

## Legal Implications of CLABSI in Acute Care: Risk and Liability Concerns

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  - Angiodynamics
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  - Hospira/ProCE
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### Objectives

- Discuss healthcare changes that made CLABSI occurrence un-reimbursable with greater liability implications
- Define steps that hospitals are taking to reduce infection risk with legal implications associated with failure to apply preventative practices
- Identify Federal and State government efforts to reduce incidence of CLABSI
- Provide examples of legal cases involving vascular access device infections with practical application for healthcare facilities

### Infections in Acute Care



- **Healthcare-associated infections (HAIs)** are among the top causes of unnecessary illnesses and deaths in the United States
- **HAIs** are infections patients get while in a hospital or other healthcare facility – infections the patients did not have before being admitted, accounting for approximately 1.7 million infections and almost 100,000 deaths annually
- **HAIs** result in extra days of hospitalization and higher health care costs
- Estimated financial impact of **HAIs** between \$28 billion and \$33 billion a year
- Any infection is now a liability to the healthcare facility

### What is CLABSI?



- **Central Line Associated Bloodstream Infections or CLABSIs** are primary bloodstream infections associated with the presence of a central vascular catheter, PICC, CVC, Port, Triple Lumen, or other CVAD
- A bloodstream infection occurs when microorganisms such as bacteria or fungi attach and multiply on a catheter, tubing or in the infusate with access or in the vessel with resultant symptoms of infection
- According to the Centers for Medicare and Medicaid (CMS) ruling- CLABSIs are preventable complications

### Reimbursement Changes

- CMS Changes in 2008 that eliminated payment for CVC infections acquired in the hospital
- Result is increased awareness of cost and impact of CLABSI with reporting
- Issues with identification of Present on Admission (POA) and CLABSI occurrence
- Emphasis on prevention and education

 Centers for Medicare & Medicaid Services

## Liability with Infection

- Failure to perform at an acceptable level based on the Standard of Care
  - What is the hospital's responsibility to patients related to infection?
  - Is there a requirement to perform at a certain level as reflected by the outcomes?
  - Are application of recommendations mandatory?



## Legal Implications with Infection

- CMS statement that CLABSIs are preventable changes the entire landscape for litigation
- Any infection that a patient contracts in a hospital is now considered a breach in care



## Hospital Liability

- Performance Related
  - Duty to perform in a manner considered the Standard of Care
  - Does a hospital have a responsibility to prevent injury and improve the patient's condition?
  - When complications occur, is this always a breach?

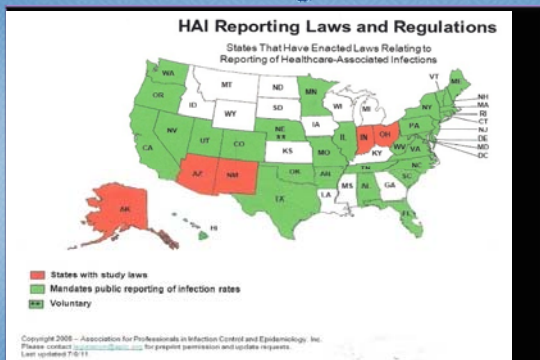


## Organizational Liability

- Performance within the Standard of Care is reflected in:
  - Up-to-date policies and procedures
  - Quality control measures to ensure standards and policies are upheld
  - Safety report card
- Reporting requirements
- Public reporting
- General quality of the hospital/facility based on morbidity and mortality statistics



## States with HAI Regulations



## Government Regulations

- Federal Mandates that allow reimbursement for Medicare/Medicaid services include:
  - Denial of payment for treatment of hospital acquired infections
  - Shift to pay for performance
  - Reduction of payment for bad outcomes
- State Mandates
- 28 States have enacted legislation requiring hospitals to report incidents of hospital acquired infections



