

Limitations of Extracting the Evidence for Guidelines in Infection Control

Kristina Bryant, M.D.

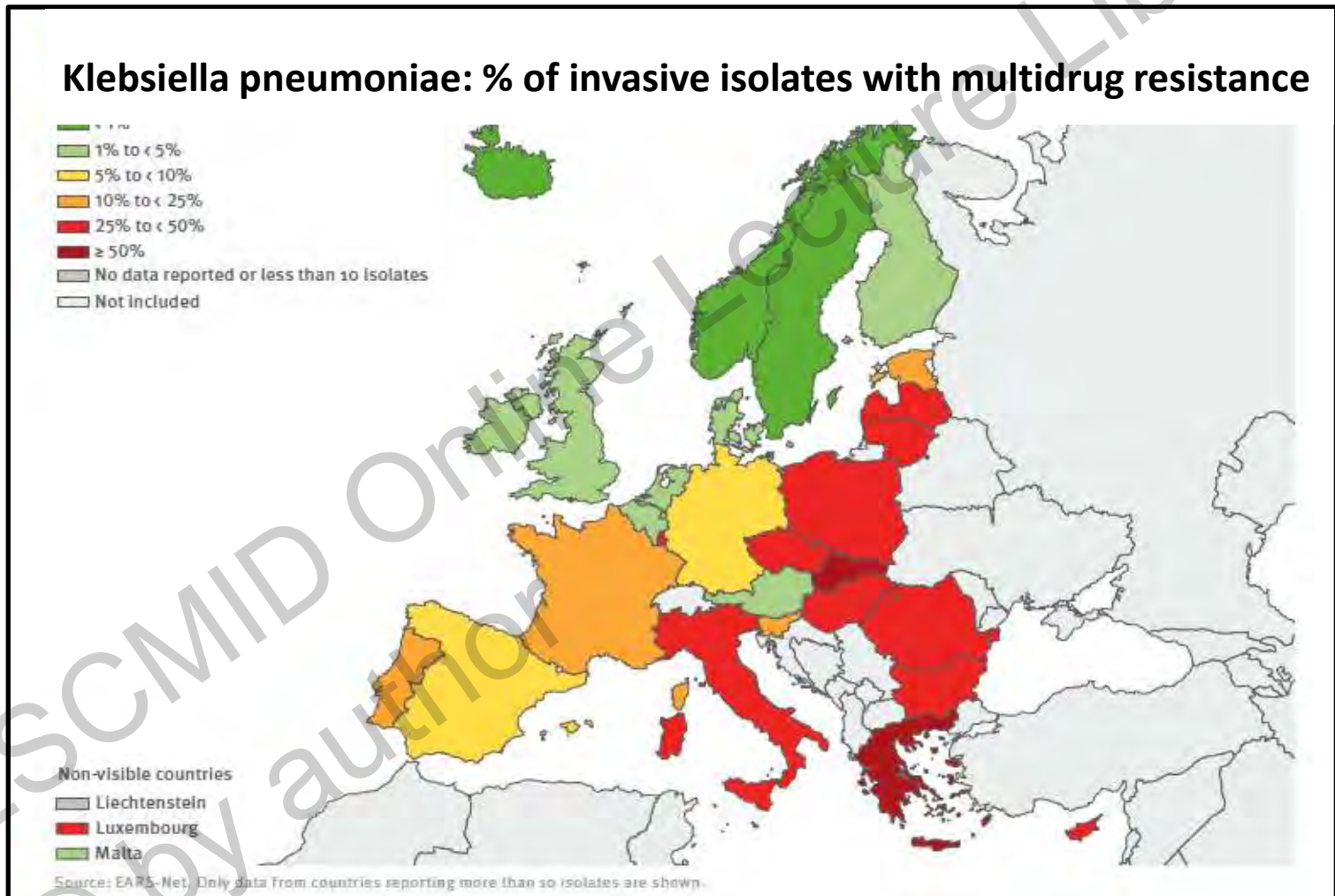
Associate Professor of Pediatrics

University of Louisville

Disclosures

- I have served as principal investigator in a vaccine clinical trial conducted by Pfizer and have received travel support to present results at a scientific meeting.

Scope of the Problem: Europe



ECDC. Annual epidemiological report Reporting on 2011 surveillance data and 2012 epidemic intelligence data. <http://www.ecdc.europa.eu/en/publications/Publications/annual-epidemiological-report-2013.pdf>

Scope of the Problem: Europe

Klebsiella pneumoniae: % of invasive isolates resistant to carbapenems



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Scope of the Problem, United States

Pathogen, Antimicrobial agent	CLABSI		CAUTI	
	ICU	Non-ICU	ICU	Non-ICU
<i>Klebsiella (pneumoniae/oxytoca)</i>				
ES cephalosporins	29.7	27.7	24.6	29.0
Carbapenems	14.2	10.9	12.4	12.6
Multidrug resistant	19.1	13.7	15.2	17.0
<i>Enterobacter</i> species				
ES cephalosporins	38.0	36.2	38.8	38.2
Carbapenems	4.9	2.2	5.5	3.5
Multidrug resistant	4.0	3.1	4.6	5.0

ES Cephalosporins = cefepime, cefotaxime, ceftazidime, ceftriaxone

Percentage of selected pathogens resistant to antimicrobial agents, NHSN, 2009-2010

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Scope of the Problem, United States

Pathogen, Antimicrobial agent	CLABSI		CAUTI	
	ICU	Non-ICU	ICU	Non-ICU
<i>Pseudomonas aeruginosa</i>				
Aminoglycosides	11.6	7.5	11.8	9.9
Cefepime, ceftaxidime	28.3	22.6	22.5	28.3
Ciprofloxacin, levofloxacin	30.3	30.8	31.8	35.5
Carbapenems	26.8	24.9	20.6	22.3
Multidrug resistant	16.8	13.3	12.6	15.6
<i>Acinetobacter baumannii</i>				
Carbapenems	64.5	56.1	73.8	75.0
Multidrug resistant	69.7	60.4	78.6	76.1

Percentage of selected pathogens resistant to antimicrobial agents, NHSN, 2009-2010

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Pathogen, Antimicrobial agent	CLABSI		CAUTI	
	ICU	Non-ICU	ICU	Non-ICU
<i>Pseudomonas aeruginosa</i>				
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Cefepime, ceftaxidime	28.3	22.6	22.5	28.3
Ciprofloxacin, levofloxacin	30.3	30.8	31.8	35.5
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Multidrug resistant	69.7	60.4	78.6	76.1

Percentage of selected pathogens resistant to antimicrobial agents, NHSN, 2009-2010

Variation in Infection Control Practices



FIGURE 1. Distribution of Society for Healthcare Epidemiology of America Research Network members responding to the survey.

