Managing Risk for HAI’s-An Emerging Perfect Storm of Liability

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OUTLINE

1. Healthcare-Associated Infections (HAI’s)-Background
2. Why Now?
   • Regulatory Changes
   • Health Care Standards Changes
   • Reimbursement Changes
   • Legal Standards Changes
3. Loss Control- How to Reduce Liability, Risk, and Infection Rates-
   Developing a Legally Defensible, Cost Effective, Infection Control
   Program
   • Hand Hygiene
   • Environmental Cleaning
   • Preadmission Screening/Visitor Protocols
   • HAI Bundling-(SSI, VAP, CAUTI, CLABSI)
4. Program Implementation
5. Conclusions
1. Healthcare-Associated Infections (HAI’s)

- CDC- 2 million patients contract HAI’s every year and the number is growing.…. 
- Of the 2 million, approx 100,000 die and the number is growing…. 
- SSI’s, VAP, CAUTI, and CLABSI account for greater than 80% of all HAIs 
- Most HAI’s are facilitated by the presence of an invasive device inserted in the patient and/or a portal of entry into the body.
WHAT DO THESE FOLKS HAVE IN COMMON?
HAI’s

More Bugs……..

• Bacteria-Acinetobacter, Campylobacter, C.diff, Enterobacter, Enterococcus, E. coli, Klebsiella, Listeria, Pseudomonas, Salmonella, Serratia, Shigella, Staph aureus, Streptococcus

• Virus-Adenovirus, Cytomegalovirus, HIV, Hepatitis, RSV, Rotavirus

• Fungi-Aspergillus, Candida
HAI’s

• Stronger Bugs…Fewer Drugs…..

• MDROs- a growing menace

- Bacterial resistance to antibiotics first seen in 1947
- Increasing numbers of bacteria have become resistant to increasing nos. of antibiotics (MRSA, VRSA, VRE, etc)
- Bacteria strains have become increasingly virulent (C. diff BI/NAP1/027-16-23 fold increase in toxins and production of new toxins-increased resistance to fluoroquinolones)
- Gram Negatives such as Klebsiella, Pseudomonas, and Acinetobacter, are mutating faster than the antibiotics and some strains are now carbapenem resistant
HAI’s

- Epidemiology-MDRO’s
  
  - Initially seen in ICU patients heavily treated with antibiotics facilitating growth of MDRO’s
  
  - Seen in patients with prolonged presence of invasive devices
  
  - Long stays in hospitals and exposure to other patients increase risk
Transmission in Healthcare Setting-HAI’s

3 Reservoirs

- Patients
- Healthcare Workers
- Inanimate Environment
HAI’s

• MDRO Transmission Examples

• Studies have shown the following:
  
  – MRSA Patient Rms. – 73% Contamination
  – MRSA Colonized Patient Rms. – 69% Contamination
  – C.diff Patient Rms.- 50% Contamination
  – C.diff Asymptomatic Patient Rms.-30% Contamination

Studies have shown:

*MRSA can survive on dry environmental surfaces for more than 8 months while C.diff can survive for 5 months !!!*
Transmission-Inanimate Environment

The Inanimate Environment Can Facilitate Transmission

\[ \times \text{represents VRE culture positive sites} \]

\[ \sim \text{Contaminated surfaces increase cross-transmission} \sim \]

HAI’s-WHY NOW?

• MORE RESISTANT STRAINS

• MORE PREVALENT

• AWARENESS-Recent media attention

• LITIGATION-A storm is brewing…..
HAI-Litigation

- United Kingdom-2006

- Previously- Required to prove causation and nearly impossible to identify exposure point
  - Kitty Cope-landmark case
  - Shifted burden to defense (hospital)
  - No longer required to prove MRSA contracted in hospital rather it is up to the hospital to prove “they are controlling exposure to hazardous substances” (Control of Substances Harmful to Health Act)

Result- UK Hospitals MUST have adequate infection control policies AND MRSA now deemed to be AVOIDABLE
HAI-Litigation

• Litigation- United States-2008

• Previously- most cases settled, difficult to prove causation, reimbursement, inherent risk of hospital stay, etc.

