The Surgical Care Improvement Project (SCIP)

Ten Years Later

Growing Surgical Interest in Quality, Safety, and Transparency

Presidential Address

Quality, Safety, and Transparency

Hiram C. Polk, Jr., MD

THE GROSS CONNECTION

The American Surgical Association (ASA) was founded by Samuel David Gross and nurtured by his pupils, David W. Yandell and Samuel W. Gross, his son. Dr. Samuel D. Gross was the second Professor of Surgery at the University of Louisville, serving from 1840 to 1856. Dr. Yandell succeeded him in that chair, no doubt because of his association with Dr. Gross, but also perhaps because his father happened to be the Dean. The rich history of Gross' life in Louisville and Philadelphia has already been mined thoroughly, but I did think recently how little the duties of the surgical chair have changed over almost 150 years.[1,2] I briefly consulted my successor on his first day in the Chair of Surgery at the University of Louisville about a complicated issue related to our Institutional Review Board. I reminded him that within my first week on the job, I was somewhat peripherally involved in a discussion that subsequently led to a lawsuit. Both of those issues paled in comparison to the fact that Dr.

PURPOSE

The purpose of this address is:

- To examine our knowledge and public attitudes regarding quality, safety, and minimization of medical error;
- To encourage surgeon-led efforts in these activities as well as sensible cost control;
- To explore the potential benefits of scientifically sound, risk-adjusted transparency as a boon to surgery as a profession; and
- A serious caution regarding the Delilah of duty hours and the problems that they pose for our once and future patients.

Quality, safety, and minimization of error are seemingly the sides of an equilateral triangle. Transparency, as I hope to develop, may provide us with assistance in bringing our specialty to a higher level of leadership. The remote history of efforts with respect to increasing the safety of

Enormous Effort and General good Faith

- Systemic review
- SSI and SCIP Bundle

Elements in SSI Prevention

- Equipment/Drapes/Gowns sterilization
- Handwashing/Patient/Site preparation
- Antibiotic Prophylaxis
- Shaving
- Normothermia
- Normoglycemia
- Hyperoxia
- *Staph aureus* screening

A mixture of large databases and institution reports – different specialties, different patients, different outcomes

Surgical Site Infection Rates: Deep Incision and Organ Space Infections NHSN 2011

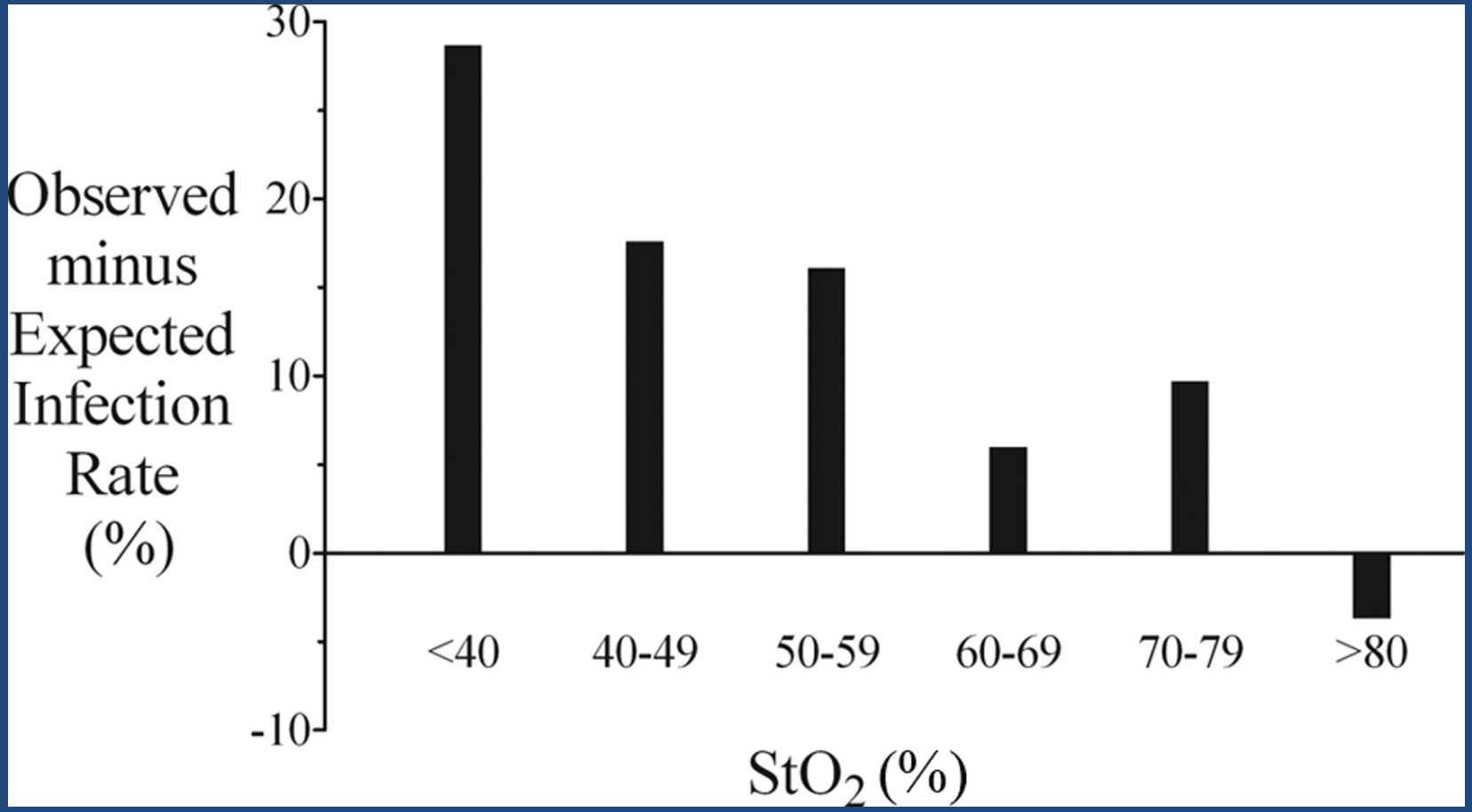
Procedure	# Procedures	# Infections	Infection Rate (%)
CABG	87,934	926	1.05
Small Bowel Surgery	12,262	259	2.11
Colon Surgery	68,702	1,663	2.42
Abdominal Hysterectomy	82,082	524	0.64
Hip Prosthesis	180,996	1,422	0.79

Mu Y, Edwards JR, Horan TC, Berrios-Torres SI, Fridkin SK: Improving risk-adjusted measures of surgical site infection for the national healthcare safety network Infect Control Hosp Epidemiol. 2011 Oct;32(10):970-86

Dose of Antibiotics for Prophylaxis

- Always give at least a full therapeutic dose of antibiotic
- Consider the upper range of doses for large patients and/or long operations
- Repeat doses for long operations

Arm Tissue O2 Saturation and SSI



Govinda R et al. Anesth Analg 2010;111:946-952

Perioperative Warming, Intraoperative Temperature and Complications

- Open abdominal operation with bowel resection
- All patients warmed in the O.R.
- Study group (perioperative) warmed 2 hours pre-op and 2 hours post-op

Wong, Br J Surgery 2007; 94: 426-6

ORIGINAL SCIENTIFIC ARTICLES

Expanded Surgical Time Out: A Key to Real-Time Data Collection and Quality Improvement

Terry Altpeter, RN, PhD, Kitty Luckhardt, LPN, John N Lewis, MD, PhD, Alden H Harken, MD, FACS, Hiram C Polk Jr, MD, FACS

Some of the *concepts* contained here have been discussed and incorporated in another publication, but the data are entirely unique to this manuscript. (See: Transforming the Surgical "Time-Out" Into a Comprehensive "Preparatory Pause." Backster A, Teo A, Swift M, MD, Polk HC Jr, MD, FACS, Harken AH, MD, FACS. J Cardiac Surg, in press.)