Variation in Infection Control Practices

	ESBL- producers	CRE	MDR <i>Pseudomonas</i>	MDR <i>Acinetobacter</i>
Isolate patients (n=66)	74.2	93.9	81.8	84.9
United States (n=46)	87.0	95.7	87.0	89.1
International (n=20)	45.0	90.0	70.0	75.0
Duration of isolation	(n=49)	(n=62)	(n=54)	(n=56)
During Active Illness	8.2	6.5	7.4	7.1
Duration of hospitalization	26.5	12.9	27.8	28.6
Until negative surveillance cultures	32.7	29.0	35.2	33.9
Indefinitely	34.7	43.5	31.5	33.9
Isolate re-admitted patients	(n=49)	(n=62)	(n=54)	(n=56)
Yes	55.6	72.1	53.2	58.1

Variation in Infection Control Practices

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Isolate patients (n=66)	74.2	93.9	81.8	84.9
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Indefinitely	34.7	43.5	31.5	33.9
Isolate re-admitted patients	(n=49)	(n=62)	(n=54)	(n=56)
Yes	55.6	72.1	53.2	58.1

Detection and Control of CRE

Variability in Detection and Control (%)

Detection

Implemented new CLSI breakpoints for GNB 61

Perform modified Hodge test 61

Control

Chlorhexidine bathing 37

Point prevalence surveys 24

Epidemiology-based screening 39

Point prevalence surveys or epidemiology-based screening 52

Active surveillance cultures 22

Limitations of the Evidence

- Small sample size
- Experience of a single medical center
- Heterogeneity in patient populations
- No discrimination between infection and colonization
- Inability to control for potential confounders
- Skew toward acute care facilities

ESCMID guidelines for the management of the infection control measures to reduce transmission of multidrug-resistant Gram-negative bacteria in hospitalized patients

E. Tacconelli¹, M. A. Cataldo², S. J. Dancer³, G. De Angelis⁴, M. Falcone⁵, U. Frank⁶, G. Kahlmeter⁷, A. Pan^{8,9}, N. Petrosillo², J. Rodríguez-Baño^{10,11,12}, N. Singh¹³, M. Venditti⁵, D. S. Yokoe¹⁴ and B. Cookson¹⁵

1) Division of Infectious Diseases, Department of Internal Medicine I, Tübingen University Hospital, Tübingen, Germany, 2) Clinical Department, National Institute for Infectious Diseases "L. Spallanzani", Rome, Italy, 3) Department of Microbiology, Hairmyres Hospital, East Kilbride, UK, 4) Infectious Diseases, Università Cattolica Sacro Cuore, 5) Department of Public Health and Infectious Diseases, Policlinico Umberto I, "Sapienza" University, Rome, Italy, 6) Division of Infection Control and Hospital Epidemiology, Department of Infectious Diseases, Heidelberg University Hospital, Heidelberg, Germany, 7) Department of Clinical Microbiology, Central Hospital, Växjö, Sweden, 8) Infectious and Tropical Diseases, Istituto Ospitalieri di Cremona, Cremona, 9) Infectious Risk Area, Health and Social Regional Agency of Emilia-Romagna, Bologna, 10) Unidad Clínica de Enfermedades Infecciosas y Microbiología, Hospital Universitario Virgen Macarena, Seville, 11) Departamento de Medicina, Universidad de Sevilla, Sevilla, Spain, 12) Spanish Network for Research in Infectious Diseases, Instituto de Salud Carlos III, Madrid, Spain, 13) Department of Pediatrics, Epidemiology and Global Health, Children's National Medical Center, The George Washington University, Washington, DC, USA, 14) Infectious Diseases Division, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA and 15) Medical Microbiology, Honorary Professor in Medical Microbiology, Division of Infection and Immunity, University College London, London, UK

The Guideline

Pathogens

ESBL-producing *Enterobacteriaceae*
MDR-*Klebsiella pneumoniae*
MDR-*Pseudomonas aeruginosa*
MDR-*Acinetobacter baumannii*
Burkholderia cepacia
Stenotrophomonas maltophilia

Interventions evaluated (Basic and *Additional*)

Hand hygiene
Contact precautions (CP)
Isolation room
Alert code and pre-emptive CP
Education
Environmental cleaning
Antimicrobial stewardship
Infection prevention/control infrastructure
Cohort patients and staff
Healthcare worker screening
Environmental screening
Chlorhexidine bathing

