ELIMINATION OF SSI: USING SCIENCE TO OVERCOME BARRIERS AND BEHAVIOR

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WILLIAM A. RUTALA RETIREMENT SYMPOSIUM – APRIL 28, 2017

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Royalties

- UpToDate, Online

General Outline

Review of SSI

- Why is SSI important?
- Pathophysiology

Discuss 3 strategies to eliminate SSI

Review - Outcomes

Occurs following 2-5% of surgical procedures

Since 16 to 20 million procedures are performed each year:

- 300,000 to 1 million SSIs each year

SSIs lead to adverse patient outcomes

- Longer hospitalization
- Longer time in ICU
- Morbidity such as disability
- Increased risk of death

SSIs lead to adverse outcomes for healthcare

- $3.5 to $10 billion annually

www.cdc.gov/nhsn/pdfs; Anderson et al ICHE 2014

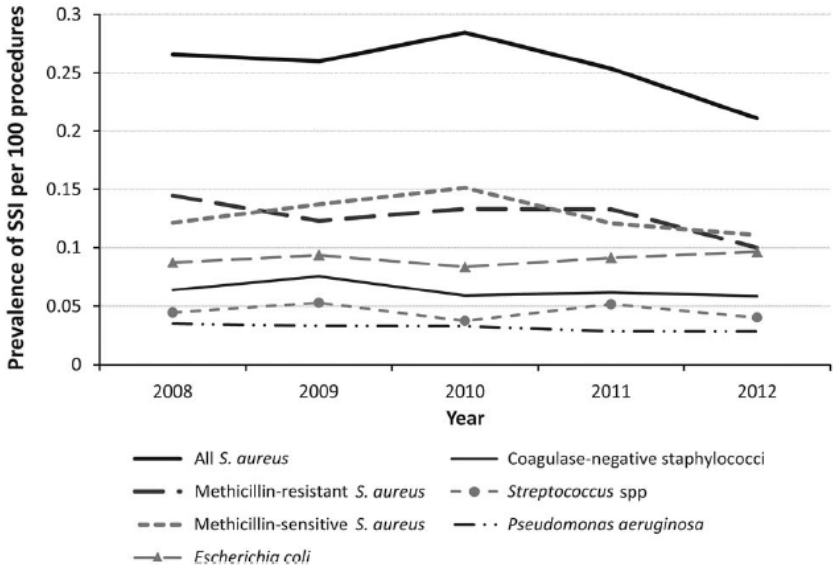
Review – Epidemiology

Most common and most costly HAI

- 38% of HAIs

Recent trends?

- SCIP let to improved adherence to performance measures
- Compared to 2008 baseline, NHSN data (2014) demonstrated 17% decrease in SSI
- Community hospitals had 10% decrease in SSI from 2008 to 2012
- BUT, progress may have stagnated
  - 5% increase in COLO SSI from 2013 to 2014



Lewis et al. ICHE 2013;34:1229. Zimlichman et al. JAMA Intern Med 2013;173:2039. Baker et al. ICHE 2016;37:519. https://www.cdc.gov/HAI/pdfs/progress-report/hai-progress-report.pdf

Review – Common Organisms

NHSN data, 2006-2009

Pathogen	Pathogenic isolates					
	CABG		Arthroplasty		Total	
	No. (%)	Rank	No. (%)	Rank	No. (%)	Rank
Staphylococcus aureus[a]						
Methicillin-sensitive *S. aureus*	616 (19)	1	904 (28)	1	1,520 (23)	1
Methicillin-resistant *S. aureus*	550 (17)	3	634 (19)	2	1,184 (18)	2
Coagulase-negative staphylococci	573 (17)	2	512 (16)	3	1,085 (17)	3
Enterococcus species	193 (6)	6	240 (7)	4	433 (7)	4
Pseudomonas aeruginosa	223 (7)	4	116 (4)	7	339 (5)	5
Escherichia coli	197 (6)	5	117 (4)	6	314 (5)	6
Streptococcus species	66 (2)	11	212 (7)	5	278 (4)	7
Enterobacter species	142 (4)	8	88 (3)	8	230 (3)	8
Proteus species	131 (4)	10	75 (2)	9	206 (3)	9
Klebsiella pneumoniae, Klebsiella oxytoca	144 (4)	7	53 (2)	10	197 (3)	10
Serratia species	137 (4)	9	47 (1)	11	184 (3)	11
Candida albicans	52 (2)	12	6 (0)	13	58 (1)	12
Acinetobacter baumannii	29 (1)	13	23 (1)	12	52 (1)	13
Other *Candida* species or NOS	14 (0)	14	5 (0)	14	19 (0)	14
Other[b]	226 (7)	15	197 (6)	15	423 (6)	15
Total	3,316 (100)		3,258 (100)		6,574 (100)	

