THE FREQUENCY AND SEVERITY OF SURGICAL SITE INFECTION: THE UNTOLD STORY

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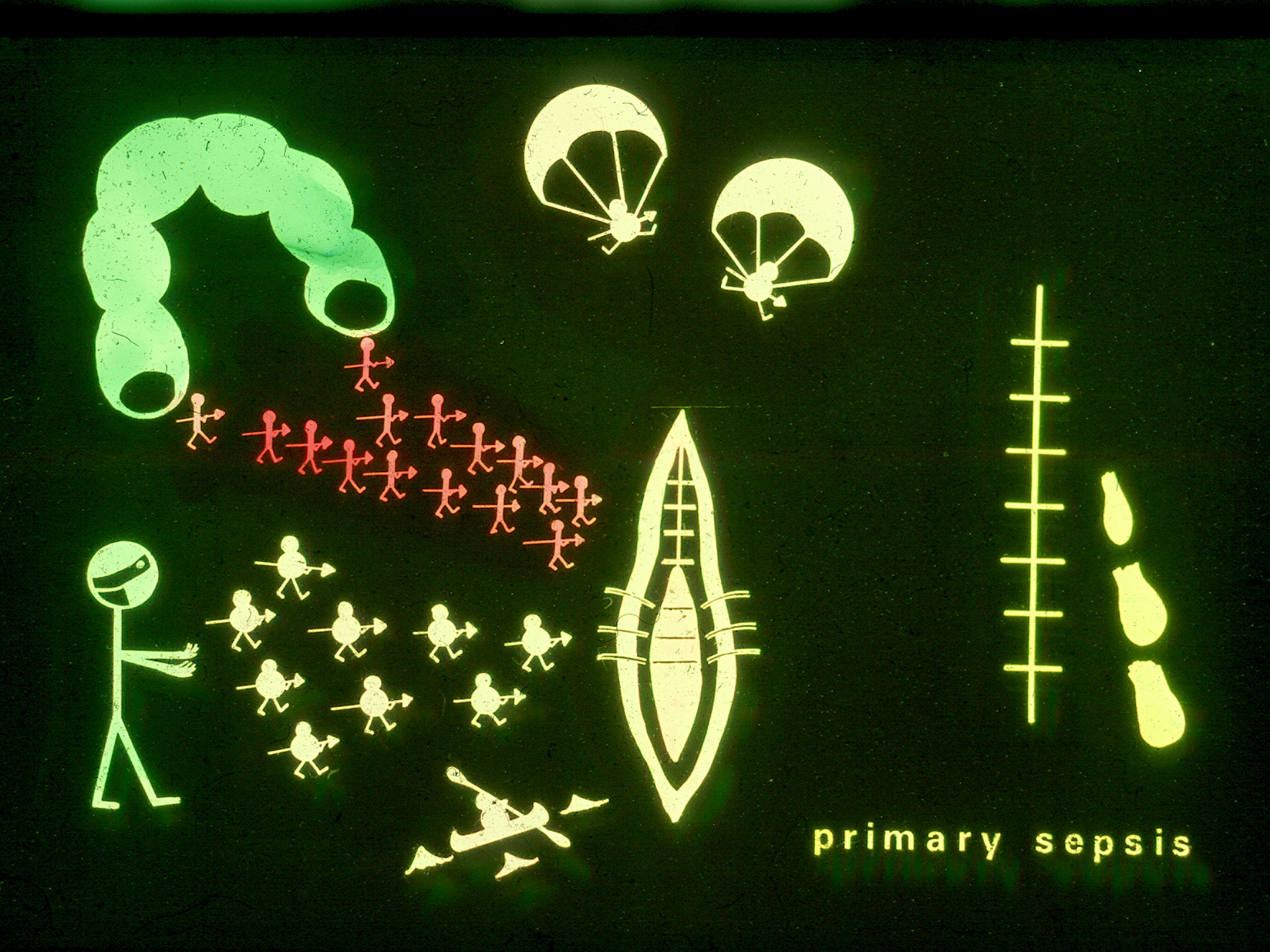

primary sepsis

Probability of SSI

$$\frac{\text{Inoculum of Bacteria} \text{ Plus } \text{Virulence of Bacteria} \text{ Plus } \text{Advuvant Effects}}{\text{Innate and Adaptive Host Defense} \text{ Minus } \text{Acute and Chronic Host-Defense Liabilities}} = \text{Probability of Infection}$$

Surgical Site Infection
History of Preventive Strategies

Antisepsis(1870s)

Asepsis(1900-10)

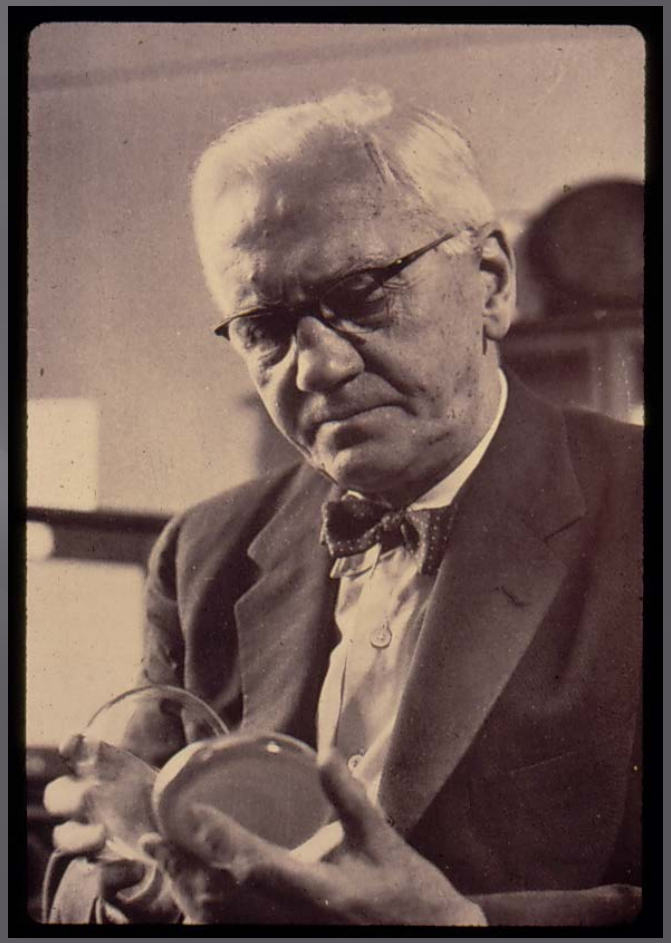
Antibiotics(1940s)

Surgical Site Infections
Preventive Strategies

- Reduce the Inoculum
  - o Good Skin Preparation
  - o Good Surgical Technique
  - o **Preventive Systemic Antibiotics**
- Minimize Adjuvant Effects
  - o Hemostasis
  - o Minimize Braided Suture
  - o Intelligent Use of the Electrocautery
- Augment the Host?
  - Supplemental oxygen
  - Maintenance of core body temperature
  - Glycemic control

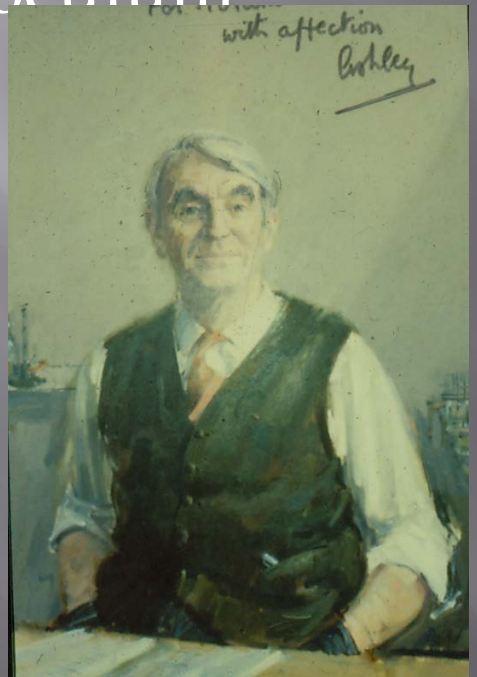
Prevention of Surgical Site Infection

- Alexander Fleming discovered Penicillin in 1929.
- The introduction of antibiotics into clinical practice(early 1940s) raised great hopes in the treatment of bacterial infection.
- In surgery, the prospects of using antibiotics for prevention was immediately recognized as a possibility.

