



Thursday June 11th, 2015

Recent Developments in Patient Safety and Reflections on the Field after 15 years

Kaveh G. Shojania, MD

Director, Centre for Quality Improvement
and Patient Safety (C-QuIPS)

University of Toronto

Editor-in-Chief,

BMJ Quality & Safety

Topics

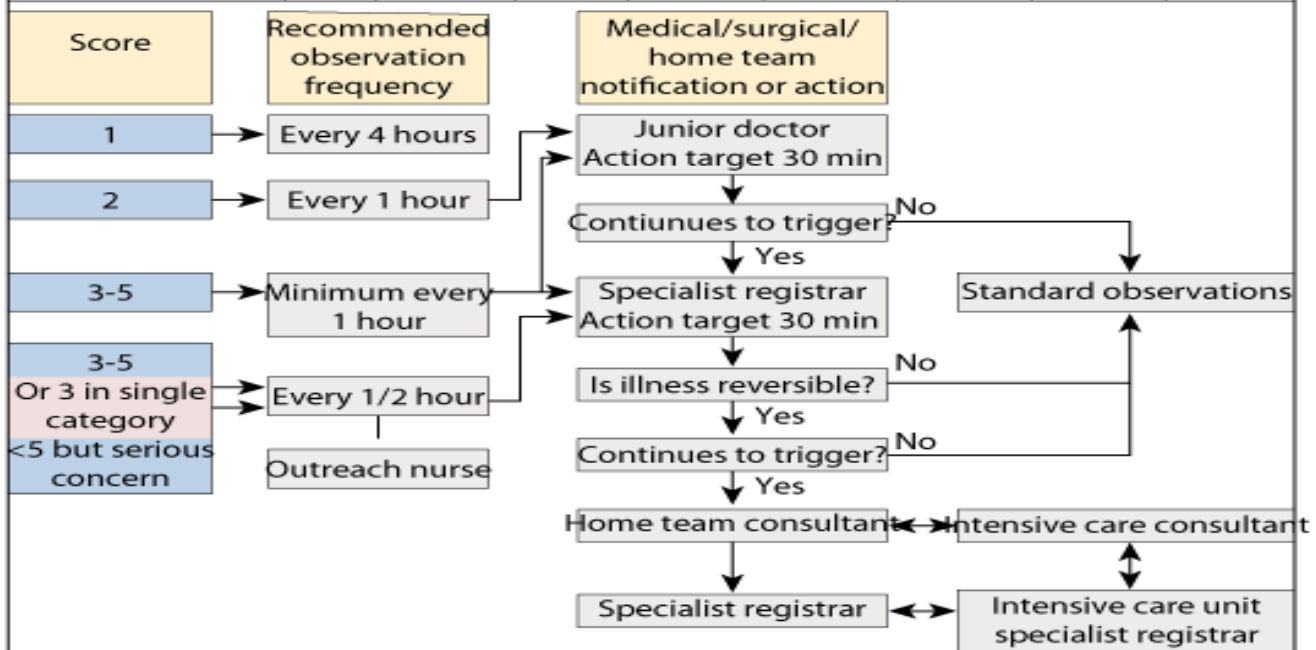
- Automatic transmission of Early Warning Scores
- VTE prophylaxis –too much of a good thing?
- The effect of hand hygiene observers on compliance
- Evolving story of surgical checklists
- Reflections on focus for future
- Nothing on falls (thank goodness)

Impact of introducing an electronic physiological surveillance system (EPSS) on hospital mortality.

Schmidt et al 2014

- Wireless handheld computing devices transmitted Early Warning Score (EWS)
 - To wireless tablets and desktop computers at Hospital A, but only to desktops on wards at Hospital B.
- Use of a paper-based EWS system and a Rapid Response Team well established for years at both hospitals

Score	3	2	1	0	1	2	3	Home team variants name & date
Central nervous system		Confused or agitated		Alert	Respond to voice	Respond to pain	U: No response	
Respiratory rate (breaths/min)	<8			8-20	21-30		>30	
Heart rate (beats/min)	<40		40-50	51-100	101-110	>111-130	>130	
Systolic blood pressure (mm Hg)	<70	71-80	80-100	101-180	181-200	201-220	>220	
Temperature (C)	<34	34.0-35.0		35.1-37.5	37.6-38.5	38.6-40.0	>40	
Oxygen saturation with appropriate oxygen therapy	<90%	91-93%		94-100%				
Urine output (over 2 hours or more)	<30 ml/hr							



Pulse



Menu

P — T — B — R — C — U — S — O — Or

Patient, A

12345678

112 /min

1	2	3	clear
4	5	6	
7	8	9	0

Store pulse



Obs. results



Menu

P - T - B - R - C - U - S - O Or

Patient, A

12345678

Tap on an item to edit the score

EWS

Pulse	112	2
Respiratory rate	25	2
Temperature	36.4	0
AVPU	alert	0
Urine output	20	2
Blood pressure	121/85	0
O ₂ saturation (%)	96%	n/a
O ₂ flowrate	10	n/a
Delivered O ₂ conc.	~55%	n/a
TOTAL EWS SCORE		6

