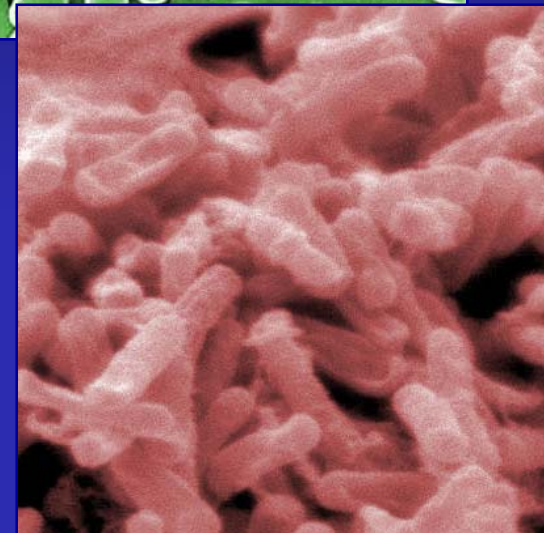
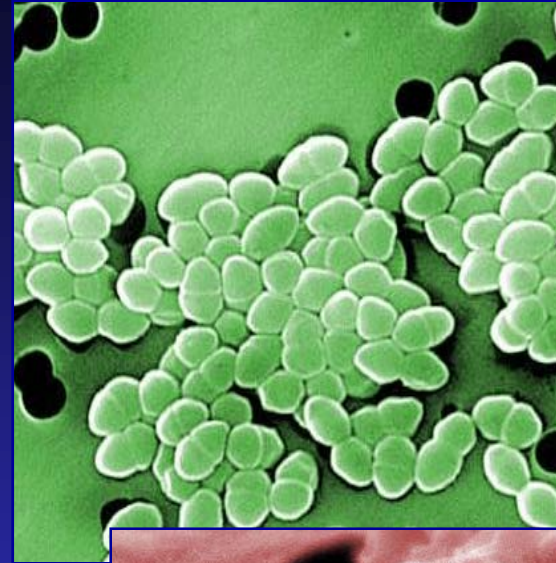


Healthcare Associated Infections

.....Current perspectives

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October 17, 2008



A Note About BD...

BD, a leading global medical technology company that manufactures and sells medical devices, instrument systems and reagents, is dedicated to improving people's health throughout the world.

BD is focused on improving drug therapy, enhancing the quality and speed of diagnosing infectious diseases, and advancing research and discovery of new drugs and vaccines.

The Company's capabilities are instrumental in combating many of the world's most devastating diseases.



Helping all people live healthy lives.



Health Care Associated Infections (HAIs)

aka Nosocomial aka hospital acquired

- Healthcare-associated infections are infections that patients acquire during the course of receiving treatment for other conditions within a healthcare setting.
- Healthcare-associated infections are one of the top ten leading causes of death in the United States.

Estimates of HAIs

- A new report from CDC updates previous estimates of healthcare-associated infections. In American hospitals alone, healthcare-associated infections account for an estimated 2 million infections and 90,000 associated deaths each year. Of these infections:
 - 32 percent of all healthcare-associated infection are urinary tract infections
 - 22 percent are surgical site infections
 - 15 percent are pneumonia
 - 14 percent are bloodstream infections

Prevalence of HAIs

- **Urinary Tract Infections (30-40%)**
 - (indwelling catheters, Longer hosp stay)
- **Lower Respiratory Infections (10-20%)**
 - (mechanical ventilation, VAP, geriatric/pediatric)
- **Surgical Wound Infections (10-20%)**
 - (acute care, surgery)
- **Skin and Soft Tissue Infections (10%)**
 - (elderly, long term care)
- **Blood Stream Infections (5%)**
 - (intravascular devices, UTI, LRTI, SWI etc)