  ➢ James Klotz-(MO)- potential land-mark case

  ➢ Awarded over $2.5M for MRSA

  ➢ Appear to have shifted burden to hospital to prove MRSA not contracted there-”75% of MRSA comes from hospitals”

  ➢ Fitzgerald (TX)-2009- 17.5M awarded
2. HAI’s-THE “PERFECT STORM” – Increasing Liability and Risk

- CHANGING GOVERNMENT REGULATIONS
  Reporting/Compliance/Protocol Requirements-”publication of infection rates”

- CHANGING HEALTH CARE STANDARDS-
  “HAIs now deemed preventable”

- CHANGING REIMBURSEMENT FROM MEDICARE/MEDICAID (CMS) AND OTHERS “payments withheld for a growing list of preventable adverse events”

- CHANGING LEGAL STANDARDS
  “a shift in the burden of proof will be a huge burden on health care facilities”
Changing Government Regulations

- Regulations

  - Hospital regulation falls primarily under the jurisdiction of the STATES
  - NO HAI reporting required till 2004 by Pennsylvania
  - Currently ONLY a small no. of states have NOT considered hospital infection legislation
  - Shea/APIC position paper
  - Despite the apparent benefit state hospital associations have opposed reporting because of

    - Fear of liability
    - Reporting logistics issues
    - Efficiency issues (divert resources from patient care/prevention)
    - Conflicting reporting requirements (by infection site/organism?)
State Legislation

- All states vary on their reporting requirements/legislation

- HAI reporting- a Pandora’s box of problems
  - Burden on hospital-time, $\$, personnel
  - Information is too complex to make simple
  - Many regulations-poorly defined
  - Florida- “Compare Care” what does it really tell you and can the public understand?
State Legislation

• Some Examples:

  ➢ Many states prohibiting health care facilities from charging a patient or a patient’s insurer or employer for “preventable adverse events” or mistakes caused by the facility.
    
    **PROBLEM-MANY STATES HAVE NOT DEFINED ‘PREVENTABLE ADVERSE EVENT’**
  
  ➢ Many states are requiring prescreening for certain MDROs such as MRSA for certain “high risk patients”
    
    **PROBLEM- MANY STATES HAVE NOT DEFINED “HIGH RISK” PATIENT.**
  
  ➢ Many states are requiring public reporting of HAI rates to the Dept of Public Health or other entity.
    
    **PROBLEM- THERE IS NO CONSISTENCY AND NOT ENOUGH INFORMATION WITH RESPECT TO TYPE OF HAI TO REPORT AND NO EFFORT TO EDUCATE THE PUBLIC**
  
  ➢ Many states are requiring continuing education, training, hand hygiene and environmental cleaning protocols be instituted.
    
    **PROBLEM- THERE ARE NO FUNDS PROVIDED AND FAILURE TO COMPLY IS A CRIMINAL OFFENSE FOR THE FACILITY IN SEVERAL STATES.**
Changing Healthcare Standards?

• 1960’s MRSA in Denmark was 33%!!!

• NOW - Denmark, Holland, Finland – Infection rates - <1%

• How?
  – Targeted screening of high risk patients upon admission or in some cases universal prescreening
  – Isolation of MRSA positive patients
  – Immediate shut down/cleaning if outbreak occurs
  – Healthcare Workers Screening and reassignment
  – Barrier Precautions
  – Restrictive Antibiotic Use
A Changing Standard of Care for Healthcare?

• Are Healthcare-Associated Infections Preventable?

Mounting evidence that hospital infections are preventable - CHANGING THE STANDARD

- US looks to MRSA control in Europe and then performs our own studies

- Univ. of Pittsburgh, Johns Hopkins, Allegheny Hospital, Brigham and Womens, Northwestern, LIJ, Hopkins-CONFIRM THAT WITH PROPER INTERVENTIONS- INFECTION RATES CAN BE REDUCED TO NEAR ZERO.
Changing Healthcare Standards-cont.