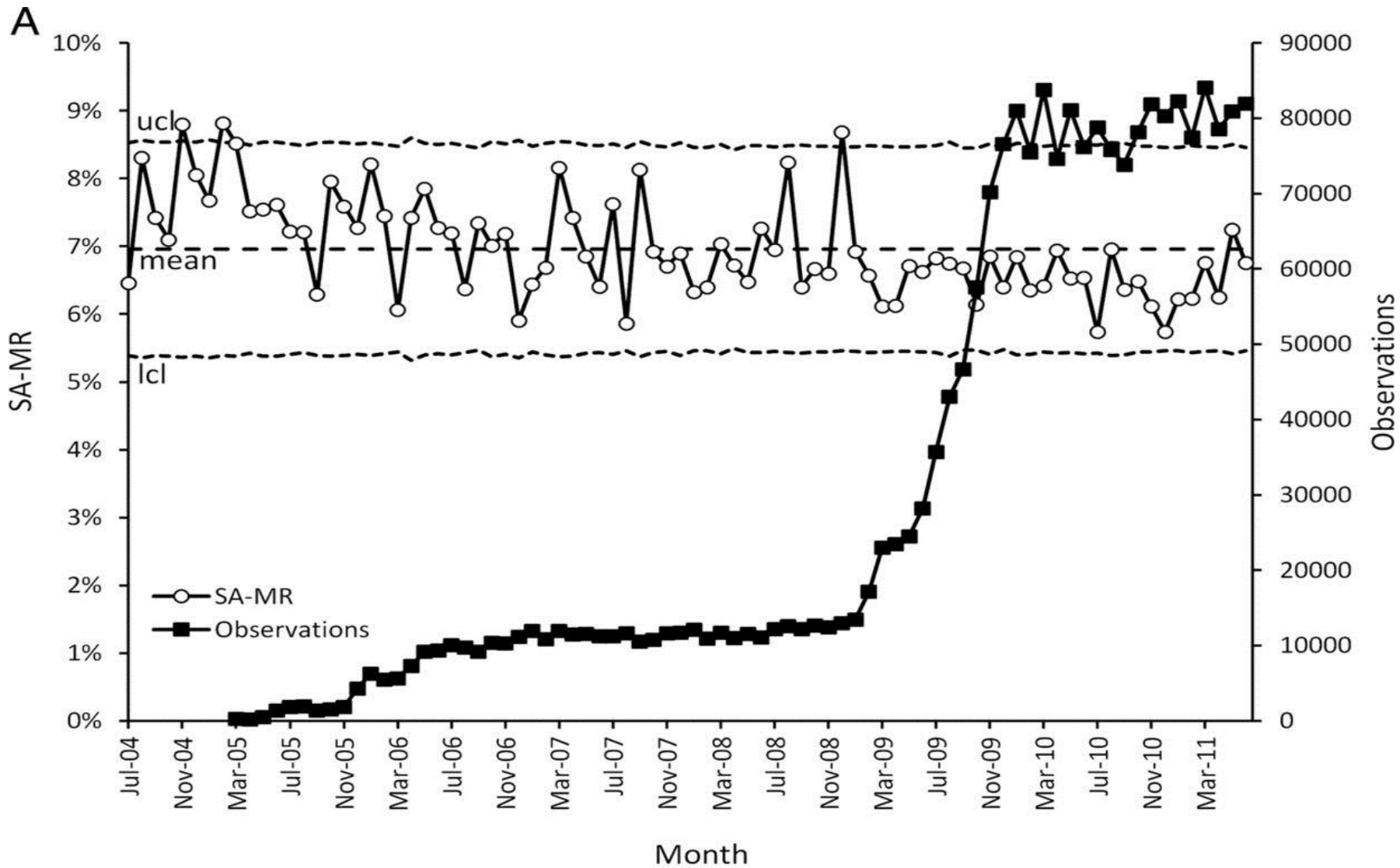


Submit
obs. results

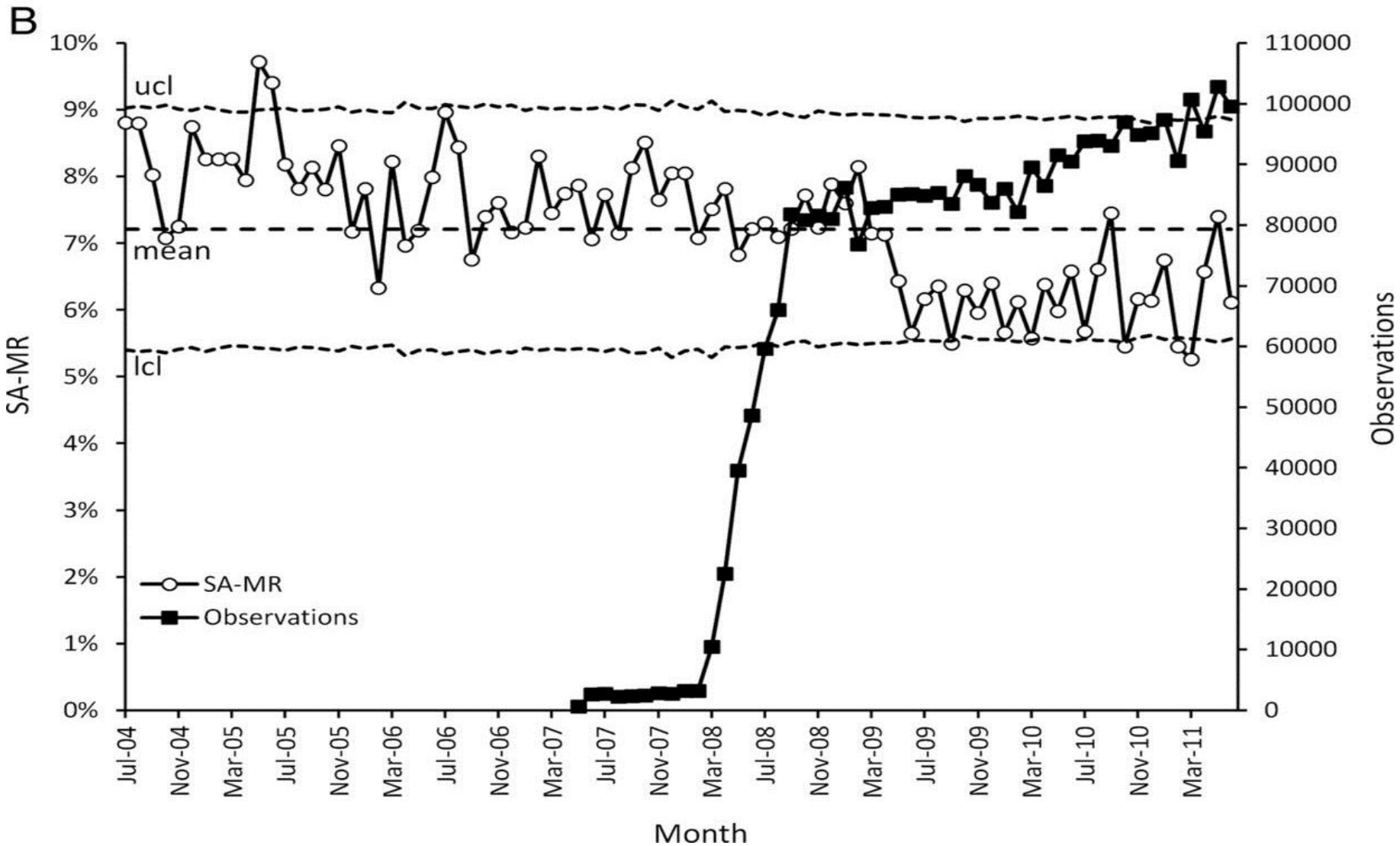
Special
obs.



Seasonally adjusted mortality rate (SA-MR) at Hospital A



Seasonally adjusted mortality rate (SA-MR) at Hospital B



Impact of introducing an electronic physiological surveillance system (EPSS) on hospital mortality.

Schmidt et al 2014

- Crude mortality fell from a baseline of 7.75% to 6.42% in one hospital (estimated 397 fewer deaths)
- Crude mortality fell 7.57% to 6.15% at the second hospital (estimated 372 fewer deaths)

Pretty Spectacular

- Not many interventions in any field save lives, never mind in safety/quality
- Two hospitals implemented system – not a particularly fancy one either – and both showed clear signals of reduced mortality that coincided with the ramp up of the electronically transmitted vitals
- Main caveat is that both hospitals already had long standing use of paper-based early warning scores and RRT

Finding patients before they crash: the next major opportunity to improve patient safety.

Bates & Zimlichman 2014

- Major improvements from combining parameters
 - E.g., ↓ blood pressure + ↑ pulse + ↓ urine output much more concerning than fall in blood pressure alone
- Further improvements from combining different types of data, such as vital signs, lab results, admission diagnoses
 - E.g., ↓ blood pressure + ↑ pulse in a patient with recent positive urine culture or surgical admission diagnosis

Topics

- Automatic transmission of Early Warning Scores
- VTE prophylaxis –too much of a good thing?
- The effect of hand hygiene observers on compliance
- Evolving story of surgical checklists
- Reflections on focus for future
- Nothing on falls (thank goodness)

Topics

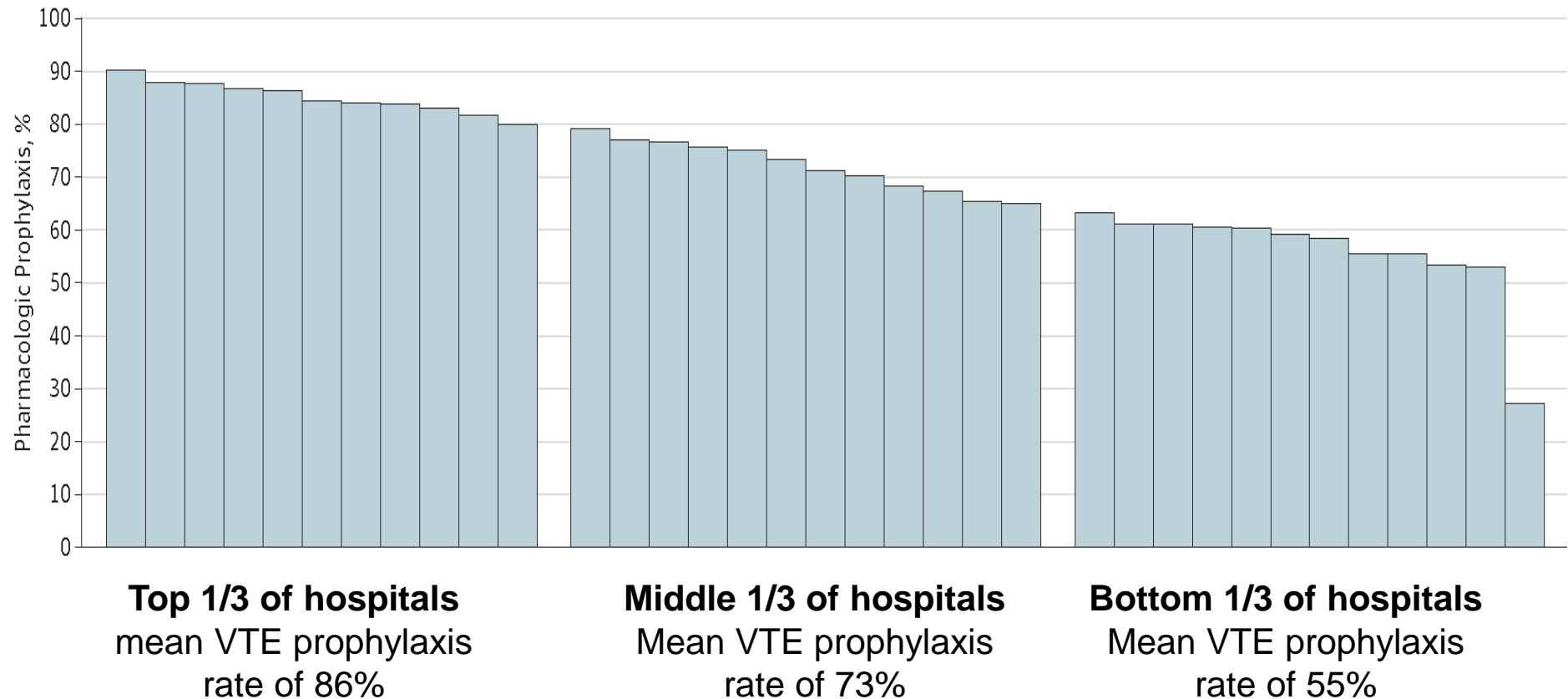
- Automatic transmission of Early Warning Scores
- **VTE prophylaxis –too much of a good thing?**
- The effect of hand hygiene observers on compliance
- Evolving story of surgical checklists
- Reflections on focus for future
- Nothing on falls (thank goodness)