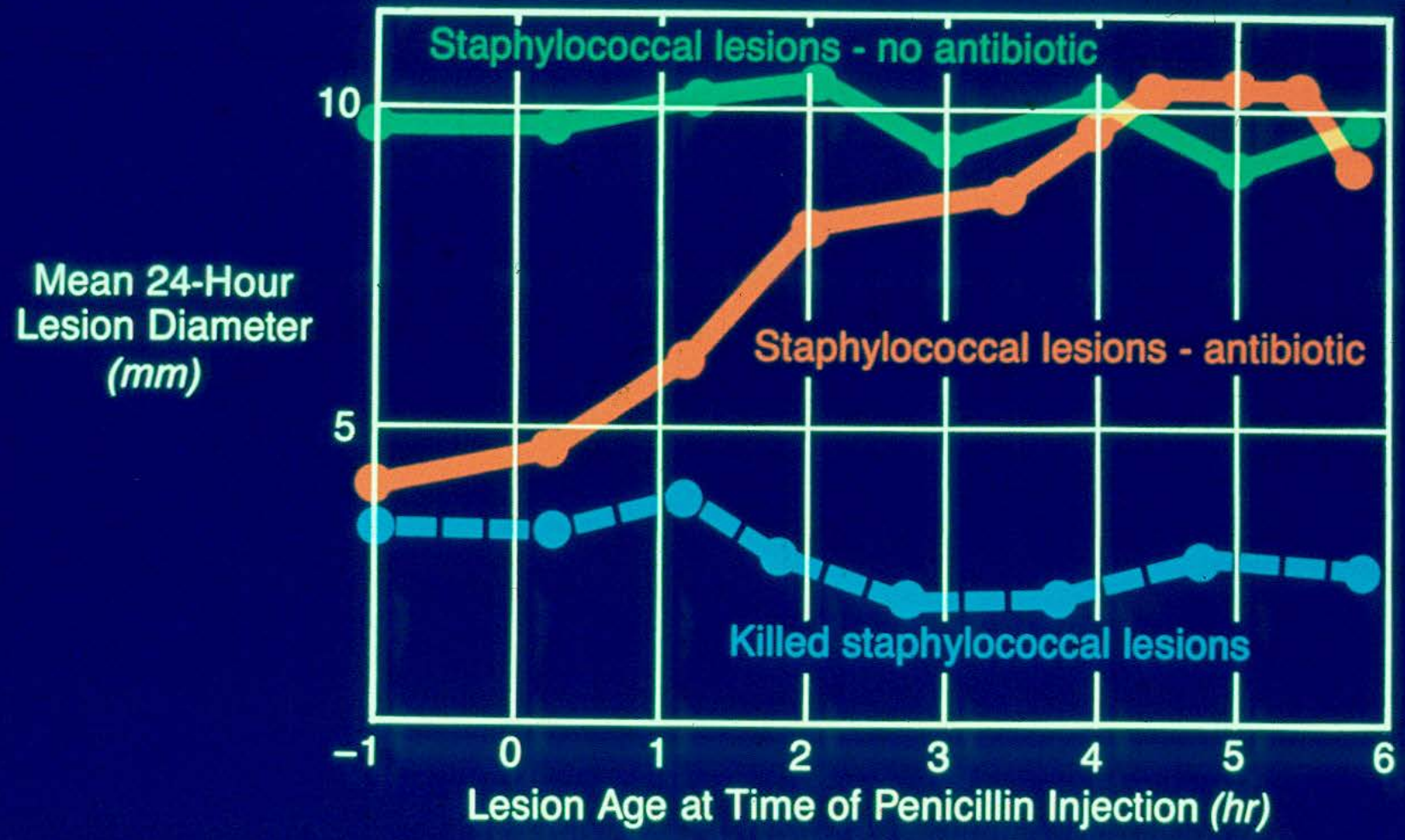


Preventive Systemic Antibiotics Experimental Evidence

- Cutaneous injection of bacteria
- Inflammation at 24-48 hrs is proportional to the logarithm of the bacterial inoculum



Timing of Penicillin Administration with Respect to Bacterial Inoculation



Adapted from the American College of Surgeons. 1988-91.

Prevention of Surgical Site Infection

Use of Preventive Antibiotics: GI Surgery

	Cephaloridine	Placebo
Patients	101	98
Colon Pts	54	50
Infections	6	29
Colon Inf	7%	30%*

(P < .05)*

(Polk and Lopez-Mayor, *Surgery* 1969; 66:97)

Surgical Care Improvement Project

Performance measures - Process

Surgical Infection Prevention

- Antibiotics
  - Administration within one hour before incision
  - Use of antimicrobial recommended in guideline
  - Discontinuation within 24 hours of surgery end
- Glucose control in cardiac surgery patients
- Proper hair removal
- Normothermia in colorectal surgery patients
- Removal of urinary catheter on Post-operative Day 1 or Day 2.

The Current State of Affairs in SSI
CDC: January 1, 2015

- 16 million Inpatient Operations Annually (less than 50% of all operations performed).
- 31% of Healthcare-Associated Infections among inpatients are SSIs.
- 157,500 SSIs annually in the U.S. (year 2011).
- NHSN overall inpatient SSI rate is 1.9%.

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NONSENSE!

SSIs: The Untold Story
The Ten Issues

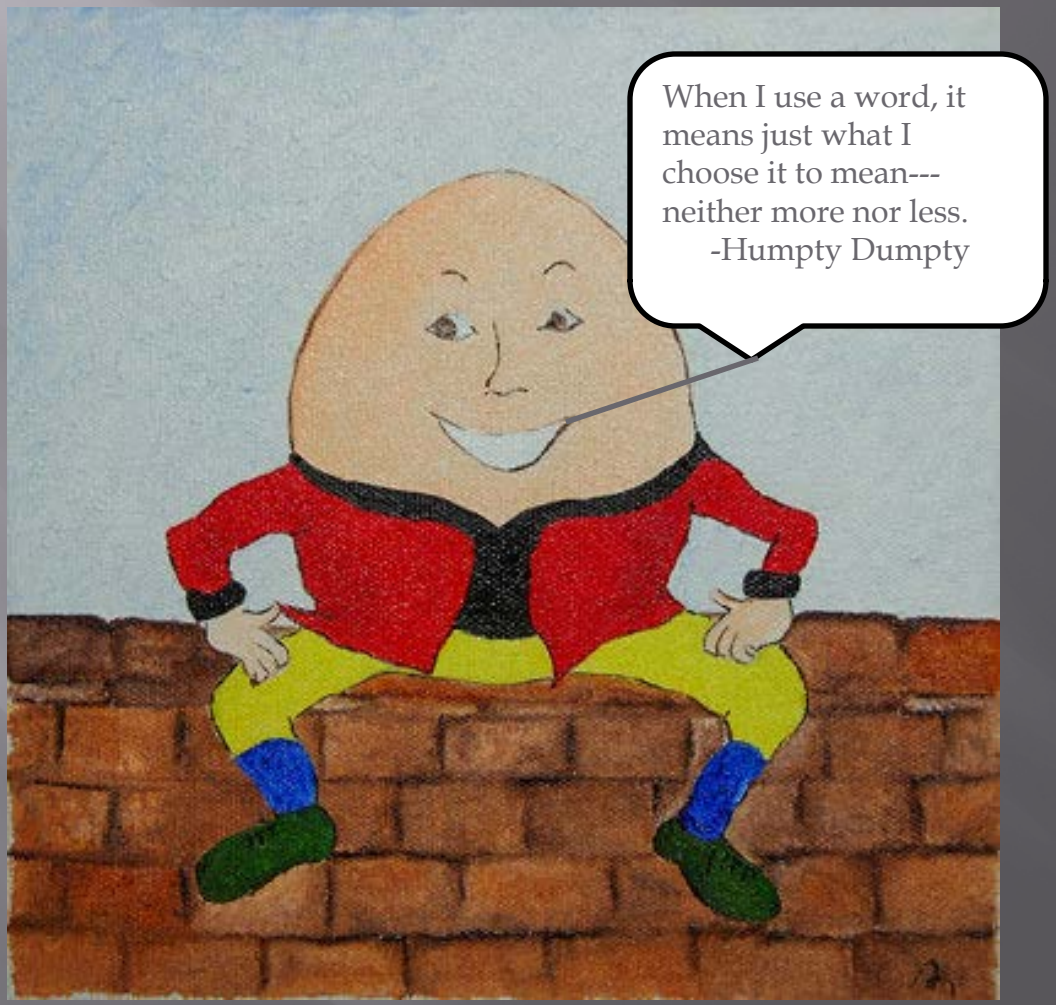
1. Surveillance is Problematic for SSI.
2. We have no information about ambulatory SSI rates.
3. Shorter hospitalization and shifts to more ambulatory operations have distorted SSI rates over time
4. SCIP has not changed SSI rates
5. The deception of Delayed Primary Closure
6. All Preventive Antibiotics are not equal.
7. One size (dose) does not fit all.
8. SCIP antibiotic recommendations are not valid for patients with recent healthcare exposure.
9. Systemic Antibiotics alone are not enough for Colon Surgery.
10. SSI is a major cause of readmissions: the price of shorter inpatient length-of-stay.

SSI: The Untold Story

Surveillance for SSI is Inconsistent, Incomplete, and Inaccurate!

- Inconsistent Definitions and Reporting
- Post-discharge Identification is poor
- We do not know the actual rate of SSI.

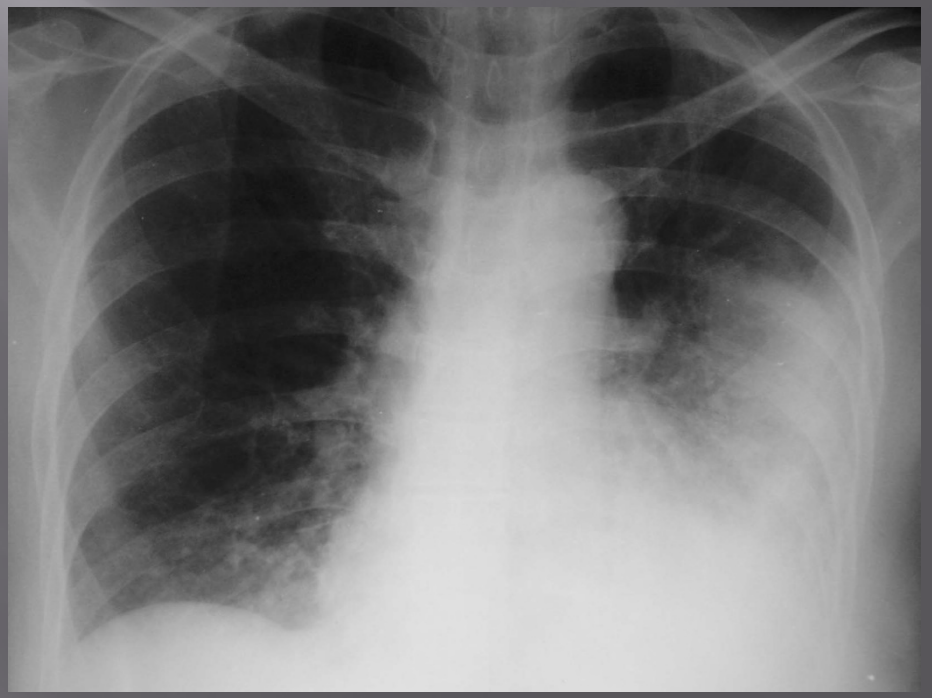
What is a Complication?



Lewis Carroll: Through the Looking Glass, Chapter 6, 1871.