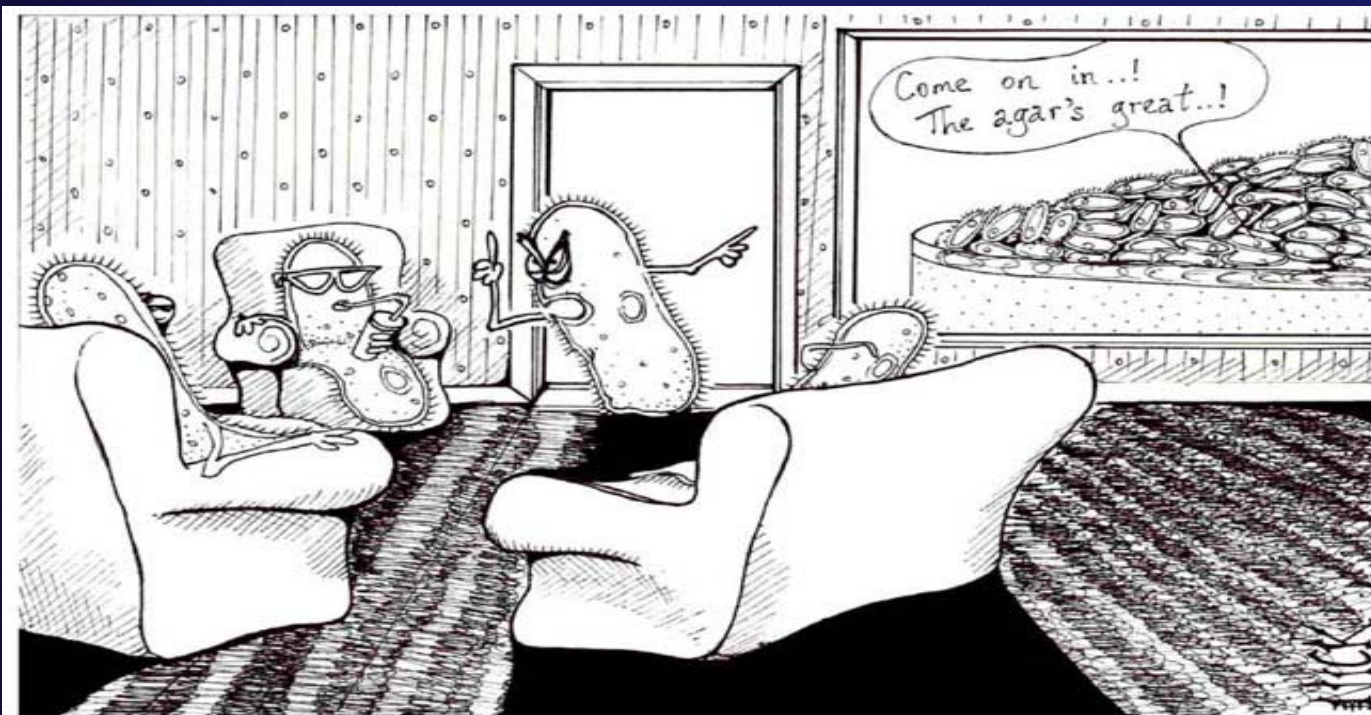
HAI Risk Factors

- **Invasive Procedures (Surgery and Intravascular Devices)**
- **Longer stay in hospitals**
- **Immunocompromised patients**

Bacterial Pathogenicity in HAIs

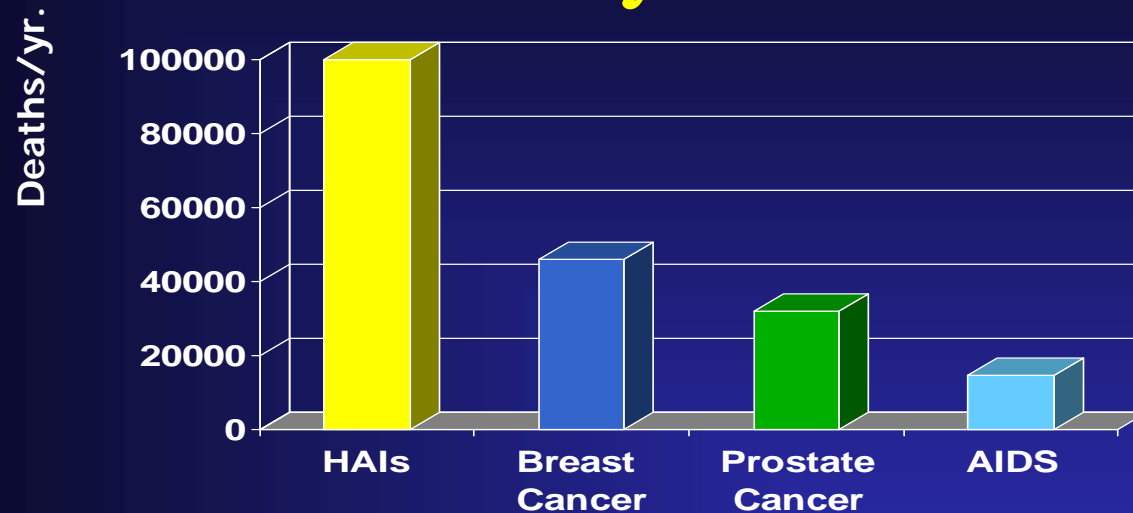
- Commensal bacteria constitute normal patient flora
 - 10^9 on skin
 - 10^{10} in Nasopharynx
 - 10^{13} in faeces
- Potential Pathogenicity of *Staph aureus*, *E coli* and *Enterococcus* species in sterile body sites
- Saprophytic bacteria that colonize patients (*Pseudomonas aeruginosa*, *Enterobacter species*, *Serratia species*, *Acinetobacter baumannii*) and can cause infections after invasive procedures

Health Care Associated Infections (HAIs)



"I wish you'd learn to put the lid on your Petri dish, Harry! We came here with four kids, and now it looks like we've got twenty million...!!"