Hospital Performance for Pharmacologic Venous Thromboembolism Prophylaxis and Rate of Venous Thromboembolism: A Cohort Study

Flanders et al 2014

- 35 Michigan hospitals participating in a collaborative (Jan 1, 2011-Sept 13, 2012)
- VTE prophylaxis, VTE risk factors, and VTE events 90 days after hospital admission were recorded using medical record review and telephone follow-up
- The rates of pharmacologic prophylaxis use at hospitals in the high-, moderate-, and low-performance tertiles were 85.8%, 72.6%, and 55.5%, respectively.

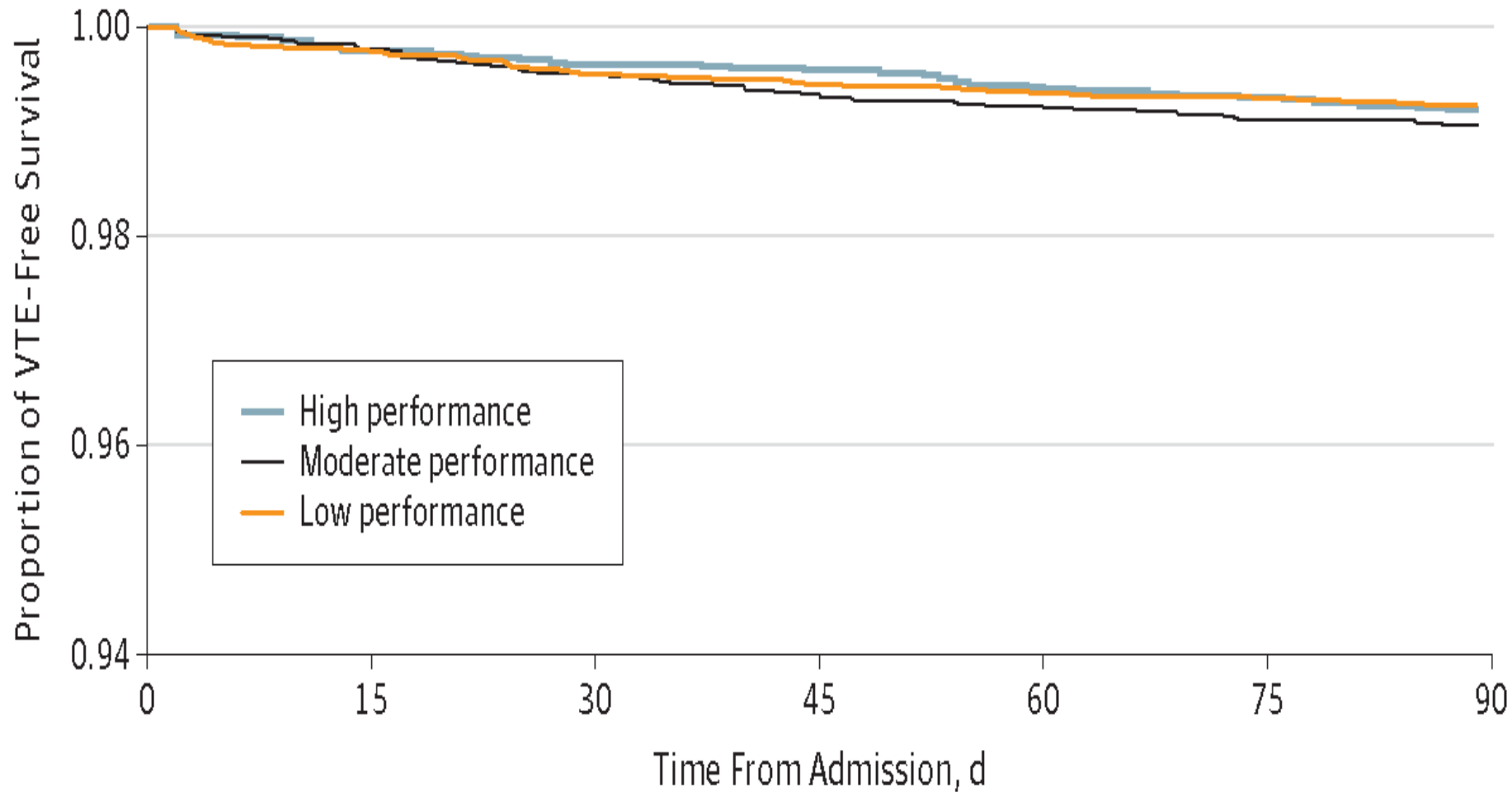
35 Hospitals Broken Down by Performance on VTE Prophylaxis



No difference in outcomes by performance

- Rates of VTE (or death) by rate of prophylaxis
 - High performing: 1.27 events/10,000 patients
 - Medium performing: 1.42 events/10,000 patients
 - Low performing: 1.15 events/10,000 patients
- Results remained robust when modeling hospital performance as a continuous variable and also when factoring in mechanical prophylaxis

VTE-Free Survival by Hospital VTE Prophylaxis Performance Category



Curves are roughly superimposed, showing no difference in the development of VTE (or death) based on rate of VTE prophylaxis

What does this mean?

- Does **Not** mean VTE prophylaxis ineffective
 - Multiple RCTs show it works
 - But, trials probably enrolled more select patients
- Risk of VTE in hospitalized, non-surgical patients is very low
 - Even in the low performing hospitals only 0.23% of patients had a VTE within 15 days of admission
- We probably prophylaxis a lot of low risk patients

Is this a problem?

- Yes, but not clear what to do about it
- Focusing prophylaxis efforts on high risk patients is harder and likely will lead to under use
- Easier to make prophylaxis the default so that prescribers have to 'opt out'
- Ensures a high rate of VTE prophylaxis, but exposes a lot of patients to injections

Topics

- Automatic transmission of Early Warning Scores
- VTE prophylaxis –too much of a good thing?
- **Effect of hand hygiene observers on compliance**
- Evolving story of surgical checklists
- Reflections on focus for future
- Nothing on falls (thank goodness)

Public Reporting of Hand Hygiene

- Ontario publicly reports HH compliance
 - Hospitals have incentive to leave bias in place
- Current provincial average is 85.6% for Moment 1 and 92.1% for moment 4*
 - By contrast, a systematic review found a median HH compliance rate of 40%**

Quantification of the Hawthorne effect in hand hygiene compliance monitoring using an electronic monitoring system: a retrospective cohort study.

