

PREVENTION OF HEALTHCARE-ASSOCIATED INFECTIONS: KEY CHALLENGES AND FUTURE DIRECTIONS

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Thanks to the following for some slides: Lauren DiBiase, Emily Sickbert-Bennett

LECTURE TOPICS

- Tribute to Dr. William Rutala
- Importance of the changing healthcare environment
 - Aging population, growth of nursing homes, introduction of MDROs from community into the hospital
- Meeting CMS and Societal Expectations
 - Expectation of a "0" HAI infection rate, lack of risk adjustment, lack of validation of surveillance data
- Device-associated infections: A tale of poor engineering
 - Phacoemulsifier, heater-cooler units, duodenoscopes
- The threat of antibiotic/germicide resistant pathogens
 - *C. difficile*, norovirus, *Candida auris*
- The growing importance of non-device associated infections

HE STANDS FOR TRUTH, RESEARCH AND THE SCIENTIFIC WAY!



It's A Bird.....It's A Plane.....No It's Superman
Who is disguised as William A. Rutala

32+ YEARS OF COLLABORATION! Rutala WA, Weber DJ – PubMed Citations (206 & counting)

Number 1, 1985, JAMA

Obesity as a Predictor of Poor Antibody Response to Hepatitis B Plasma Vaccine

David J. Weber, MD, MPH; William A. Rutala, PhD, MPH; Gregory P. Samsa, MS;
Jane E. Santimaw, RN; Stanley M. Lemon, MD

Number 100, 2007, ICHE

Compliance With Isolation Precautions at a University Hospital

David J. Weber, MD, MPH;
Emily E. Sickbert-Bennett, MS;
Vickie M. Brown, RN, MPH; Rebecca H. Brooks, RN;
Irene P. Kittrell, RN; Brenda J. Featherstone, RN;
Tina L. Adams, RN; William A. Rutala, PhD, MPH

Disinfectants used for environmental disinfection and new room decontamination technology

William A. Rutala PhD, MPH^{a,b,*}; David J. Weber MD, MPH^{a,b}

A Prolonged Outbreak of KPC-3- Producing *Enterobacter cloacae* and *Klebsiella pneumoniae* Driven by Multiple Mechanisms of Resistance Transmission at a Large Academic Burn Center

Hajime Kanamori,^{a,b} Christian M. Parobek,^c Jonathan J. Juliano,^a David van Duin,^a
Bruce A. Cairns,^a David J. Weber,^{a,b} William A. Rutala^{a,b}

Number 150, 2013, AJIC

Number 200, 2017, AAC

WILLIAM A. RUTALA, PhD, MPH

Award and Honors

- Only person to have named awards by both APIC and SHEA
- Editorial Board, ICHE
- Advisor to CDC, FDA, EPA, FTC, US Congress
- Carole M DeMille Lifetime Achievement Award, APIC, 1999
- Barr Distinguished Alumni Award, UNC SPH, 2012
- SHEA Lectureship, 2012
- Kelsey Lecture, UK, 2001 and 2012
- Favero Lectureship, APIC, 2009

Accomplishments

- ~40 years in infection prevention
- >600 publications
- World's leading authority on sterilization and disinfection (author of CDC Guideline on S/D)
- Developed SPICE Program which has trained the IPs at >90% of all NC hospitals
- >370 invited presentations at state, national and international symposia

FAMILY IS IMPORTANT TO A SUCCESSFUL CAREER



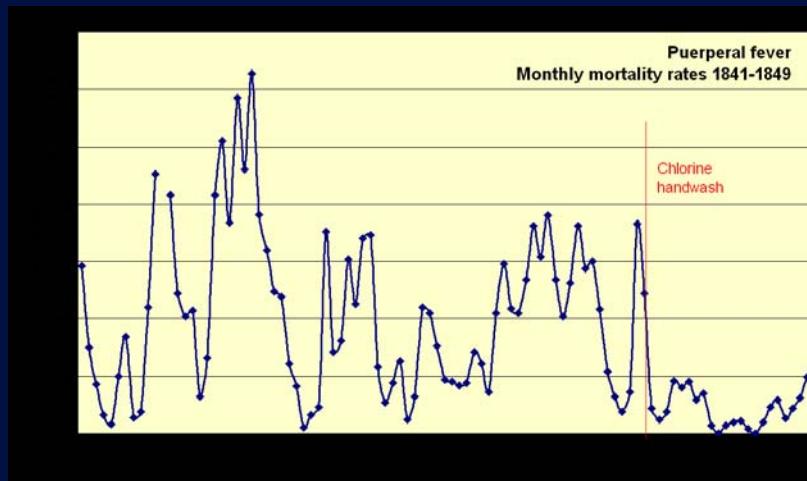
BILL'S SIGNIFICANT OTHER



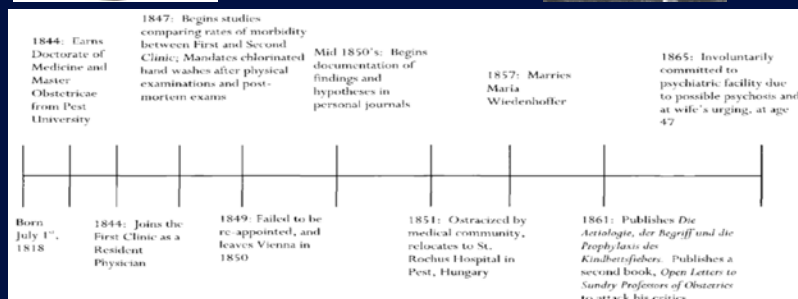
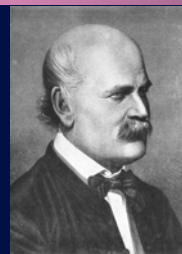
NO OFFENSE - DONNA



INTRODUCTION OF HAND HYGIENE TO REDUCE HAIs BY IGNAZ SEMMELWEIS



PERSONAL IMPACT OF INTRODUCING HAND HYGIENE ON DR. SEMMELWEIS



CLEARLY BILL HAS WEATHERED HOSPITAL EPIDEMIOLOGY BETTER THAN SEMMELWEIS



Unlike Semmelweis, Bill will spend his future enjoying his family, traveling (goal=100 countries), continuing to direct SPICE, and conducting infection prevention research

WELCOME UNC HOSPITALS' NEW HOSPITAL EPIDEMIOLOGIST, EMILY SICKBERT-BENNETT, PhD, MS

Awards and accomplishments

- 14 years experience in infection prevention
- Adjunct Asst. Professor, Epidemiology
- Research Asst. Professor, Medicine
- Bernard Greenberg Award for Excellence in Doctoral Research, Gillings SPH 2011
- Associate Editor, American Journal of Infection Control
- >45 peer-reviewed publications