Control Charts in Elective Colon Surgery

Coded Event	#Patients
C. difficile Inf.	71 (0.5%)
Acute MI	115 (0.9%)
UTI	270 (2%)
SSI	510 (3.9%)
Pneumonia	335 (2.5%)
Pulmonary Dys	631 (4.8%)
Ileus	2033 (15.4%)



Fry et al: Am J Surg 2012; 203:392.

Colon Surgery SSIs in NHSN

			NHSNRisk Index		
Procedure	Cut Point (min)	0 (%)	1 (%)	2 (%)	3 (%)
Colon resection	187	3.99	5.59	7.06	9.47
Coronary artery bypass with donor incision	301	0.35	2.55	4.26	8.49
Spinal fusion	239	0.70	1.84	4.15†	–
Herniorrhaphy	124	0.74	2.42	5.25†	–
Hip prosthesis	120	0.67	1.44	2.40†	–
Abdominal hysterectomy	143	1.1	2.2	4.05†	–

*The cut point is identified in minutes. Procedures that exceed the cut point in duration have one risk point added to the NHSN risk index.
†Indicates that risk index groups 2 and 3 have been pooled together because of small total cases.

Edwards JR et al: Am J Infect Control 2009;37:783-805.

Colon Surgery SSIs in NSQIP

Table 3. Unadjusted Analyses of Postoperative Mortality, LOS, and Morbidity

	No. (%)		
	Right-Sided Colectomy	Left-Sided Colectomy	*P* Value
30-d mortality	40 (1.8)	32 (1.2)	.08
Postoperative LOS, mean (SD)	6.9 (5.5)	6.5(5.2)	<.001
Median	6	5	<.001
Patients with >7 d postoperative LOS	804 (36.2)	840 (31.7)	<.001
Patients with no medical or surgical complications	1852 (83.4)	2199 (82.9)	.55
Surgical complications			
Superficial SSI	130 (5.9)	217 (8.2)	.002
Deep SSI	17 (0.8)	25 (0.9)	.50
Organ space SSI	44 (2.0)	48 (1.8)	.66
Wound dehiscence	25 (1.1)	26 (0.9)	.62
Sepsis	102 (4.6)	106 (4.0)	.31
Reoperation	98 (4.4)	118 (4.5)	.95
Bleeding requiring ≥5 U	8 (0.4)	7 (0.3)	.55

Kwaan et al: JAMA Surgery 2013; 148:504

Elective Colorectal Surgery: Preventive Antibiotics and SSIs

	Ertapenem (n=346)*		Cefotetan (n=339)	
Reason for Failure	n	%	n	%
Any Failure	102	29.5	145	42.8
Surgical Site Infection	63	18.2	105	31
Unexplained Antibiotic Use	29	8.4	26	7.7
Anastomotic Leak	10	2.9	14	4.1

* *P<0.001*

(Itani KMF et al: New Engl J Med 2006; 355:2640-51)

SSIs: The Untold Story

Ambulatory SSI rates?

- Not amenable to conventional surveillance.
- Requires self-reporting which is problematic.
- Patients return to ERs at hospitals other than where the procedure was performed.
- ER visits, readmissions, subsequent ambulatory procedures (e.g., wound drainage or debridement), and antibiotic prescriptions may be necessary metrics: these will require better data systems (e.g., Healthcare Information Exchanges).

SSIs: The Untold Story

Process Measures are not Outcomes:
SCIP has failed to improve SSI Rates

SCIP Compliance and SSIs

Hawn MT, et al: Association of timely administration of prophylactic antibiotics for major surgical procedures and surgical site infections. JACS 2008; 206:814-19.

- 9,195 elective VA operations (orthopaedic, colon, peripheral vascular)
- 86.4% complied with timely antibiotic administration. (SCIP-1).
- Poor timing of antibiotic administration was not associated with increased SSI rates (Overall SSI rate =4.7%).

SCIP Compliance and SSIs

Stulberg JJ et al: Adherence to surgical care improvement project measures and the association with postoperative infections. JAMA 2010; 303:2479-85.

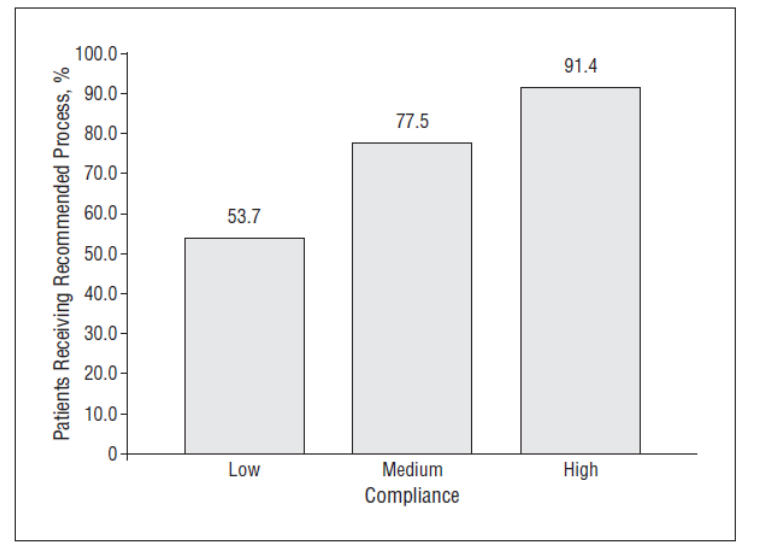
- 405,720 cases from Premier Database.
- 68% elective; overall SSI rate = 1%.
- Adherence with individual SCIP measures by hospitals was not associated with reduced SSI rates.

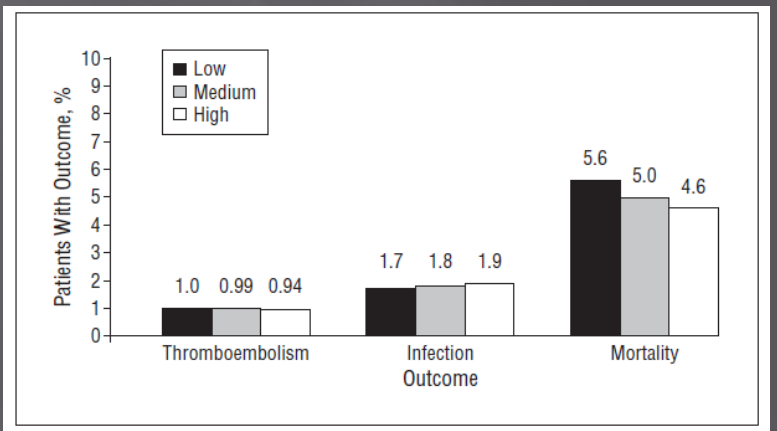
Hospital Process Compliance and Surgical Outcomes in Medicare Beneficiaries

Lauren H. Nicholas, PhD; Nicholas H. Osborne, MD; John D. Birkmeyer, MD; Justin B. Dimick, MD, MPH

Arch Surg 2010; 145:999-1004.

- 325, 052 surgical patients from national Medicare database undergoing high-risk surgical procedures (aorta, heart, esophagus, pancreas)
- 2,189 hospitals
- Compliance with SCIP criteria at the hospital-level made no difference in SSI infection outcomes.





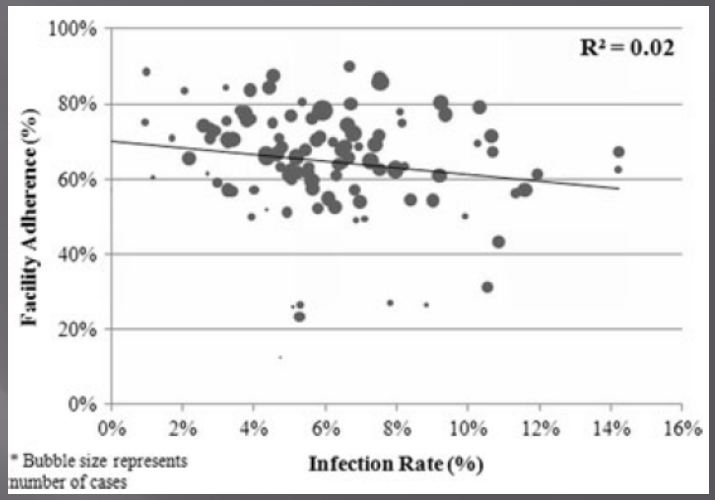
Surgical Site Infection Prevention

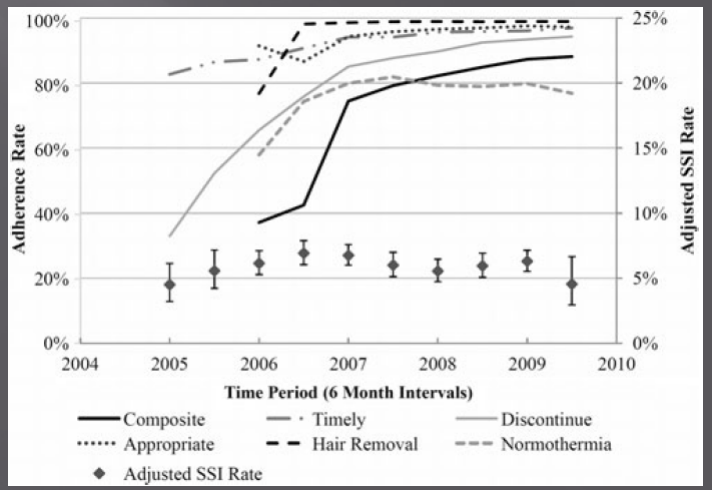
Time to Move Beyond the Surgical Care Improvement Program

Mary T. Hawn, MD, MPH,† Catherine C. Vick, MS,* Joshua Richman, MD, PhD,*† William Holman, MD,*† Rhiannon J. Deierhoi, MPH,* Laura A. Graham, MPH,* William G. Henderson, MPH, PhD,‡ and Kamal M.F. Itani, MD§*

Ann Surg 2011; 254:494-501

- VASQIP Database: 2005-2009
- 60,853 operations of the 5 SCIP procedure groups performed at 112 VA Hospitals
- SSI rates measured against hospital compliance with all 5 SCIP performance measures.
- Overall SSI rate (30 days) of 6.2%
  - Colon surgery= 11.3%
  - Orthopaedic surgery= 1.6%
- Compliance with SCIP measures did not lower the odds of SSI or reduced hospital SSI rates!