Srigley et al 2014

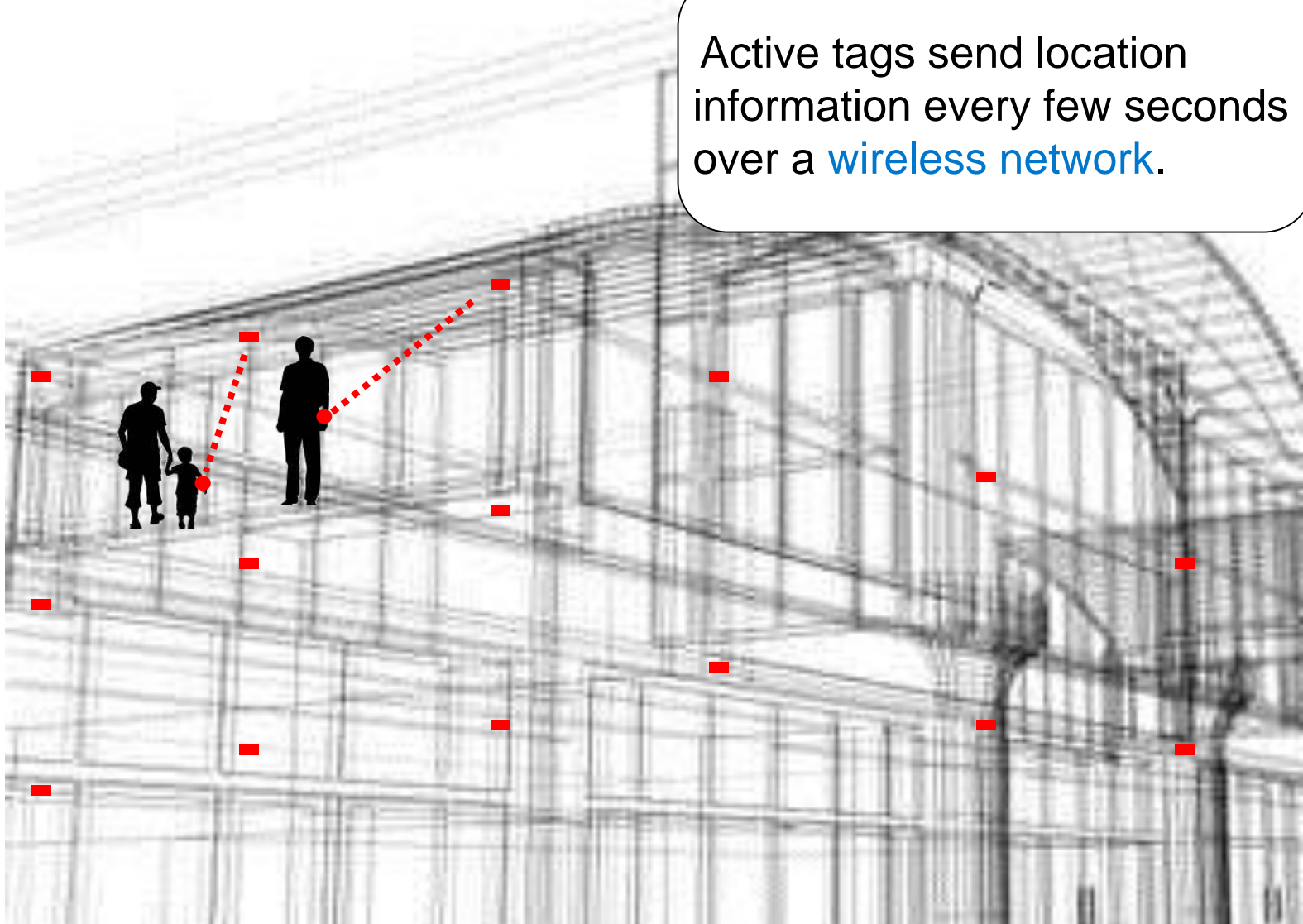
- Fascinating history and debate about what the original experiments at Hawthorne plant really showed
- But, Hawthorne effect still refers to the *tendency of experimental subjects to alter their behavior when aware of being observed*
- In case of hand hygiene, really just refers to bias from staff seeing the observers auditing compliance

Electronic Monitoring System

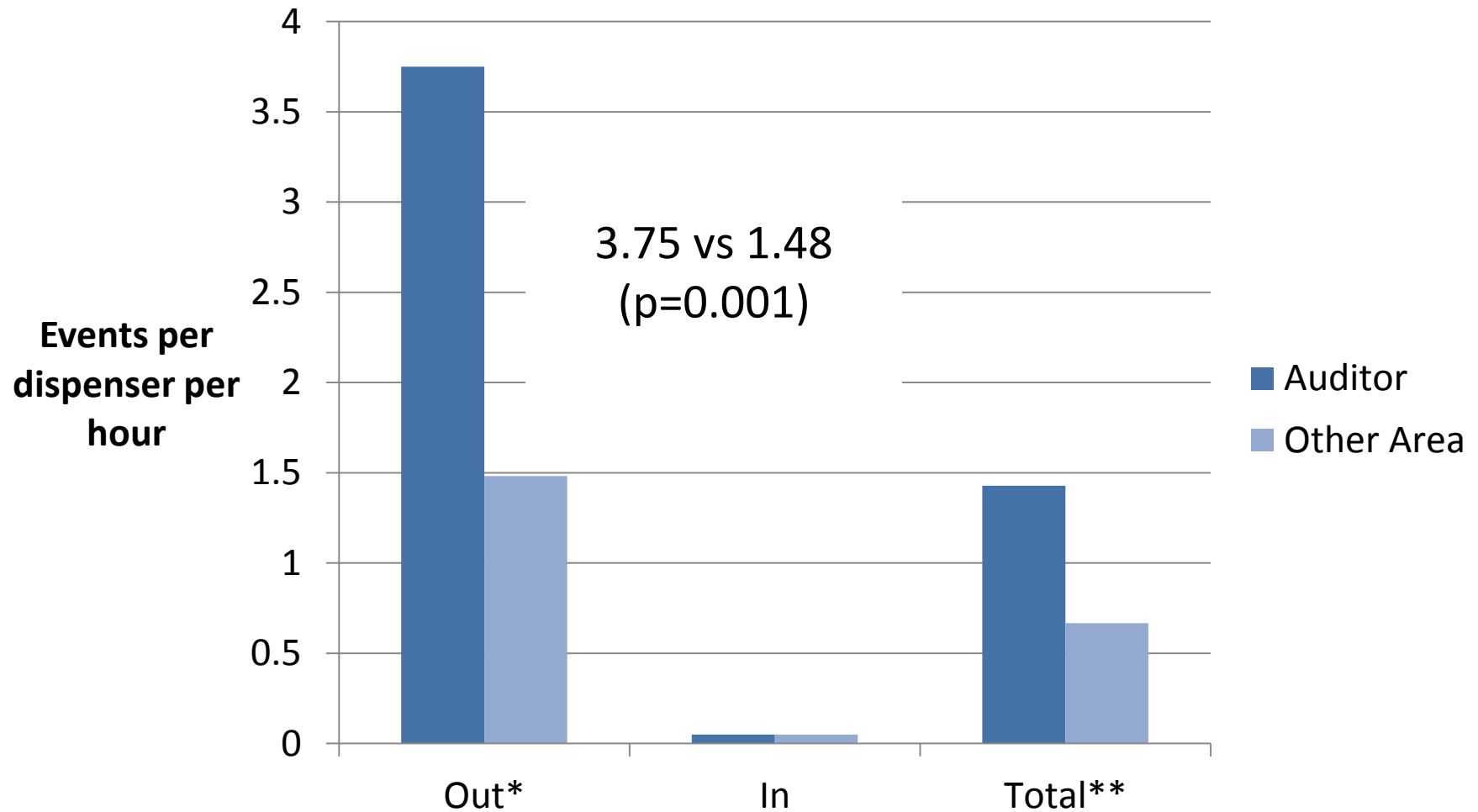
- Real-time locating system (RTLS) was installed on two multi-organ transplant units from July 2012 to March 2013
- Generated continuous real-time location data via ultrasound tags worn by staff and patients
- Measured every use of alcohol-based hand rub and soap dispensers



Active tags send location information every few seconds over a [wireless network](#).