The Guideline

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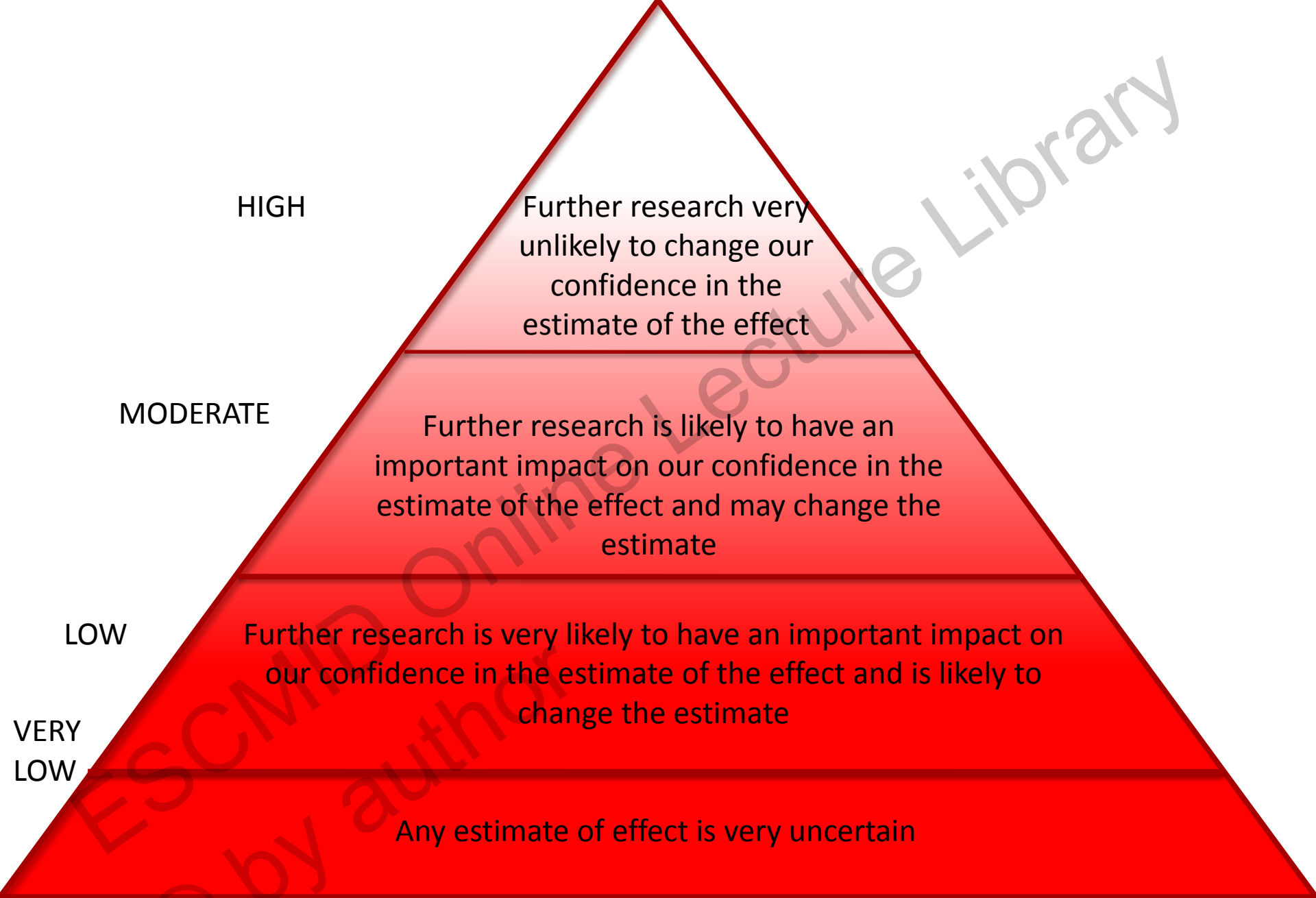
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Infection prevention/control infrastructure
Cohort patients and staff
Healthcare worker screening
Environmental screening
Chlorhexidine bathing

The Guideline

Setting	Endemic Outbreak
Potential Recommendations	124
Quality of evidence	60 Moderate 10 Low 18 Very Low
Strength of recommendations	40 Strong 49 Conditional

Grading the Evidence

Type of evidence	Initial grade	Criteria to decrease grade	Criteria to increase grade	Overall quality grade
RCT	High	<u>Study quality limitations</u> Serious (-1) or very serious (-2) study quality limitations	<u>Strength of Association</u> Strong (+1) or very strong evidence of association (+2)	High
				Moderate
Observational study	Low	<u>Inconsistency</u> Important inconsistency (-1)	<u>Dose-Response</u> Evidence of a dose-response gradient (+1)	Low
Any other evidence (e.g. expert opinion)	Very low	<u>Indirectness</u> Some (-1) or major (-2) uncertainty about directness <u>Imprecision</u> Imprecise or sparse data (-1) <u>Publication bias</u> High risk of bias (-1)	<u>Confounding</u> Inclusion of unmeasured confounders increases the magnitude of effect (+1)	Very Low



HIGH

Further research very unlikely to change our confidence in the estimate of the effect

MODERATE

Further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate

LOW

Further research is very likely to have an important impact on our confidence in the estimate of the effect and is likely to change the estimate

VERY LOW

Any estimate of effect is very uncertain

GRADE: Recommendations

Strong

Conditional/Weak

Patients

Most people in the patient's situation would want the recommended course of action; only a small proportion would not

Most people in the patient's situation would want the recommended course of action, but some may not

Clinicians

Most patient should receive the recommended course of action

Different choices will be appropriate for different patients; clinicians must help patients arrive at management decisions consistent with their values/preferences

Policy-makers

The recommendation may be considered for policy in many situations

Policymaking requires substantial debate and involvement of many stakeholders

What Affects the Strength of Recommendation?

- Quality of Evidence
- Balancing desirable/undesirable consequences
- Certainty about values and preference
- Resource Implications

MDR-*Klebsiella pneumoniae*

Endemic Setting

Intervention	Evidence	Recommendation
Hand Hygiene	Moderate	Strong
Contact Precautions	Moderate	Strong
Alert Code	Moderate	Conditional
Isolation Room	Moderate	Strong
Education	Moderate	Conditional
Environmental Cleaning	Moderate	Conditional
Antimicrobial Stewardship	Moderate	Conditional
Infection Prevention and Control Infrastructure	NA	NA

MDR-*Klebsiella pneumoniae*

Basic Measures in the Endemic Setting

Microorganism	MDR-K pneumoniae			Overall quality of evidence
	Quality of studies [ref.]			
Intervention	Moderate	Low	Very low	
Hand hygiene	2 [122,265]	–	–	Moderate
Education	1 [122]	–	–	Moderate
Contact precautions	2 [122,265]	–	–	Moderate
Isolation room	1 [265]	–	–	Moderate
Environmental cleaning	2 [122,265]	–	–	Moderate
Antimicrobial stewardship	1 [268]	1 [269]	–	Moderate