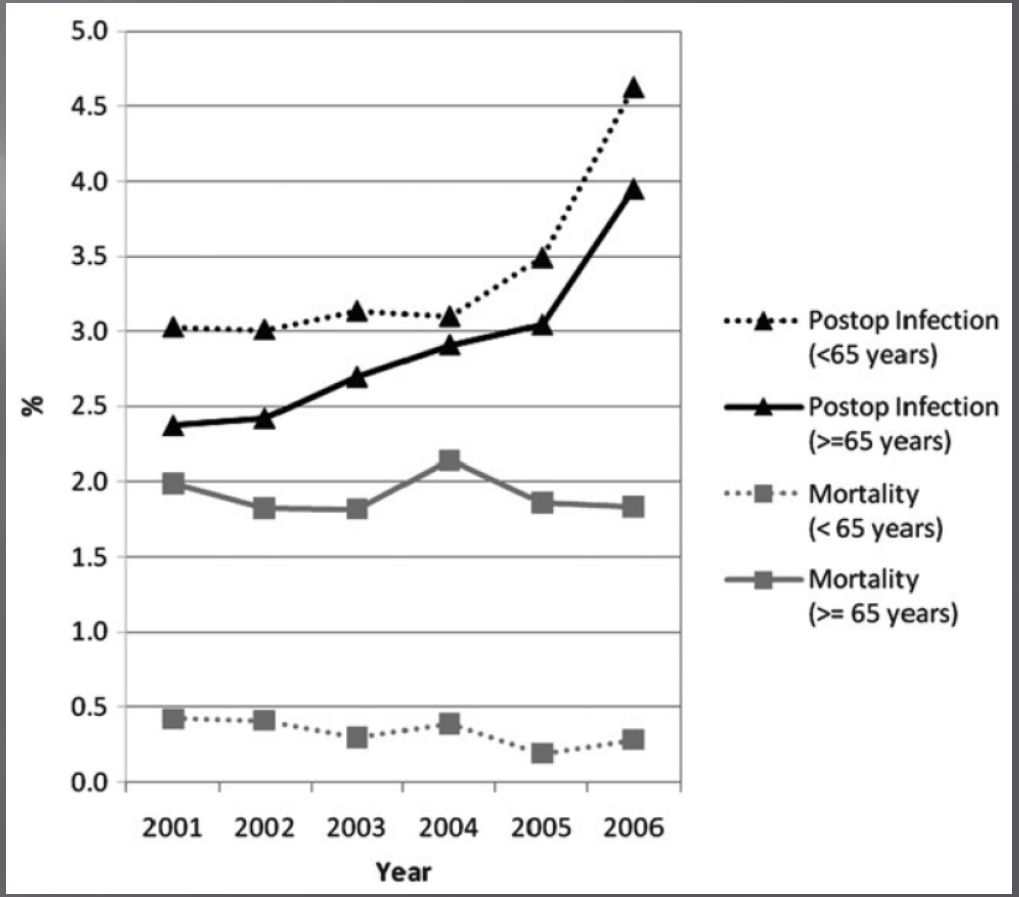


Report Card on Surgical Care Improvement Project (SCIP): Nationwide Inpatient Sample Infection Data 2001–2006

John Mihran Davis,[1] Yen-Hong Kuo,[2] Nasim Ahmed,[1] and Yen-Liang Kuo[3]

Surg Infect 2011; 12:1-6.

- HCUP-NIS Database for 2001-2006.
- Colectomy and Open/Laparoscopic Cholecystectomy procedures.
- N= 245,974 colectomies ≥ 65 years of age
- N= 196,852 colectomies < 65 years of age
- Mortality rates and length of stay declined over the 6 years.
- SSI rates progressively increased.



Colectomy Patients

Why Have SIP/SCIP Appeared to Fail?

- Are the Performance Measures Invalid?
- Are there not enough measures?
- Are Hospitals and Physicians misrepresenting compliance?
- Are SSIs pre-ordained based upon risk?

Performance Measures are not Outcomes

Surgery is not Synchronized Swimming

SURGICAL INFECTIONS
Volume 12, Number 6, 2011

DOI: 10.1089/sur.2011.091

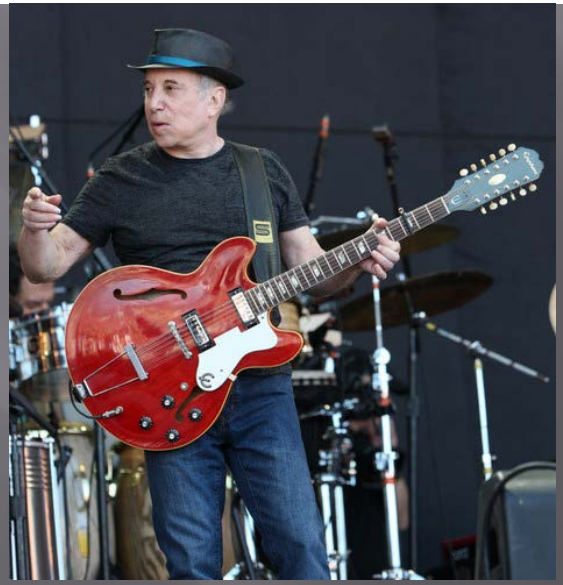
Commentary

Fifty Ways to Cause Surgical Site Infections

Donald E. Fry

"…it's really not my habit to intrude. Furthermore, I hope my meaning won't be lost or misconstrued. But I'll repeat myself, at the risk of being crude. There must be fifty ways…"

Paul Simon



SSIs: The Untold Story

The Deception of Delayed Primary Closure

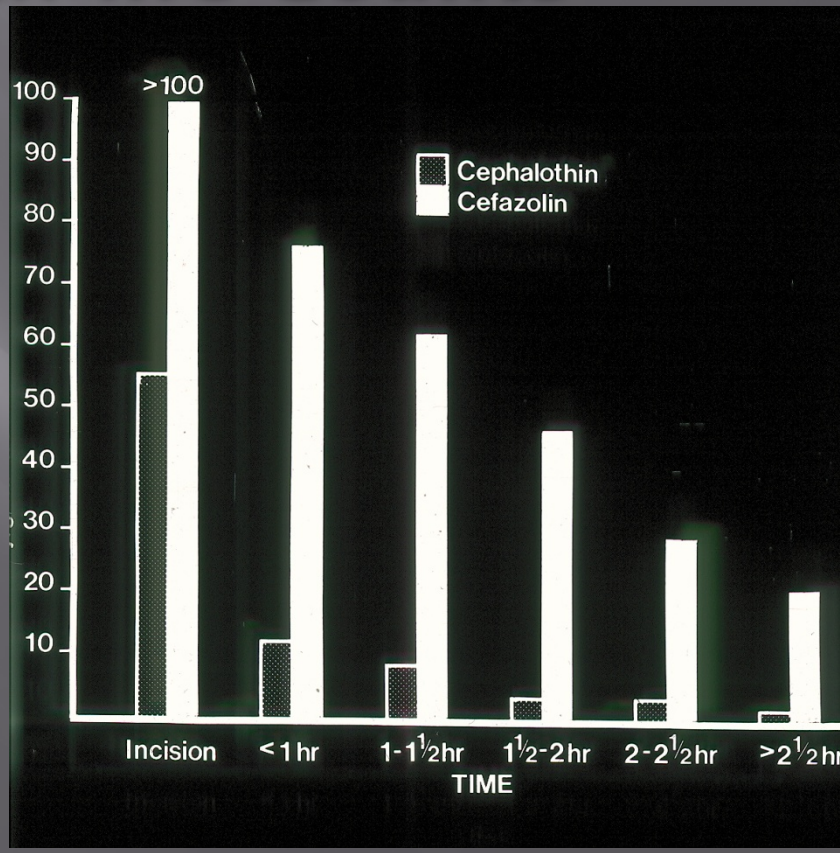
- In high risk cases, the skin and subcutaneous tissues are left open for topical management.
- This leaves the open wound vulnerable to continued environmental contamination.
- In theory, the wound is to have delayed closure at day 3-5; in reality, this does not happen.
- Hospitals can report all non-closed wounds as not infected
- Patient morbidity of the non-closed wound is the same as a superficial SSI where the wound is opened: All patients sustain open wound morbidity, not just the infected ones!

SSIs: The Untold Story

In Surgical Prophylaxis, All Antibiotics are not created equally!

Systemic Preventive Antibiotics
Elimination Half-life Counts

- Cephalothin is gone from the wound in 90 min from time of administration.
- Cefazolin in therapeutic concentrations beyond 2½ hours.



SSIs: The Untold Story

Colorectal Antibiotic Recommendations:

- Cefoxitin
- Cefotetan
- Ampicillin/Sulbactam
- Ertapenem
- Cefazolin + Metronidazole

Preventive Antibiotics in Surgery Coverage of MRSA?

- Randomized trial in cardiovascular procedures.
- An environment with high rates of MRSA infection
- Randomization of vancomycin vs. cefazolin
- Overall SSI rates were the same.
- Cefazolin-associated infections had high frequency of MRSA
- Vancomycin-associated infections had high frequency of MSSA

Finkelstein et al: JTCVS, 2002;123:326

TABLE 2. Outcomes of 885 patients receiving vancomycin or cefazolin prophylaxis for cardiovascular operations

	Vancomycin (n = 452)	Cefazolin (n = 433)
Superficial incisional SSI (No.)		
All	25 (5.5%)	20 (4.6%)
Donor site	7 (1.5%)	10 (2.3%)
Chest	18 (4%)	10 (2.3%)
Deep incisional SSI (No.)		
All	12 (2.6%)	7 (1.6%)
Donor site	2 (0.4%)	2 (0.4%)
Chest	10 (2.2%)	5 (1.2%)
Organ-space SSI (No.)		
All	6 (1.3%)	12 (2.7%)
Mediastinitis	5 (1.1%)	7 (1.6%)
Osteomyelitis	0	3 (0.7%)
Endocarditis	1 (0.2%)	2 (0.4%)
Pericarditis	0	0
Any SSI (No.)	43 (9.5%)	39 (9.0%)
Duration of postoperative hospitalization (d, mean ± SD)	8.7 ± 8	9.3 ± 11
Deaths (No.)	13 (2.9%)	14 (3.2%)

No differences were significant at $P \leq .05$.