- Great debate over universal prescreening MRSA patients (Active Surveillance Cultures-ASC’s)
  - Logistical issues
  - Legal issues - who, how, when, what to do with results, establishes potentially problematic benchmarks
  - Financial issues
  - Isolation, psychological issues, physician visits, pressure ulcers
  - SHEA/APIC - screen high risk only/CDC - screen only for outbreaks/States (CA) screen those “at risk”

- C.diff - Not recommended to screen unless patient is experiencing symptoms
Expert MRSA Nasal Sampling

• Her Majesty demonstrates a self collected sample....
Changing Reimbursement-(NQF and NEVER EVENTS)

• 2002- National Quality Forum- developed “NEVER EVENTS” list-events which should never occur in a hospital (now called “serious preventable events” OR “selected hospital acquired conditions”).

• Currently includes 28 serious reportable preventable events and the LIST IS GROWING EVERY YEAR….. (does not YET include HAIs specifically)
Changing Reimbursement (CMS-IPPS)

• CMS changes Inpatient Prospect Payment System (IPPS) reimbursements for discharges after 10/08

  ➢ Purpose- to “reduce costs, improve patient outcome, and encourage accountability for complications that occur after admission”
Changing Reimbursement (CMS-IPPS)

• WHAT DO THE CHANGES TO THE IPPS MEAN????

➢ “Hospitals will no longer receive payment at a higher rate for an inpatient stay when the sole reason for the enhanced payment was that the patient had incurred a condition during the stay that was reasonably preventable through adherence to evidence based guidelines.”

NOTE: Not applicable to rehab, long term care, psych, children’s, cancer hospitals or to religious non-medical health care facilities
Changing Reimbursement (CMS-IPPS)

- Selected Hospital Acquired Conditions Included in 2009 Rule
  - Retention of foreign object after surgery
  - Air embolism
  - Blood incompatibility
  - Catheter associated UTI
  - Pressure Ulcer
  - Vascular catheter associated infection
  - Poor glycemic control
  - Surgical site infection including mediastinitis
  - DVT and pulmonary embolism
  - Hospital acquired injuries, falls, burns, fracture electric shock
Changing Reimbursement (CMS-IPPS)

• Impact

➢ Initial Impact- slight financial affect

➢ Future Impact- HUGE

❖ List of events is likely to grow quickly (staph bloodstream infections, VAP, etc)

❖ Door is now open to reduce payments for hospital acquired conditions and will in all likelihood follow state regulations/NQF, etc.

❖ Increased importance of patient admission coding and screening
CMS/NQF Where is the Overlap?

Currently- 3 events endorsed by CMS for nonpayment are also on the NQF “Never Events” list:

- Object left in surgery
- Air embolism
- Blood incompatibility

But the list will grow............
Will the NQF “Never Events” Impact Reimbursements?

Many payers are currently supporting nonpayment for the occurrence of a “serious preventable event” including:

- HealthPartners
- States of MN, MA, WA, VT, PA, ME, CT, MD, MO, NY, CO, TX - will not bill patients for serious preventable adverse events
- Aetna
- Wellpoint
- Geisinger
- Adventist
- United Health, Cigna, Blue Cross/Blue Shield considering support now
Changing Reimbursements and Liability

• Many insurance carriers have endorsed the NQF concept of “Never Events”

Many carriers will continue to cooperate and support healthcare facilities that acknowledge the occurrence of a “Never Event” but ONLY if the facility:

- Apologizes to impacted parties
- Waives all costs related to the “Never Event”
- Performs a root cause analysis of WHY
- Reports the incident to an agency such as TJC
Legal Standards Changes

• Healthcare-associated infections no longer seen as inherent acceptable risk of hospitalization

• Healthcare-associated infections now viewed as “preventable” and potential “never events”

• Plaintiff attorneys already advertising—”If you or a loved one have been diagnosed with an infection after a hospital stay, contact Parker & Waichman today”

• If preventable—will hospitals be held to a strict liability standard in the event of an HAI?
Legal Standards Changes (cont.)

- The Strict Liability Standard (res ipsa) – Does it pass?
  