HAI...Burden to the U.S. Healthcare System

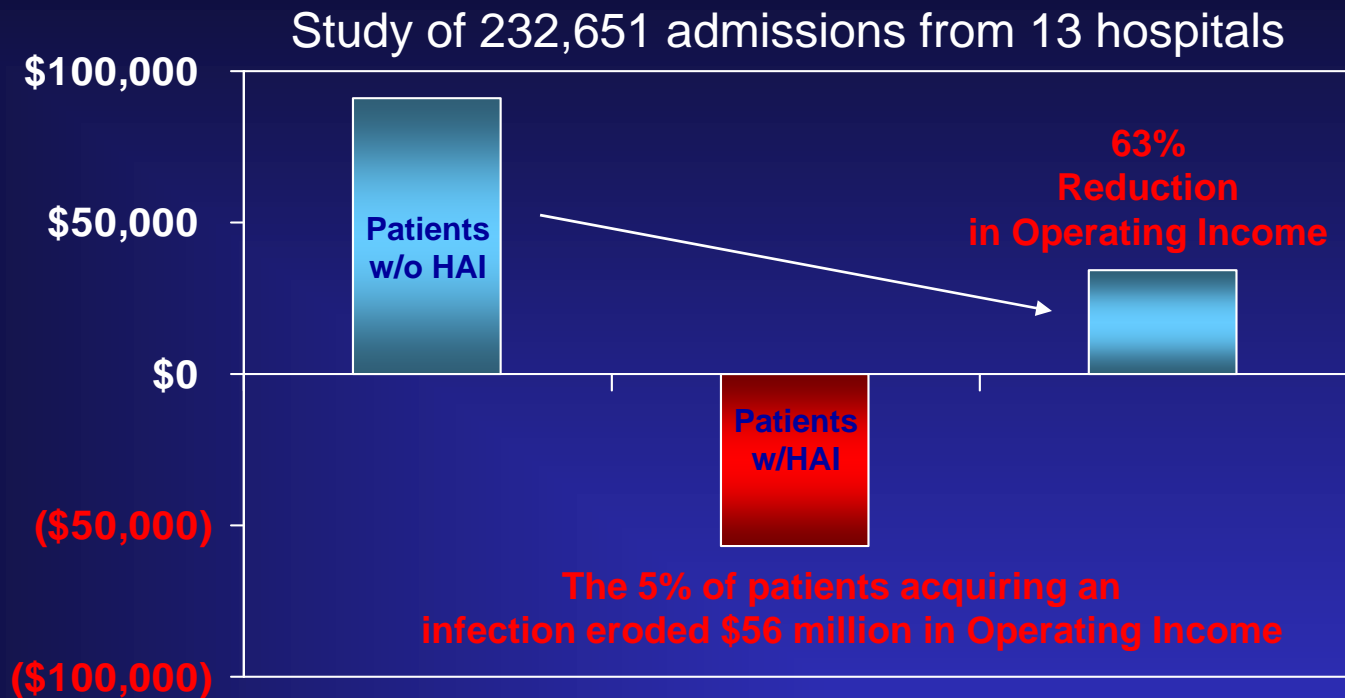


- 8 million excess hospital days
 - ✓ 16 extra hospital days per patient
- Over \$5 billion in excess healthcare costs
- Mortality Rate of 12.9% (6x Greater Than Patients without HAIs)
- >70% due to MDROs—Multi Drug-Resistant Organisms
 - ✓ Microbe is Resistant to More Than 1 Commonly-Used Anti-Infective

Source: CDC



Impact of HAIs to Healthcare Financials



Inpatient Operating Income (\$000)	\$91,091	(\$56,663)	\$34,427
% Patients	95%	5%	100%
# Patients	221,225	11,426	232,651

Source: MedMined, June 2005

Pay for Performance

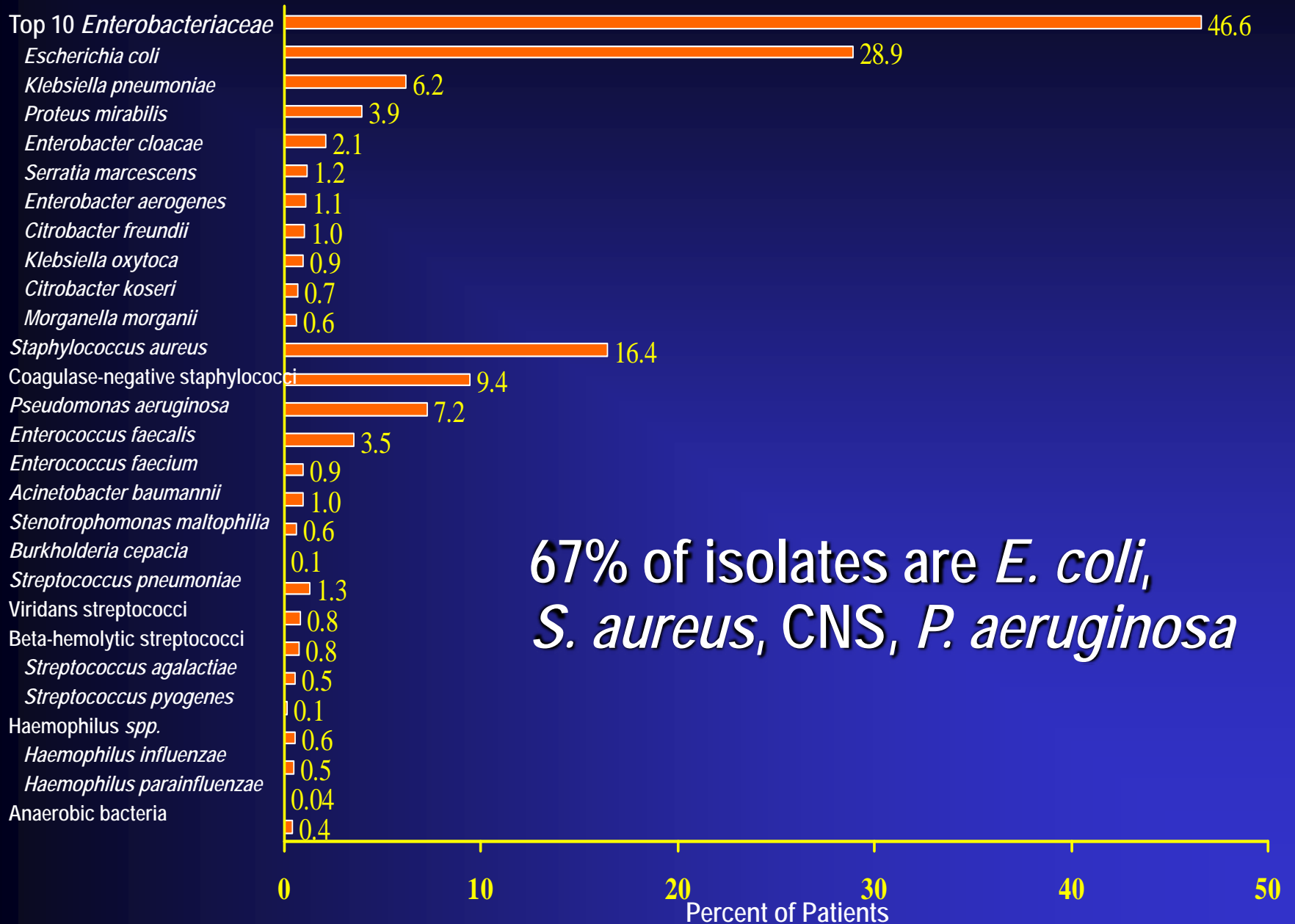
the changing Reimbursement Environment

The Centers for Medicare & Medicaid Services is moving to a pay for performance system. As of October 1, 2008, Medicare will no longer pay hospitals for certain conditions that patient acquires while in the hospital, and hospitals also will not be allowed to bill patients for these costs.