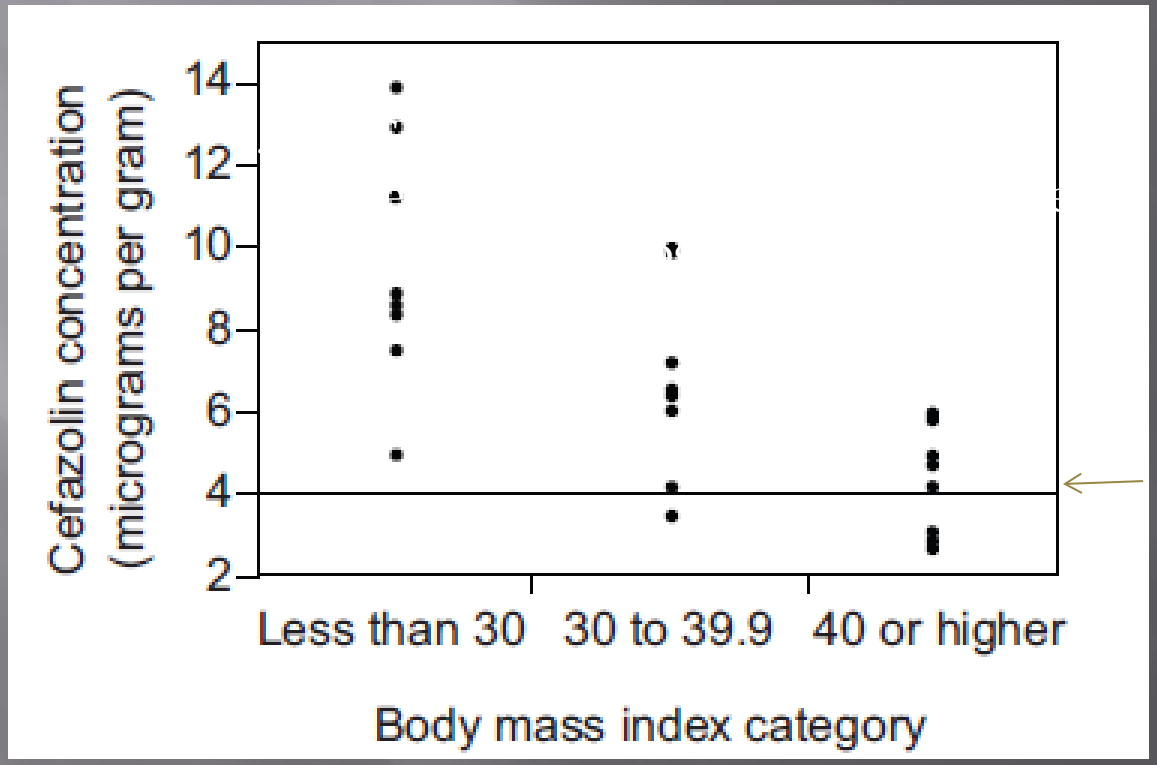
SSIs: The Untold Story

With Preventive Antibiotics, one size (dose) does not fit all!

- Dose adjustment for patient BMI?
- Dose adjustment for duration of operation?

Preventive Antibiotics Effects of Obesity

Adipose Cefazolin concentrations at opening of C-sections



Pevzner et al: Obstet Gynecol 2011; 117:877-82.

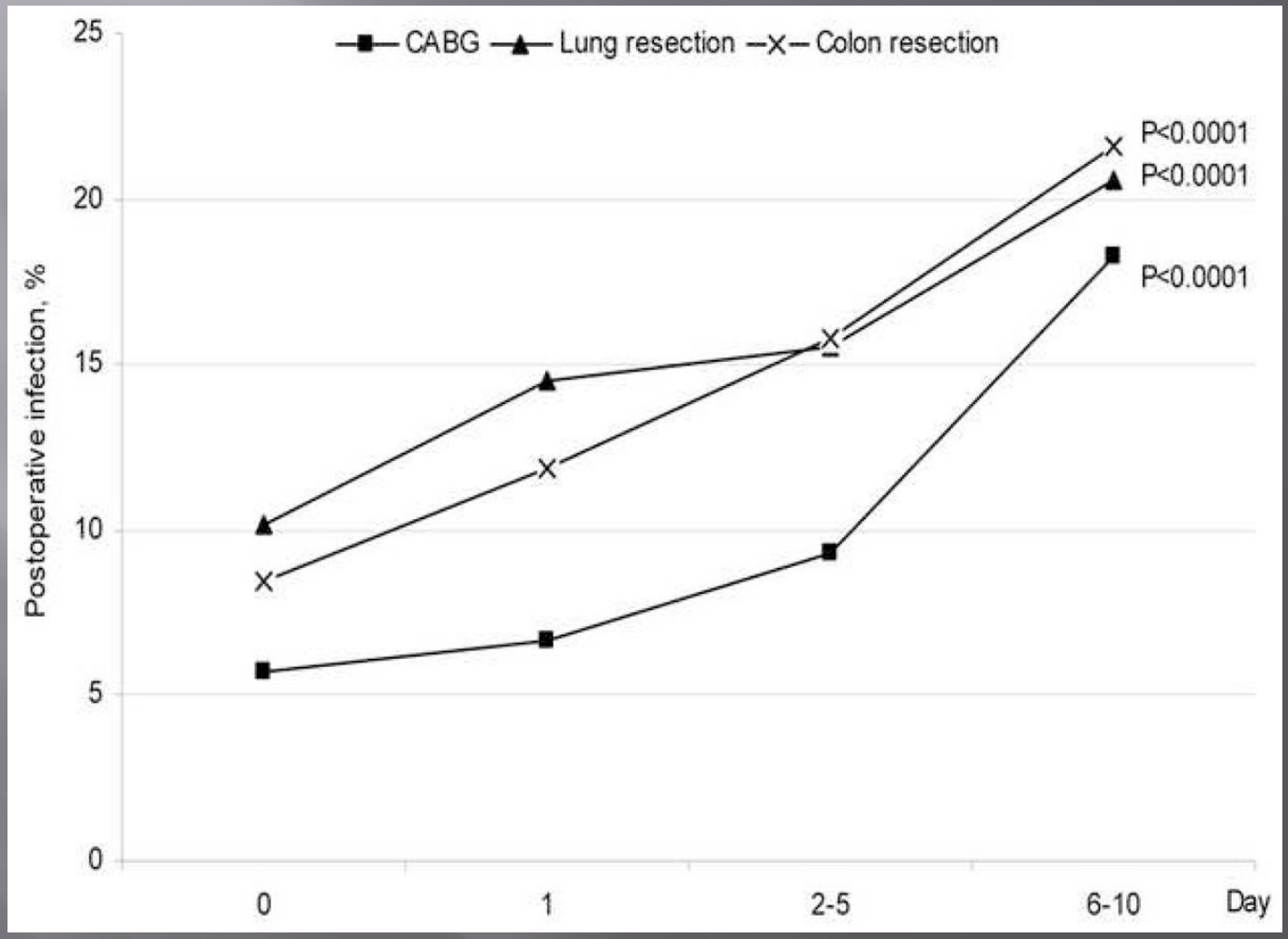
SCIP antibiotic recommendations are not valid for patients with recent healthcare exposure.

SSIs: The Untold Story

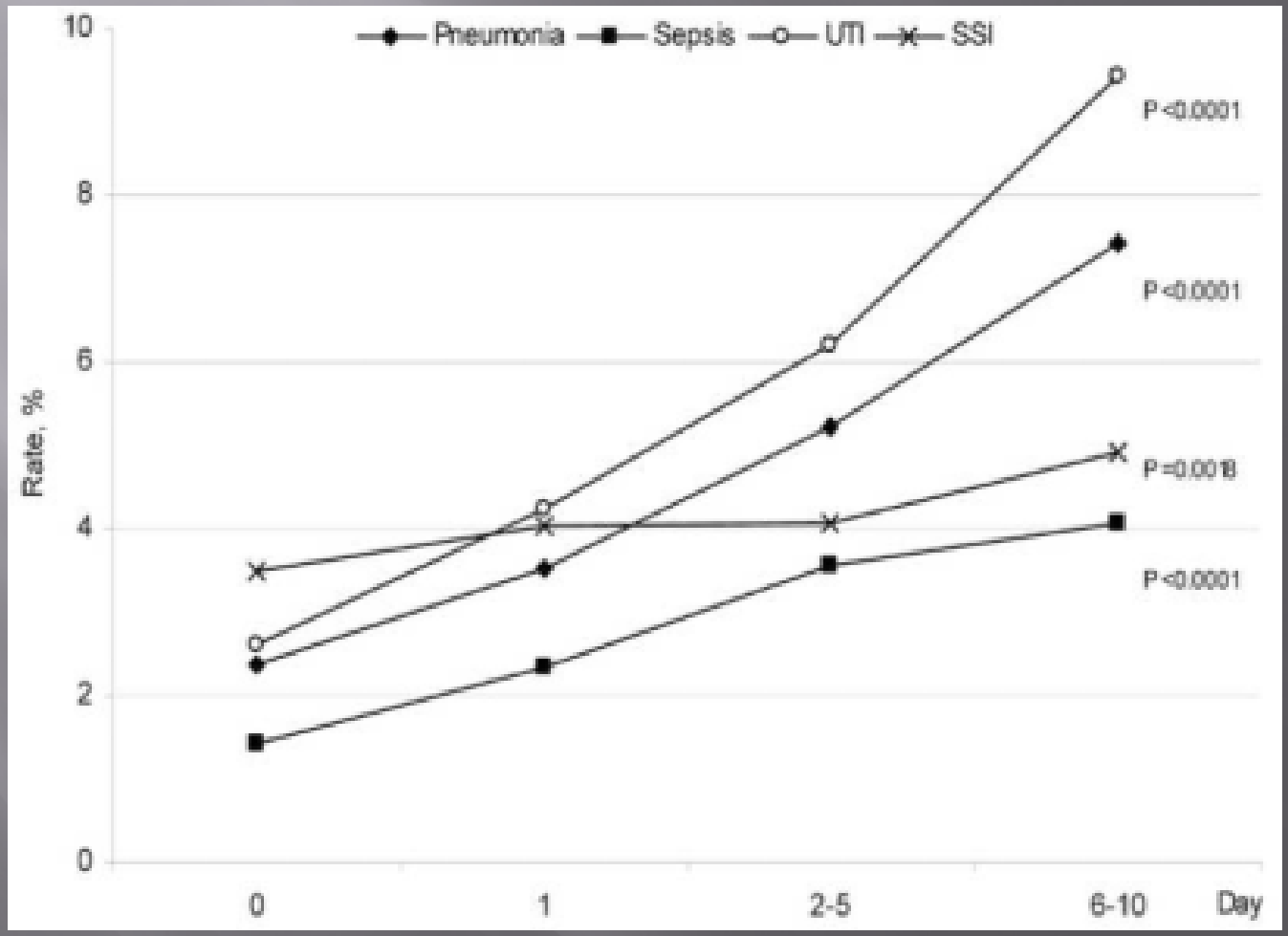
Hospital and/or Antibiotic Exposure increases colonization with gram-positive and gram-negative resistant bacteria.