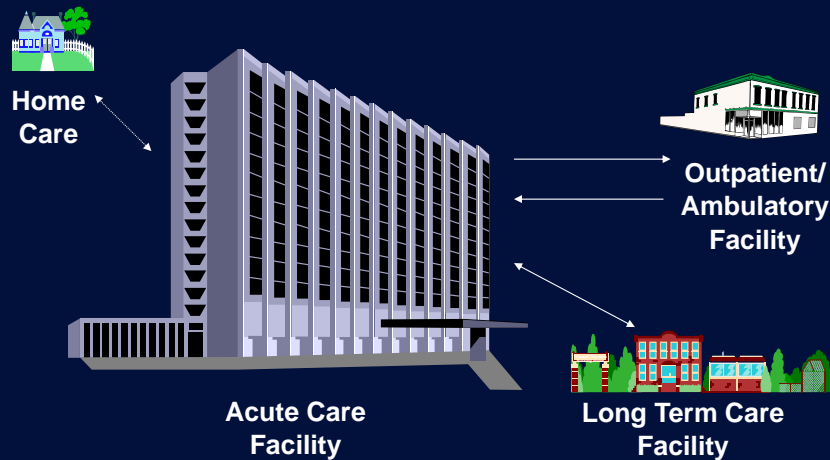
IMPORTANCE OF THE CHANGING HEALTHCARE ENVIRONMENT

Aging Population

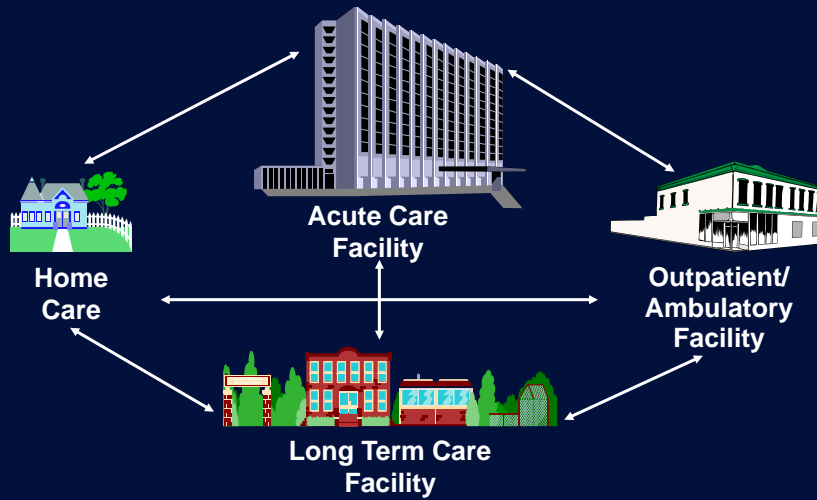
Growth of extended care facilities

Increased introduction of MDROs from the community into the hospital

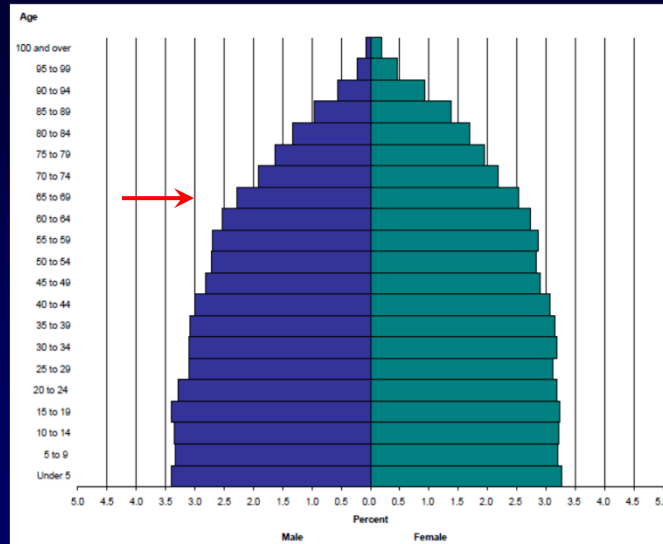
HEALTHCARE SYSTEM OF THE PAST



CURRENT HEALTHCARE SYSTEM



PROJECTED US POPULATION, 2050



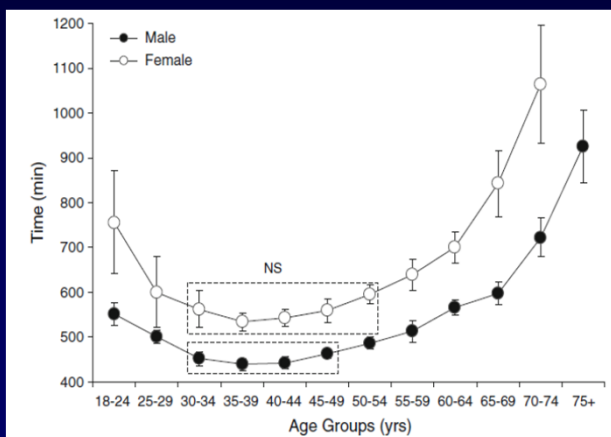
AGE

>100 =	1,095
95-99 =	2,764
90-94 =	6,030
85-89 =	9,463
80-84 =	12,225
75-79 =	14,407
70-74 =	16,537
65-74 =	19,477
65-79 =	35,541
80+ =	31,577

Numbers in thousands

US Census

AGE-RELATED CHANGES IN 100-km ULTRA-MARATHON RUNNING PERFORMANCE



Knuchtle B, et al. Age 2012;34:1033

IMPACT OF HAIs IN LONG-TERM CARE

- ~3.2 million Americans live in extended care facilities, 2008¹
- ~1.0 million Americans reside in assisted living facilities, 2008¹
- 1.6-3.8 million infections per year²
- Incidence of endemic infections = 1.8-13.5 infections per 1,000 resident days²
- Estimated several thousand outbreak occur per year²
- Infections are the leading reason for hospital transfer²

IMPACT OF HAIs IN NURSING HOMES

Nursing Homes

- Number of nursing homes: 15,600 (2014)
- Proportion of nursing homes with for-profit ownership: 69.8% (2014)
- Number of licensed beds: 1.7 million (2014)
- Number of residents: 1.4 million (2014)

Nursing facilities, alternative residential care places, home care

- 2000=15 million; 2050=27 million

Impact

- 1.6-3.8 million infections per year
- Incidence of endemic infections = 1.8-13.5 infections per 1,000 resident days
- Estimated several thousand outbreak occur per year
- Infections are the leading reason for hospital transfer

CDC

OUTBREAKS OF HEPATITIS B DUE TO GLUCOSE MONITORING, UNS, 2009-10

Table 1.
Analysis of Data from Epidemiologic Studies Conducted among Residents of Assisted Living Facilities during HBV Infection Outbreak Investigations Found to Be Associated with AMBG—United States, 2009–2010

State (reference) ^a	Total number of residents tested	Residents included in epidemiologic study ^b				RR (95% CI)
		Receiving AMBG		Not receiving AMBG		
		Tested	Acute HBV infection (%)	Tested	Acute HBV infection (%)	
NC (14)	61	15	8 (53%); 6 died	25	0 (0%)	27.6 (1.7–446.7)
VA (15)	44	5	3 (60%)	26	1 (4%)	15.6 (2.0–121.3)
VA (16)	126	13	12 (92%)	75	2 (3%)	34.6 (8.7–137)
FL (17)	48	10	6 (60%)	38	1 (3%)	22.8 (3.0–168.3)

^a NC = North Carolina; VA = Virginia; FL = Florida

^b Includes only residents with acute HBV infection and those susceptible to HBV.