BACKGROUND: The increasing push for quality improvement coincides with the slowly growing use of surgical time out (STO) to lessen the likelihood of wrong-site operation. We believe that the use of STO as a reflective pause or a preoperative briefing has broader value. The purpose of this article is to describe one institution's experience with this technique and to validate its potential use by others.

Expense of Implementation

- Much time and money required
- Dedicated hospital taskforces
- In-service education for physicians and staff
- Need administrative leader, system leader, and day-to-day process leaders
- Data collection and analysis – careful/expensive
- Frequent meetings for feedback/monitoring of compliance and performance

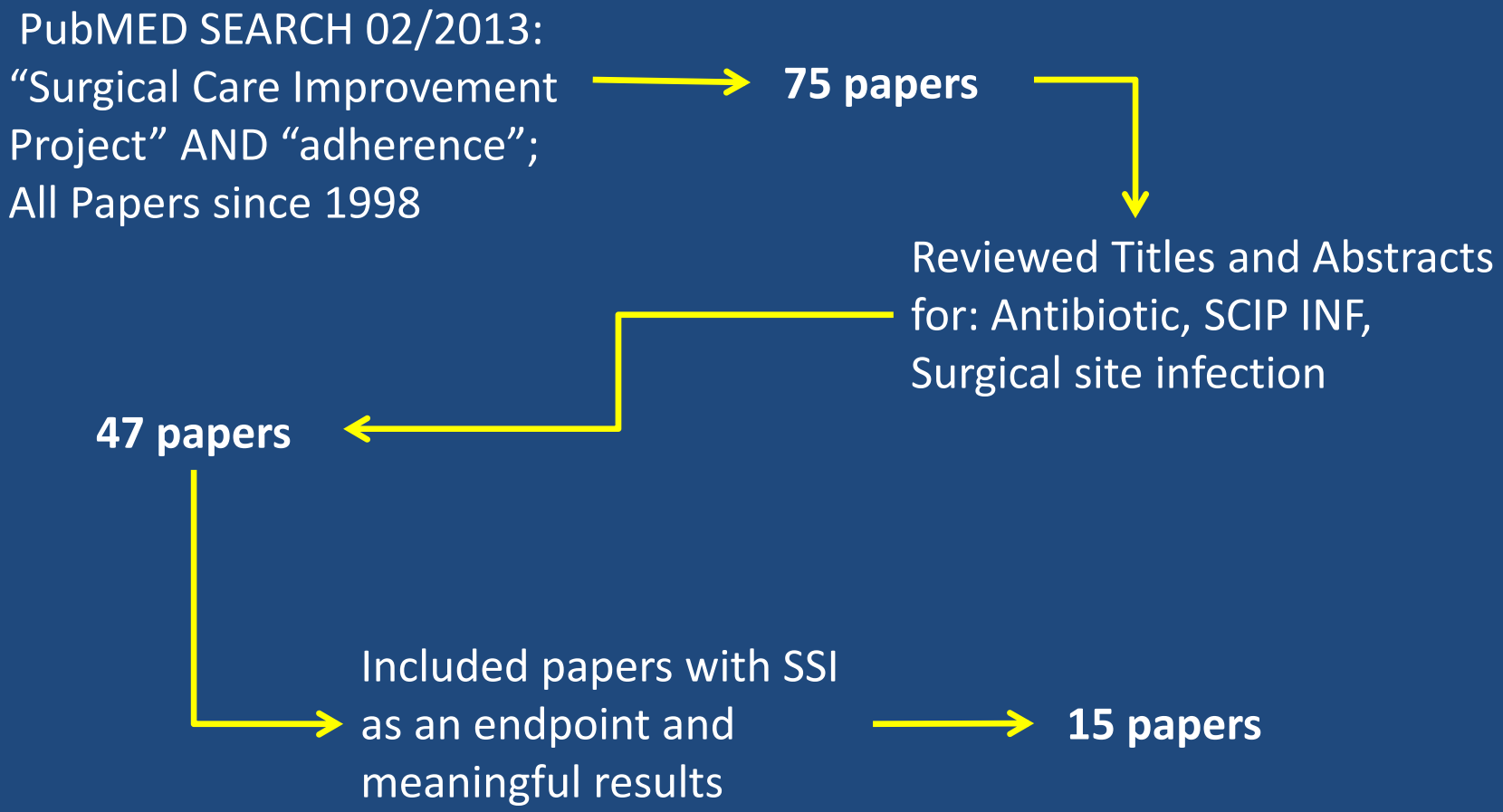
Positive Effects of SCIP

- Largest decrease in SSI observed in poorest performing facilities
- Still observed after Risk Adjustment for confounding infection risks
- Compliance with whole SCIP bundle was demonstrated to be more effective
- Possibly reduced hospital and pharmacy expenditures

The “NON-” Effects of SCIP

- No increase in SSI, morbidity, or mortality consistently demonstrated with any aspect of SCIP implementation
- No measurable decrease in SSI was observed in hospitals with >90% compliance at start of study
- SCIP compliance is at best a weak measure of hospital quality and unrelated to reimbursements