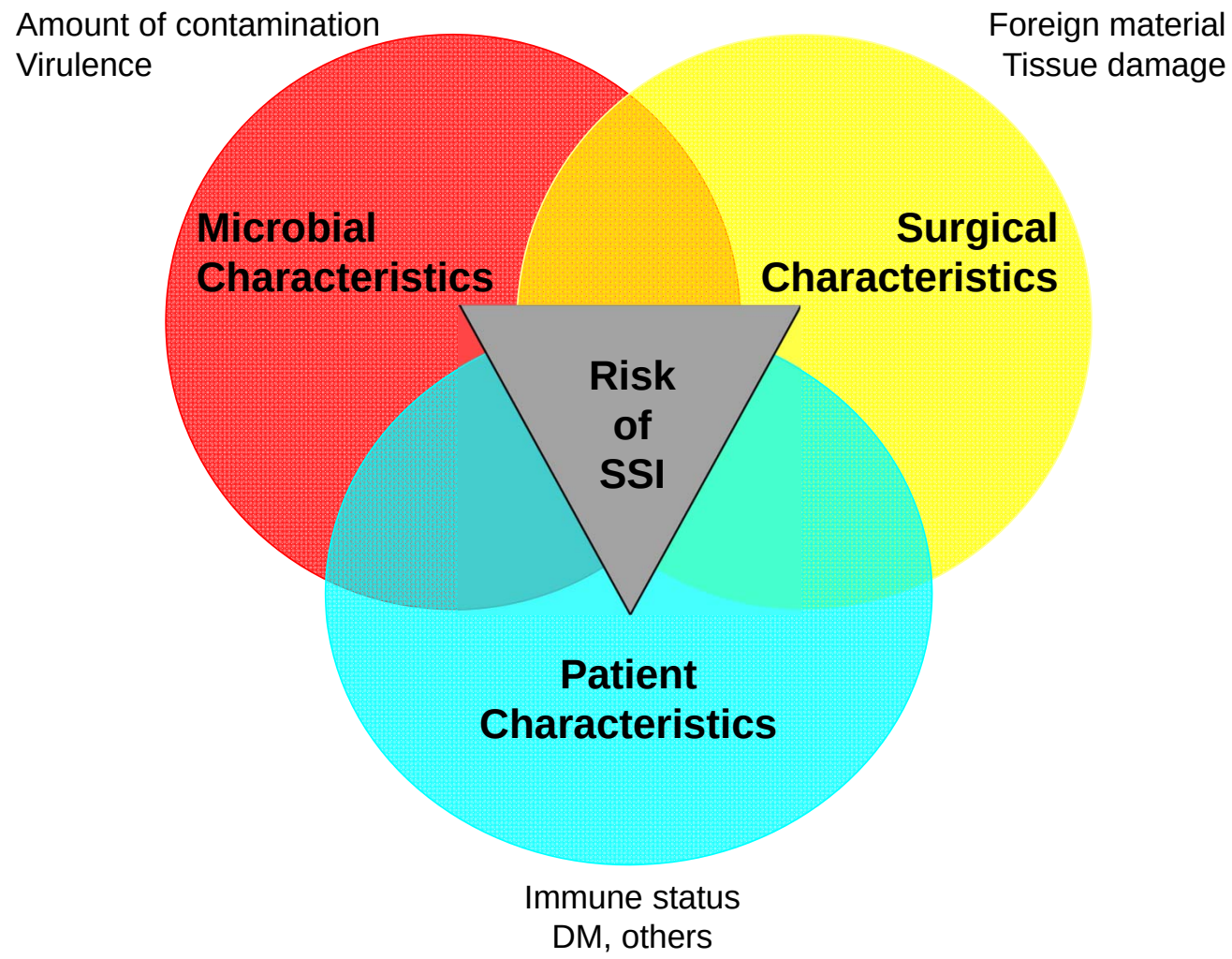
29 Community Hospitals, 2008-2012

Organism	No. (%) of SSIs (n = 3,988)
Bacteria	
Staphylococcus aureus	1,357 (34)
MSSA	683 (17)
MRSA	674 (17)
Escherichia coli	482 (12)
Enterococcus spp.	467 (12)
Coagulase-negative staphylococci	340 (9)
Klebsiella spp.	246 (6)
Streptococcus spp.	242 (6)
Pseudomonas aeruginosa	168 (4)
Enterobacter spp.	161 (4)
Other	
Fungi	121 (3)
Polymicrobial[a]	787 (20)
No pathogen identified[b]	566 (14)

Berrios-Torres et al. ICHE 2014;35:231. Baker et al. ICHE 2016;37:519.

Review –

Patho-physiology



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Review – Risk Factors

Anderson et al. ICHE 2014;35:605-627.

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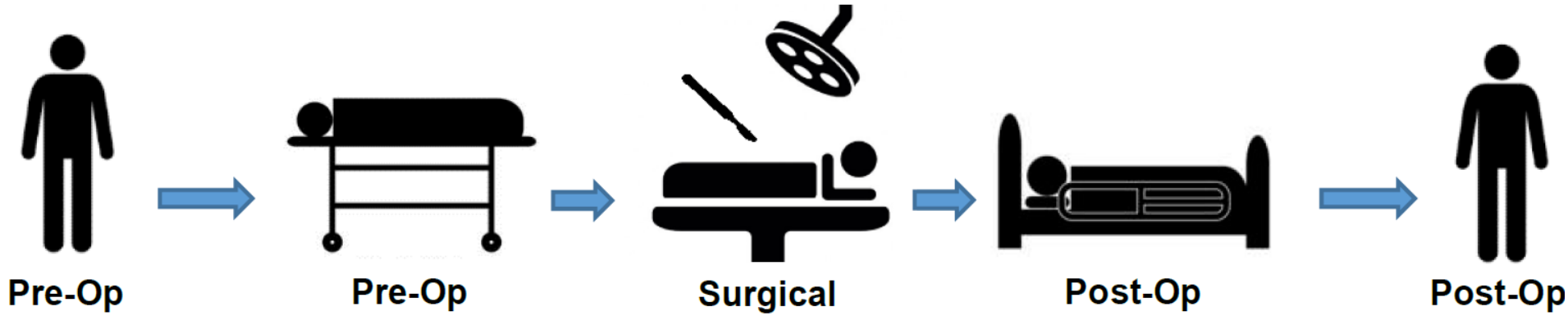
Risk factor	Recommendation
Intrinsic, patient related (preoperative)	
Unmodifiable	
Age	No formal recommendation. Relationship to increased risk of SSI may be secondary to comorbidities or immunosenescence.[216-218]
History of radiation	No formal recommendation. Prior irradiation at the surgical site increases the risk of SSI, likely due to tissue damage and wound ischemia.[219]
History of SSTIs	No formal recommendation. History of a prior skin infection may be a marker for inherent differences in host immune function.[220]
Modifiable	
Glucose control	Control serum blood glucose levels for all surgical patients, including patients without diabetes.[17] For patients with diabetes mellitus, reduce glycosylated hemoglobin A1c levels to less than 7% before surgery, if possible.[94]
Obesity	Increase dosing of prophylactic antimicrobial agent for morbidly obese patients.[76,221]
Smoking cessation	Encourage smoking cessation within 30 days of procedure.[17,222-226]
Immunosuppressive medications	Avoid immune-suppressive medications in perioperative period, if possible.
Hypoalbuminemia	No formal recommendation. Although a noted risk factor,[227] do not delay surgery for use of TPN.
Extrinsic, procedure related (perioperative)	
Preparation of patient	
Hair removal	Do not remove unless hair will interfere with the operation.[17] If hair removal is necessary, remove outside the OR by clipping. Do not use razors.
Preoperative infections	Identify and treat infections (eg, urinary tract infection) remote to the surgical site prior to elective surgery.[17] Do not routinely treat colonization or contamination.
Operative characteristics	
Surgical scrub (surgical team members' hands and forearms)	Use appropriate antiseptic agent to perform preoperative surgical scrub.[17,228] For most products, scrub the hands and forearms for 2–5 minutes.
Skin preparation	Wash and clean skin around incision site. Use a dual agent skin preparation containing alcohol, unless contraindications exist.[17]
Antimicrobial prophylaxis	Administer only when indicated.[17]
Timing	Administer within 1 hour of incision to maximize tissue concentration[76,a]
Blood transfusion	Blood transfusions increase the risk of SSI by decreasing macrophage function. Reduce blood loss and need for blood transfusion to the greatest extent possible.[229-231]
Choice of prophylactic agent	Select appropriate agents on the basis of surgical procedure, most common pathogens causing SSIs for a specific procedure, and published recommendations.[76]
Duration of prophylaxis	Stop agent within 24 hours after the procedure for all procedures.[76]
Surgeon skill/technique	Handle tissue carefully and eradicate dead space.[17]
Appropriate gloving	All members of the operative team should double glove and change gloves when perforation is noted.[208]
Asepsis	Adhere to standard principles of OR asepsis.[17]
Operative time	No formal recommendation in most recent guidelines. Minimize as much as possible without sacrificing surgical technique and aseptic practice.
OR characteristics	
Ventilation	Follow American Institute of Architects' recommendations for proper air handling in the OR.[17,232]
Traffic	Minimize OR traffic.[17,135,136]
Environmental surfaces	Use an EPA-approved hospital disinfectant to clean visibly soiled or contaminated surfaces and equipment.[17]
Sterilization of surgical equipment	Sterilize all surgical equipment according to published guidelines.[233] Minimize the use of immediate-use steam sterilization.[17]

Risk Factors – Framework for Prevention



- Age
- Radiation
- Infection
- DM
- Obesity
- Smoking
- Nutrition

Peri-Op

- Hair
- Skin prep
- Surgeon prep
- AMP

- Hypoxemia
- Duration
- Hypothermia
- Transfusion

- Environment
- Sterile equip
- OR Traffic
- Technique

- Wound care
- DM
- Transfusion

STRATEGY 1

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Quiz #1 – How frequently are wounds contaminated with bacteria during surgery?