Thompson ND, et al. J Diabetes Sci Technol 2011;5:1396-1402

INFECTION CONTROL PRACTICES IN ASSISTED LIVING FACILITIES

TABLE 3. Survey Data on Infection Control Practices and Compliance with Bloodborne Pathogens (BBP) Standard in 50 Assisted Living Facilities (ALFs) in Virginia, 2006

Characteristic	ALFs, by size			P, size	ALFs, by type of ownership		P, type of ownership
	<17 beds (n = 10)	17–50 beds (n = 15)	>50 beds (n = 25)		Individual (n = 16)	Not individual (n = 34)	
Shared glucose monitoring devices	1 (10)	2 (13)	7 (28)	.46 ^a	2 (13)	8 (24)	.47 ^a
Did not use safety devices ^b	10 (100)	15 (100)	16 (64)	.01 ^a	14 (88)	27 (79)	.70 ^a
Did not comply with OSHA BBP standard ^c	10 (100)	11 (73)	6 (24)	<.001 ^a	13 (81)	14 (41)	.01 ^d
Did not require infection control training	5 (50)	5 (33)	2 (8)	.01 ^a	6 (38)	6 (18)	.16 ^a

- 16% shared glucose monitoring devices (without cleaning) between residents
- 34% did not offer employees HBV vaccine

Patel AS, et al. ICHE 2009;30:209-214

CHALLENGES IN INFECTION PREVENTION

- Patients
 - Patients frequently have risk factors for infection/colonization
 - ◆ Older age, incontinence, poor functional status, malnutrition
 - ◆ Chronic diseases: Diabetes, renal dysfunction, neurologic impairment
 - ◆ Use of medical devices: Foley catheters
 - ◆ Non-intact skin: Decubiti, diabetic foot ulcers
 - ◆ Frequent hospital contact (e.g., dialysis)
 - ◆ Medications (drugs that affect level of consciousness, immune function, gastric acid secretions, and normal flora)
 - Patients frequently colonized/infected with MDROs
 - Patients frequently receive antibiotics

CHALLENGES IN INFECTION PREVENTION

- Infection control
 - Patients often housed in multi-bed rooms
 - Patients, even if colonized/infected, have contact with each other (e.g., common areas, dining area)
 - Limited or no access to hallway sinks or alcohol-based hand rubs
 - Facility may not have trained infection preventionist
 - Facility unlikely to have an MD infection preventionist
 - Likely low compliance with hand hygiene and environmental disinfection
 - Limited studies in long-term care facilities on which to base recommendations

CHALLENGES IN INFECTION PREVENTION

- Environmental services (EVS)
 - Potentially less trained staff
 - Lack of infection control leadership (i.e., trained IP and hospital epidemiologist)
 - Terminal disinfection occurs infrequently (i.e., most patients long-term)
 - Many rooms will be multi-bed limiting use of “no touch” methods
 - Product cost likely to be more of an issue than for acute care hospitals

DIVERSE SOURCES OF *C. difficile* INFECTION IDENTIFIED ON WHOLE GENOME SEQUENCING

Table 1. Classification of 957 Cases of *C. difficile* Infection According to the SNV Threshold Used to Define a Genetic Relationship.^a

Classification	Main Analysis	Sensitivity Analysis	
	0–2 SNVs	0 SNVs	0–10 SNVs
	number of cases (percent)		
Genetically distinct	624 (65)	717 (75)	428 (45)
Genetically linked to any previous case	333 (35)	240 (25)	529 (55)
Closest genetic link through hospital contact			
Any hospital contact within plausible limits†	181 (19)	144 (15)	224 (23)
Ward contact‡	126 (13)	98 (10)	136 (14)
Ward contamination only‡	5 (1)	7 (1)	8 (1)
Shared medical specialty only†	17 (2)	15 (2)	28 (3)
Other hospital-wide contact only†	12 (1)	9 (1)	22 (2)
Ward contamination and hospital-wide contact	21 (2)	15 (2)	30 (3)
Closest genetic link through community contact, with no hospital contact			
Any community contact	32 (3)	23 (2)	63 (7)
Same general medical practice	15 (2)	10 (1)	37 (4)
Same residential postal-code district, but different general medical practice	17 (2)	13 (1)	26 (3)
Genetically related but no known hospital or community contact	120 (13)	73 (8)	242 (25)

Site: Oxfordshire, UK
2007-2011

1250 *C. difficile* cases
98% sequenced
Only 33% linked

Of 333 patients with linked cases; 38% had close hospital contact with another patient and 36% had no hospital or community contact with another patient

Eyre D, et al.
NEJM 2013;369:1195

MEETING CMS AND SOCIETAL EXPECTATIONS

Expectation of “0” infection rate

Lack of risk adjustment

Lack of validation of individual hospitals reporting

VALUE BASED PURCHASING: BENCHMARKS AND THRESHOLDS

FY2019 VBP HAI Benchmarks & Thresholds		
Measure	Benchmark	Threshold
CLABSI	0.000	0.860
CAUTI	0.000	0.822
COLO SSI	0.000	0.783
HYST SSI	0.000	0.762
LabID MRSA	0.000	0.854
LabID CDI	0.113	0.924