SCIP Literature Search Flow Sheet



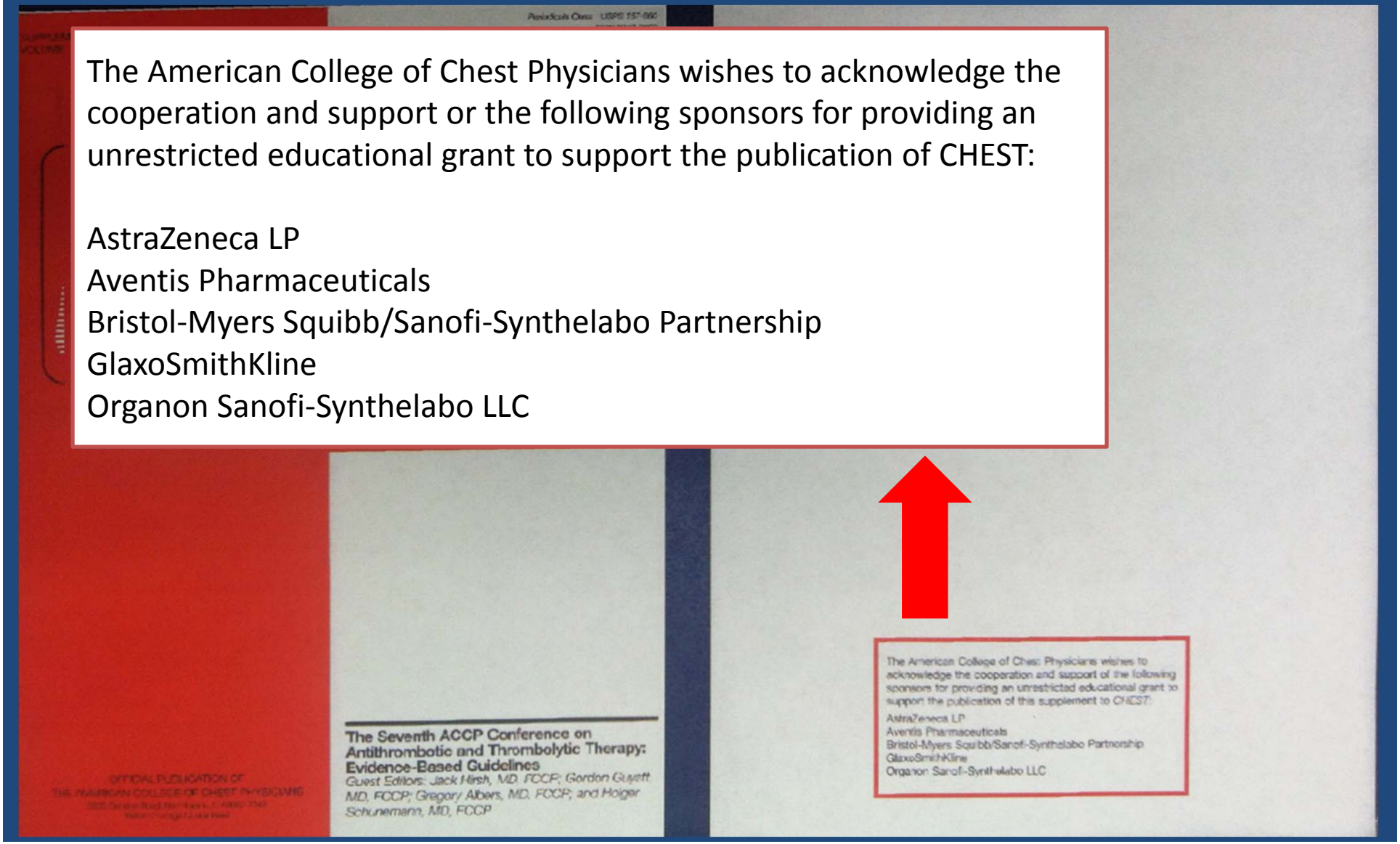
How difficult is it to learn/know the truth and remain current with data sources and their credibility


The Bones of Copernicus
Owen Gingerich
Remembering Reynolds Price
David Gray
The Perils of Plunging to Earth
Rob Zaretsky
Book Reviews
Michael Dirda, Hampton Sides
Emily Bernard, Mark Bertogaard
The AMERICAN SCHOLAR
PUBLISHED BY PHI BETA KAPPA
How big drug companies compromise doctors, undermine the top journals, and skew medical research
Medicine for Sale
HARRIET A. WASHINGTON
Also
Winston Churchill
Flea Circuses
The Mexican Border
New Fiction, New Poetry

Chest Supplement

The American College of Chest Physicians wishes to acknowledge the cooperation and support or the following sponsors for providing an unrestricted educational grant to support the publication of CHEST:

AstraZeneca LP
Aventis Pharmaceuticals
Bristol-Myers Squibb/Sanofi-Synthelabo Partnership
GlaxoSmithKline
Organon Sanofi-Synthelabo LLC



Conflict of Interest

Nature (20 October 2005)

nature

Vol 437|20 October 2005

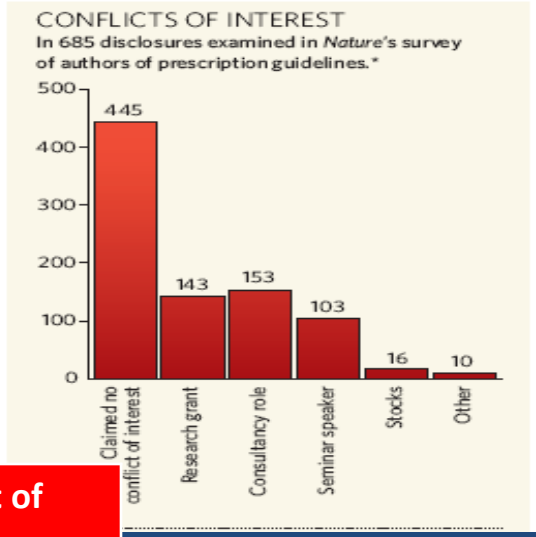
NEWS

Cash interests taint drug advice

Researchers and physicians who write the rules on prescribing drugs have extensive financial connections with the pharmaceutical industry, an investigation by *Nature* has revealed. Public-health experts say that the results of the survey, which is the largest of its kind, suggest that drug companies are distorting decisions about how their products are being prescribed.

In the investigation of the panels that write clinical guidelines — documents that govern the diagnosis and treatment of patients — *Nature* found that more than one-third of authors declared financial links to relevant drug companies, with around 70% of panels being affected. In one case, every member of the panel had been paid by the company responsible for the drug that was ultimately recommended.

These links with pharmaceutical companies are more worrying than the financial conflicts



In one example uncovered by *Nature*, guidelines for the treatment of anaemia in HIV-positive patients were written by a working group selected by Paul Volberding, a leading AIDS researcher and physician, and vice-chairman of the Department of Medicine at the University of California, San Francisco. Volberding convened the group at the request of Ortho Biotech, a pharmaceutical company based in Bridgewater, New Jersey. Ortho Biotech funded the group's meetings, and all six members, including Volberding, had been paid by the company for lecturing or consultancy jobs. The group's latest guidelines, published last year (P. Volberding *et al. Clin. Infect. Dis.* **38**, 1454–1463; 2004), recommend the use of epoetin alpha, a drug marketed by Ortho Biotech.