- 1.5 million U.S. people are in nursing homes.
- 500,000 people are on chronic hemodialysis
- 3,000,000 people are within 30 days of inpatient care.
- Millions are within 30 days of a course of antibiotics.
- SCIP Antibiotic choices are not appropriate for these patients.

Preoperative Stay and HAIs Vogel et al: JACS, Dec 2010



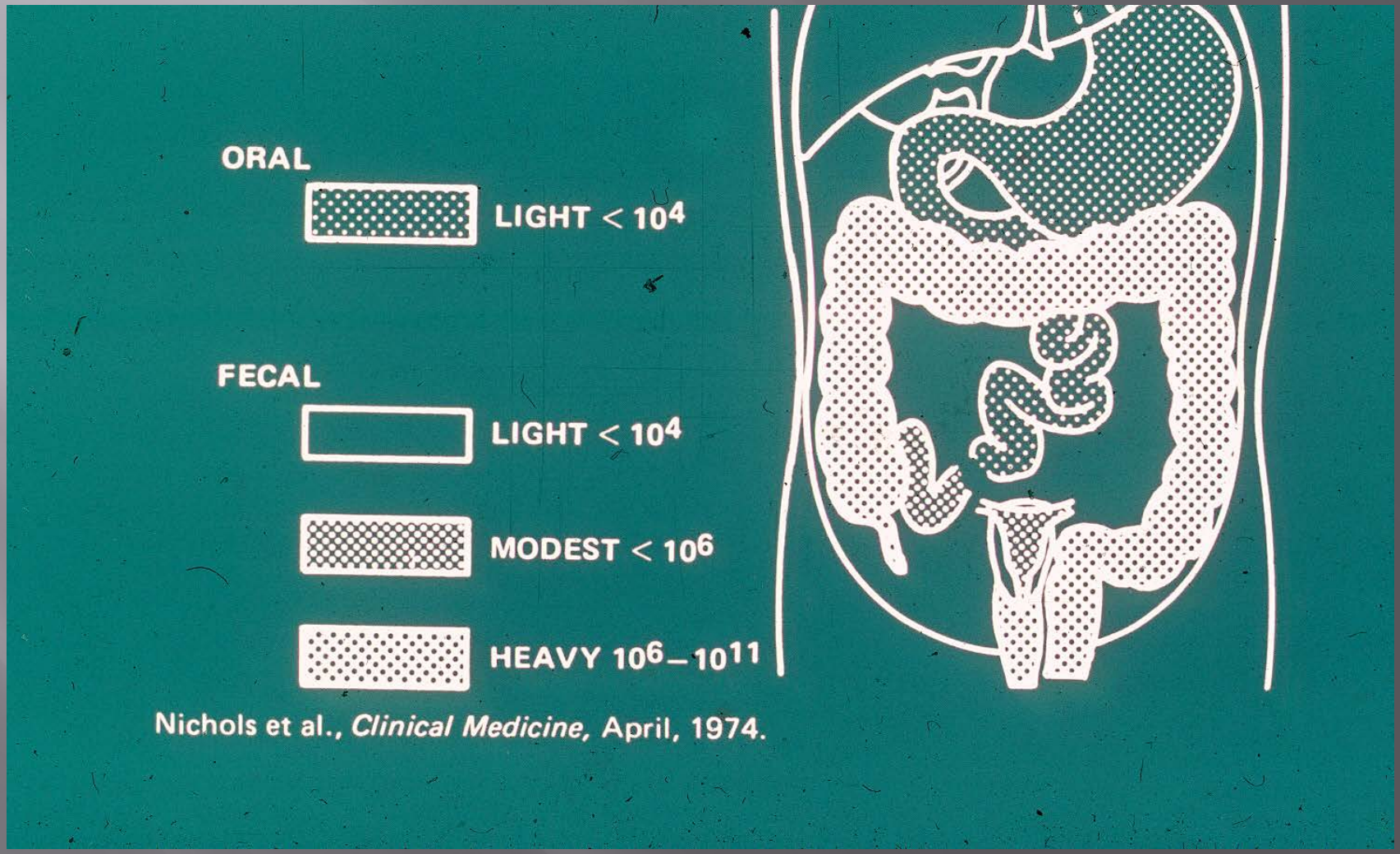
Preoperative Stay and SSIs Vogel et al: JACS, Dec 2010



SSIs: The Untold Story

Preventive Systemic Antibiotics do not prevent organ/space SSIs!

Mechanical Bowel Preparation? Elective Colon Surgery



Preventive Oral Antibiotics for Colon Surgery

	SSIs/Patients	Infection Rate
Placebo	21/60	35%
Neomycin/ Erythromycin	5/56	9%*

(Clarke et al: Ann Surg 1977; 186:251-258

(P<0.05)*

Mechanical Bowel Preparation vs. No Bowel Preparation

	Without Mechanical Preparation		With Mechanical Preparation	
Author, year	**No. Patients**	**No. Infections**	**Patients**	**Infections**
Miettinen, 2000	129	10	138	13
Bucher, 2005	75	6	78	17
Fa-Si-Oen, 2005	125	13	125	16
Ram, 2005	165	13	164	18
Zmora, 2006	129	17	120	15
Jung, 2007	657	106	686	103
Contant, 2007	684	96	670	90
Pena-Soria 2008	64	11	65	19

Oral vs Systemic Antibiotics

Elective Colon Surgery

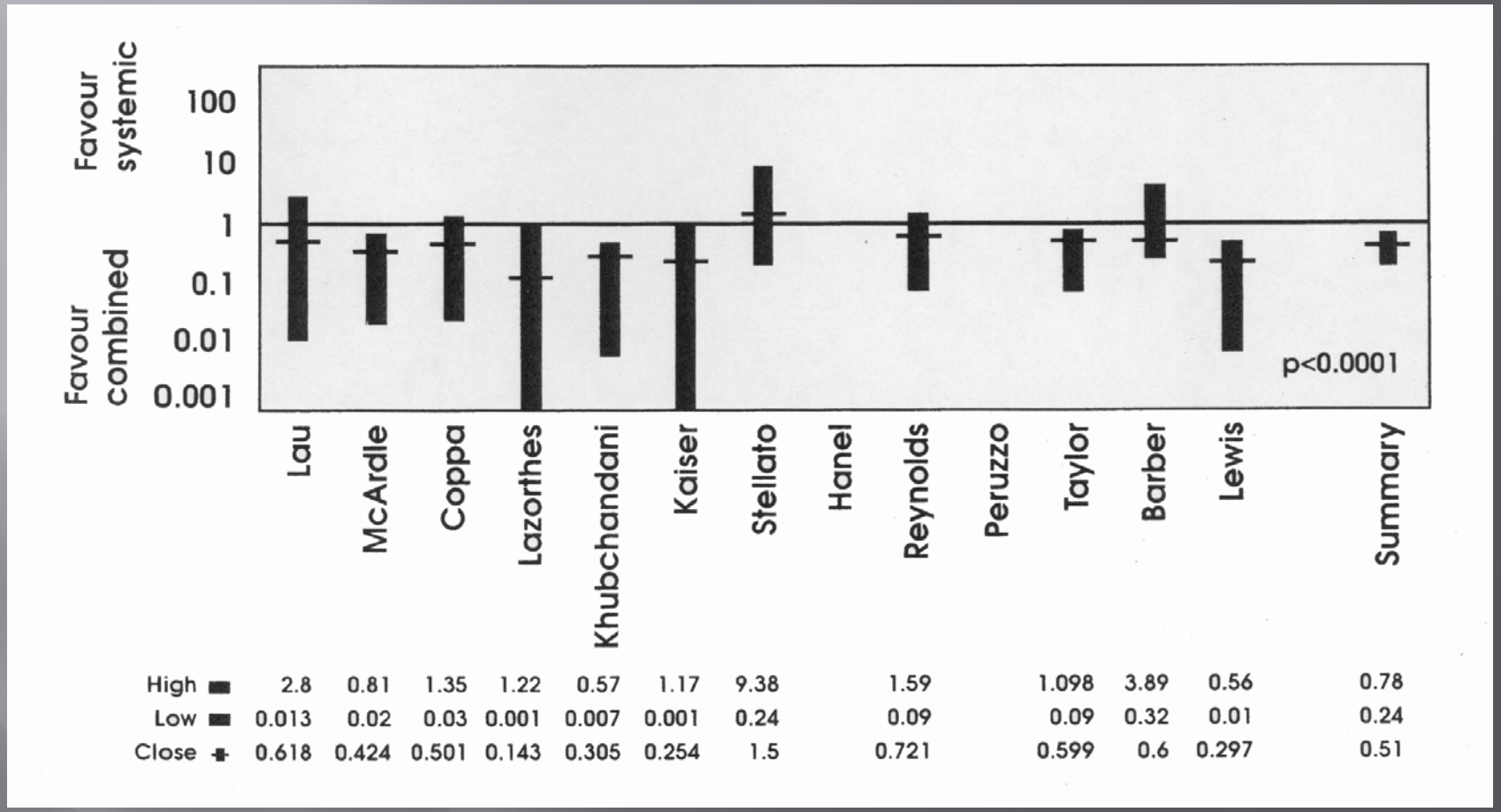
- All patients received systemic preoperative amikacin and metronidazole
- Oral neomycin and metronidazole were randomized