Reporting HAI

- Catheter-associated urinary tract infections
- Vascular catheter associated infections
- Mediastinitis (after coronary artery bypass graft surgery) SSI rates (eg, rates for hip or knee arthroplasty, abdominal and vaginal hysterectomy, coronary artery bypass graft)

Prevalence of Clinically Relevant Species from All Specimen Sources



Major HAI Pathogens

- MRSA
- CA-MRSA
- ESBL producing *Enterobacteriaceae*
- Vancomycin Resistant *Enterococci*
- *Clostridium difficile*

MRSA

- Methicillin-Resistant Staphylococcus aureus (MRSA), a virulent MDRO, is typically carried by 5% of healthy people* who, upon admission to a healthcare setting, can transmit MRSA to healthcare workers and patients causing adverse outcomes
 - For these healthy people, the bacterium is usually harmless, but it can cause infection if it gets into the body through a cut or during surgery.

**Association for Professionals in Infection Control and Epidemiology (APIC) June 2007 Nationwide Study Press Release*

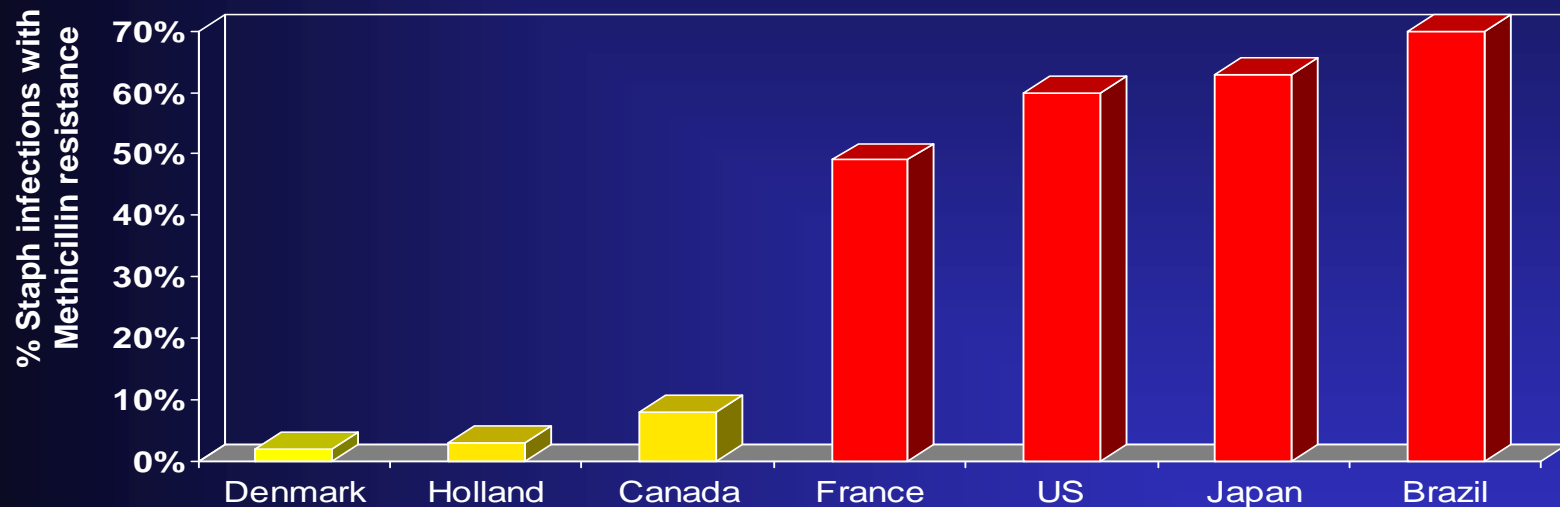
MRSA: What to Do?

Transmission is Preventable!

- “Search and Destroy”
 - Detect MRSA through active surveillance (i.e., nasal-swab cultures or rapid diagnostic methods) for patients entering healthcare facility
 - Prevent Transmission by Practicing Barrier Precautions (i.e., use of gowns & gloves), hand hygiene and isolation of patients
 - Research by the National Quality Forum shows hospital clinicians’ compliance with handwashing is <50%
 - Environmental and Equipment Cleaning and Decontamination (especially bedrails/ bedside equipment)

Impact of Active Surveillance Testing with Isolation/Contact Precautions

MRSA Prevalence



- Routine Active Surveillance
- Limited Active Surveillance

Super bugs in Hospitals

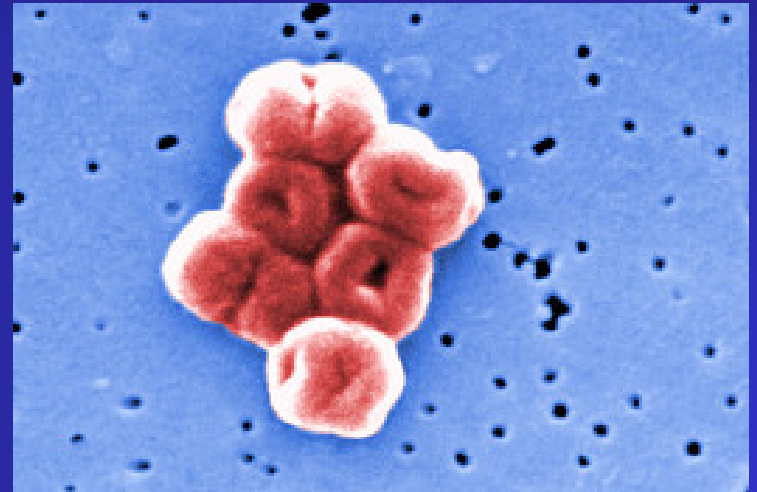
- *Multi-Drug Resistance*
 - *Limited treatment options*
- *Klebsiella pneumoniae*
 - *Carbapenem Resistant*
- *Prevention will require*
 - *early detection*
 - *Control at source*