  - Hospital owes a DUTY to the patient to use due care;
  
  - Accident (infection, adverse condition) is caused by the thing or instrumentality UNDER CONTROL OF THE HOSPITAL; and
  
  - Accident that caused the injury is one that, IN THE ORDINARY COURSE OF THINGS WOULD NOT OCCUR, if those having control and management of the instrumentality used proper care.
Legal Standards Changes (cont.)

- Increasing Liability for Health Care Providers??
  - Will serious reportable adverse events ("Never Events") become the new standard of care for the health care industry and result in strict liability?
  - If CMS is not reimbursing a hospital for a serious reportable adverse event, will a jury interpret this as a liability determination?
  - Will a hospital apology along with an agreement not to charge = admission of liability?
  - Klotz Standard-Will burden now be on the hospital to prove infection did NOT occur during patient stay?
3. How To Reduce Liability, Risk, and Infection Rates?

Program Foundations

• Focus on LOWEST COMMON DENOMINATORS OF INFECTION:
  ➢ Hand Hygiene
  ➢ Environmental Cleaning
  ➢ Preadmission Screening/Visitor Protocols
  ➢ Intervention Bundling (SSI, CAUTI, VAP, CLABSI)

Theory- Focusing on the simplest LCDs will result in the biggest infection rate reduction

• BENCHMARK and then START SMALL (single unit)
• DOCUMENT-(don’t have it, don’t want it and/or have documentation they should never have)
HAI Focus-A Legally Defensible I.P. Program

• Program Components

- Document- checklists, verifiable data, questionnaires
- Consistency- whatever you do- do it on a regular basis
- Validation- multidisciplinary involvement/champions/internal and external audits
- Educate- behavior modification
- Communicate- create goals/feedback/publicize
- Constantly improve and/or correct deficiencies
- Utilize incentives/sanctions
HAI Focus- Legally Defensible I.P. Program

• Program Components- Specific

➤ HAND HYGIENE

– Most recognized measure to reduce HAI’s
– Average compliance- 40-70%
– Compliance Data-not consistent, legally incriminating
– Reasons for noncompliance- time, inconvenience, irritation, lack of materials, lack of education and prioritization
– WARNING-NOT AS SIMPLE AS IT APPEARS!!!!
– NEED TO REACH THE “TIPPING POINT”
Hand Hygiene Tipping Point

• Factors To Create A Hand Hygiene Epidemic
  ➢ Law Of The Few
    ❖ Some people matter more than others- 20%/80% rule, Gaetan Dugas (patient zero), Baltimore carriers, hush puppy hipsters

  ➢ Stickiness- Make the message memorable

  ➢ Power of Context
    ❖ Baltimore winters, hush puppie awareness, bystander theories
    ❖ Environment matters
HAI Focus-Hand Hygiene Programs

• Key Issue-Why Don’t People Wash Their Hands????

  • One size does NOT fit all (POWER OF CONTEXT) MUST EVALUATE THE “WHY” IN YOUR FACILITY

  • Must involve ALL staff (multidisciplinary team) especially champions in the process (THE POWER OF THE FEW)

  • Get Creative- (Ex. Color coding) (STICKINESS)
HAI Focus-Hand Hygiene Programs

• Components

  ➢ Materials

  ➢ Personnel

  ➢ Education

  ➢ Finance
HAI Focus-Legally Defensible I.P. Program

- Program Components-Specific

  - Environmental Cleaning/Disinfection

    - Environmental surfaces in hospitals may be significant vectors for HAI transmission
    - Program should be based on type bacteria/fungi present and the surface/location to be cleaned
    - All items should NOT be cleaned/disinfected in the same way with the same materials as this will result in both “over and under” cleaning.
    - Reasons for noncompliance-insufficient funding, materials, lack of dept recognition, education, communication, and protocols
HAI Focus-Environmental Cleaning

• Key Issue-How Clean is Clean?