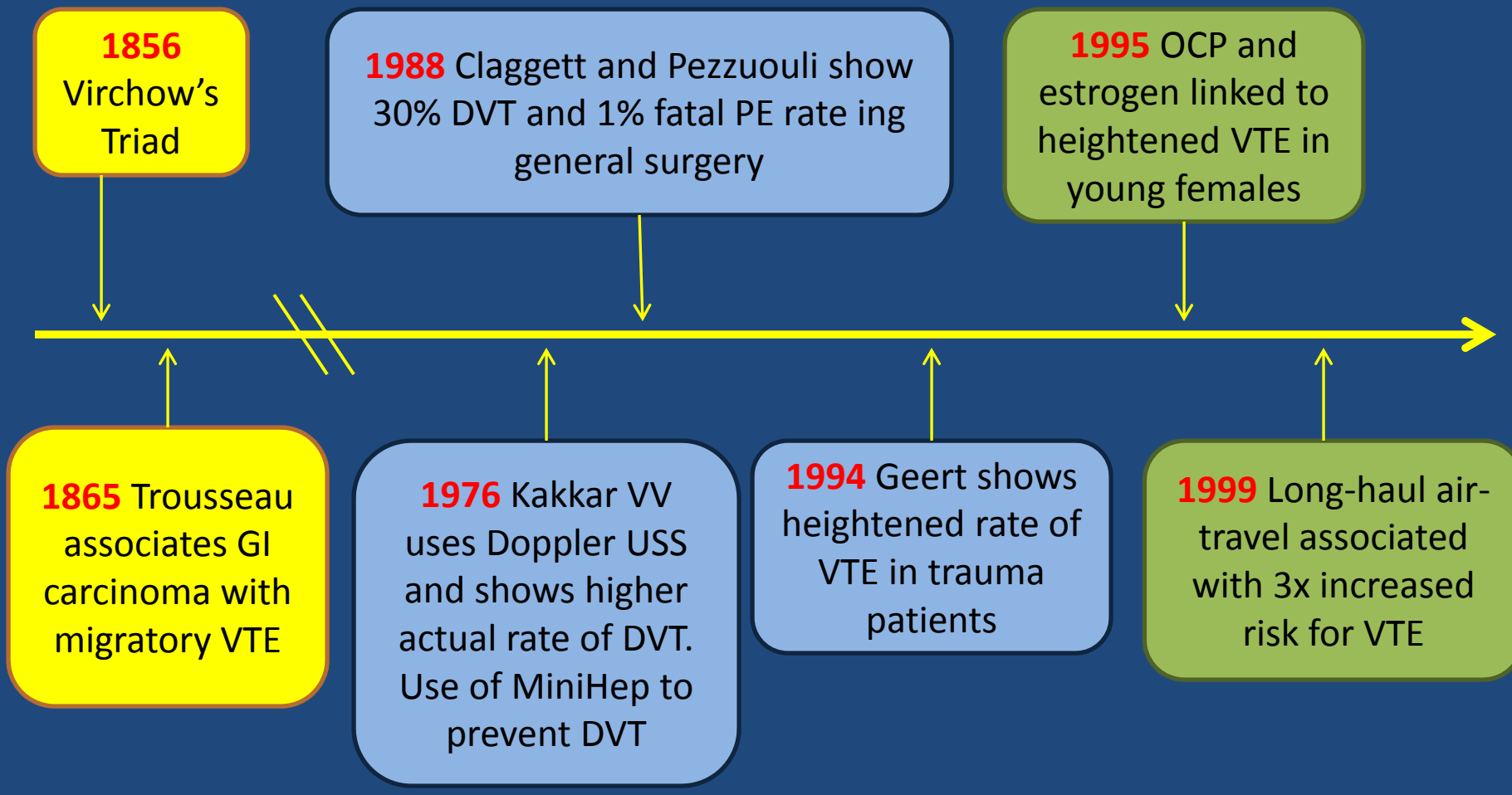
Slippery stats

Physicians' organizations say that one or two authors with a conflict of interest could not influence a panel containing tens of mem

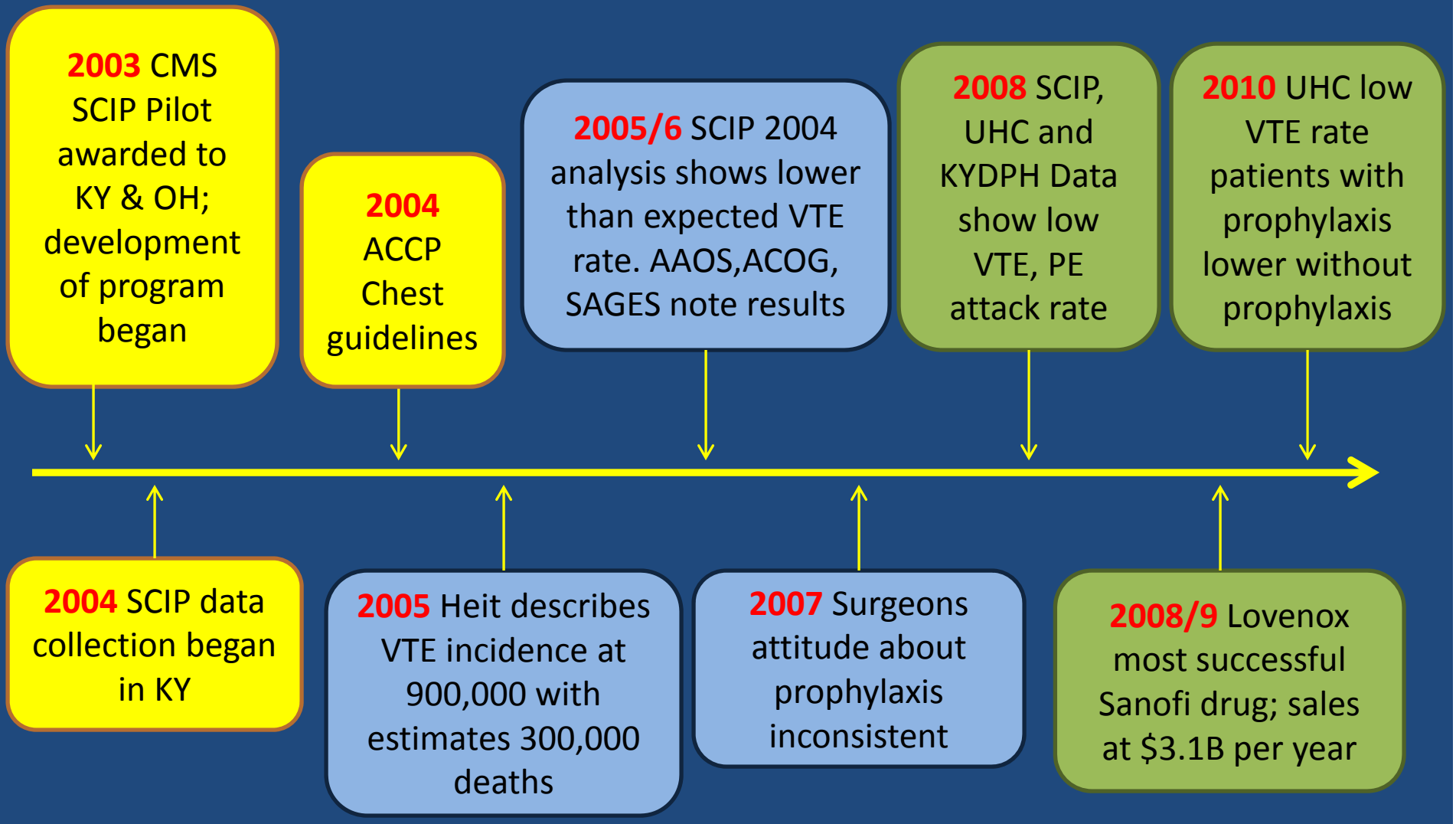
35%	**of Authors sais they had a conflict of interest of some kind**
16%	**Authors helped to write guidelines on illnesses relevant to companies in which they owned stock**
49%	**of guidelines did not include any details of authors conflicts' of interest**