Gram negative Pathogens

*Some Gram negative bacteria (that normally don't cause disease), cause devastating infections in those with weak immune systems: **wounded soldiers, burn victims, cancer and AIDS patients, the elderly, premature infants and those with severe injuries or illnesses.***

- ***Acinetobacter baumannii***
- ***Enterobacter aerogenes***
- ***Pseudomonas aeruginosa***



Epidemiology of Antibiotic Resistance

- ICU higher than other wards
- Europe – lowest rates in Scandinavia to highest rates in Mediterranean countries
- North America – US higher than Canada
- East Asia and South America – worst resistance rates

ESBLs among Gram-negative bacteria

- ESBL enzymes are most commonly produced by two bacteria – *Escherichia coli* (otherwise known as *E. coli*) and *Klebsiella pneumoniae*. But ESBL enzymes can also be found in bacteria such as *Salmonella*, *Proteus*, *Morganella*, *Enterobacter*, *Citrobacter*, *Serratia*, and *Pseudomonas*.
- ESBL-producing bacteria are spread through feces either by self-infection or direct contact with feces of an infected person. It can, for example, spread from patient to patient on the hands of healthcare workers or the patients themselves. This is why hospitals and seniors' homes are particularly prone to outbreaks.
- ESBL enzymes can also spread by passing from one bacterium to another.
- Use of successive generations of beta-lactam antibiotics has resulted in successively more potent beta-lactamase enzymes resulting in multi drug resistance

Antimicrobial Resistant Mechanisms among Gram-Positive Bacteria that grow aerobically

- Methicillin-Resistant *Staphylococci*: *MRS*
- Community-Acquired *Staphylococcus aureus*: *CA-MRSA*
- Decreased Susceptibility to Glycopeptides (Vancomycin) among *Staphylococcus aureus*
- Vancomycin Resistance in *Enterococci*: *VRE*
- Resistance among *Pneumococci* (Pen, Macrolides)

Laboratory Methods to Detect Antimicrobial Resistant Mechanisms

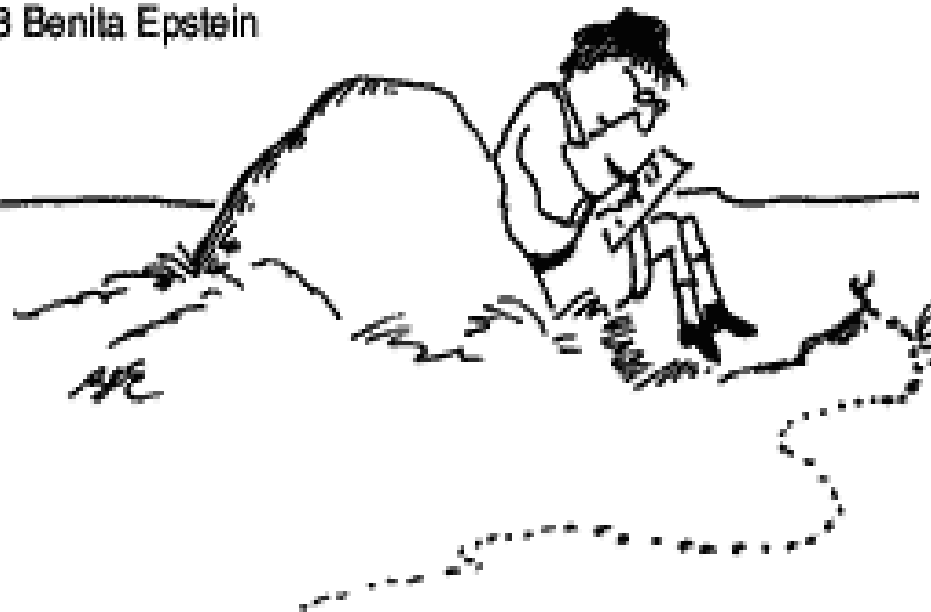
- All Clinical Labs Perform Phenotypic Susceptibility Test Methods Because it is the Only Way to Detect the impact of the Hundreds of Antimicrobial Resistance Mechanisms Both Known as well as Emerging



Resistance Mechanisms

© 1998 Benita Epstein

www.benitaeinstein.com



"Day 573 of the project: Let's just say there are many, many, many, many ants and leave it at that."

Are HAIs Preventable?