Gase K. Presented at SHEA, St. Louis, 2017

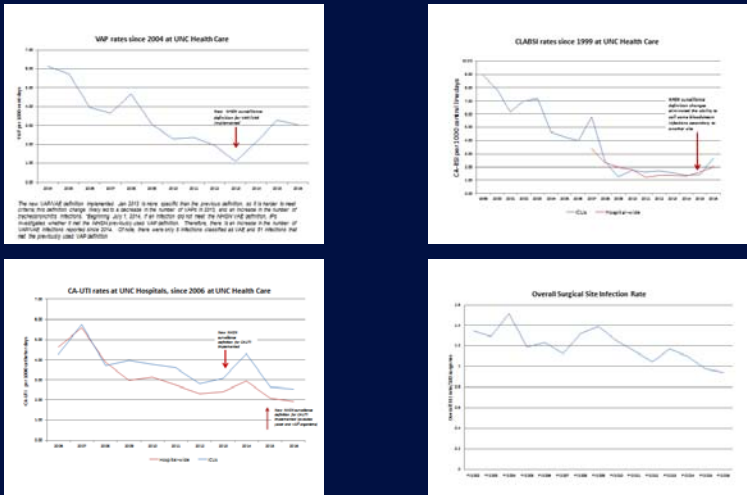
LEADING CAUSES OF DEATH, US, 2014

	Deaths	Rate	Age-Adjusted Rate 2014, 2010, 2005	% Total Deaths
Accidents	136,053	42.7	40.5, 38.0 (+6.1%), 39.5 (+2.5%)	5.2%
MVA	35,092	10.8	13.1, 10.6 (+19/1%), 8.0 (+38.9%)	
Diabetes	76,488	24.0	20.9, 20.8 (+0.5%), 24.9 (-16.0%)	2.9%
Influenza and pneumonia	55,227	17.3	15.1, 15.1 (0%), 21.0 (-39.3%)	2.1%
Suicide	42,773	13.4	13.0, 12.1 (+6.9%), 10.9 (+16.1%)	1.6%

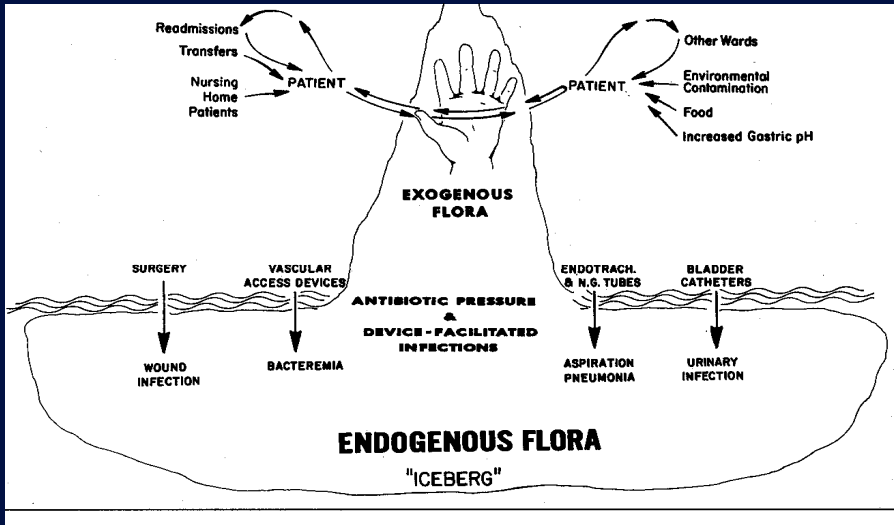
HAIs = ~75,000 deaths (rank = #8)

<http://www.medicalnewstoday.com/articles/282929.php>; Health, US, 2015, CDC

HAI INCIDENCE OVER TIME, UNC



HAZARDS IN THE ICU



Weinstein RA. Am J Med 1991;91(suppl 3B):180S

DENSITY OF BACTERIA ON THE HUMAN BODY

Table 1. Bounds for bacteria number in different organs, derived from bacterial concentrations and volume.

Location	Typical concentration of bacteria ⁽¹⁾ (number/mL content)	Volume (mL)	Order of magnitude bound for bacteria number
Colon (large intestine)	10^{11}	400 ⁽²⁾	10^{14}
Dental plaque	10^{11}	<10	10^{12}
Ileum (lower small intestine)	10^9	400 ⁽⁵⁾	10^{11}
Saliva	10^9	<100	10^{11}
Skin	$<10^{11}$ per m^2 ⁽³⁾	1.8 m^2 ⁽⁴⁾	10^{11}
Stomach	10^3 – 10^4	250 ⁽⁵⁾ –900 ⁽⁶⁾	10^7
Duodenum and Jejunum (upper small intestine)	10^3 – 10^4	400 ⁽⁵⁾	10^7

Sender R, et al. PLoS Biol 2016;14:e1002533

CONCLUSIONS

- Decrease in HAIs greater than decrease in many other important causes of death
- Reaching “0” HAIs is not possible given the following: large numbers of microbes on body surfaces, inability to sterilize human body surfaces, and need for indwelling devices to provide medical care
- Cost of HAI prevention, per case prevented, will rise as we decrease HAI incidence

PATIENT LEVEL RISK FACTORS FOR HAIs – ADJUSTMENT BY NHSN

CLA-BSI	CA-UTI	SSI	<i>C. difficile</i>
Device	Device	Glucose control	Age
ICU location	Gender	Type of hair removal	Antibiotics
Prolonged hospitalization prior to catheter	Drainage system	Antibiotic prophylaxis	Broad spectrum antibiotics
IJ catheter	Age	Temp control	Community colonization
Femoral catheter		Supplemental O2	Immunosuppression
Neutropenia		ETOH-antiseptic skin prep	
Prematurity		Wound protectors (GI)	
Parenteral nutrition		Diabetes*	
Blood transfusion (kids)		ASA score*	
Reduce RN to Pt ratio, ICU		Gender*	
		BMI*	* Included in for some ops
		Duration*	Risk factors based on SHEA
		Scope *	Guidelines

Risk factors for COLO and HYST

NHSN operative procedures	Risk factors included in SIR logistic regression model
Colon surgery (COLO)	Age, anesthesia, ASA, duration, endoscope, medical school affiliation, location bed size, wound class
Abdominal hysterectomy (HYST)	Age, anesthesia, ASA, duration, endoscope, location bed size

http://www.cdc.gov/nhsn/PDFs/pscManual/SSI_ModelPaper.pdf

Limitations of NHSN SSI Risk Adjustment

- Model generated from **predictor variables of convenience** that exist in NHSN database rather than all known risk factors
 - Patient level variables = Age, gender, wound class, ASA score, and 2-3 other variables
- Predictor variables chosen for inclusion in the model on the basis of **statistical parameters alone**
 - Unknown relevance of bed size and medical school affiliation
- Study sample over emphasized large hospitals
- Overall change in c-index is modest
 - Only 16 (41%) of procedure-specific models have c-index >0.7

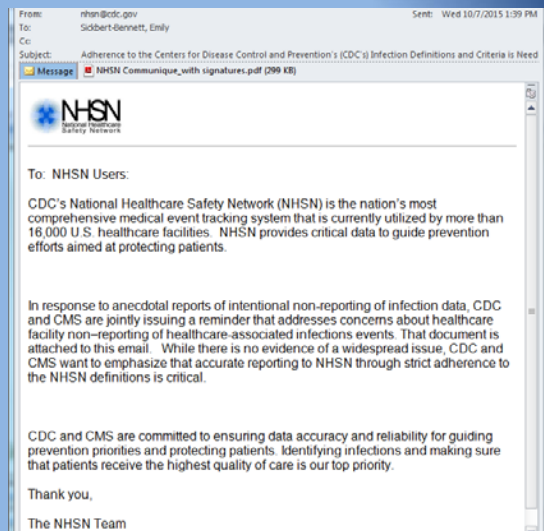
Moehring RW, Anderson DJ. ICHE 2011;32:987

Validation of HAI Surveillance Data – Where Do We Begin?