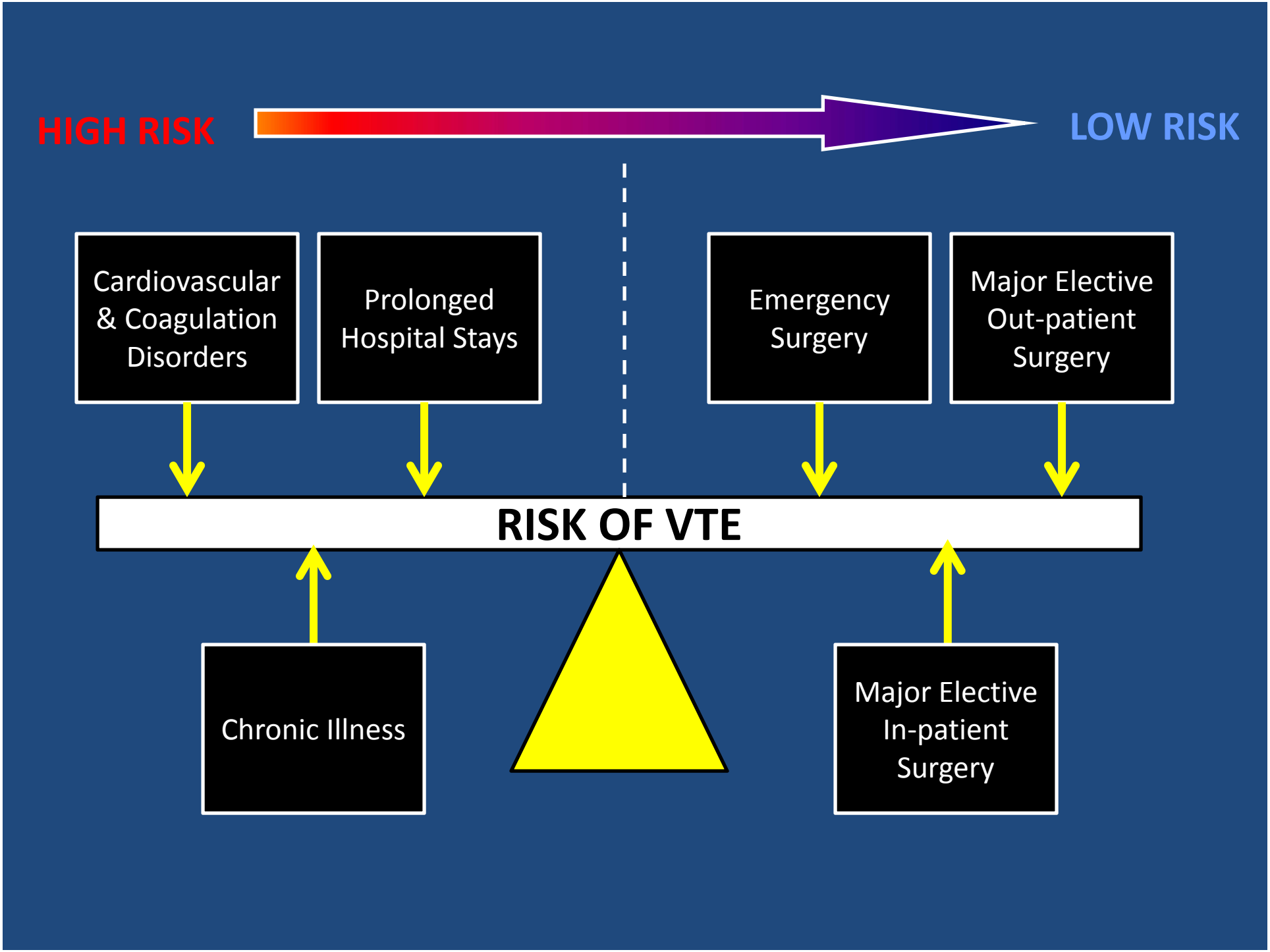
…bodies that produce guidelines maintain that there aren't enough experts without conflicts of interest

VTE Timeline 1850-2000



VTE Timeline 2000-2010




HIGH RISK
LOW RISK
Cardiovascular & Coagulation Disorders
Prolonged Hospital Stays
Emergency Surgery
Major Elective Out-patient Surgery
RISK OF VTE
Chronic Illness
Major Elective In-patient Surgery

SCIP 2004			
All SCIP Surgery	n	DVT (%)	PE (%)
	5,285	20 (0.4)	15 (0.3)

UHC 2004			
All UHC Surgery	n	DVT (%)	PE (%)
	966,474	11,456 (1.2)	5,298 (0.5)

KYDPH 2004			
All SCIP Surgery	n	DVT (%)	PE (%)
	20,563	-	56 (0.3)