- **Reduction in Central line-related bloodstream infections and ventilator associated pneumonia (VAP) and MRSA infections**
 - **Pittsburgh Regional Healthcare Initiative,**
 - (a consortium of health care facilities)
 - 68% reduction in Central Line related BSI during a four-year period.
 - **Keystone Project (Michigan),**
 - (intervention to prevent catheter-related infections in hospitals)
 - reduction of up to 66% of central line-associated bloodstream infections during an 18-month period)

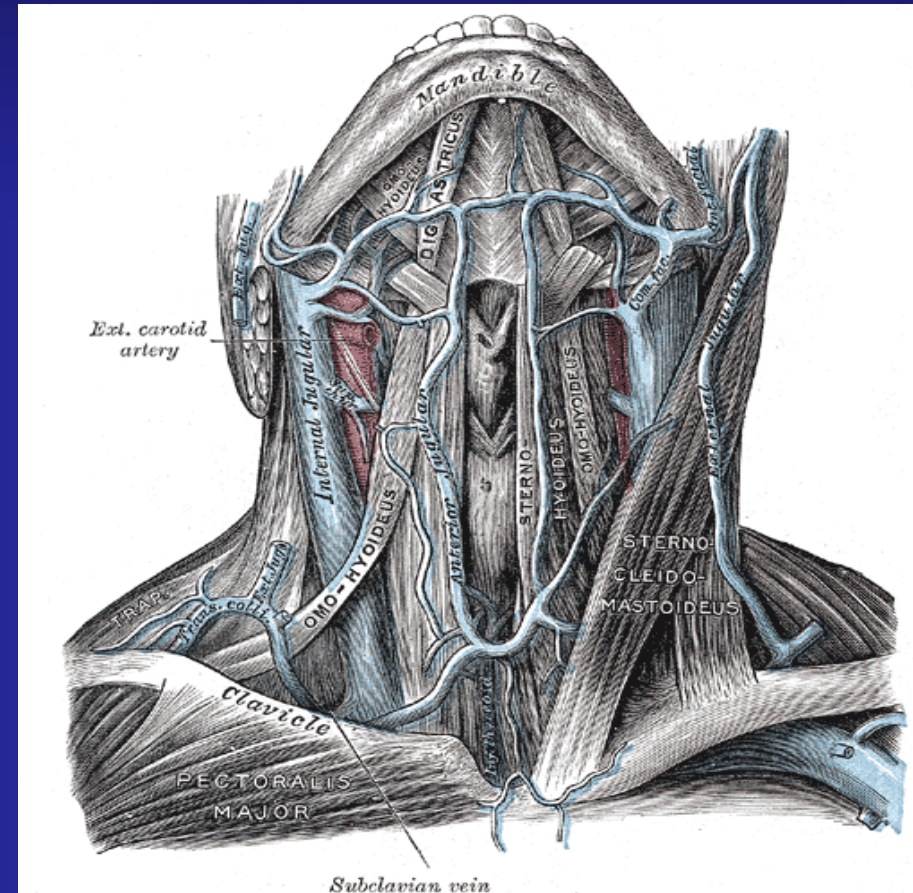
Interventions to reduce CR-BSI related HAIs

100k
lives

ICUs that have implemented multifaceted interventions similar to the central-line bundle have nearly eliminated CR-BSIs.

The key components of the Central Line Bundle are:

- Hand Hygiene
- Maximal Barrier Precautions Upon Insertion
- Chlorhexidine Skin Antisepsis
- Optimal Catheter Site Selection, with Subclavian Vein as the Preferred Site for Non-Tunneled Catheters
- Daily Review of Line Necessity with Prompt Removal of Unnecessary Lines



HAI's are Preventable:

IHI 100,000 *Lives* Campaign

- The Institute for Healthcare Improvement (IHI) is a not-for-profit organization leading the improvement of health care throughout the world. IHI was founded in 1991 and is based in Cambridge, Massachusetts.
- On December 14, 2004, at its 16th Annual National Forum on Quality Improvement in Health Care, IHI launched the “100,000 Lives Campaign”—a national initiative to engage thousands of U.S. hospitals in an effort to prevent 100,000 needless inpatient deaths by implementing improvements in care.
- Declaring that “Some is not a number; soon is not a time,” Don Berwick, MD, IHI’s President and CEO, challenged U.S. hospitals to commit to reaching a bold goal: saving 100,000 lives by June 14, 2006. To help hospitals reach this goal, IHI outlined six clinical interventions that hospitals could focus on to reduce mortality and morbidity.
- Three of the six intervention bundles (i.e., Proven Best Practices or Standard of Care) focus on prevention of HAIs:
 - ✓ Intravascular central catheter infections
 - ✓ Surgical Site infections
 - ✓ Ventilator-associated pneumonia

100k *lives* Campaign

SOME IS NOT A NUMBER. SOON IS NOT A TIME.

HAI's are Preventable: IHI 100,000 Lives Campaign

- On June 14, 2006, the 100,000 Lives Campaign ended and IHI announced that after 18 months, the 3,100 Campaign hospitals had exceeded the goal of 100,000 lives saved by a significant margin.
 - ✓ The result: hospitals participating in the Campaign had prevented an estimated 122,300 needless deaths.

100k *lives* Campaign

SOME IS NOT A NUMBER. SOON IS NOT A TIME.

Concept of Zero Tolerance to HAIs

- Does not mean “No infections”
- HAIs - **not** an inevitable outcome of care
- Requires a culture change among care providers
- Clear guidelines
- Continuing education / peers /team members

Best Practice: Active Surveillance via Rapid Molecular Testing



- First in U.S. to screen 100% of patients for MRSA colonization upon admission
- 2 hours to result enabled with BDD IDI-MRSA Assay
- Patients with positive results immediately put into isolation, with contact precautions and decolonization protocol
- Objective is to reduce MRSA-associated infections by 50% in 2 years
- First 7-month results ahead of target – more than 50% reduction in infections, with substantial net cost savings

BD's HAI Focus Areas

- ✓ **Prevent MDRO-associated hospital-acquired infections via rapid active surveillance testing and patient management protocols**

- ✓ **Two Main Diagnostic Assays:**

- **Nasal Cultures (e.g., BD CHROMagar MRSA)**
- **Molecular Nasal Assay (e.g., BDD-GSI MRSA)**