2%

15%

40%

50%

75%

100%

Wound Contamination is Universal

Antiseptics and antibiotics cannot eliminate all bacteria

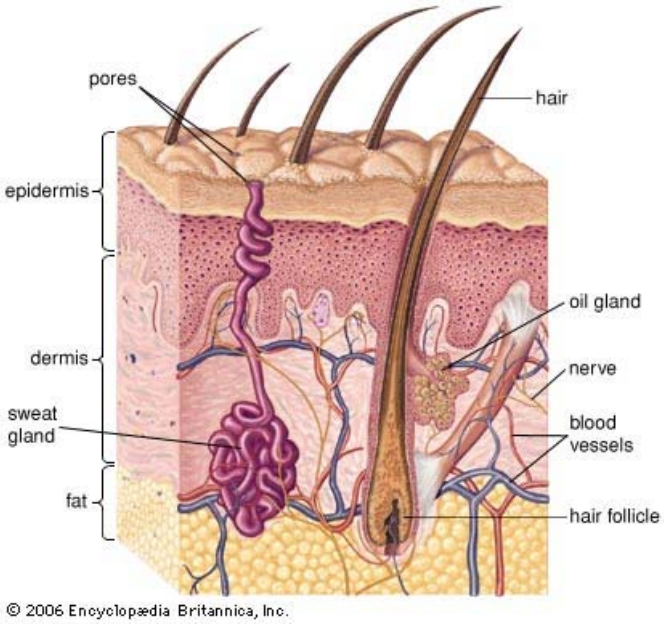
- 20% of bacterial skin flora “hide” in skin appendages (e.g., sebaceous glands, hair follicles, sweat glands)

Experiments using human albumin microspheres prove that 100% of wounds are contaminated with particles **from the patient**

- Endogenous contamination

All surgical wounds are contaminated during the procedure

- Largest contamination at time of incision
- Wound contamination increases as the procedure progresses
- Contamination comes from the patient



Tuazon CU. Am J Med 1984;76:166. Wiley and Ha’eri. Clin Orthop Relat Res 1979:150.

IS THERE SOME WAY TO USE UNIVERSAL CONTAMINATION TO PROTECT AGAINST SSI?

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STRATEGY 1 – CUTANEOUS MICROBIOME

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Human Microbiome - What is it?

Community of microorganisms that share a location on the body

A few facts for you:

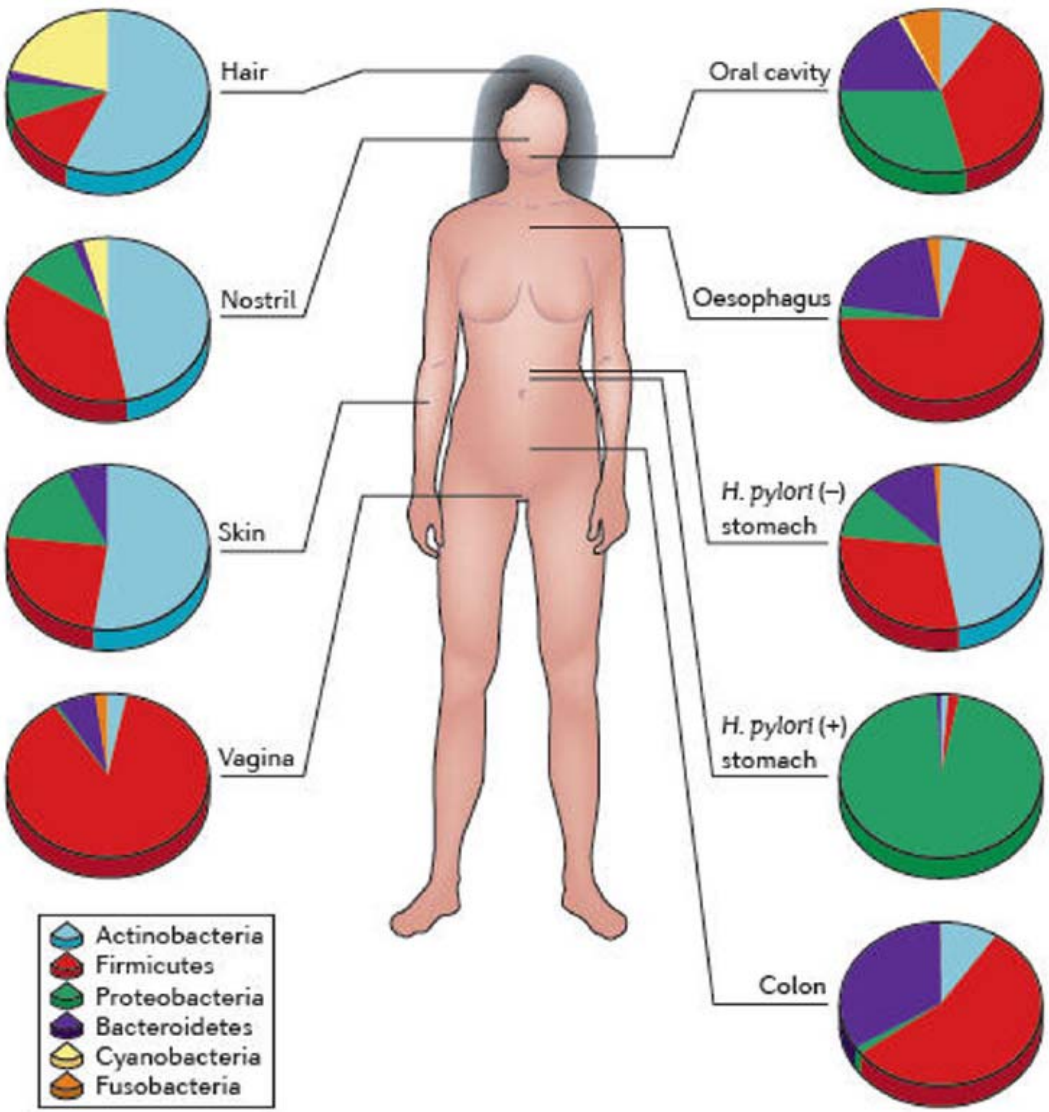
- By some estimates, the average human has ~3 pounds of bacteria in/out/on their body
- Microbial cells outnumber human cells 10:1
- Significant variation between individual people
- Important part of your health
- Dynamic – changes from infancy to old age
  - Higher level (phylum) taxonomic features display temporal stability at specific anatomic sites

The newest organ?