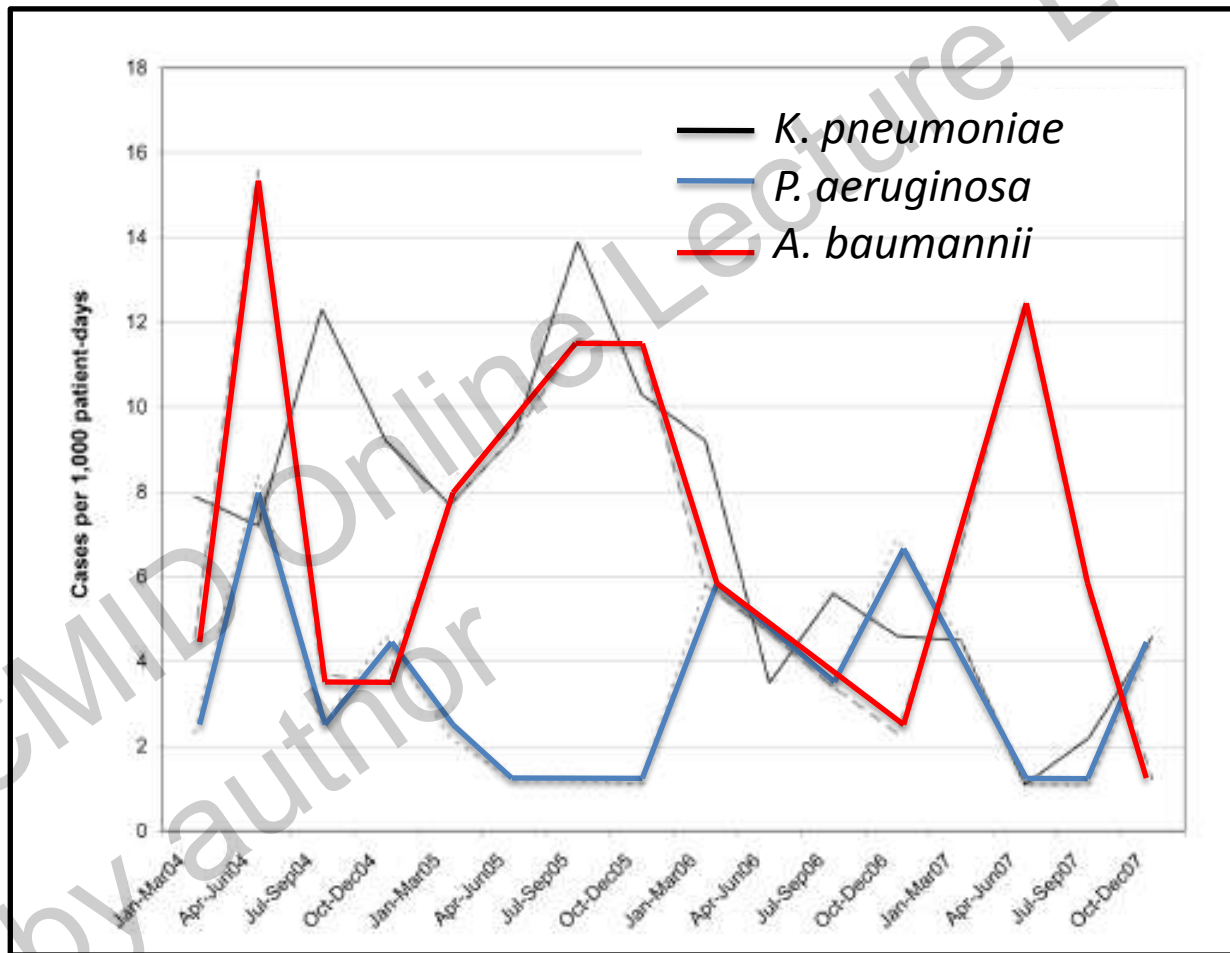
The Evidence

- Setting
 - 10-bed medical-surgical ICU in university hospital
- Study design
 - Retrospective observational study with pre- and post-intervention phases
- “Comprehensive infection control program”
 - Baseline (1/2004 to 12/2005)
 - Contact isolation for MRSA, VRE, CR-*Acinetobacter*
 - Environmental cleaning daily
 - Infection control team member participated in rounds
 - Active surveillance cultures at admission and weekly