An Example of Protocol in Management: The case of Tight Glucose Control

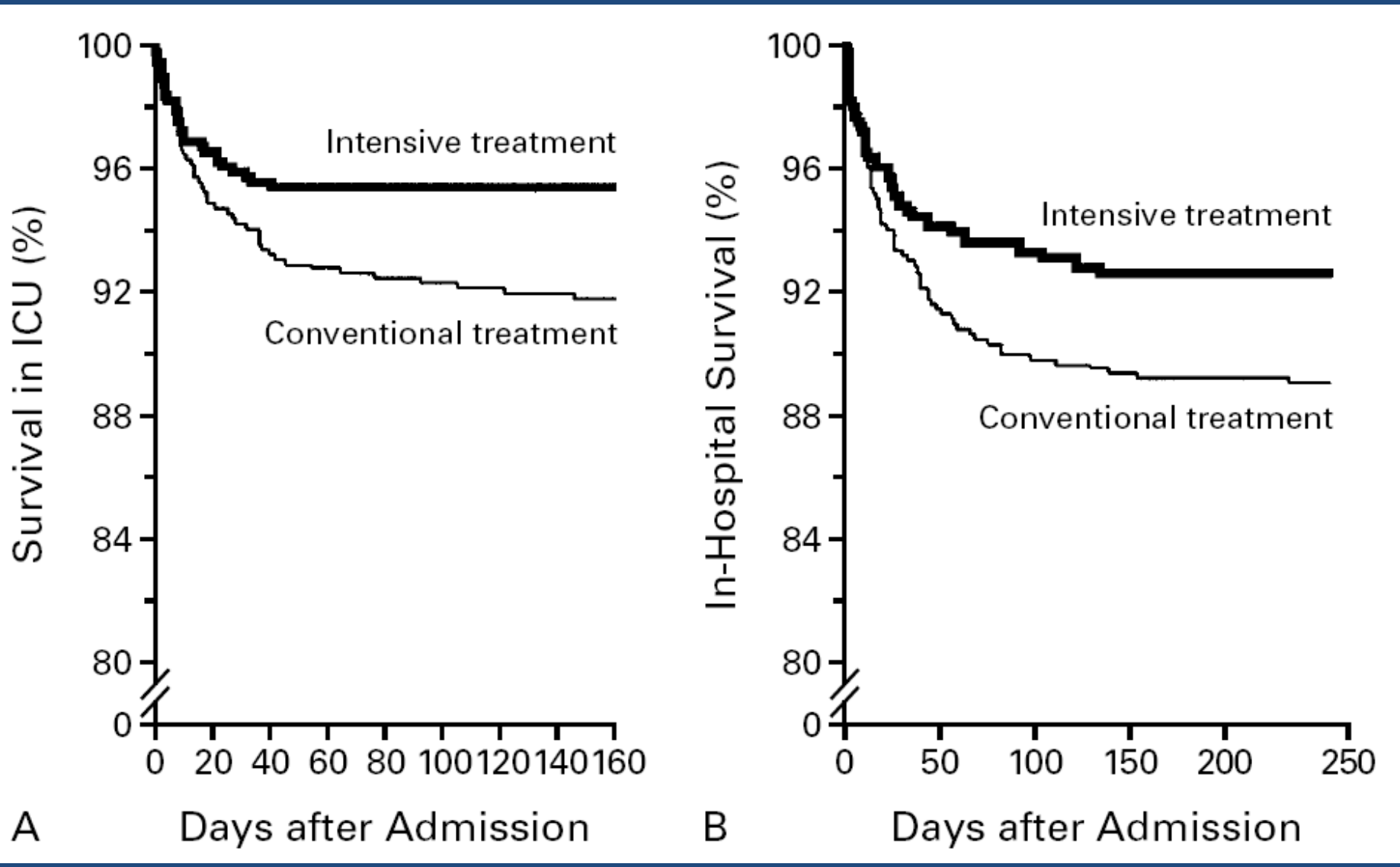
The New England
Journal of Medicine

VOLUME 345 NOVEMBER 8, 2001 NUMBER 19

INTENSIVE INSULIN THERAPY IN CRITICALLY ILL PATIENTS

GREET VAN DEN BERGHE, M.D., PH.D., PIETER WOUTERS, M.SC., FRANK WEEKERS, M.D., CHARLES VERWAEST, M.D.,

A randomized-control trial of 1548 critically-ill patients were assigned to conventional vs. intensive insulin therapy in an attempt to tightly lower glucose and prevent infection


Survival in ICU (%)
100
96
92
88
84
80
0
Intensive treatment
Conventional treatment
0 20 40 60 80 100 120 140 160
Days after Admission
A
In-Hospital Survival (%)
100
96
92
88
84
80
0
Intensive treatment
Conventional treatment
0 50 100 150 200 250
Days after Admission
B

However, a recent meta-analysis in *JAMA* of all trials to date failed to demonstrate any benefit on survival, hospital length of stay, or septic sequelae.

Wiener RS, et al. 2008

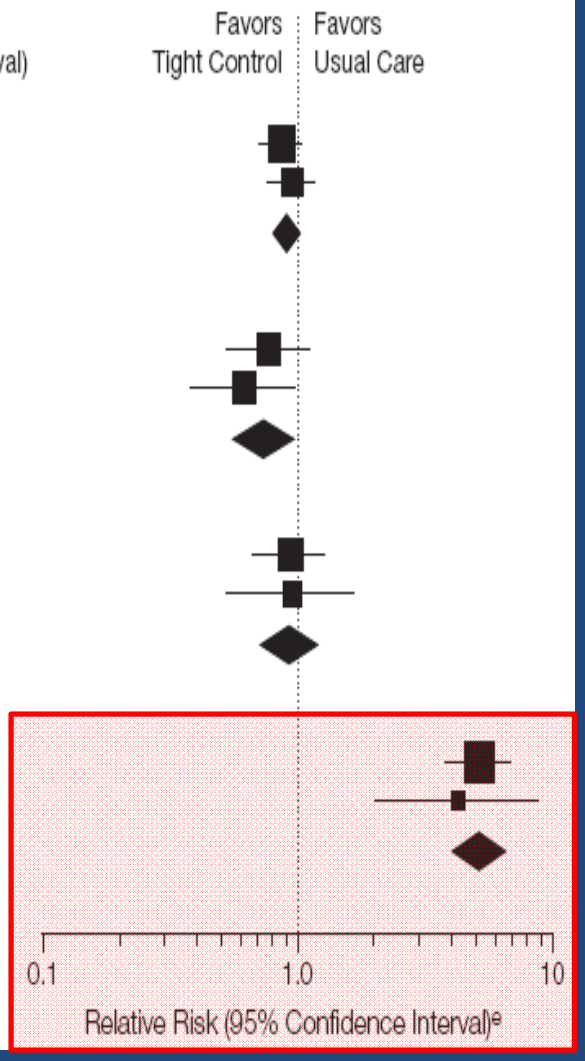
Benefits and Risks of Tight Glucose Control in Critically Ill Adults

A Meta-analysis

Renda Soylemez Wiener, MD, MPH
Daniel C. Wiener, MD
Robin J. Larson, MD, MPH

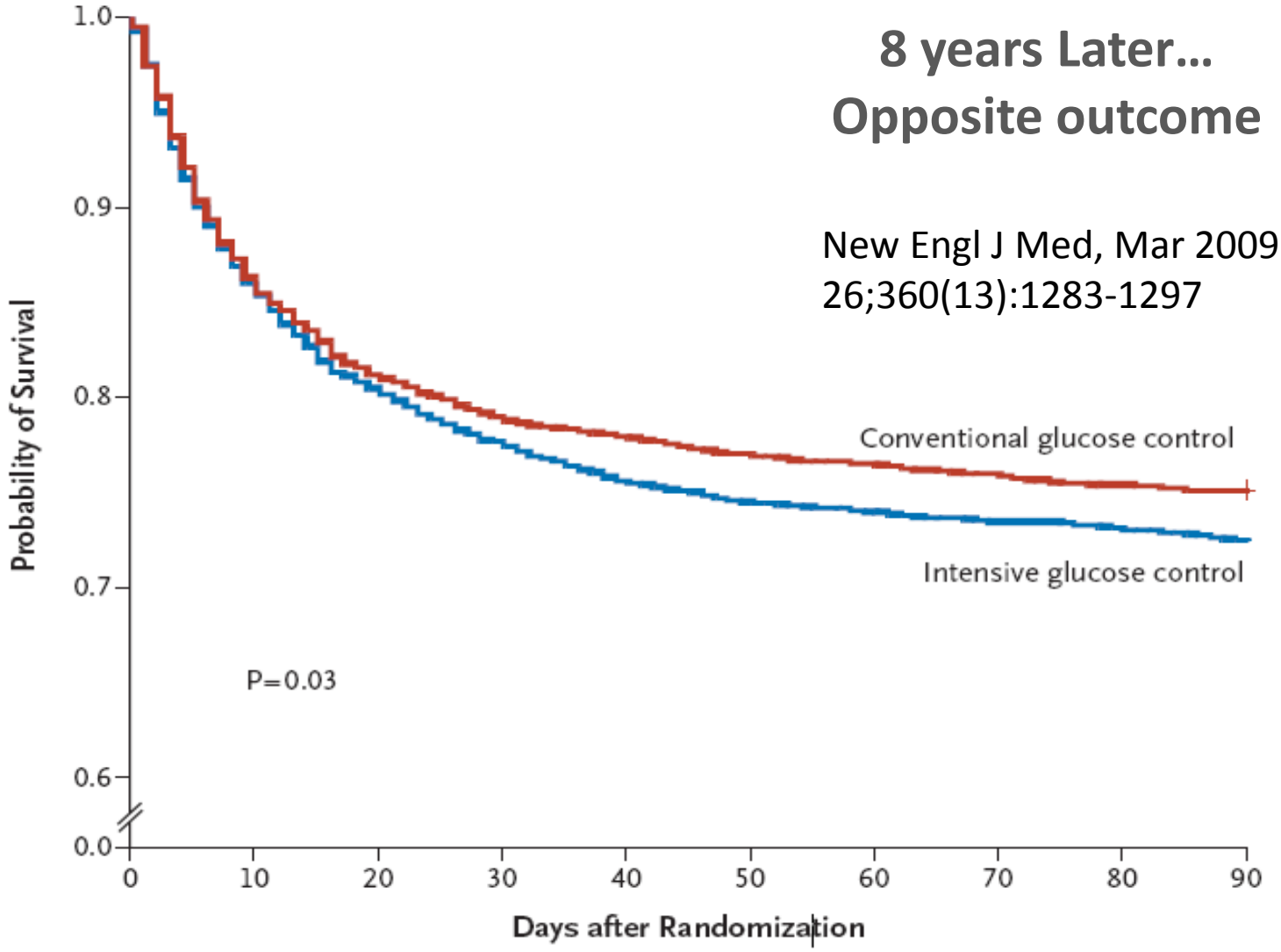
Context The American Diabetes Association and Surviving Sepsis Campaign recommend tight glucose control in critically ill patients based largely on 1 trial that shows decreased mortality in a surgical intensive care unit. Because similar studies report conflicting results and tight glucose control can cause dangerous hypoglycemia, the data