  • One size does NOT fit all- look to dept type, occupancy, history, risk determination (CONTEXT)

  • Multidisciplinary Team (POWER OF THE FEW)

  • Get Creative- Color Coding/Checklists (STICKINESS)
HAI Focus-Environmental Cleaning

• Components
  ➢ Materials
  ➢ Personnel
  ➢ Education
HAI Focus-Environmental Cleaning

• Pilot Studies
  • Environmental Services-BIGGEST area of risk
    - Cleaning products-strength, employee exposure, etc
    - Staff coverage
    - Emergency Rooms, Pharmacies, Patient Rooms dirty
    - Food everywhere
    - Dirty COWs
    - Scrubs in “Starbucks”
    - Use of unoccupied patient rooms by staff, equipment
    - Lack of consistency
    - Wandering carts
    - Poor documentation
HAI Focus-Patient Screening/Visitor Protocols

- **Patient Screening**
  - Develop improved admission forms to better identify high risk patients
  - Train intake personnel on risk factors for HAI’s
  - Consider color coding based on risk score

- **Visitor Protocol (no data-no guidelines…yet)**
  - Base on patient susceptibility/occupancy/location
  - Need to balance health/safety issues vs. psychological impacts
  - Videos, posters, have been effective
  - Develop visitor education program
HAI Focus-Intervention Bundles

• Key Issue- Bundles create a legal Standard of Care. Therefore, all tasks in the bundle MUST be completed for the intervention to be successful and meet the Standard of Care.

_bundle Components

• Interventions MUST be based on “evidence based practice”
• Straightforward
• Incorporate the smallest number of tasks to accomplish the goal
• Incorporate FAILSAFE MECHANISMS/Checklists
HAI Focus-Intervention Bundles

• Bundle Development

  ➢ Select champions

  ➢ Incentives for compliance/infection reduction

  ➢ Multidisciplinary team to develop specific interventions, education, failsafe mechanisms
HAI Focus-Intervention Bundles

• Education

  ➢ Videos, posters, hands on training

  ➢ Web based training with exams

  ➢ EMPOWERING NURSES- MUST permit nurses to make decisions developed by the “bundle team” in the absence of countermanding conditions/orders
HAI Focus-Intervention Bundles

- Failsafe Mechanisms
  - Automatic default for device removals
  - Chart reminders
  - Posters/Fact Sheets at bedsides
  - Computerized prompts, alerts, checklists
  - Bundle specific carts
Key Components-Program Implementation

• Comprehensive

• Medically Sound

• Defensible

• Economically Feasible

• Insurable !!!
Key Components-Program Implementation

• Comprehensive/Medically Sound

  ➢ Need “Buy In”

  ➢ Need Medical Champions

  ➢ Need Multidisciplinary Teams

  ➢ Focus on LCDs of infection transmission

  ➢ Start Small

  ➢ Determine baselines and create realistic goals
Key Components-Program Implementation

• Defensible

- DOCUMENT !!!!!!!
- Develop checklists, failsafe mechanisms
- Track compliance, improvements, deficiencies
- CONSISTENCY
- Develop only programs that can be fully implemented, monitored, and complied with. Failure to comply with internally developed procedures may bring greater risk of liability than having no program at all.
Key Components-Program Implementation

• Economic Feasibility

- Should be a “no brainer”
- HAIs erode the bottom line
- APIC-HAIs reduced net inpatient margins by over $5000/patient with direct costs of over $8800/patient
- Reimbursements do not often cover the cost of additional care for HAIs
- Frees up bed days for patients bringing in higher levels of reimbursement
Key Components-Program Implementation

• Insurability

  • Insurance is NOW available in the event of Unit shutdown due to outbreaks
  • Will cover business income loss, nosocomial extra expenses, crises response expenses
  • Must demonstrate good risk management and response programs
  • Track record/Trends
  • “Ensurance for Insurance”
Conclusion/Summary

• Looking Forward????
  ➢ Regulatory Changes
  ➢ Reimbursement Changes
  ➢ Legal Changes
  ➢ Health Care Changes

• Failure to Respond???
  ➢ Increased HAIs
  ➢ Increased liability/costs
  ➢ Decreased reimbursements
  ➢ Decreased quality of care/patient satisfaction
  ➢ Declining reputation/stigma
  ➢ Failure to obtain now available coverage