The Evidence

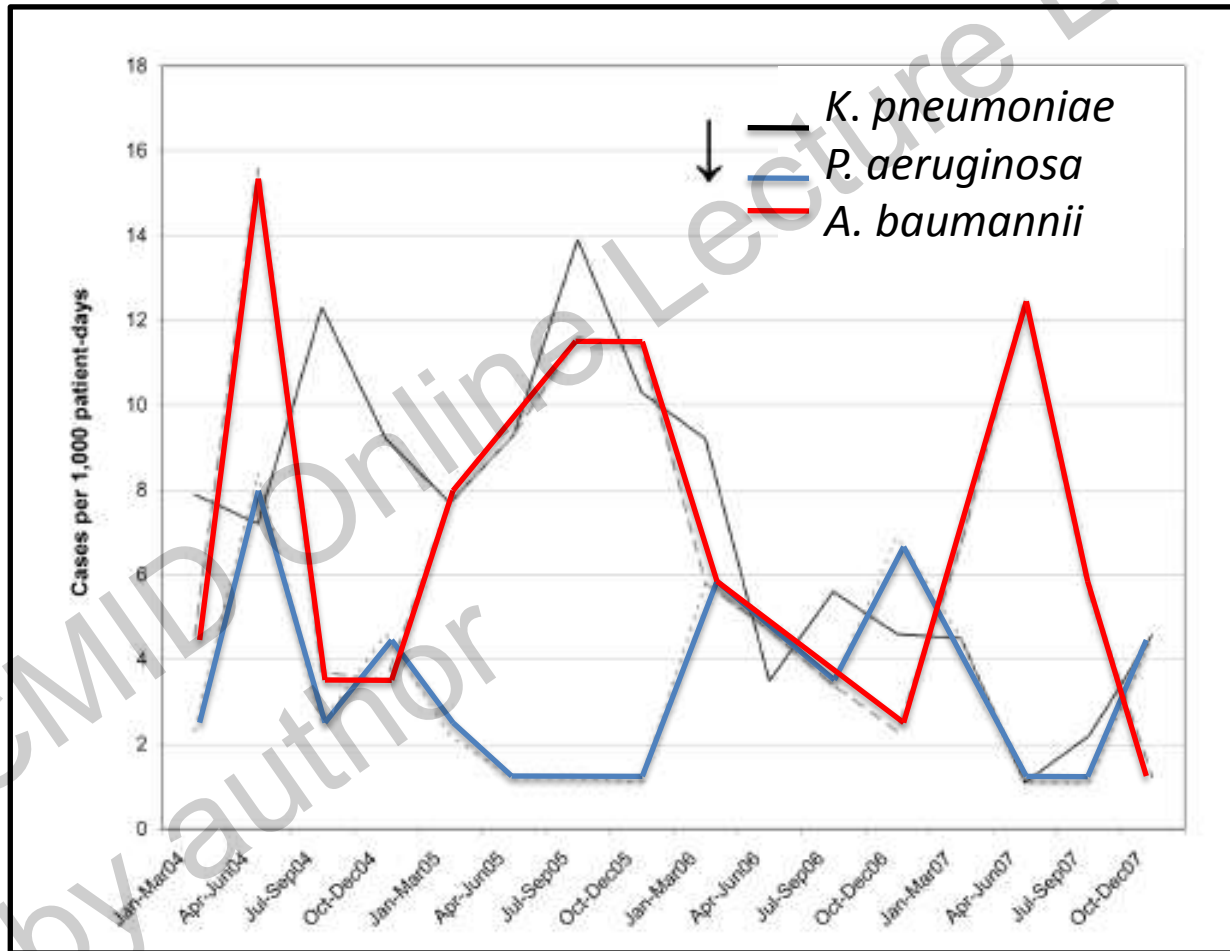
- “Comprehensive infection control program”
 - Intervention (1/2006 – 4/2006)
 - Active screening for CR-*K. pneumoniae* and *P. aeruginosa*
 - Copy of antibiogram placed in medical record
 - ICU closed for two days for extensive cleaning and decontamination
 - Patient with CR-GNB were placed at one end of ICU with designated nursing staff (cohorting)
 - Free-standing alcohol dispensers installed
 - Meetings with nursing to encourage compliance
 - Nurses clean environmental surfaces “at the start of most 12-hour shifts”

Review of the Evidence



Review of the Evidence

New patients with clinical cultures yielding CR-Klebsiella decreased from 9.7 ± 2.2 to 3.7 ± 1.6



Review of the Evidence

To our knowledge, this is the first report of a successful infection control intervention aimed at reducing the incidence of carbapenem-resistant *K. pneumoniae*. As with most other interventions, it is difficult to discern which of the measures impacted the transmission of *K. pneumoniae*.

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To our knowledge, this is the first report of a successful infection control intervention aimed at reducing the incidence of carbapenem-resistant *K. pneumoniae*. As with most other interventions, it is difficult to discern which of the measures impacted the transmission of *K. pneumoniae*. The fact that

The determination of whether this intervention is applicable to other clinical settings and the identification of the essential components of the intervention will require further investigation.

What is a Bundle?

- Structured way of improving process
- 3-5 evidence-based practices
- *Collective*, reliable execution improves outcome
- “All or nothing”

Review of the Evidence

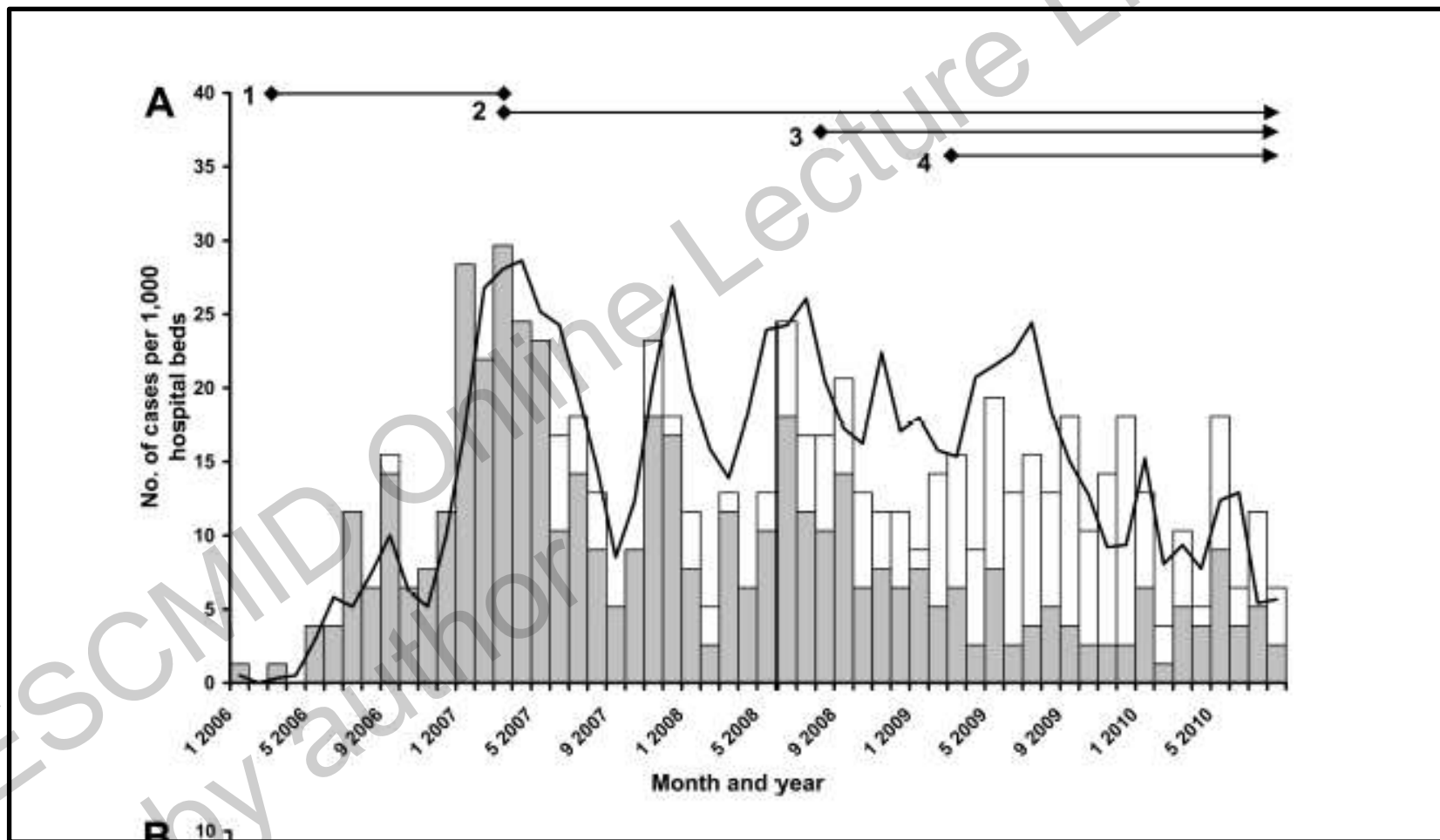
- Setting
 - 775-bed acute care hospital in Israel
- Study Design
 - Consecutive intervention analyses
- Background
 - National epidemic of carbapenem-resistant *K. pneumoniae* (CRKP)
 - Patients with CRKP infection or colonization identified prospectively over ~5 year period