Subgroup	No. of Studies	Outcome, No./Total No. of Patients (%)		Relative Risk (95% Confidence Interval)
		Tight Control	Usual Care	
Hospital mortality[a]				
Very tight control	14	702/3031 (23.2)	781/3099 (25.2)	0.90 (0.77-1.04)
Moderately tight control	13	190/1096 (17.3)	196/1089 (18.0)	0.99 (0.83-1.18)
Overall	27	892/4127 (21.6)	977/4188 (23.3)	0.93 (0.85-1.03)
Septicemia[b]				
Very tight control	4	186/1654 (11.2)	221/1672 (13.2)	0.80 (0.57-1.11)
Moderately tight control	5	26/295 (8.8)	43/295 (14.6)	0.64 (0.41-1.00)
Overall	9	212/1949 (10.9)	264/1967 (13.4)	0.76 (0.59-0.97)
New need for dialysis[c]				
Very tight control	5	172/1424 (12.1)	193/1475 (13.1)	0.95 (0.70-1.29)
Moderately tight control	4	28/366 (7.7)	29/364 (8.0)	0.98 (0.59-1.61)
Overall	9	200/1790 (11.2)	222/1839 (12.1)	0.96 (0.76-1.20)
Hypoglycemia (glucose ≤40 mg/dL)[d]				
Very tight control	11	409/2895 (14.1)	75/2952 (2.5)	5.23 (4.12-6.64)
Moderately tight control	4	41/380 (10.8)	9/386 (2.3)	4.37 (2.19-8.72)
Overall	15	450/3275 (13.7)	84/3338 (2.5)	5.13 (4.09-6.43)



Same Journal…
8 years Later…
Opposite outcome

New Engl J Med, Mar 2009
26;360(13):1283-1297



No. at Risk				
Conventional control	3014	2379	2304	2261
Intensive control	3016	2337	2227	2182

NICE-SUGAR Study Investigators 2009

Definition of Ideal Surgical Technique

- The way I would do it
- The way my chief made me do it
- Minimal tissue trauma
- Minimal blood loss
- Minimal foreign bodies
- Short operating time (without sacrificing the above)

Surgical Care Improvement Project (SCIP)

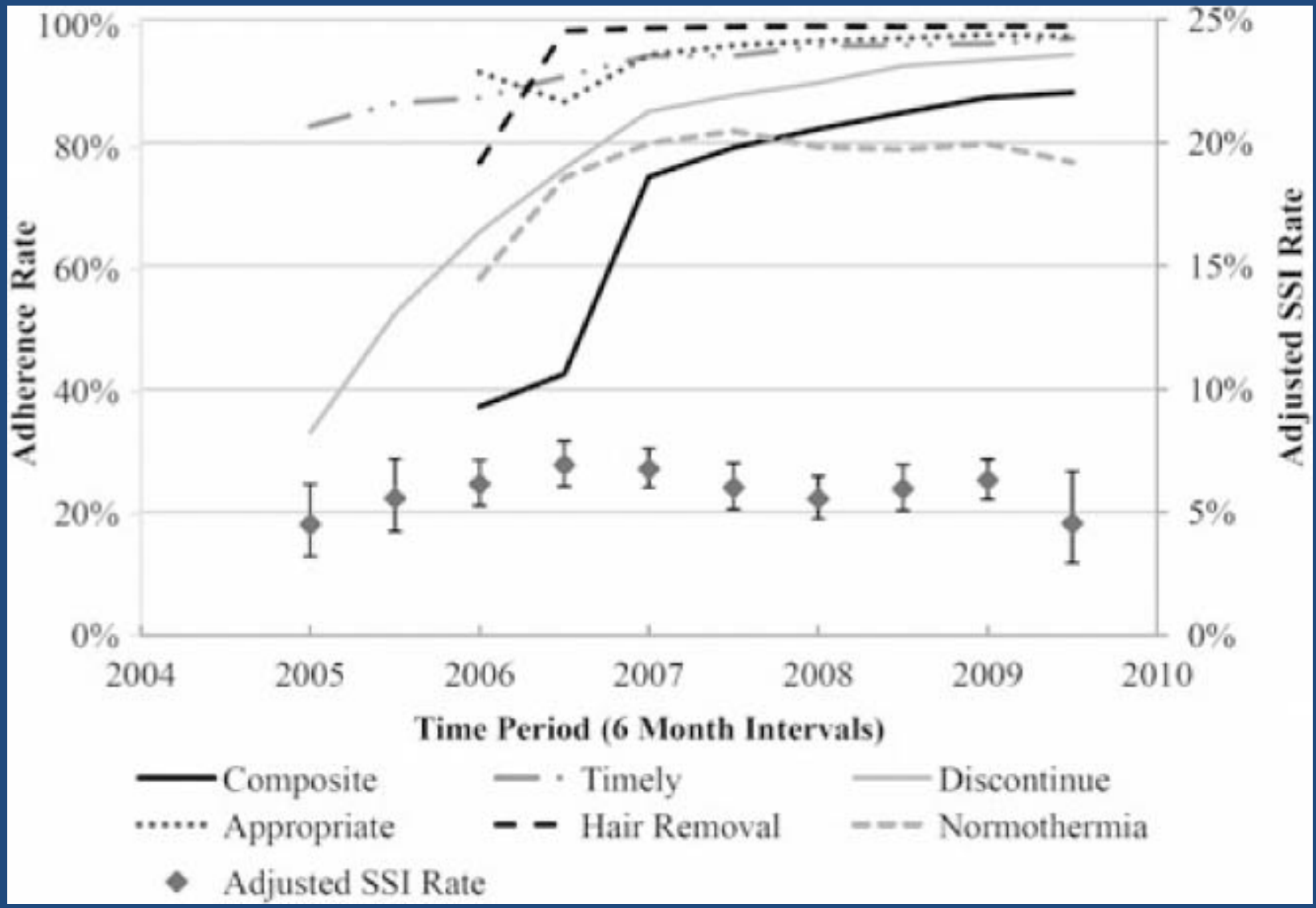
The Goal of this initiative is to prevent surgical site infections by implementing our four components of care