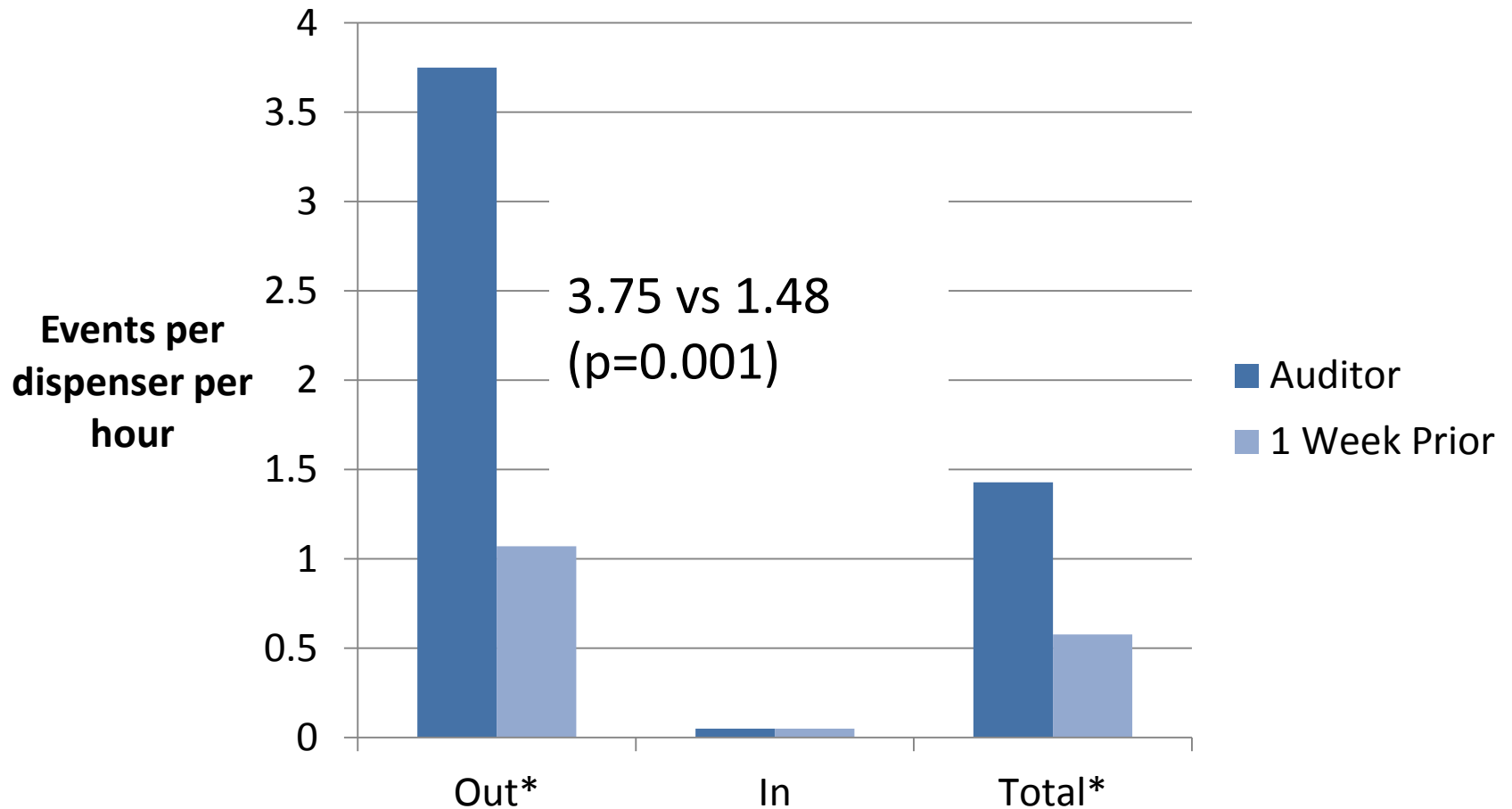


Auditor Visible vs. Other Areas



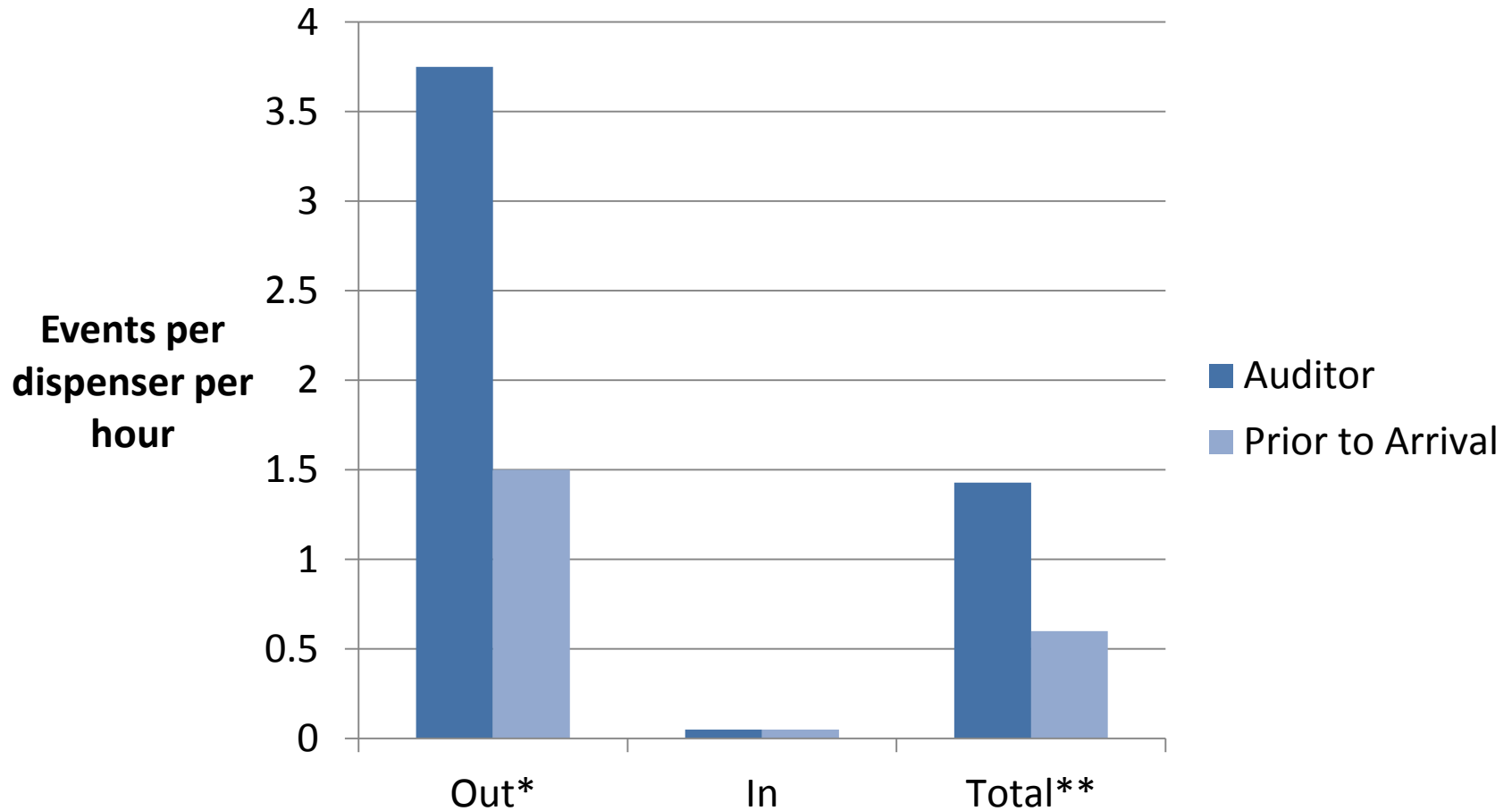
* $p=0.001$ ** $p=0.008$

Auditor Present vs. Previous Week



* $p < 0.001$

1-5 min Prior to Auditor's Arrival



* $p=0.009$ ** $p=0.003$

Quantification of the Hawthorne effect in hand hygiene compliance monitoring using an electronic monitoring system: a retrospective cohort study.

Srigley et al 2014

- Overall, HH rate ~ 3 times higher within eyesight of auditor compared with times not present or not visible
- Consistent with results of “secret shopper” studies, which show much lower HH compliance

Holy cow! Does this mean I have to divide my hospital's HH rate by 2 -3?