The Evidence

Interventions to Curtail Epidemic Spread of CRKP

<i>Intervention</i>	<i>Description</i>	<i>Date Begun</i>
Intervention 1	Single room isolation Contact precautions	March 2006
Intervention 2	Cohorting of patients and nursing staff Screening of roommates of CRKP carriers Cohorting of returning patients	March 2007
Intervention 3	Weekly active surveillance in ICU	August 2008
Intervention 4	Active surveillance on admission to ED	March 2009

The Evidence



The Evidence

The report shows that use of isolation precautions alone was ineffective but that use of patient cohorting was associated with a rapid decline in the spread of the bacteria in the hospital. This was the most significant intervention in this study.

MDR-*P. aeruginosa*

Endemic Setting

Intervention	Evidence	Recommendation
Hand Hygiene	Moderate	Strong
Contact Precautions	Moderate	Strong
Alert Code	NA	
Isolation Room	NA	Conditional
Education	Moderate	Conditional
Environmental Cleaning	Moderate	Conditional
Antimicrobial Stewardship	Moderate	Conditional
Infection Prevention and Control Infrastructure	NA	NA

The Evidence

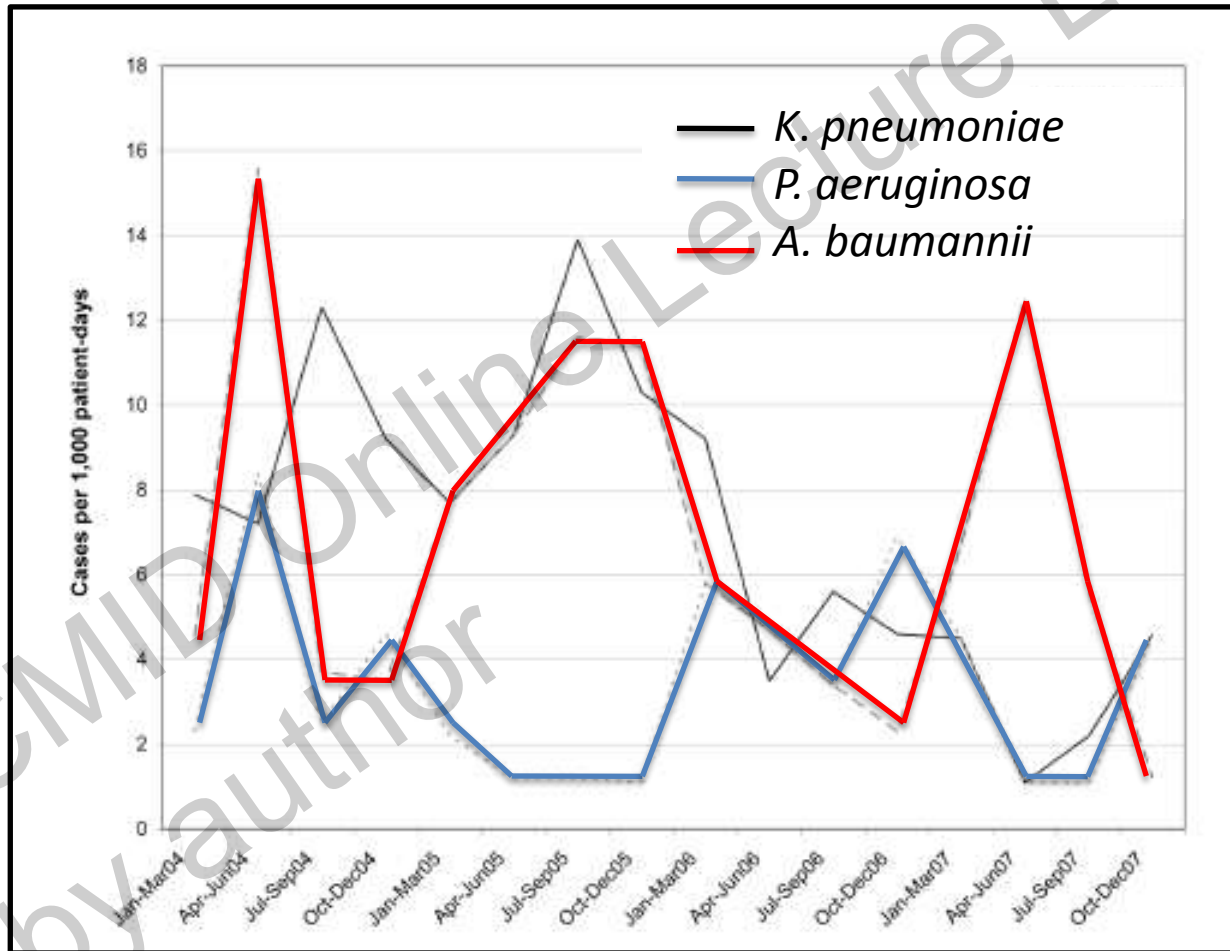
Microorganism	MDR-A. baumannii				MDR-P. aeruginosa			
	Quality of studies			Overall quality of evidence	Quality of studies			Overall quality of evidence
Intervention	Moderate	Low	Very low		Moderate	Low	Very low	
Hand hygiene	4 [81,122,153,157]	1 [274]	–	Moderate	2 [122,275]	1 [274]	–	Moderate
Education	4 [81,122,153,157]	1 [274]	–	Moderate	1 [122]	1 [274]	–	Moderate
Contact precautions	4 [81,122,153,157]	–	–	Moderate	1 [122]	–	–	Moderate
Isolation room	1 [81]	–	–	Moderate	–	–	–	Insufficient
Environmental cleaning	4 [81,122,153,157]	–	–	Moderate	1 [122]	–	–	Moderate
Antimicrobial stewardship	1 [268]	2 [269,272]	–	Moderate	2 [268,275]	2 [269,272]	–	Moderate