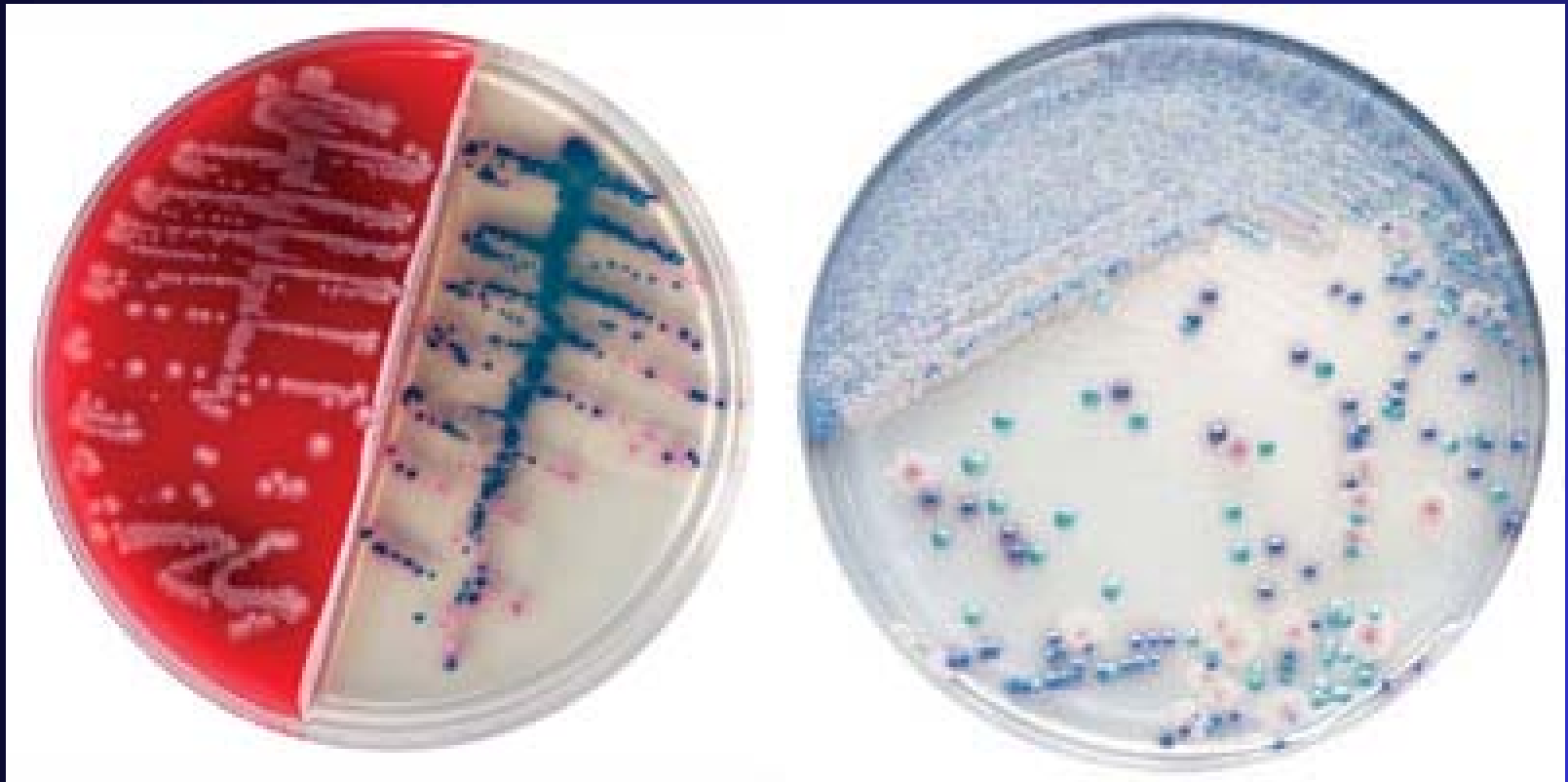
Strongly recommended by SHEA (from 2003 Guidelines):

Active surveillance testing is essential to identify the reservoir for spread of MRSA and VRE infections and make control possible using the CDC's long-recommended contact precautions.



BD CHROMagar

Chromogenic Media for surveillance



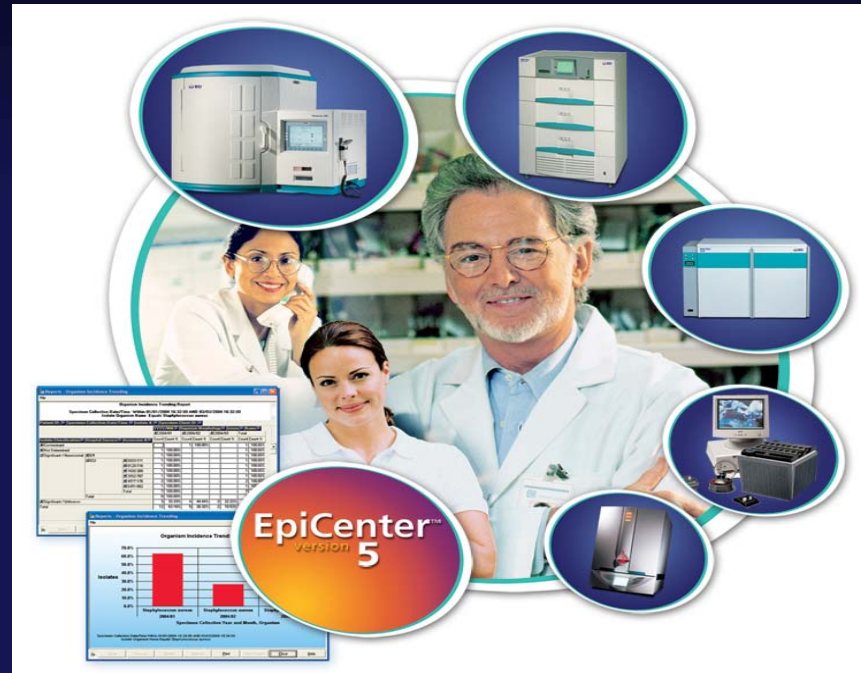
BDD GeneOhm

BD GeneOhm™ MRSA Assay is a qualitative in vitro diagnostic test for the direct detection of MRSA from a nasal specimen

The BD GeneOhm™ StaphSR Assay identifies and differentiates MRSA and SA directly from positive blood culture.