“Don’t look, don’t find...”

NORTH CAROLINA
Hospitals that report zero MRSA infections
Catawba Valley Medical Center, Hickory
Frye Regional Medical Center, Hickory
Halifax Regional Medical Center, Roanoke Rapids
Iredell Memorial Hospital, Statesville
Margaret R. Pardee Memorial Hospital, Hendersonville
Morehead Memorial Hospital, Eden
Novant Health Brunswick Medical Center, Bolivia
Randolph Hospital, Asheboro
Hospitals that report zero C. diff infections
Hugh Chatham Memorial Hospital, Elkin
J. Arthur Doshier Memorial Hospital, Southport
Kings Mountain Hospital, Kings Mountain
Person Memorial Hospital, Roxboro
Sandhills Regional Medical Center, Hamlet
Transylvania Regional Hospital, Brevard



DEVICE-ASSOCIATED INFECTIONS: A TALE OF POOR ENGINEERING

Phacoemulsifier
Heater-Cooler Units
Duodenoscopes

P. aeruginosa-RELATED POSTOPERATIVE ENDOPHTHALMITIS LINKED TO A CONTAMINATED PHACOEMULSIFIER

Table 1. Clinical Characteristics of Patients Who Underwent Cataract Extractions on the Outbreak Day*

Clinical Characteristic	Patient No.†								
	1	2	3	4	5	6	7	8	9
Demographic features									
Age, y	74	70	83	84	64	61	66	48	85
Sex	Male	Female	Female	Female	Female	Male	Male	Male	Male
ADD	Yes	Yes	No	No	No	No	No	No	No
Operative features									
Eye involved	Right	Left	Right	Left	Right	Right	Left	Right	Left
Lens implanted	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Cataract extraction method	Phaco	Corneal relaxation	Phaco	Phaco	Phaco	Phaco	Phaco	Phaco	Corneal transplantation
Phacoemulsification time, s	57	NA	42	44	25	37	39	22	NA
Endophthalmitis onset	POD 1	NA	POD 1	NA	POD 1 (PM)	POD 3	NA	POD 2	NA
Cultures									
Site	AC	NA	AC	NA	PC	PC	NA	PC	NA
Results	NG	NA	PA‡	NA	PA	PA	NA	PA and PM	NA
Intravitreal antibiotic therapy§									
Without vitrectomy	1	NA	1	NA	0	1	NA	0	NA
With vitrectomy	1	NA	1	NA	2	1	NA	2	NA
Visual acuity									
Preoperative	20/50	NA	20/100	NA	20/50 ⁻¹	20/400	NA	20/200	NA
Postoperative									
Worst	HM	NA	HM	NA	HM	HM	NA	HM	NA
Best	20/30	NA	20/20	NA	20/20	20/20	NA	20/20	NA

*ADD indicates type 2 diabetes mellitus; Phaco, cataract extraction using phacoemulsification; POD, postoperative day; PM, *Proteus mirabilis* (2 colonies); AC, anterior chamber; PC, posterior chamber (vitreous tap); NG, no growth; PA, *Pseudomonas aeruginosa*; HM, hand movements; and NA, data not applicable.

†The operative order is the same as the patient number.

‡In addition, α -hemolytic streptococcus and *Enterococcus* species grew from the broth only.

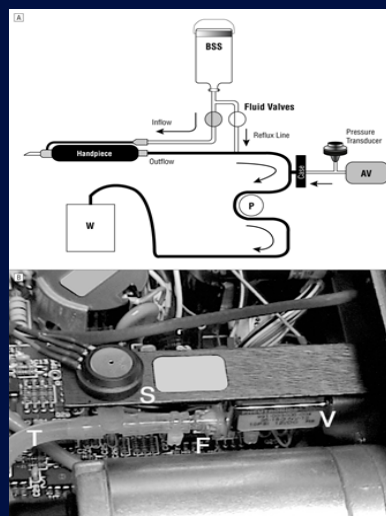
§Data are given as the number of times therapy was administered.

||This patient experienced late development of retinal detachment.

Hoffmann KK, Weber DJ, Gergen MF, Rutala WA. AMA

P. aeruginosa-RELATED POSTOPERATIVE ENDOPHTHALMITIS LINKED TO A CONTAMINATED PHACOEMULSIFIER

- Background: Cataract extraction is common medical procedure
- Outbreak: SPICE notified in 1999 about a cluster of postoperative endophthalmitis (AR = 5 of 7; all right eye)
- Evaluation:
 - Cultures of all medications negative
 - Scrub sink = *P. aeruginosa* (not outbreak strain)
 - Phacoemulsifier internal channel = *P. aeruginosa* (outbreak strain by PFGE)
- Conclusion
 - Poorly designed device which allowed contamination of internal channels



***M. CHIMAERA* OUTBREAK ASSOCIATED WITH CONTAMINATED HEATER-COOLER UNITS**

- July 2015: Invasive *M. chimaera* reported in 6 patients who underwent cardiac surgery with implants, 2008-2012, at one hospital in Zurich, Switzerland
- Investigations revealed *M. chimaera* in the water tanks of heater-cooler units (HCU); air sampling also positive for *M. chimaera* when the units were running
- Additional cases confirmed in several European countries and in US
- Studies suggest NTM from the HCU aerosolized from contaminated water in the device into the air
- Risk of disease not entirely clear
 - 0.39 cases per 10,000 person-years (5 year risk) (Chand M, et al. CID 2017;64:335-42)
 - If hospital has had 1 case, patient risk between 0.1% and 1% (CDC)
 - Risk higher if prosthetic material implanted
 - Mortality >50%
- Impact of outbreak: >250,000 cardiac bypass procedures done each year in US using HCU (CDC 2016).