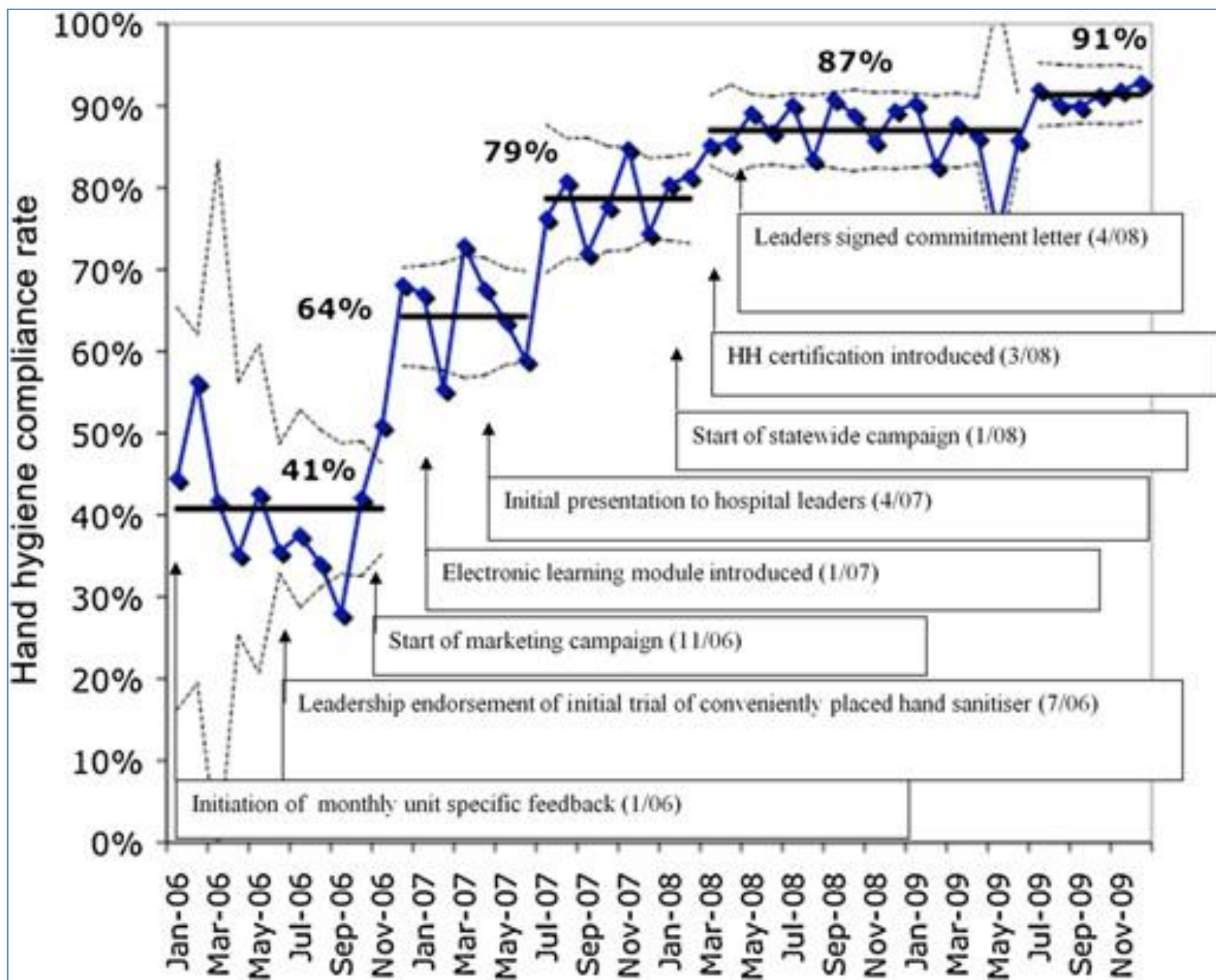


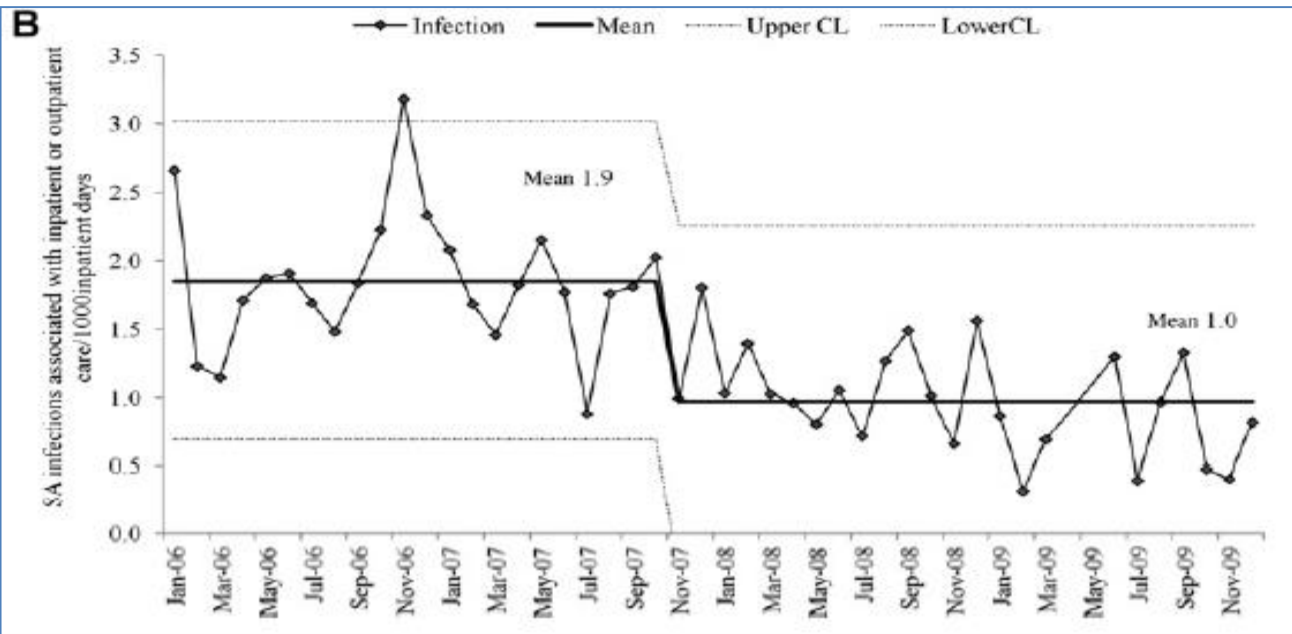
It Depends

- Hospital A has HH rate of 35% and increases over 6-12 months to 85% just from memos and posting HH rates
 - Probably mostly due to bias
 - Consider “secret shoppers” as reality check
- Hospital B has HH rate of 35% & implements multifaceted strategy and incrementally increases to 50%, 60%, 70%, 90% over 2 years
 - Probably mostly real. In the absence of auditor, hand hygiene might be closer to 80%