Enhancing Diagnostic Value: Earlier, Actionable Information



The *BD EpiCenter™* System Collates BD Diagnostic Data and Provides Timely, Actionable Epidemiological Information to Clinicians, Epidemiologists, Microbiologists and Pharmacists. For example:

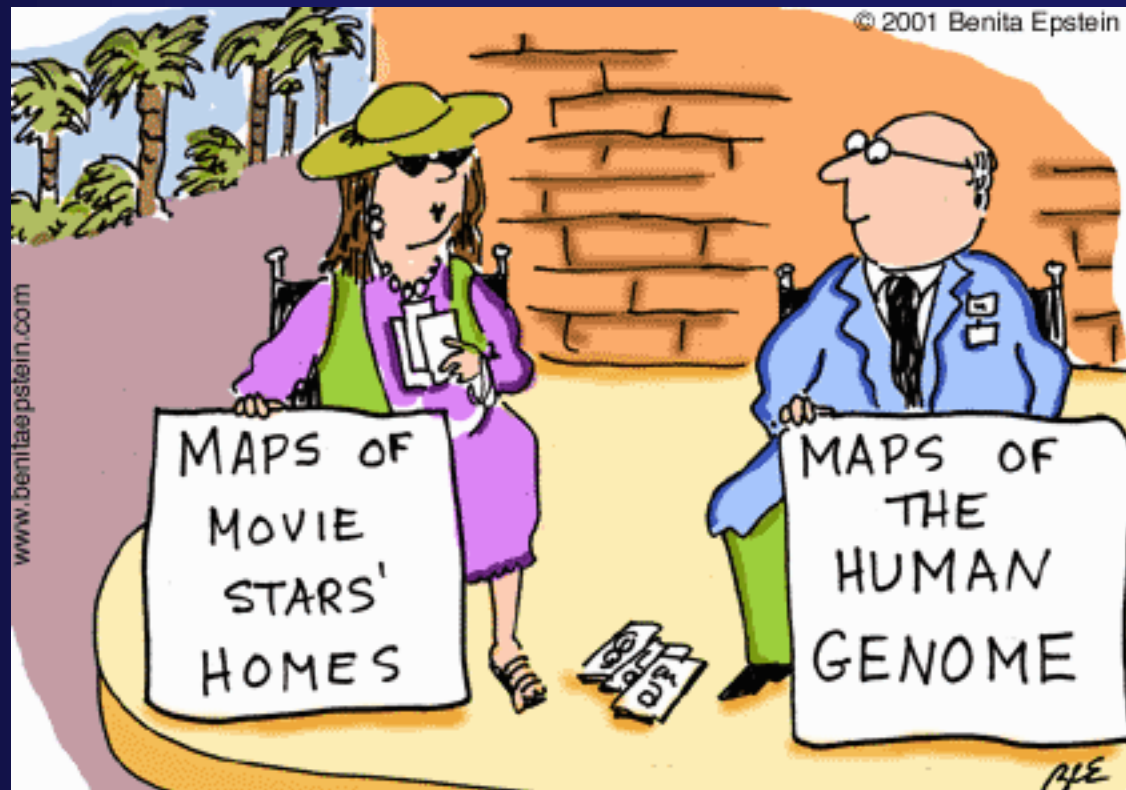
- HAI Detection, Tracking, Monitoring
- Resistance Detection and Automated Alerts

The BDD-GSI Platform Further Secures this Strategy

Summary of BD HAI's Focus Areas

- ✓ *Prevent MDRO-associated hospital-acquired infections via rapid active surveillance testing and patient management protocols*
- ✓ *Optimize patient management relative to the diagnosis and treatment of Staph-associated infections – provide earlier actionable information to get patients on proper antibiotic therapies more rapidly*
- ✓ *Reduce catheter-related bloodstream infections (CR-BSIs) with clinically proven best-in-class closed intravascular catheter access systems*

Keeping up with Technology Trends....



Trends from an Industry Perspective

- Laboratory Automation
 - Diminishing Supply of Medical Technologists
- Clinical Decision-Making Software
 - Places Real-time, Mission-critical knowledge at Clinician's Fingertips
 - For example, IHI Care Guidelines
 - May Enable State Mandatory Reporting Requirements
- Predictive Diagnostics
 - A Number of Companies are Investing in Identifying and Mining Host-Response Markers to Detect Disease States Prior to their Clinical Onset

Summary

- **Laboratory Medicine/ Clinical Microbiology Continues to Add Significant Value to Healthcare**
 - ✓ In Rapid Screening and Containment of HAIs
 - ✓ In Detecting MDRO's and Effectively Directing Therapeutic Interventions
 - ✓ In Adopting Molecular-Based Diagnostic Methods (in addition to Phenotypic Methods) Add "Real-Time" Value to Patient Care

BD's Aspiration:

*.....to be acknowledged by our customers around the world
as the company best known for its commitment and
collaborative efforts to prevent HAIs - pursuing our purpose
of "helping all people live healthy lives"*



My Sincere Thanks to Prof Vasse Ware and
Lehigh U for this Opportunity

And...

Thank you in advance for all your future contributions!