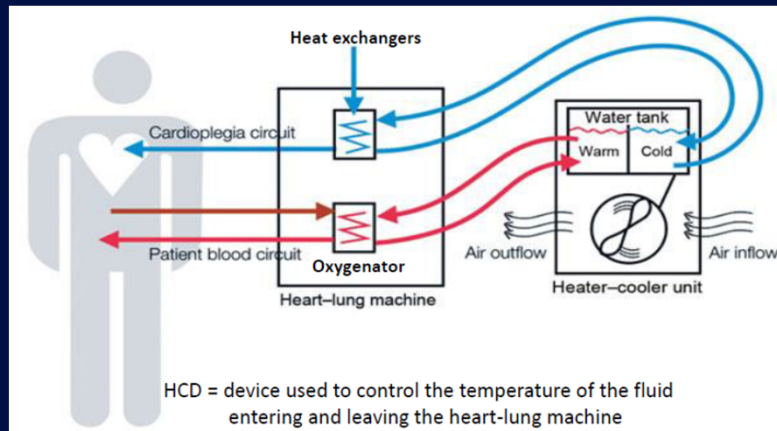
Global outbreak of HCU-associated *M. chimaera*



- Switzerland
- Germany
- France
- Spain
- Netherlands
- United Kingdom
- Hong Kong
- Australia
- Canada

Worldwide case count unknown, >110

HOW HCU WORK



Sommerstein et al. EID 2016;22(6)



Figure 2. Video image captures showing effect of heater-cooler unit orientation on smoke dispersal in a cardiac surgery room and transmission of *Mycobacterium chimaera* during cardiac surgery despite an ultraclean air ventilation system (Video, <http://wwwnc.cdc.gov/EID/article/22/6/16-0045-V1.htm>). The device was switched on and began to ventilate 10 s after the start of the video. Frames on the left show an overview including unit placement. Frames on the right provide a lateral view of the operating field under the laminar airflow. Simultaneously recorded videos in the upper 2 frames show the first scenario, in which the main ventilation exhaust was directed away from the operating field. Simultaneously recorded videos in the lower 2 frames show the second scenario, in which the main ventilation exhaust was directed toward the operating field.

Sommerstein R, et al. EID 2016;22:1008-1013

RECENT DUODENOSCPE-RELATED OUTBREAKS OF MRDO WITHOUT REPROCESSING BREACHES

MDRO	Resistance	No. Pts (infected)	Propagated Outbreak	Positive Scope(s)	Molecular Link	Reference
<i>K. pneumoniae</i>	CRE (bla _{oxa-232})	15 (8)	No	No	PCR*	Kim S, 2016
<i>E. coli</i> (Amp C)	CRE (bla _{cmv-2})	35	No	Yes (2)	PCR*, PFGE	Wendorf KA, 2015
<i>K. pneumoniae</i>	CRE (bla _{oxa-48})	12	Yes	No	PCR*, PFGE	Kola A, 2015
<i>K. pneumoniae</i>	CRE (bla _{KPC})	?	No	Yes (3)	PCR*, PFGE, WGS	Marsh J, 2015
<i>E. coli</i>	CRE (NDM)	39	Yes	Yes	PFGE	Epstein L, 2015
<i>P. aeruginosa</i>	VIM-2	22	Yes	Yes	Yes	Verfaillie C, 2015
<i>E. coli</i>	NDM-1	3 (3)	No	No	Not done	Smith Z, 2015.
<i>K. pneumoniae</i>	CRE (bla _{KPC-2,SHV})	13	Yes	Yes	PCR*, PFGE	Carbonne A, 2010

PCR*, PCR for resistance gene; CRE, carbapenem-resistant enterobacteriaceae; WGS, whole genome sequencing

Endemic Transmission of Infections Associated with GI Endoscopes May Go Unrecognized



- Inadequate surveillance of outpatient procedures for healthcare-associated infections
- Long lag time between colonization and infection
- Low frequency of infection
- Pathogens "usual" enteric flora
- Risk of some procedures might be lower than others (colonoscopy versus ERCP where normally sterile areas are contaminated in the latter)

PREVENTING INFECTIONS ASSOCIATED WITH ENDOSCOPY (especially ERCP)



Current Enhanced Methods for Reprocessing Duodenoscopes

Hospitals performing ERCPs should do one of the following (priority ranked); **doing nothing is not an option:**

1. Ethylene oxide sterilization after high level disinfection with periodic microbiologic surveillance
2. Double high-level disinfection with periodic microbiologic surveillance
3. High-level disinfection with scope quarantine until negative culture
4. Liquid chemical sterilant processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance
5. High-level disinfection with periodic microbiologic surveillance

Potential Future Methods to Prevent GI-Endoscope Related Outbreaks

- Steam sterilization for GI endoscopes
- Disposable sterile GI endoscopes (disposable bronchoscopes available)
- Improved GI endoscope design (to reduce or eliminate challenges noted earlier)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, blood tests to detect GI cancer, stool DNA test)
- New low temperature sterilization methods proving SAL 10^{-12} achieved (or optimizing current LTST)

Rutala WA, Weber WA. Infect Control Hosp Epidemiol 2015, In press

DEVICE-ASSOCIATED OUTBREAKS: SOLUTIONS

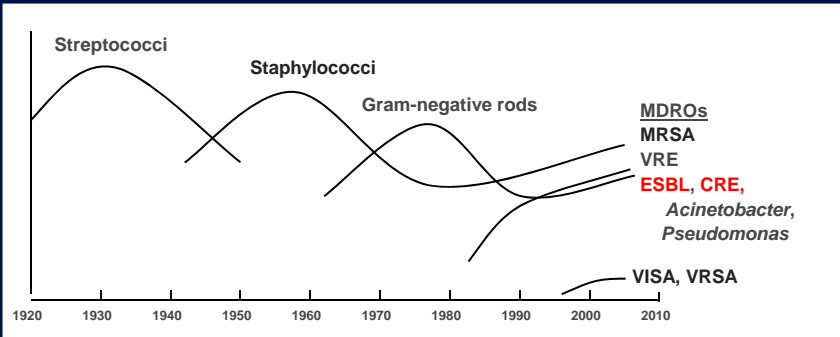
- FDA responsibilities
 - Ensure that all medical devices are safe and effective
 - Ensure that all manufacturer's of a re-usable medical device provide a validated method for cleaning and disinfection/sterilization
 - Require that all re-usable semicritical devices (e.g., duodenoscopes, arthroscopes) that enter sterile tissue/body spaces can be sterilized
- Manufacturer's responsibilities
 - Develop new devices that eliminate hazards associated with heater-cooler units and duodenoscopes
 - Demonstrate safety and efficacy (i.e., reduction in HAIs) in RCTs

THE THREAT OF ANTIBIOTIC/GERMICIDE RESISTANT PATHOGENS

MULTIDRUG-RESISTANT PATHOGENS

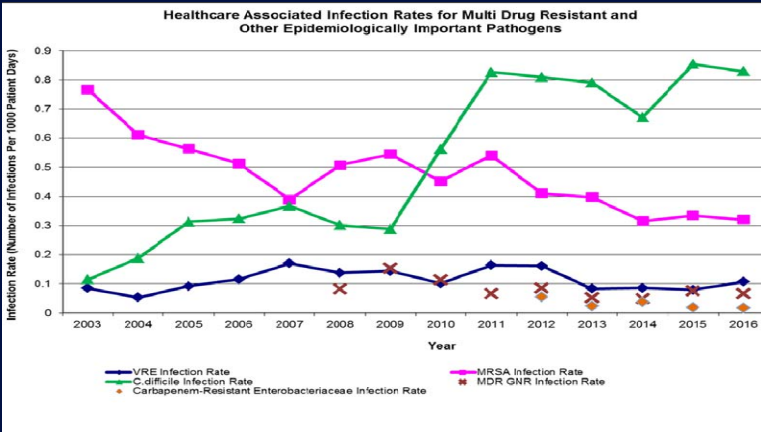
- Germicide resistant
 - *C. difficile*
 - HPV
 - Norovirus
 - *Candida aureus*
- Antibiotic resistant
 - MRSA
 - VRE
 - MDR-*Acinetobacter*
 - MDR-*P. aeruginosa*
 - Extended-spectrum beta-lactamase producers (ESBLs)
 - Carbapenem-resistant *Enterobacteriaceae* (CRE)