Description is based on DNA sequencing

Composition Depends on Location

Cho and Blaser. Nat Rev Genet 2012;13:260



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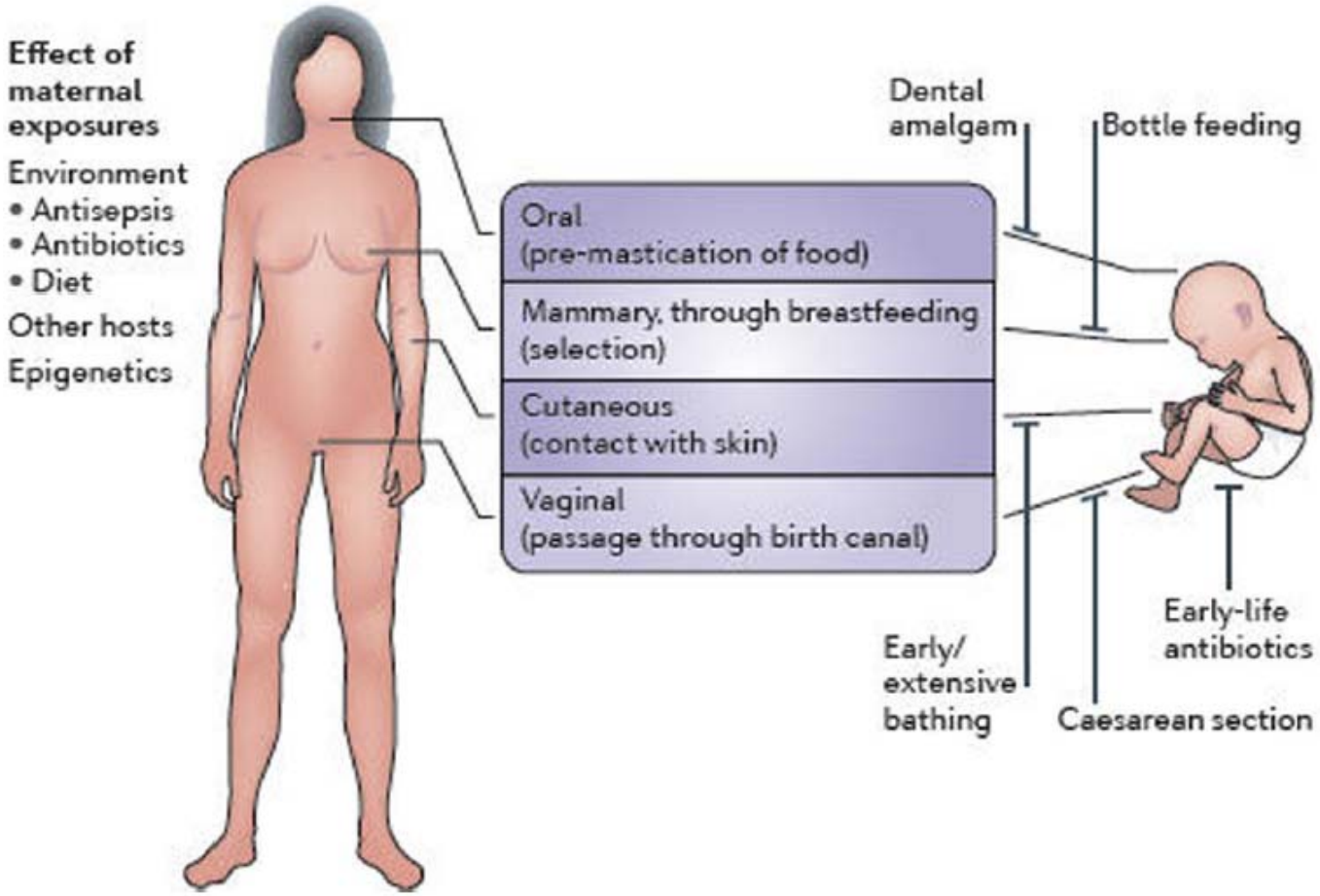
Starts from Birth

Cho and Blaser. Nat Rev Genet 2012;13:260



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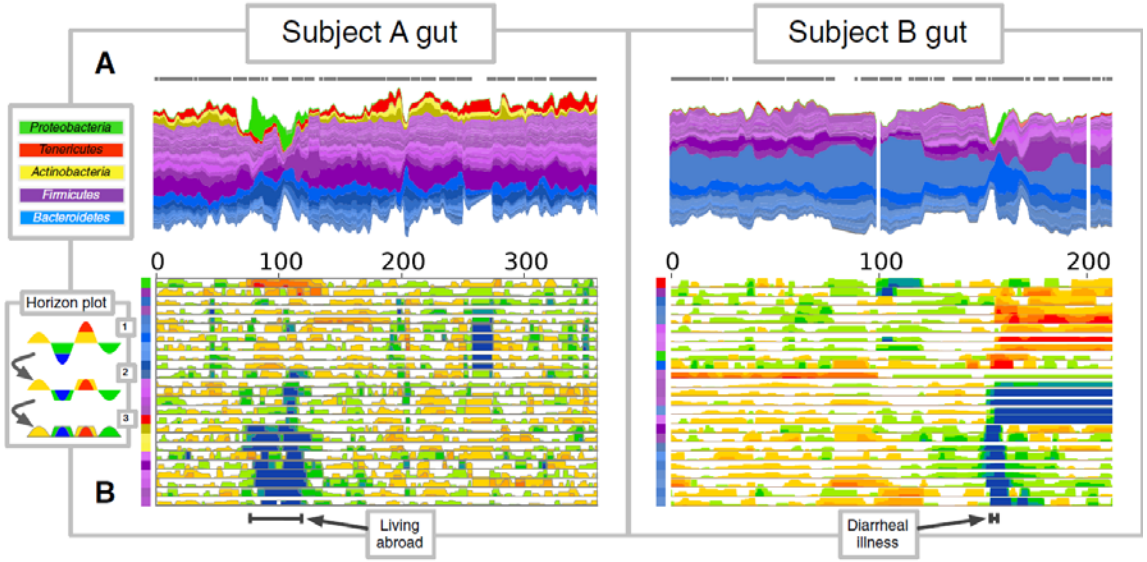
Changes Over Time

Diet (your bacteria are what you eat)

- Meat predominant
  - Increased bile-tolerant bacteria (Alistipes, Bilophila, and Bacteroides)
  - Decreased Firmicutes
- Foodborne microbes from both diets transiently colonized the gut

Impact of lifestyle – some events can drastically change microbiome

- 10,000 longitudinal measurements of human wellness from 2 people over a year
- Microbial communities generally stable but abrupt changes evident
  - Travel
  - Enteric infection (Salmonella)



David LA et al. Nature 2014;505:559. David LA Genome Biol 2014;17:117.

Diseases Associated with Specific Microbiota Characteristics (Microbiome "Disruption")

Disease	Disruption
Psoriasis	Increased ratio of Firmicutes to Actinobacteria
Reflux esophagitis	Esophageal microbiota dominated by gram-negative anaerobes Gastric microbiota with low or absent *H. pylori*
Obesity	Reduced ratio of Bacteroidetes to Firmicutes
Childhood-onset asthma	Absent gastric *H. pylori* (especially cytotoxin-associated gene (cagA) genotype)
IBD	Increased Enterobacteriaceae
Functional bowel disease	Increased Veillonella and Lactobacillus
Colorectal carcinoma	Increased Fusobacterium spp.
Cardiovascular disease	Gut microbiota-dependent metabolism of phosphatidylcholine
C. difficile colitis	Decreased Firmicutes and Bacteroidetes, increased Proteobacteria

Shreiner et al. Curr Opin Gastroenterol 2015;31:69.