## Federal and State Efforts to Reduce CLABSI

- CDC 2011 Guidelines for Prevention of Infection
- AHRQ Agency for Healthcare Research and Quality Recommendations
- NHSN National Health and Safety Network - CVC Checklist and Infection Criteria
- Other Association Standards and Recommendations
- Accreditation requirements - Joint Commission National Patient Safety Goals
  - [Healthcare Facilities Accreditation Program \(HFAP\)](#)
  - [Joint Commission \(JC\)](#)
  - [Community Health Accreditation Program \(CHAP\)](#)
  - [Accreditation Commission for Health Care Inc \(ACHC\)](#)
  - [The Compliance Team: "Exemplary Provider Programs"](#)
  - [Healthcare Quality Association on Accreditation \(HQAA\)](#)
  - [DNV Healthcare Inc. DNVHC](#)

## Reporting Risk for Hospitals

- Good Results - Positive outcomes
  - Increased client satisfaction
  - Positive image to attract qualified practitioners
  - Improved image in the community
  - Increased revenue with cost savings associated with avoidance of HAI



## Reporting Risk for Hospitals

- Poor results - Negative impact
  - Continued patient morbidity/mortality from infections
  - Damage to reputation and census reduction
  - Increase length of stay with unreimbursed costs and loss of revenue
  - Poor response in attracting qualified specialists
  - Impact on staff, retention, respect, performance
  - Increased litigation and revenue losses due to failure to implement recognized measures of prevention



## Informed Consent

- Every patient has a right to understand risks and benefits associated with a procedure
- Do hospitals include the risk of infection in the general hospital consent?
- Does the patient know there is a risk of acquiring and infection that could kill them and do they consent to treatment despite the risk?
- Will hospitals be required to inform patients in the future statistics on what their risk really is for treatment in that hospital?



## Legal Implications and Concerns

### Negligence

- Failure to perform at the established Standard when there is a duty. Negligence is a violated duty causing unintentional harm.
- Stated more formally, negligence is "conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm."
- Is an infection always NEGLIGENCE??



## Standards of Care and Practice

### Standard of Care

- The Standard is that level of care expected of the reasonably competent clinician, rather than the reasonably prudent person. Alabama, for example, has held that a clinician must "exercise such reasonable care, diligence, and skill as reasonably competent physicians" would exercise in the same or similar circumstances.
- In other words "what a similar nurse would do in the same situation".



## Standards of Care and Practice

### Standard of Practice

- Standard of Practice is defined by an expert
- As a rule, expert testimony is required to establish the custom of the profession. Both the complaining patient and the defendant clinician are required to produce experts to legally establish what constitutes the standard of care as opposed to substandard care. Experts, by virtue of their skills, knowledge, experience or education — supported by authoritative texts, articles and research as necessary — then articulate the standard as it applies to the particular case. In reaching their verdict, the jurors listen to all the evidence and decide which expert, and therefore which of the parties, is the more credible



## Hospitals Accountability for Infection

- Joint Commission now requires compliance with National Patient Safety Goals (NPSG)
- This is considered a duty to perform
- NPSG can now be considered a Standard of Practice and a requirement including
  - Insertion checklists measuring compliance with Central Line Bundle
  - Monitoring, surveillance, reporting
  - Education
  - Disinfecting protocols, carts for CVC insertion



## Steps that Hospitals Take for Prevention

- Follow the BUNDLE (hand hygiene, max barriers, CHG/alcohol prepping, optimal site selection and removal when IV meds completed)
- For all CVC/PICC insertions use CLIP – checklist with independent observer
- Educate insertion and maintenance staff
- Consider antimicrobial dressings/catheters/caps/devices when zero not met
- Establish surveillance and accountability for compliance
- Daily assessment and device removal



## How Will You Answer?

- In a courtroom there are certain questions put to the witness:
  - What could you have done differently to avoid the infection to this patient?
  - When antimicrobial products were available, why weren't they used?
  - What practices do you have that safeguard patients?
- Think about this: Are we currently doing everything we can to avoid complications?



## Legal Examples

- Acute care patient died from infection – case review with settlement
- Home Infusion patient receiving TPN – nurse did not wash hands
- Acute care PICC infected



## Avoiding Liability: The Challenge!



- Educate staff for all areas of Vascular Access recommendations
- Evaluate new products and provide the best antimicrobial protection
- Challenge your facility to improve practices and incorporate those products that safeguard patients
- Read Research and Journals monthly
- Benchmark acceptable levels of complications
- Forever strive for Best Practice!

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Thank you!

Questions?

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