The Evidence

Microorganism	MDR-A. baumannii				MDR-P. aeruginosa			
	Quality of studies			Overall quality of evidence	Quality of studies			Overall quality of evidence
	Moderate	Low	Very low		Moderate	Low	Very low	
Hand hygiene	4 [81,122,153,157]	1 [274]	–	Moderate	2 [122,275]	1 [274]	–	Moderate
Education	4 [81,122,153,157]	1 [274]	–	Moderate	1 [122]	1 [274]	–	Moderate
Contact precautions	4 [81,122,153,157]	–	–	Moderate	1 [122]	–	–	Moderate
Isolation room	1 [81]	–	–	Moderate	–	–	–	Insufficient
Environmental cleaning	4 [81,122,153,157]	–	–	Moderate	1 [122]	–	–	Moderate
Antimicrobial stewardship	1 [268]	2 [269,272]	–	Moderate	2 [268,275]	2 [269,272]	–	Moderate

Review of the Evidence

New patients with clinical cultures yielding CR-*Pseudomonas* did not change significantly (3.3 ± 2.5 to 3.8 ± 2.1)



S. maltophilia

Outbreak Setting

Intervention	Evidence	Recommendation
Hand Hygiene	Moderate	Strong
Active Screening Cultures	NA	
Contact Precautions	Moderate	Conditional
Alert Code	NA	
Cohort Patients	NA	
Cohort Staff	NA	
Isolation Room	NA	
Education	Moderate	Conditional
Environmental Cleaning	Moderate	Conditional
Antimicrobial Stewardship	NA	
Infection Prevention and Control Infrastructure	NA	NA

S. maltophilia

Outbreak Setting

Intervention	Evidence	Recommendation
Chlorhexidine gluconate for patient bathing	NA	
Healthcare workers screening	NA	

Stenotrophomonas maltophilia

Basic/Additional Measures in the Epidemic Setting

Microorganism	<i>S. maltophilia</i> Quality of studies			Overall quality of evidence
	Moderate	Low	Very low	
Intervention				
Hand hygiene	1 [315]	—	—	Moderate
Education	1 [315]	—	—	Moderate
Active surveillance cultures	—	—	—	Insufficient
Healthcare workers screening	—	—	—	Insufficient
Contact precautions	1 [315]	—	—	Moderate
Isolation room	—	—	—	Insufficient
Pre-emptive CP/alert code	—	—	—	Insufficient
Cohort patients	—	—	—	Insufficient
Cohort staff	—	—	—	Insufficient
Environmental cleaning	1 [315]	—	—	Moderate
Environmental screening	1 [315]	—	—	Moderate
Antimicrobial stewardship	—	—	—	Insufficient

CP, contact precautions.

Review of the Evidence

- Setting:
 - Single center
- Study Design:
 - Epidemiological Investigation
- Background:
 - February 1993 to February 1994
 - *S. maltophilia* recovered from 14 ICU patients
 - 12 sputum
 - 1 blood
 - 1 central line
 - Molecular typing suggested two distinct outbreaks

Review of the Evidence

Date	Intervention	Comments
04/1993	Environmental sampling Ventilator inspiratory circuit Ventilator keyboards External surface of inline suction catheter Contact precautions	<i>S. maltophilia</i> recovered from inline suction catheter
07/1993	Additional environmental sampling Room vents and window ledges Faucets Ventilators Solutions kept at patient bedside Use of inline suction catheter limited	<i>S. maltophilia</i> identified in medicated nebulizer

Review of the Evidence

Date	Intervention	Comments
10/1993	Unit dose medication vials Metered dose inhalers substituted for nebulizers	Subsequent isolates different by RFLP
12/1993	Additional environmental sampling	<i>S. maltophilia</i> identified on ventilator humidifier
02/1994	Heat and moisture exchange filters in ventilators	No new cases identified for next six months

Review of the Evidence

Contact Precautions

- Transmission continued despite contact precautions
- Compliance not reported

Education

- Educational intervention not well defined
- “Education was ongoing”
- “Respiratory therapy practice reviewed in detail”
- Not clear who was educated
- No assessment of educational effectiveness

Review of the Evidence

Hand Hygiene

- No specific hand hygiene intervention
- “Hand washing and proper gloving emphasized”
- No data about compliance

Review of the Evidence

Hand Hygiene

- No specific hand hygiene intervention
- “Hand washing and proper gloving emphasized”
- No data about compliance

Handwashing facilities in the ICU were recognized as insufficient. Improvement of facilities and reinforcement of the value of hand washing was well received by ICU staff, with increased compliance. The installation of two additional sinks for hand washing may have helped to terminate the first outbreak, as subsequent isolates of *S maltophilia* from patients in the ICU were of a different genotype.