Modify the Microbiome to Improve Health

Perhaps a future component of “Precision Medicine” or “Personalized Medicine”?

- Cancer therapy based on genomic tests
  - Classify subpopulations **of patients** that differ in susceptibility or response to disease or treatment
- Change to “*of microbiome*”?

Right now, modifying with broad strokes

- FMT for recurrent *C. difficile*

More Precise Manipulation

Use nontoxigenic *C. difficile* (NTCD-M3) to prevent *C. difficile* infection

- Phase 2, RCT, double-blind, placebo-controlled
- 173 patients enrolled, 157 completed therapy

Decrease in 6 week recurrence, particularly if remained colonized

Events in Intention-to-Treat Safety Population	Placebo (n = 43)	NTCD-M3 Dosage 10^4 Spores/d for 7 d (n = 41)	10^7 Spores/d for 7 d (n = 43)	10^7 Spores/d for 14 d (n = 41)	All (n = 125)
CDI recurrence, No. (%)	13 (30)	6 (15)	2 (5)	6 (15)	14 (11)
Unadjusted comparison with placebo, *P* value[a]		.09	.002	.09	.003
Adjusted comparison with placebo[b]					
Odds ratio (95% CI)		0.4 (0.1-1.2)	0.1 (0.0-0.6)	0.4 (0.1-1.2)	0.28 (0.11-0.69)
P value		.11	.01	.10	.006

Gerding et al. JAMA 2015;313:1719.

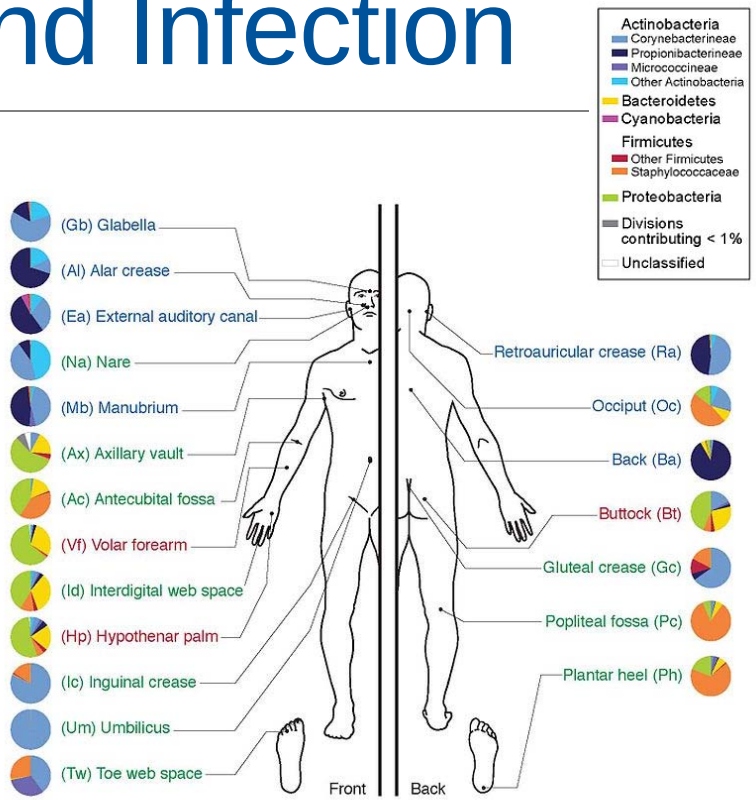
Cutaneous Microbiome and Infection

Cutaneous microbiome is diverse

Surprisingly few studies on the impact of antibiotics

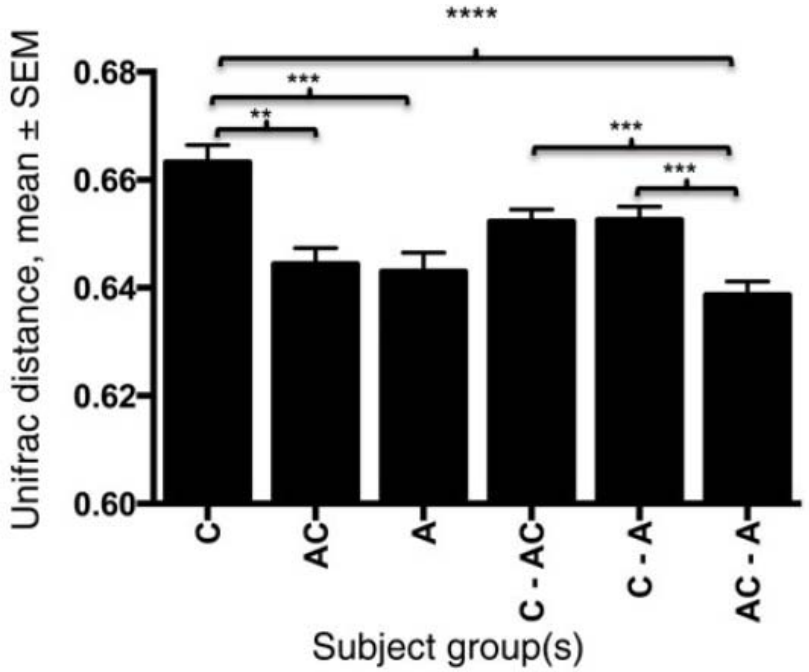
Disruptions lead to risk of infection

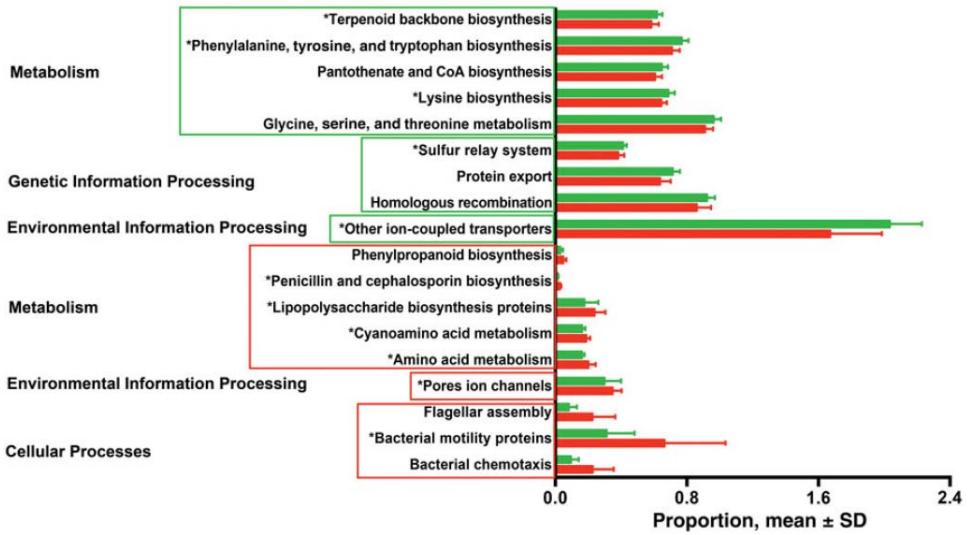
- Case-control study
  - 25 patients with skin abscess
  - 25 matched controls
- Cutaneous microbiome of patients with infection was different than uninfected controls, particularly if received antibiotic therapy BEFORE abscess
  - Decreased diversity
  - Increased metabolic markers



Horton et al. JID 2015;211:1895.