MAJOR NOSOCOMIAL PATHOGENS OF THE 20TH AND 21ST CENTURIES

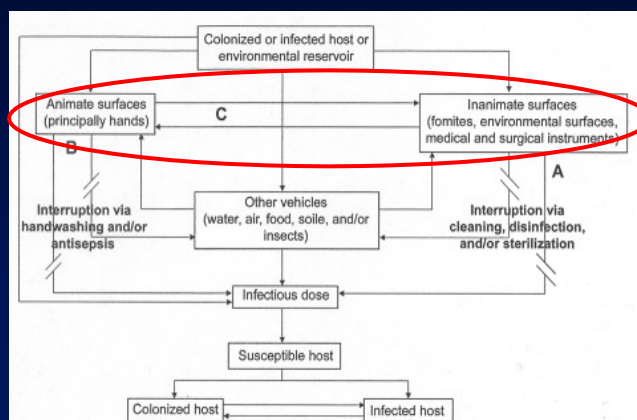


Courtesy of Dr. Robert Weinstein

UNC RATES OF MULTIDRUG RESISTANT PATHOGENS, 2003-2016



TRANSMISSION MECHANISMS INVOLVING THE SURFACE ENVIRONMENT



Rutala WA, Weber DJ. In: "SHEA Practical Healthcare Epidemiology" (Lautenbach E, Woeltje KF, Malani PN, eds), 3rd ed, 2010.

EFFICACY OF ALCOHOL AS A HAND HYGIENE AGENT AGAINST *C. difficile*

TABLE 1. Mean *Clostridium difficile* Colony Counts after Different Hand Hygiene Interventions According to the Whole-Hand Protocol

Intervention	Mean count (95% CI), log ₁₀ CFU/mL
Warm water and plain soap	1.99 (1.80–2.09)
Cold water and plain soap	1.90 (1.58–2.22)
Warm water and antibacterial soap	2.31 (2.04–2.58)
Antiseptic hand wipe	3.25 (3.04–3.45)
Alcohol-based handrub	3.74 (3.40–4.07)
No intervention	3.82 (3.54–4.10)

- Probability of heavy contamination (TNTC) following different HH interventions: warm water and plain soap = 0, cold water and plain soap = 0, warm water and antibacterial soap = 0, antiseptic hand wipe = 0.05, alcohol-based handrub = 0.43, and no hand hygiene = 1

Oughton MT, et al. ICHE 2009;30:939-944

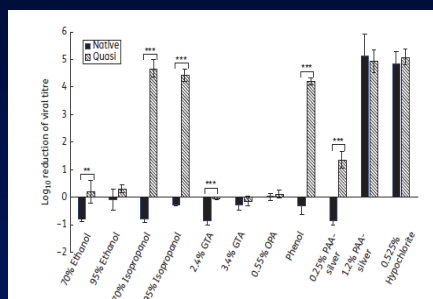
SURFACE DISINFECTION: EFFECTIVENESS OF DIFFERENT METHODS vs *C. difficile*

Product	Wipe and/or spray method				
	Saturated cloth*	Spray (10 s) and wipe	Spray, wipe, spray (1 min), wipe	Disposable pop-up wipes	Spray, wipe, spray, air dry
Ecolab QC-53, detergent					
Reduction	3.38 (1.61–5.16)	3.28 (2.18–4.38)	4.02 (3.68–4.35)	NT	2.90 (1.34–4.45)
Drying time, mins	2:09	4:18	3:34	NT	24:26
Ecolab A456-II					
Reduction	3.14 (2.01–4.27)	2.98 (1.92–4.04)	4.18 (3.46–4.90)	NT	2.90 (1.52–4.27)
Drying time, mins	2:26	6:18	4:44	NT	24:00
1:10 Bleach					
Reduction	3.90 (2.87–4.92)	4.48 (4.26–4.69)	4.48 (4.26–4.69)	NT	4.48 (4.26–4.69)
Drying time, mins	1:45	5:18	5:21	NT	51:08
Kimtech One-Step Germicidal Wipe					
Reduction	NT	NT	NT	4.18 (4.18–4.18)	NT
Drying time, mins	NT	NT	NT	4:06	NT
Clorox Germicidal Wipe					
Reduction	NT	NT	NT	3.98 (3.23–4.72)	NT
Drying time, mins	NT	NT	NT	1:47	NT
Clorox #9255-41-1 and 3					
Reduction	NT	6.14 (6.14–6.14)	NT	NT	NT
Drying time, mins	NT	2:49	NT	NT	NT

Rutala WA, Gergen MF, Weber DJ. ICHE 2012;33:1255-58

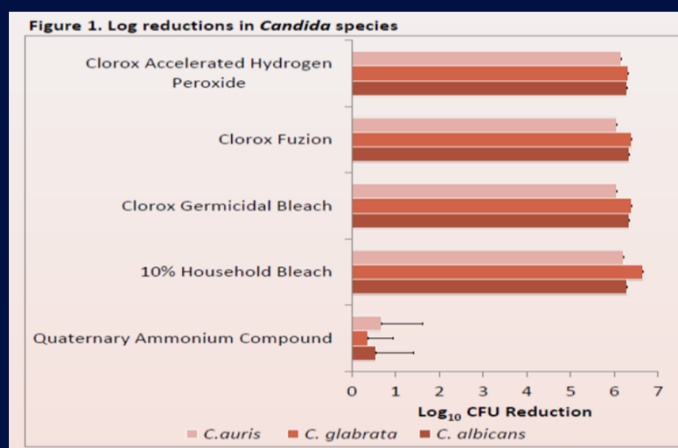
ENDOSCOPE REPROCESSING: CHALLENGES Susceptibility of Human Papillomavirus

- Most common STD
- In one study, FDA-cleared HLD, no effect on HPV
- Finding inconsistent with other small, non-enveloped viruses such as polio and parvovirus
- Further investigation needed: test methods unclear; glycine; organic matter; comparison virus
- Conversation with CDC: validate and use HLD consistent with FDA-cleared instructions (no alterations)



J Meyers et al. J Antimicrob Chemother, Epub Feb 2014

EFFECTIVENESS OF DISINFECTANTS AGAINST CANDIDA AURIS



Cadnum JL,Donskey CJ. Poster #243, SHEA, St. Louis, 2017.