1. **Appropriate use of prophylactic antibiotics**
2. Appropriate hair removal
3. Controlled 0600 postoperative serum glucose in cardiac surgery patients
4. Immediate postoperative normothermia for colorectal patients

Antibiotics

- Antibiotic administration is prescribed preoperatively at 30 to 60 or 120 minutes prior to the incision, depending on the type of antibiotic
- The antibiotics should be continued for at most 24 hours postprocedure
- Dosage should be adjusted for patient weight to prevent larger individuals from being underdosed
- Patients must be redosed during long procedures to maintain appropriate serum antibiotic levels

Bratzler Houck, Am J Surg 2005
Bratzler DW, Houck PM. Antimicrobialprophylaxis for surgery: an advisory statement from the National Surgical Infection Prevention Project. Clin Infect Dis 2004;38(12)1706-15
QualityNet Website. www.qualitynet.org

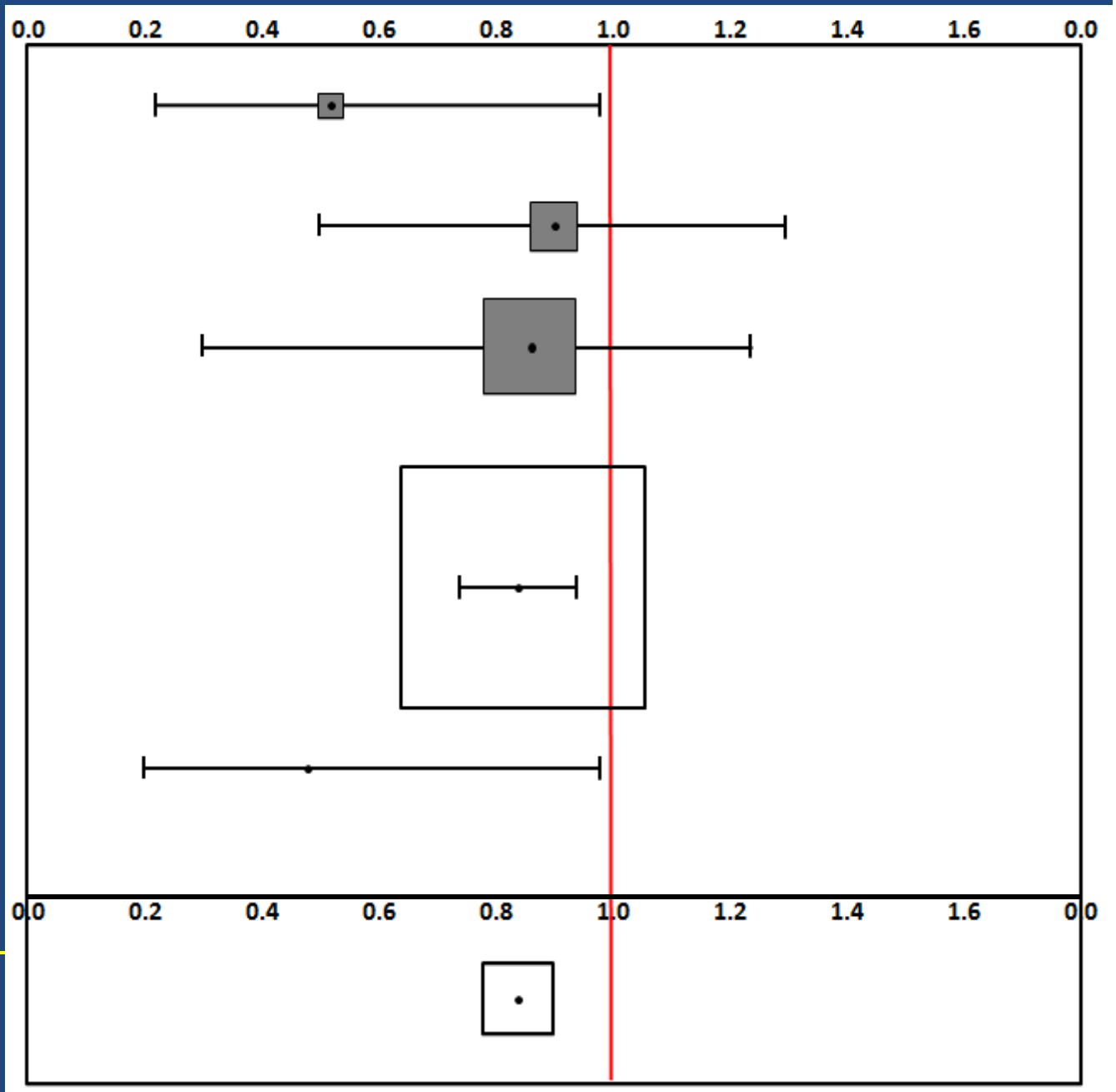


Surgical Site Infection Prevention: Time to Move Beyond the Surgical Care Improvement Program
Hawn, Mary; Vick, Catherine; Richman, Joshua; et al:
Annals of Surgery. 254(3):494-501 September 2011

Preventing SSI

- Have good teamwork at all times
- Prewarm the patient
- Enough of the right antibiotic at the right time and repeat if necessary
- Don’t shave
- Thorough skin prep
- Warm the patient in the O.R.
- High FiO_2
- Control glucose
- Good teamwork

Paper	n
1. Hendren (CRS)	4,331
2. Wang (THR)	17,714
3. Hawn (Multi VAMC)	60,853
4. Stulberg (Multi Premier)	405,720
5. Smith (Trauma)	306
Total	**488,924**



Studies That Relate Compliance to Outcome

Authors	N=	Operations	Focus	Outcomes		Changes in Compliance	
Garcia	703	Multi sp.	SCIP 1	+SSI +Sepsis +mt	0.25 0.22 0.001	both	>94%
Wick	602	Multi sp.	SCIP +	+SSI	<0.05	both	>90%
Larochelle	706	GI	SCIP 1-3, 7	0 all		both	>90%
Berenguer	113	CRS	SCIP all	+SSI	0.36		38-92%
Pastor	491	CRS	SCIP all	0 all			40-68%
Sim	133	CABG	SCIP 1-3	0 SSI		1 3	67-97% 3-67%

SCIP

Success	**Non-effective**
Perform poorly	High performers
Risk adjustment	Threats
National Groups	Surgical champion
Bundle costs	Revenues
Current literature	Changing keystones

What Now My Love?

Quality Care Essential

Inexpensive Monitoring

Pilot studies (Campbell, Mich. BC BS)

Periodic Reassessment of Results

Threat vs $--

None to doctors

Affordable Care Act

1. Expansion of Benefits
2. Control of Costs

   Industry, hospitals, doctors
3. Quality suffers

Patient Always Comes First

- Public need is our first determinant
- Surgical Time-Out and Post-op “Huddles”
- Real SCIP

  Glucose, VTE, antibiotic choice and first dose

  Forget: clip, baths and nasal swabs

Your Work is Vital

Teamwork and Professional Cohesion Are Essential

Reward the guilty and punish the innocent