	Oral Drugs	No Oral Drugs
SSIs/Patients	5/109	17/106
Infection Rate	5%	16%

($P<0.01$)

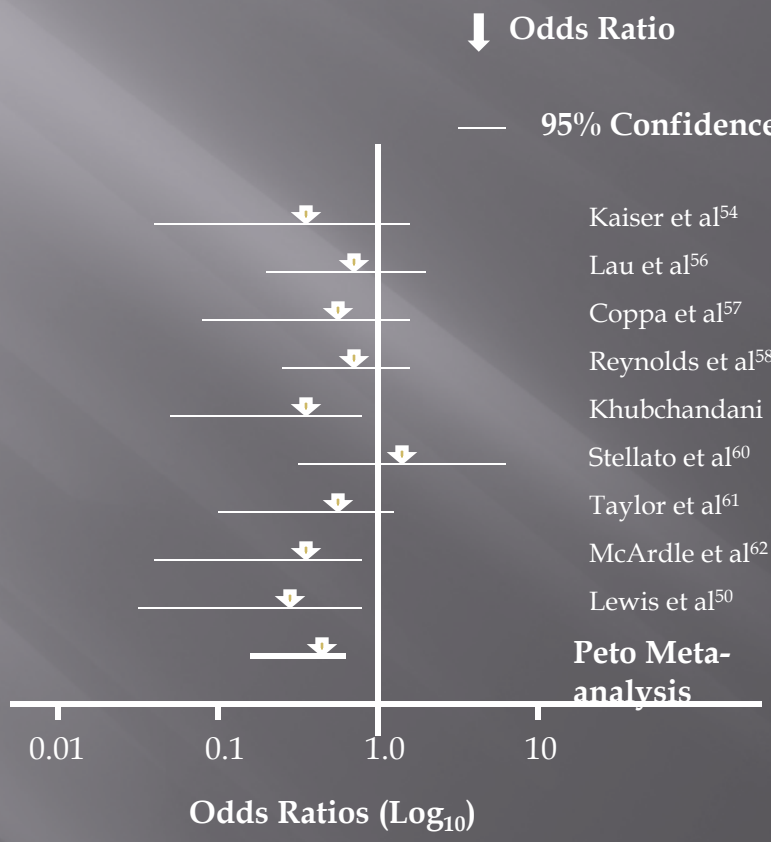
Lewis. *Can J Surg*. 2002;45:173-180.

Preventive Antibiotics in Colon Surgery: Systemic vs. Systemic + Oral Antibiotics



Lewis RT: Can J Surg 2002; 45:173.

Preventive Antibiotics in Colon Surgery: Systemic vs. Systemic + Oral Antibiotics

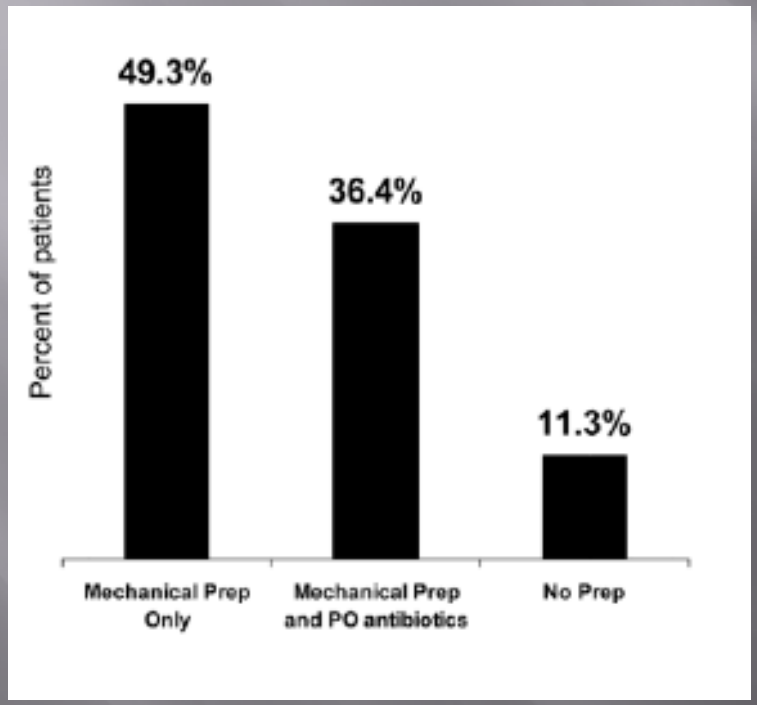


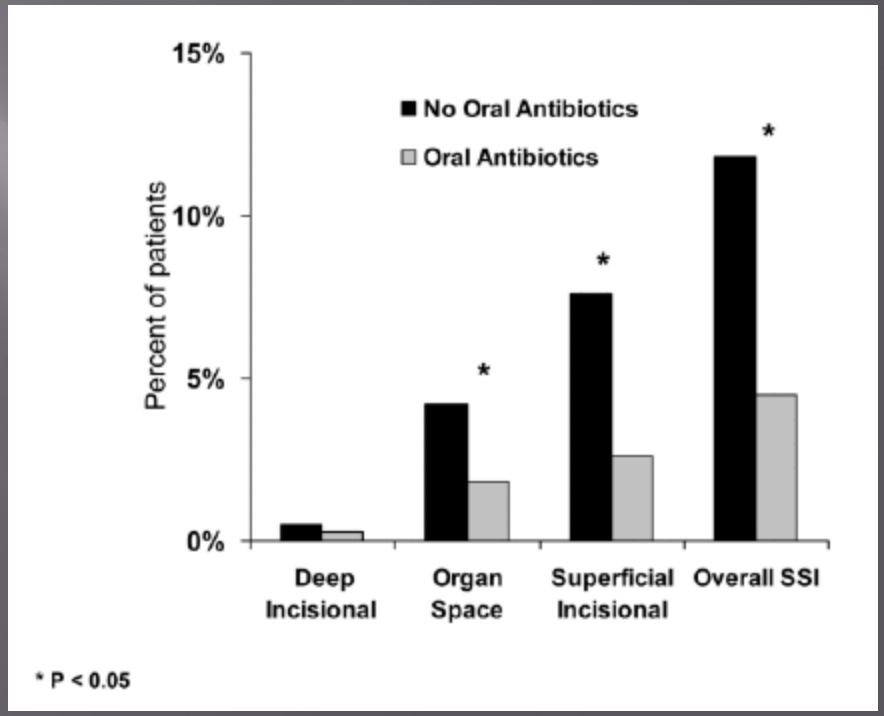
P< 0.0001

Fry: American Journal of Surgery, 2011

Oral Antibiotics v. No Oral Antibiotics Michigan Surgical Quality Collaborative

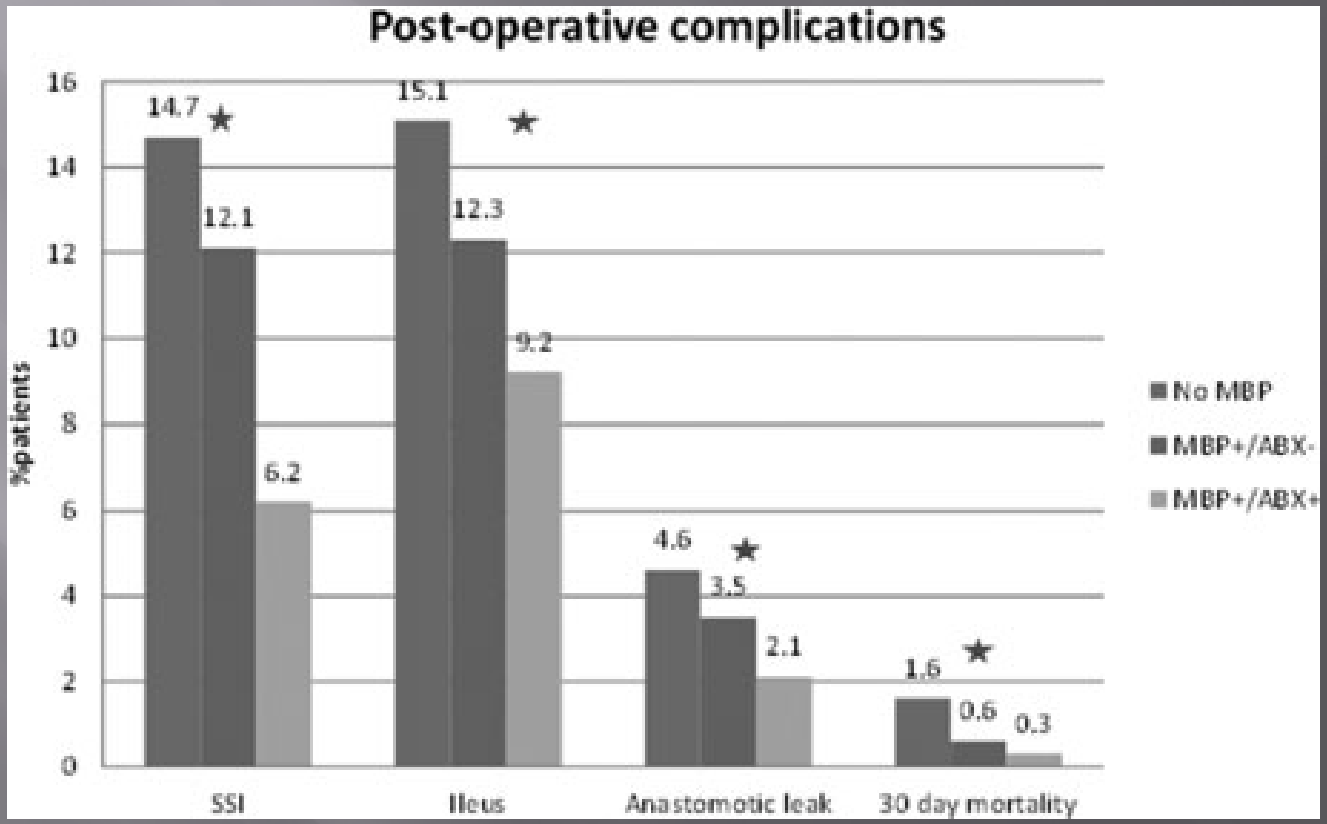
16 month study; n=2011 patients; all received systemic antibiotics