The Guideline

MAJOR ARTICLE

Effect of Influenza Vaccination of Healthcare Personnel on Morbidity and Mortality Among Patients: Systematic Review and Grading of Evidence

Faruque Ahmed,¹ Megan C. Lindley,¹ Norma Allred,¹ Cindy M. Weinbaum,² and Lisa Grohskopf³

¹Immunization Services Division, National Center for Immunization and Respiratory Diseases, ²Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, and ³Influenza Division, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia

(See the Editorial Commentary by Griffin on pages 58–60.)

Some of the Evidence

Table 3. Effect of Influenza Vaccination of Healthcare Personnel: Quality of Evidence

Outcome Among Patients	Design (No. of Studies)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Considerations ^a	Quality of Evidence (GRADE)
Mortality	RCT (4)	Not serious	No serious	Serious ^b	No serious	None	Moderate
Hospitalization	RCT (2)	Not serious	No serious	Serious ^b	Serious ^c	None	Low
Influenza-like illness	RCT (3)	Serious ^d	No serious	Serious ^b	No serious	None	Low
Influenza-like illness	OBS (3)	Serious ^e	No serious	Serious ^b	No serious	None	Very low
Laboratory-confirmed influenza	RCT (2)	Very serious ^f	No serious	No serious	Serious ^g	None	Very low
Laboratory-confirmed influenza	OBS (2)	No serious	No serious	No serious	No serious	None	Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development and Evaluation; OBS, observational study; RCT, randomized controlled trial.

^a Strength of association, dose response, opposing plausible residual confounding or bias, publication bias.

^b The study outcomes all-cause mortality, all-cause hospitalization, and influenza-like illness are surrogates for influenza-specific mortality, influenza-specific hospitalization, and influenza cases, respectively.

^c The 95% confidence interval of the pooled risk ratio includes both no effect and appreciable benefit.

^d Completeness of assessing influenza-like illness in intervention and control groups was unclear.

^e Completeness of assessing influenza-like illness and healthcare personnel vaccination was unclear.

^f Completeness of obtaining patients' samples for laboratory confirmation of influenza was low or differed between intervention and control groups. Intervention and control groups were not well matched for patients' Barthel disability scores in 1 of the 2 studies.

^g Sample size was small (effective sample size was less than study sample size because of clustering).

Sir Austin Bradford Hill



“All scientific work is incomplete—whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or postpone the action that it appears to demand at a given time.”

From the London School of Hygiene and Tropical Medicine

Kochar et al., *Infect Control Hosp Epidemiol* 2009;30

SHEA WHITE PAPER

The Evolving Landscape of Healthcare-Associated Infections: Recent Advances in Prevention and a Road Map for Research

Nasia Safdar, MD;¹ Deverick J. Anderson, MD, MPH;² Barbara I. Braun, PhD;³ Philip Carling, MD;⁴ Stuart Cohen, MD;⁵ Curtis Donskey, MD;⁶ Marci Drees, MD, MS;⁷ Anthony Harris, MD, MPH;⁸ David K. Henderson, MD;⁹ Susan S. Huang, MD, MPH;¹⁰ Manisha Juthani-Mehta, MD;¹¹ Ebbing Lautenbach, MD, MPH, MSCE;¹² Darren R. Linkin, MD, MSCE;¹³ Jennifer Meddings, MD, MSc;¹⁴ Loren G. Miller, MD;¹⁵ Aaron Milstone, MD;¹⁶ Daniel Morgan, MD;¹⁷ Sharmila Sengupta, MD;¹⁸ Meera Varman, MD;¹⁹ Deborah Yokoe, MD, MPH;²⁰ Danielle M. Zerr, MD;²¹ on behalf of the Research Committee of the Society for Healthcare Epidemiology of America

High Priority Topics in Infection Prevention: MDROs

- Assessment of transmission dynamics and novel interventions to prevent transmission
 - Acute care settings
 - Non-acute care setting
 - Pediatrics
- Evaluation of the role of the environment and the impact of environmental disinfection on transmission
- Evaluation of the role of laboratory technology to identify MDROs and guide infection prevention measures

ESCMID guidelines for the management of the infection control measures to reduce transmission of multidrug-resistant Gram-negative bacteria in hospitalized patients

E. Tacconelli¹, M. A. Cataldo², S. J. Dancer³, G. De Angelis⁴, M. Falcone⁵, U. Frank⁶, G. Kahlmeter⁷, A. Pan^{8,9}, N. Petrosillo², J. Rodríguez-Baño^{10,11,12}, N. Singh¹³, M. Venditti⁵, D. S. Yokoe¹⁴ and B. Cookson¹⁵

1) Division of Infectious Diseases, Department of Internal Medicine I, Tübingen University Hospital, Tübingen, Germany, 2) Clinical Department, National Institute for Infectious Diseases "L. Spallanzani", Rome, Italy, 3) Department of Microbiology, Hairmyres Hospital, East Kilbride, UK, 4) Infectious Diseases, Università Cattolica Sacro Cuore, 5) Department of Public Health and Infectious Diseases, Policlinico Umberto I, "Sapienza" University, Rome, Italy, 6) Division of Infection Control and Hospital Epidemiology, Department of Infectious Diseases, Heidelberg University Hospital, Heidelberg, Germany, 7) Department of Clinical Microbiology, Central Hospital, Växjö, Sweden, 8) Infectious and Tropical Diseases, Istituto Ospitalieri di Cremona, Cremona, 9) Infectious Risk Area, Health and Social Regional Agency of Emilia-Romagna, Bologna, 10) Unidad Clínica de Enfermedades Infecciosas y Microbiología, Hospital Universitario Virgen Macarena, Seville, 11) Departamento de Medicina, Universidad de Sevilla, Sevilla, Spain, 12) Spanish Network for Research in Infectious Diseases, Instituto de Salud Carlos III, Madrid, Spain, 13) Department of Pediatrics, Epidemiology and Global Health, Children's National Medical Center, The George Washington University, Washington, DC, USA, 14) Infectious Diseases Division, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, USA and 15) Medical Microbiology, Honorary Professor in Medical Microbiology, Division of Infection and Immunity, University College London, London, UK