Cutaneous Microbiome and Infection





Horton et al. JID 2015;211:1895.

How Translate to SSI Elimination?

Contamination is universal, so use to our benefit

Microbiome-precision medicine

Screen cutaneous microbiome composition

- If not “acceptable”
  - Eliminate or decrease pathogenic organisms
  - Increase (or add) “helpful” (non-pathogenic) organisms

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QUIZ #2 – BIGGEST Risk Factor?

Age

Obesity

DM

Smoking

Hair removal

Skin prep

AMP

Hypoxemia

Hypothermia

Sterile equipment

Surgeon technique

Wound care

Technique = Holy Grail of SSI Prevention

Believed to be the most important aspect of SSI prevention

Why important for SSI?

- Duration
- Tissue handling/trauma/dead space
- Hemostasis/hematomas
- Tissue debridement/necrosis/hypoxemia

Inevitable that some surgeons are better than others

No way to study “technique”

- No controlled experiments

Some studies on specific components, but not convincing evidence

- Diathermy vs. scalpel
- Suture technique

McHugh et al. J Hosp Infect 2011;78:1.

Technique Matters – Indirect Evidence

Surgeons who perform fewer procedures typically have worse outcomes

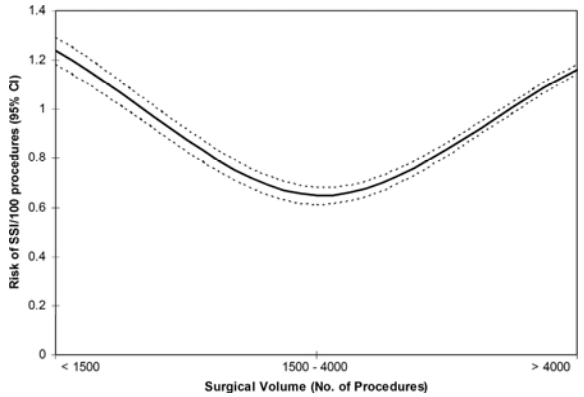
- 4552 patients with traumatic femoral fx
- 10 hospitals
- Decreased rates in
  - High volume hospitals
  - Trauma surgeons (vs. general surgeons)

Hospitals that perform fewer procedures typically have worse outcomes

- 18 hospitals
- Small hospitals (<1500 procedures/yr) had worse rates of SSI

Emergence of “Centers of Excellence”

- Movement of complicated care to specific locations



Treskes et al. Injury 2017;48:339. Anderson et al. Ann Surg 2008;247;343.

SO HOW CAN WE MAKE SYSTEMATIC IMPROVEMENT IN SURGICAL TECHNIQUE?

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STRATEGY 2 - ROBOTIC-ASSISTED SURGERY

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What is it?

What is it?

Computer-controlled device that can be programmed to aid in the positioning and manipulation of instruments

- 3-dimensional camera system
- Better ergonomics
- Expensive, but increasing used

Minimally invasive technique

Strategy increasingly used in multiple types of surgery

- Colorectal, ENT, urologic, CT, breast, GYN, thyroid

Associated with better patient outcomes and satisfaction

- Decreased pain
- Less blood loss
- Shorter recovery time
- Shorter hospitalization

Different Functions

PASSIVE

Autonomous

- Pre-programmed movements

Supervisory

- Positioning system

ACTIVE

Immersive

Haptics (tactile feedback)

- Learn visual cues

Teleoperated - Not at the table

Telepresence - Not in the OR

Telestration - Teaching

Dual-console

- Multiple surgeons

Example 1

Lobectomy

Several methods of port placement can be utilized

In general, place camera port approximately 15-20 cm away from surgical site

In general, instrument ports (#s 1 & 2) must be a 8-10 cm away from the camera port

Can setup the 4th arm (robot arm #3) to perform retraction

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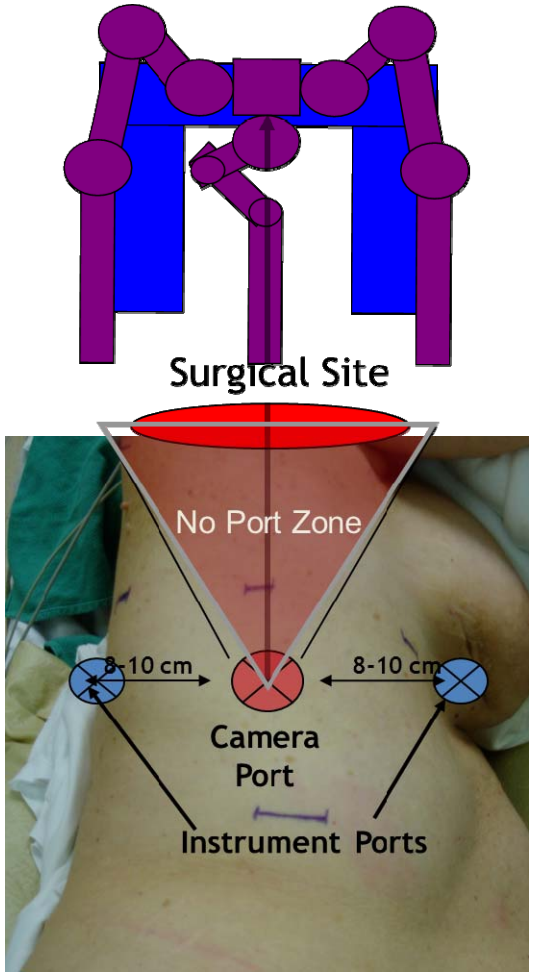

Slides courtesy of Dr. Matthew Hartwig

Port Placement

Camera port placed in the 8th-9th intercostal space in the posterior axillary line

One robot port placed one hands-breadth anteriorly in the 5th-6th intercostal space

Second robot port placed one hands-breadth posteriorly and superiorly in approximately the seventh intercostal space

12 step port placed between the anterior incision and the camera in the 8th-10th intercostal space

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Slides courtesy of Dr. Matthew Hartwig