NOROVIRUS

- Norovirus outbreaks in healthcare facilities
 - Accounts for >90% of nonbacterial and ~50% of all-cause epidemic gastroenteritis¹
 - Hospitals and LTCF account for >25% of outbreaks¹
 - Most common pathogen associated with ward closures (44%)²
 - UNC 2012-2016, ~14% (7/51) outbreaks due to norovirus
- Management issues
 - Stable in the environment - Very low inoculating dose
 - Relatively resistant to ethanol (perform HH with soap and water)
 - Resistant to Quats (use hypochlorites for room disinfection)
 - No evidence any interventions can control outbreak³ – therefore goal is to contain outbreak to single affected ward (limit staff and patient transfers, close ward to admissions, improved HH and environmental cleaning)

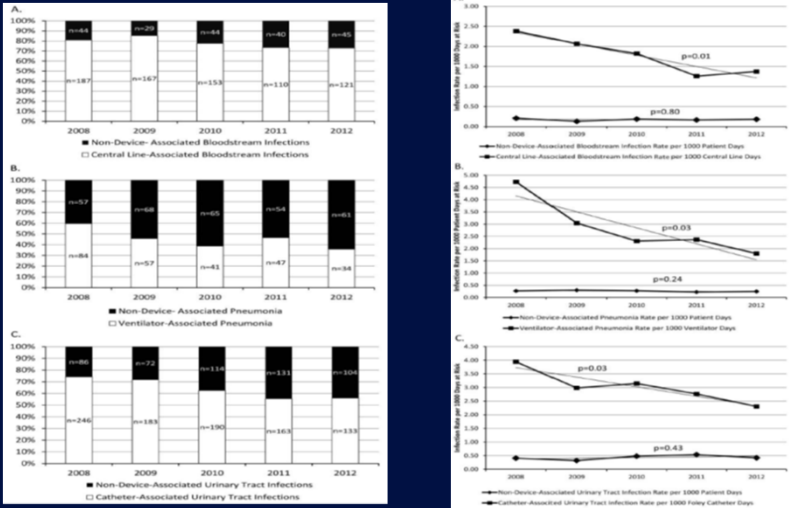
¹Weber DJ, et al. AJIC 2010;38:S25-33; ²Hansen S, et al. JHI 2007;65:348-53; ³Harris JP, et al. JHI 2010;74:1-9

SOLUTIONS

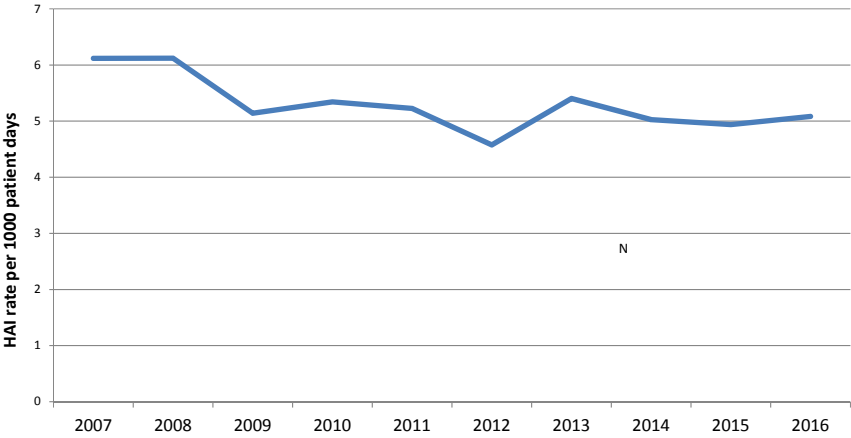
- MDR pathogens
 - Anti-infective stewardship
 - Develop new anti-infectives
 - Develop non-antibiotic methods to treat infection
 - Vaccine development (e.g., MRSA, *C. difficile*, TB, malaria)
- Germicide resistant or reduced susceptibility pathogens
 - Develop new germicides
 - Revise recommendations to use appropriate cidal agents
 - Develop new methods of killing pathogens (e.g., UV devices, hydrogen peroxide systems)

IMPORTANCE OF NON-DEVICE ASSOCIATED INFECTIONS

NON-DEVICE ASSOCIATED HAIs, UNC, 2008-2012 (DiBiase LM, et al. ICHE 2014;35:200-02)



**Overall HAI rate per 1000 patient days
at UNC Health Care**



*Significant modifications were made to the NHSN definitions in 2013 and again in 2015 that may have impacted infection rates

RECOMMENDATIONS TO DECREASE RISK OF VAP, US

Recommendation	CDC, 2003	IDSA, 2005	APIC, 2005	SHEA, 2014
Hand hygiene	Yes	Yes	Yes	----
Microbiologic monitoring	Yes	Yes	Yes	Yes
Device removal	----	----	Yes	Yes
Avoid intubation	Yes	Yes	Yes	----
Reduction of antibiotics	----	----	Yes	----
Avoid reintubation	Yes	Yes	----	----
Promote NIV if possible	Yes	Yes	Yes	Yes
Orogastric tube	Yes	Yes	----	----
Bed elevation	Yes	Yes	Yes	Yes
Subglottic aspiration	No	Yes	Yes	Yes
Oral decontamination	No	No	No	No
Selective gut decontamination	No	No	No	No

No guideline has any recommendation to reduce HAP!

Adapted from Passaro L, et al. Antimicrobial Resistance Infect Control 2016;5:43

CONCLUSIONS

- Expand surveillance to track non-device associated HAIs
- Determine risk factors for non-device associated HAIs
- Develop interventions to reduce non-device associated HAIs

ADDITIONAL CHALLENGES

- New complex devices (e.g., da Vinci surgery)
- Obtaining behavioral change
- Meeting expectations
- We have moved from seeking percent reductions in HAIs each year to competition to see who can decrease HAIs fastest
- Maintaining preparedness for highly-communicable disease (e.g., Ebola)
- Infection control in ambulatory care
- Maintaining proficiency in disinfection and sterilization
- Lack of new antimicrobials
- Integrating with institutions larger QI concerns
- Xenotransplantation?

NEW TOOLS

- New diagnostics (MACDI-TOF)
- Rapid diagnostics (influenza, RSV, TB, etc.)
- New germicides (e.g., improved hydrogen peroxide)
- New room disinfection technologies (i.e., UV devices, H₂O₂ systems)
- Tools for monitoring room cleaning (e.g., fluorescent dye)
- New tools of molecular epidemiology for assessing outbreaks (e.g., whole genome sequencing)
- Non-observed based methods for assessing hand hygiene compliance

HE STANDS FOR TRUTH, RESEARCH AND THE SCIENTIFIC WAY!



It's A Bird.....It's A Plane.....No It's Superman
Who is disguised as William A. Rutala