Englesbe et al: Ann Surg 2010; 252:514-520

Bowel Preparation and SSIs



Kirin et al: Annals of Surgery, September 2015

Mechanical Bowel Preparation

	Polyethylene Glycol	Sodium Phosphate
N=	303	367
SSIs	103 (34%)	87 (24%)

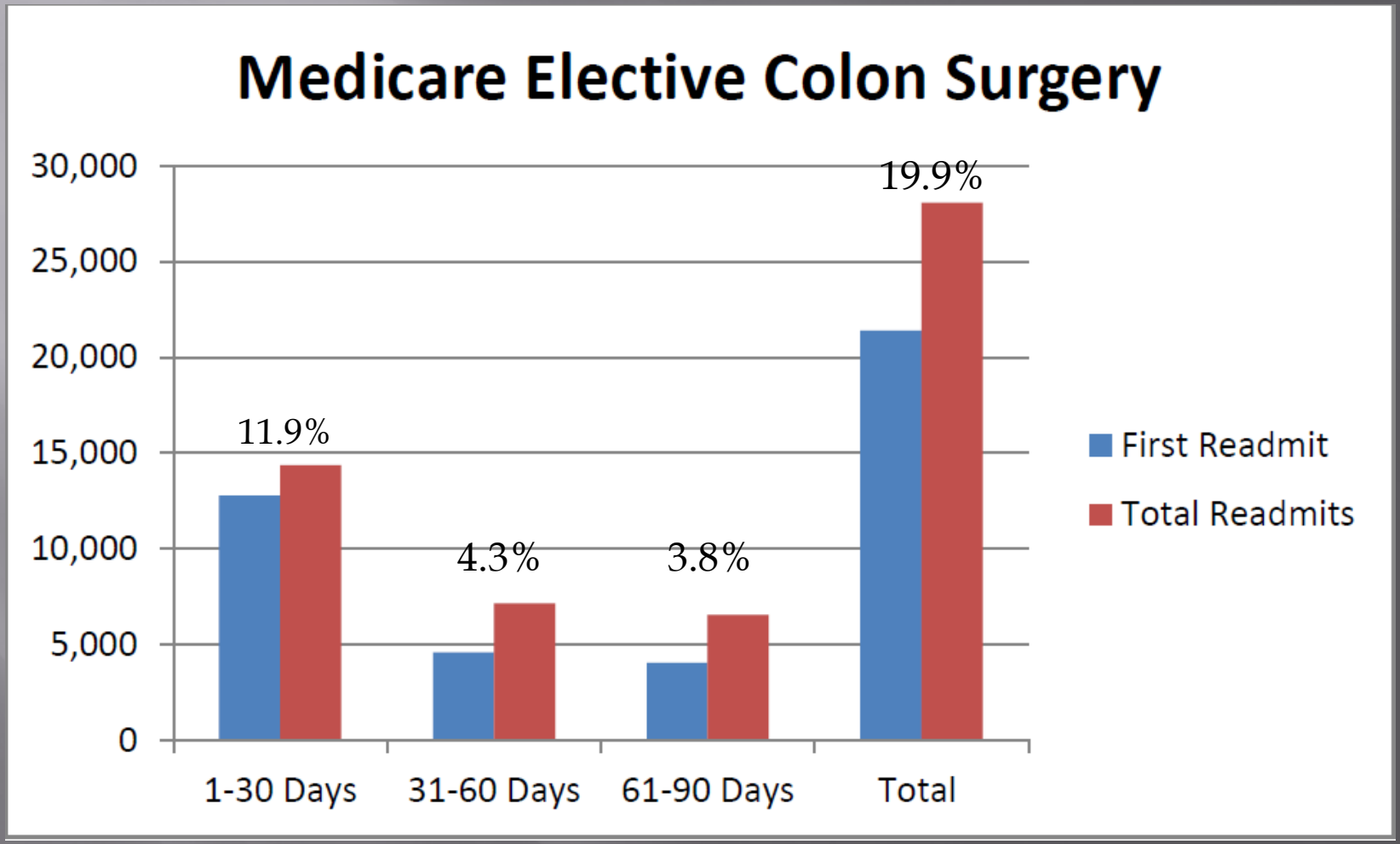
P = 0.03 (Univariant analysis)
P = 0.065 (Multi-variant analysis)

Itani KM et al: Am J Surg 2007; 193:190

SSIs: The Untold Story

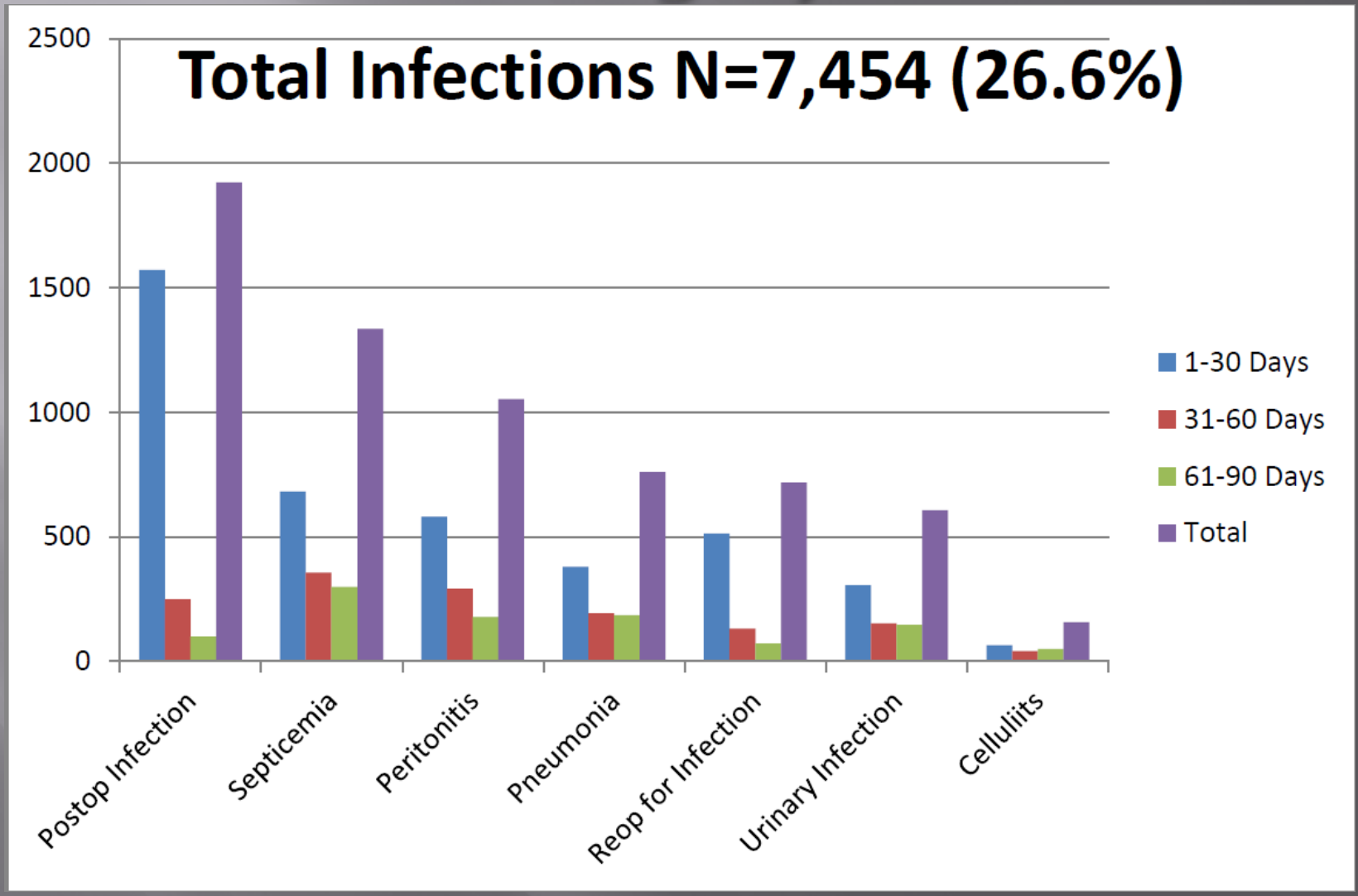
SSI is a major cause of readmissions: the price of shorter inpatient length-of-stay.

Readmissions After Colon Surgery
90 Day Live Discharges = 107,459
21,407 Patient; 28,073 Readmit Events



Fry et al: American Journal of Surgery, In press, 2016.

Readmissions After Colon Surgery



SSIs: The Untold Story

Conclusions:

- Many effective preventive strategies have been defined for prevention of SSI in controlled trials
- Consistent surveillance of SSI remains a problem
- Government programs have not reduced SSI rates.
- Antibiotic choice needs to be individualized to the patient's weight, and healthcare exposure.

SSIs: The Untold Story

Conclusions:

- Mechanical bowel preparation and oral antibiotics need to be consistently used for the prevention of organ/space infections in colon surgery
- Readmission and Emergency Department visits need to be evaluated as a measure of SSIs following discharge from the hospital.