System Position

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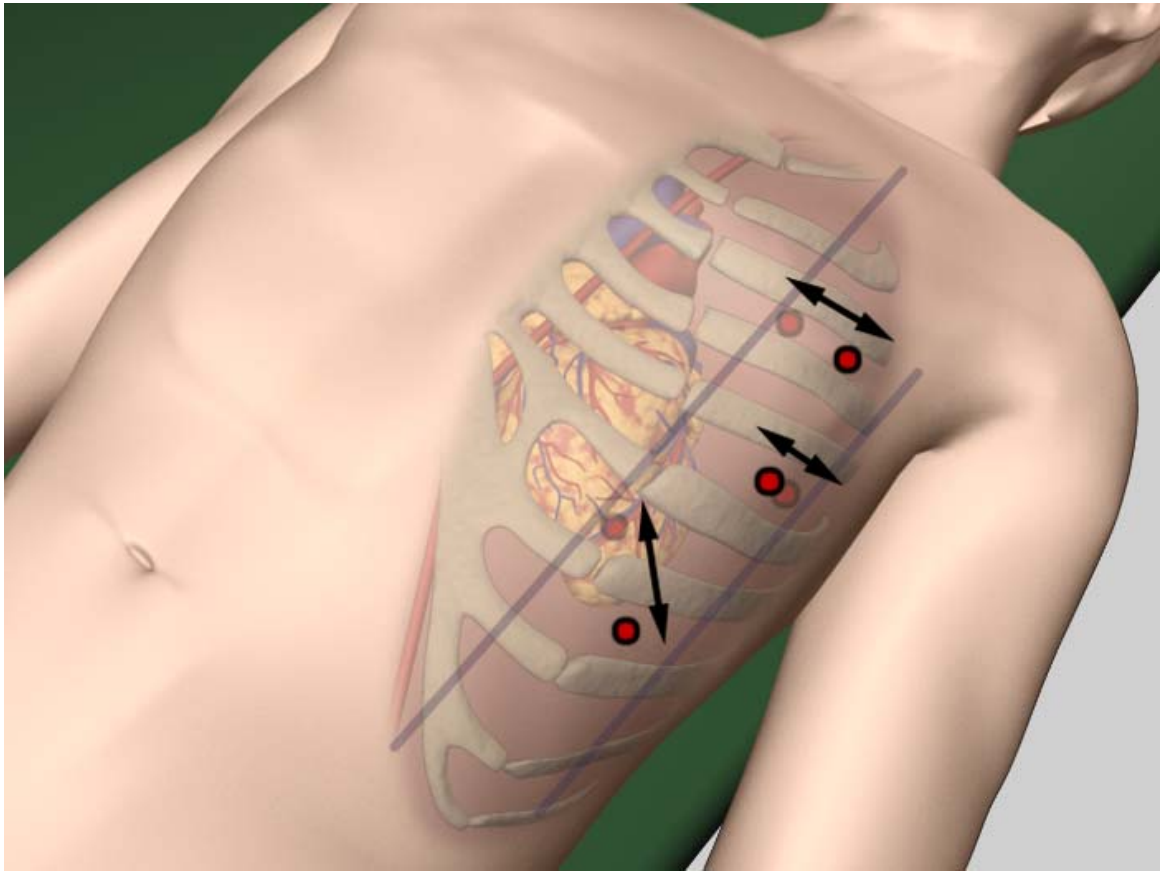
Slides courtesy of Dr. Matthew Hartwig

Example 2

Robotic Thymectomy



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Slides courtesy of Dr. Matthew Hartwig

Example 2

Robotic Thymectomy

- Position patient on edge of table
- Insert roll sub-scapularly to allow patient shoulder to drop.
- Arm of patient positioned below table in a sling.
- Roll table to provide proper exposure of chest wall (Approximately 30°)
- Bring Robot in from opposite side

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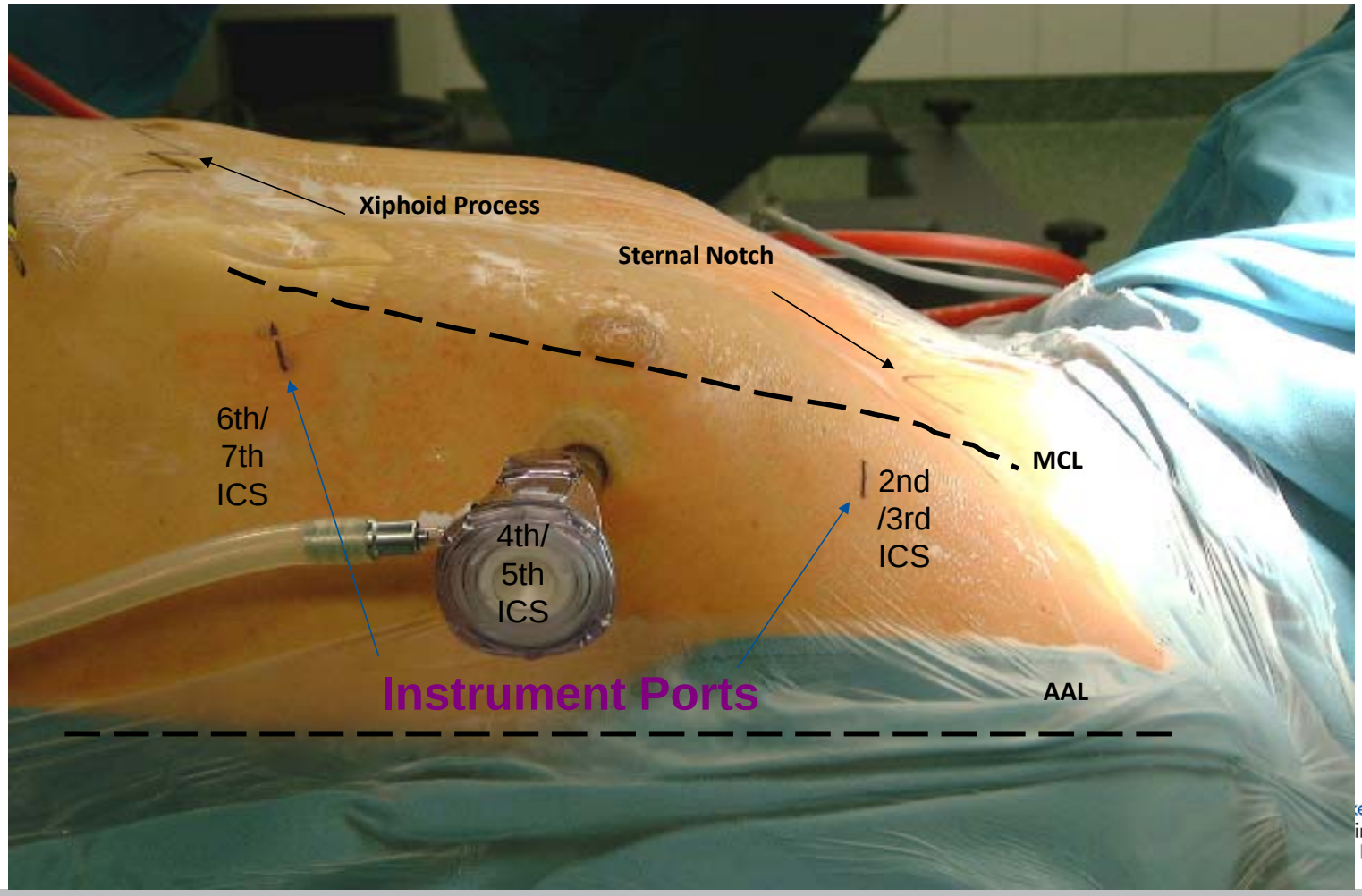
Slides courtesy of Dr. Matthew Hartwig



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Left Side Approach

Slides courtesy of Dr. Matthew Hartwig

Impact on SSI?

First reports – NOT GOOD

- Rates of SSI actually higher with RAS
- Tertiary care center described first 273 uses – 16 (6%) SSIs
  - GU/Prostate – 5.7 vs. 0.85
  - GYN – 10 vs. 1.7
  - COLO – 33 vs. 6

Recent data suggests improves rates of SSI

Hermsen ED et al. ICHE 2010; 31:822.