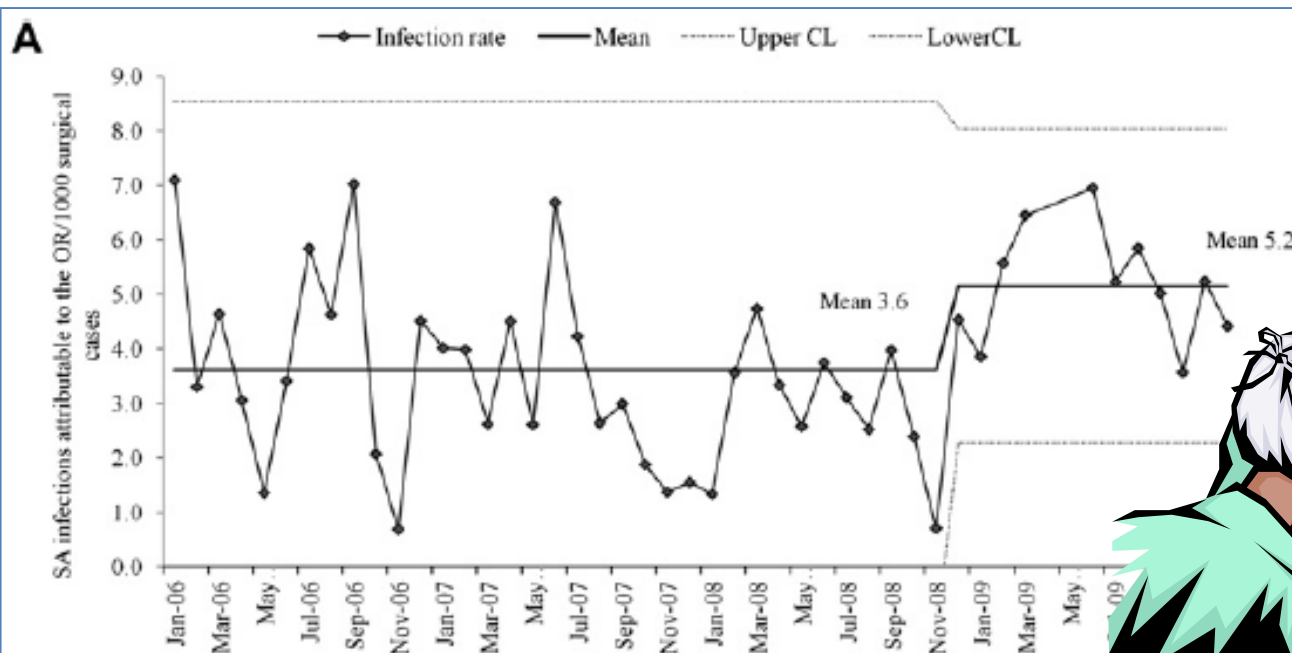
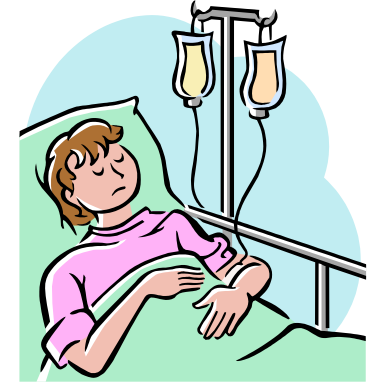
Impact of a Hospital-wide Hand Hygiene Initiative on Healthcare Associated Infections: an interrupted time series Kirkland K 2012

- **Objective** To improve hand hygiene rates and reduce healthcare associated infections
- **Design:** Interrupted time series over 3 years with sequential interventions and a 1 year post intervention follow up
- **Results:**
 - Hand Hygiene compliance: 41 → 91%
 - Healthcare Associated Infection: 4.4 → 3.3/ 1000 pt days





***S. aureus* HAIs from hospital wards**



***S. aureus* HAI in Operating Rooms**



Conclusion

- It is possible to improve hand hygiene and for the improvement be real
 - Can even achieve reductions in infections
- But, probably a lot of hospitals have had inflated improvements as a result of staff recognizing the auditors of hand hygiene
 - Sadly, little incentive for hospitals to look into this

Topics

- Automatic transmission of Early Warning Scores
- VTE prophylaxis –too much of a good thing?
- The effect of hand hygiene observers on compliance
- **Evolving story of surgical checklists**
- **Reflections on culture and teamwork as focus for future**
- Nothing on falls (thank goodness)



Introduction of surgical safety checklists in Ontario, Canada.

Urbach et al. 2014

Methods: Surveyed all acute care hospitals in Ontario to determine timing of adoption

Compared mortality and complications 3 months before and 3 months after adoption of a checklist.

Results: Across 109,341 surgeries before adoption and 106,370 after, respectively... *no significant change in mortality or complications*

Conclusions

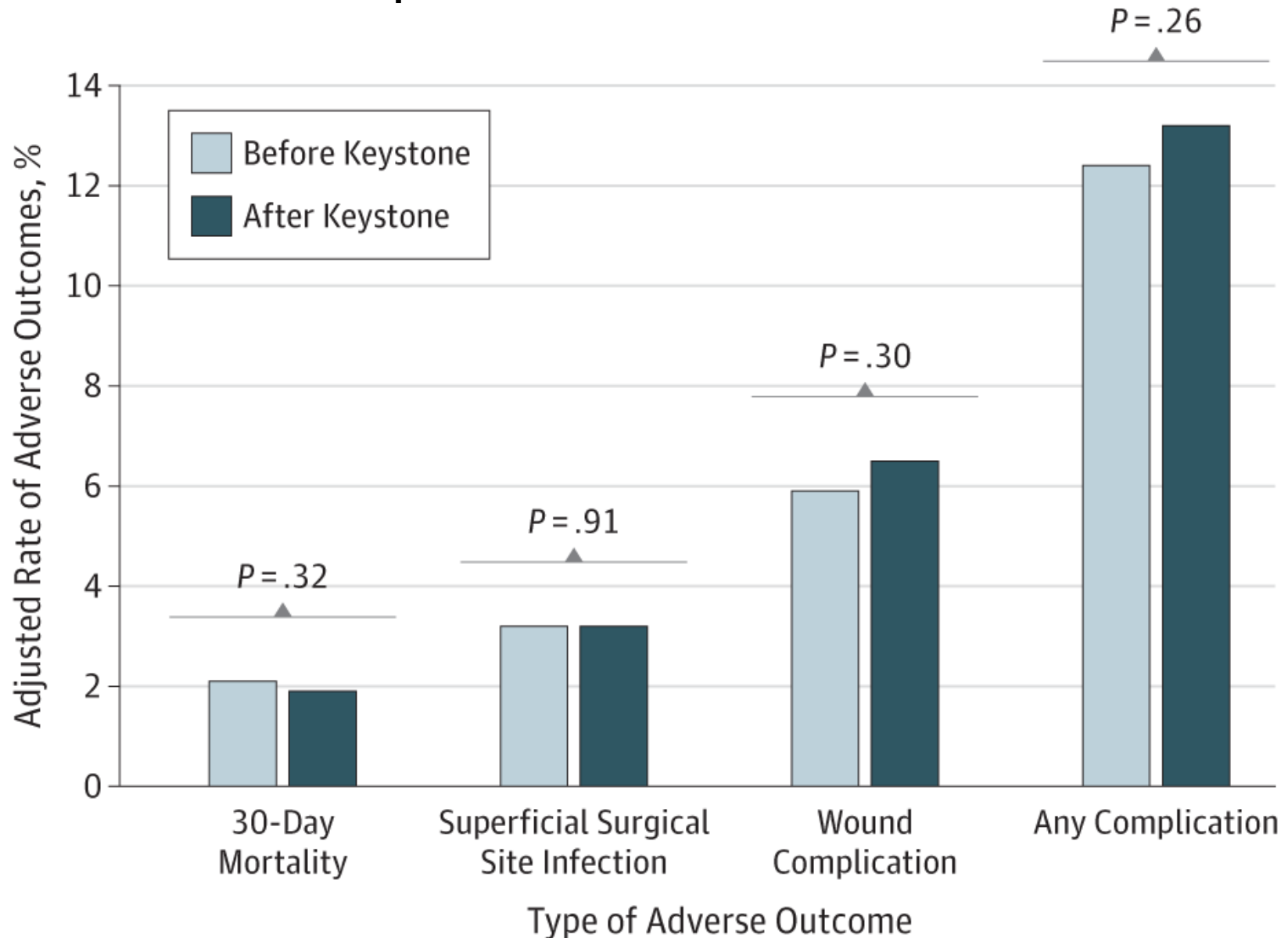
- Mandating surgical checklist achieved no impact
 - Possible trend towards improved mortality in cardiac and neurosurgery
 - But, why study just 3 months?
 - If use of the checklist were all that mattered, 3-months at high compliance would be enough
- ***Checklist not the whole intervention. Real changes in communication need to occur; not a 'tick box' exercise***

A Checklist-Based Intervention to Improve Surgical Outcomes in Michigan: Evaluation of the Keystone Surgery Program

Reames et al 2015

- 64,891 patients in 29 hospitals using Michigan Surgical Quality Collaborative clinical registry data from (2006-2010)
- Checklist focused on compliance with 6 CMS SCIP processes
 - appropriate selection, timing, and discontinuation of prophylactic antibiotics, appropriate hair removal, maintenance of perioperative normothermia, and glucose control
- Implementation involved the Comprehensive Unit-based Safety Program (CUSP), the same approach used in the famous Keystone central line bundle project

Adjusted Rates of Adverse Outcomes Before and After Implementation of Checklist



Conclusion

- Ontario study: “you get what you pay for”
 - mandate checklists → superficial implementation
- Not as easy to dismiss Michigan study as an implementation problem– was a very earnest effort
- Extent to which hospitals truly embraced the culture changes and implemented as intended not known

But, why expect average hospitals not even part of a collaborative to fare any better with implementation?

