radiologic technologists
  - Respiratory therapists
  - Unlicensed assistive personnel
    - State board of nursing rules about delegation

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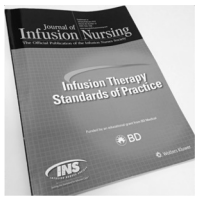
Evidence-Based Resources

- Professional organization standards and guidelines
  - American Nurses Association
  - Infusion Nurses Society
    - Infusion Therapy Standards of Practice
      - Updated and published every 5 years
  - Oncology Nursing Society
    - Chemotherapy and Biotherapy Guidelines and Recommendations of Practice



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Evidence-Based Resources

- Professional Organizations cont
  - American Society of Parenteral and Enteral Nutrition
  - American Society of Blood Banks
  - Society of Healthcare Epidemiology of America
    - CLABSI prevention guideline
  - Association for Practitioners in Infection Control and Prevention
    - Safe injection practices
    - Hand hygiene
    - Implementation guide for CLABSI prevention
  - American College of Radiology
    - Manual on Contrast Media

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Evidence-Based Resources

- Federal agencies
  - Centers for Disease Control
    - Guidelines for the Prevention of Intravascular-related Infection
    - Hand hygiene guidelines
    - Safe injection practices
  - United States Pharmacopeia
    - Compounding Sterile Preparations, Chapter <797>
    - Hazardous Drugs, Chapter <800>
- Others
  - Institute for Safe Medication Practices

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Evidence-Based Resources

- Textbooks
  - *Intravenous Medications*
    - Published annually
  - *Manual of I.V. Therapeutics*
  - *Plumer's Principles and Practice of Infusion Therapy*
- Numerous published studies
  - Medical, nursing, pharmacy journals
- Manufacturers' instructions for use

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Take-Away Message

- Infusion therapy and vascular access
  - – MUCH more than sticking a vein!!
  - Specialty nursing practice BUT all nurses have some level of responsibility for safe delivery
  - Most have not received education about infusion therapy
  - Involves other healthcare personnel
  - All are held accountable to the standard of care
- Patient outcomes can be devastating
- Most cases settle out of court

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Questions

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