Original Contribution

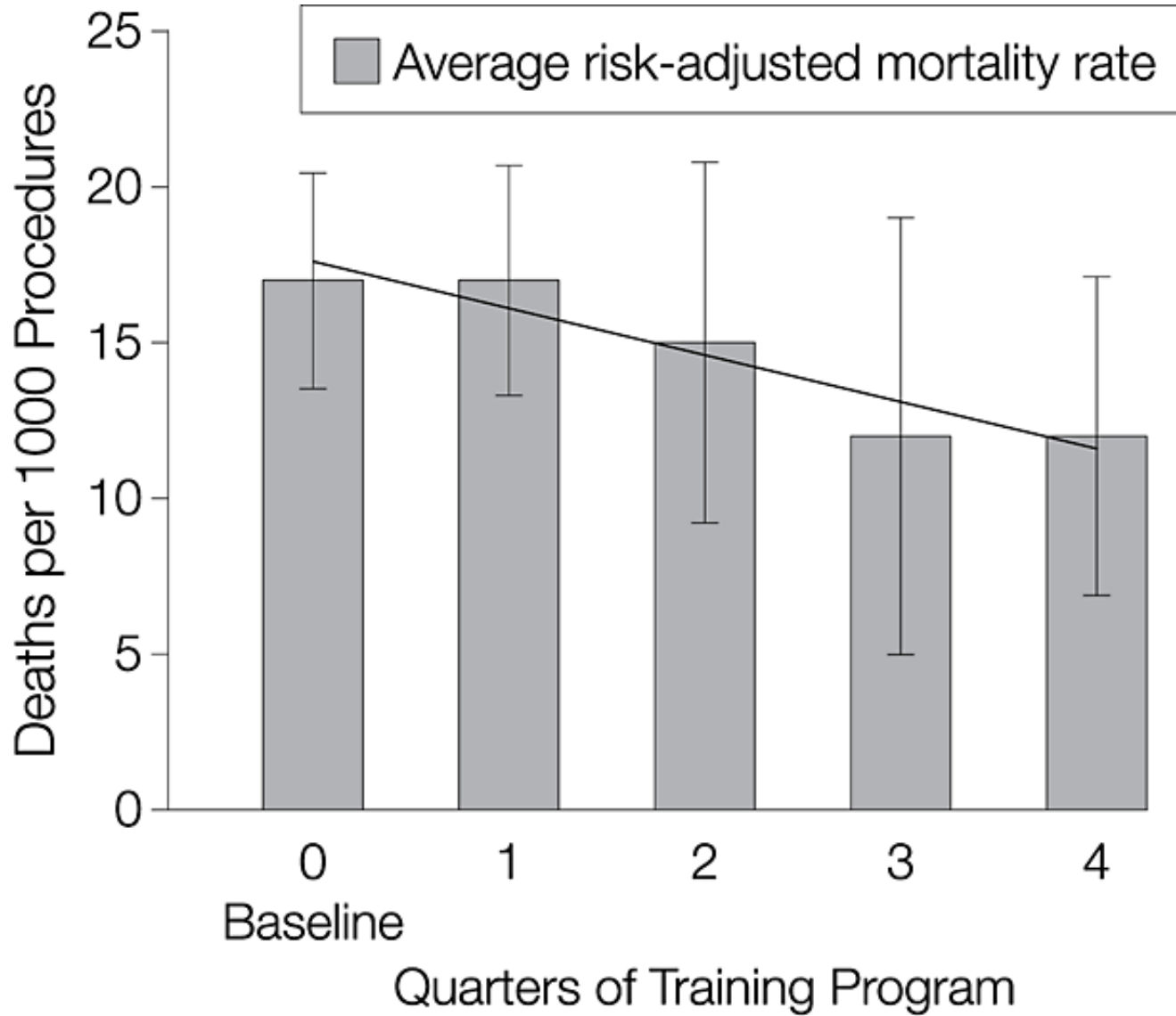
Association Between Implementation of a Medical Team Training Program and Surgical Mortality

- **Design:** Retrospective study with contemporaneous control including 182,409 sampled procedures from 108 VA facilities (data from VA Surgical Quality Improvement Program)and from structured interviews in fiscal years 2006 to 2008.
- Also included structured interviews
- The VA's nationwide training program required briefings and debriefings in the operating room and included checklists as an integral part of this process.

Medical Team Training program

- 2 months of preparation and planning with each facility's implementation surgical care team.
- Onsite learning session including lecture, group interaction, and videos—Operating Rooms closed for the day (!)
- Principles of CRM used:
 - team members encouraged to speak up about safety risks
 - conduct checklist-guided pre- and post-op briefings
 - communication strategies such as recognizing red flags, rules of conduct for communication, stepping back to reassess a situation, more effective hand-offs during care transitions
- Follow-up calls to support and assess implementation issues

Quarterly Risk-Adjusted Surgical Mortality



Observed decrease ~ 50% greater than control group

Table 3. Improvements Reported by Medical Team Training Facilities From Structured Interviews

Reported Improvements	No. (%) of Facilities (n = 74)
Communication among operating room staff	35 (47.2)
Staff awareness	34 (46.0)
Overall efficiency	49 (66.2)
Equipment use during surgery	44 (59.9)
Reduced length of procedures	15 (20.3)
Improved first-case start times	30 (40.5)
Other types of efficiency improvements ^a	6 (8.1)

^aFor example, reduced delays for surgical consent, decreased turnover time between cases, reduction in staff over-time hours.

What does this have to do with checklists?

- Robust study demonstrated concrete impacts of team training on hard patient outcomes
 - Intervention included checklists, debriefings, communication, teamwork skills
 - This was not a “one off training session”; ORs closed for attendance, intensive pre- and post-education activities

Level of teamwork required to improve safety requires intensive training, more than the level of teamwork associated with checklist implementation as a goal in itself

SIMPLICITY AND COMPLEXITY IN 15 YEARS OF PATIENT SAFETY

1. Superficial simplicity: we started by thinking that checklists were simple interventions from aviation that we could easily emulate
2. confusing complexity – then we teamwork was required to get it right, with lots of recommendations for how to implement effectively
3. Profound simplicity – better teamwork key

Better teamwork not just the
means to an end (checklist
implementation)

It's the main event



“ON THE FAR SIDE OF COMPLEXITY LIES PROFOUND SIMPLICITY”

Knowledge often moves in three phases:

1. A superficial simplicity;
2. confusing complexity, as underlying, previously unidentified problems surface;
3. finally, profound simplicity.

*Karl Weick, Professor of Organizational Behavior and Psychology,
University of Michigan*

SIMPLICITY AND COMPLEXITY IN 15 YEARS OF PATIENT SAFETY

1. Superficial simplicity: emulate other high risk industries – incident reporting, “systems approach,” checklists
2. confusing complexity – multiple safety targets, implementation problems, changing evidence
3. finally, profound simplicity – teamwork, communication, culture



Swings of the pendulum

- Initial enthusiasm for emulating aviation– incident reporting, human factors engineering, culture, teamwork
 - Pendulum swung towards specific complications of care – central line bundle, surgical checklists, VTE prevention
 - Many did not pan out or target very narrow problems
- pendulum now swinging back more towards teamwork, communication, culture, but with more evidence to support specific ways of doing this



Summary

- Electronic early warning systems emerging frontier
- We may have gone too far with VTE prophylaxis
- Hand hygiene compliance likely inflated at many hospitals due to recognizing the auditors
- Surgical checklist, even when implemented as intended, probably needs more intensive teamwork
- Hard to avoid conclusion that culture is key and the rest is mostly rearranging deck chairs on the titanic