Decreased SSI

Obese patients undergoing pancreaticoduodenectomy

- N=474 in cohort
- 70% lower rates of SSI (adjusted) and other improved outcomes

Case-control study of laparoscopic procedures

- 26 Robot vs. 23 conventional
- >50% reduction in SSI (unadjusted)

Radical prostatectomy

- N=5908
  - 4824 retropubic
  - 1084 RA radical prostatectomy
  - 80% reduction in SSI (unadjusted)

Meta-analysis of technique for kidney transplant (n=18)

- Overall, minimally invasive techniques had lower rates of SSI
  - RA kidney transplant rates practically zero

Girgis et al. HPB (Oxford) 2017;19:93. Law et al. J Hosp Infect 2011;77:364. Tollefson et al. Lap Robotics 2011;78:827. Wagenaar et al. Eur Urol 2017, *in press*.

Decreased SSI

Cohort detailing the implementation of robotic colorectal surgery in a community hospital

- 41 patients with open COLO and 38 RCS
  - Comparable patients

Robotic colorectal surgery took longer (222 vs. 141 min)

Hospital stay shorter after RCS (5.7 v. 6.7 days)

Significantly lower rates of SSI (11% vs. 29%, p=0.04)

Zawadzki M et al. Dig Surg 2017;epub ahead of print

How Translate to SSI Elimination?

Make surgical technique more systematic

Robotic approach can improve outcomes

- More systematic approach to surgical technique
- Less invasive
- Ceiling is unknown (or ROOF?)

Barriers remain, but can be overcome

- Learning curve
  - Additional training required (and credentialing?)
    - Both surgeons and nurses
- No high quality data
- Costs

STRATEGY 3

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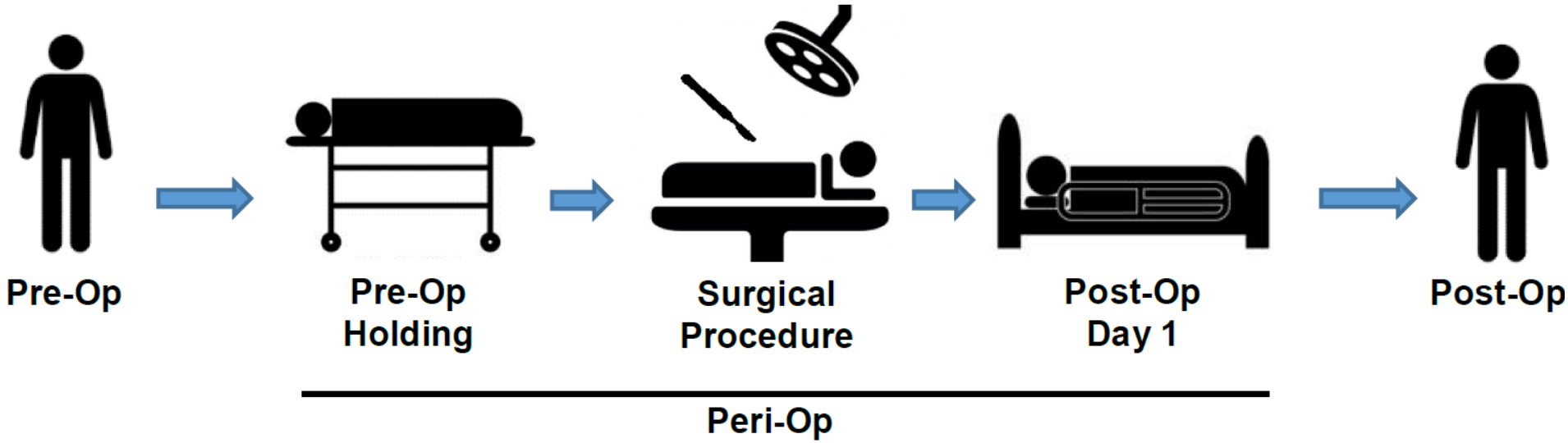
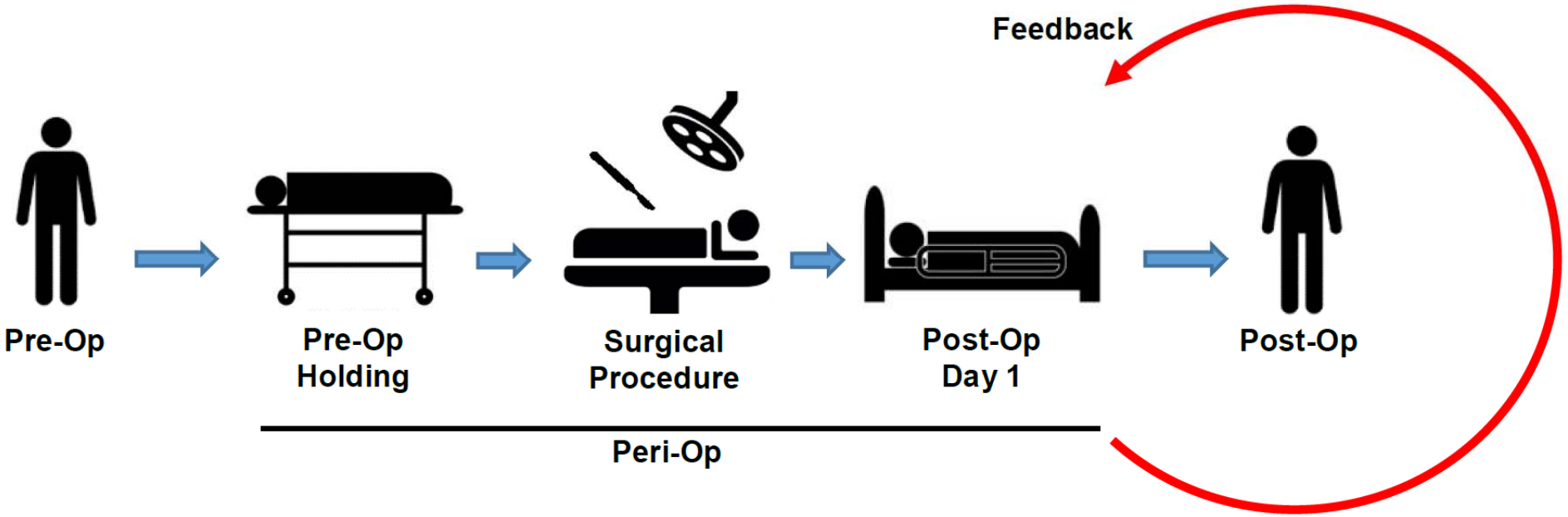
Risk Factors – Framework for Prevention



Additional (Important) Component



SENIC – Classic Study for IC

Series of publications

- Early risk adjustment

Infection prevention program that includes feedback of SSI rates to surgeons

- Lower rate of SSI by 35%

Why does surveillance and feedback work?

- Increased awareness
- Anxiety
- Introspection concerning systematic, procedural, or technical errors

Traditional approach

- Provide summary data 1 or 2 times each year

Haley et al. Am J Epidemiol 1985;121:182. Wong ES. Surgical Site Infections. 3rd ed.; Mayhall ed.

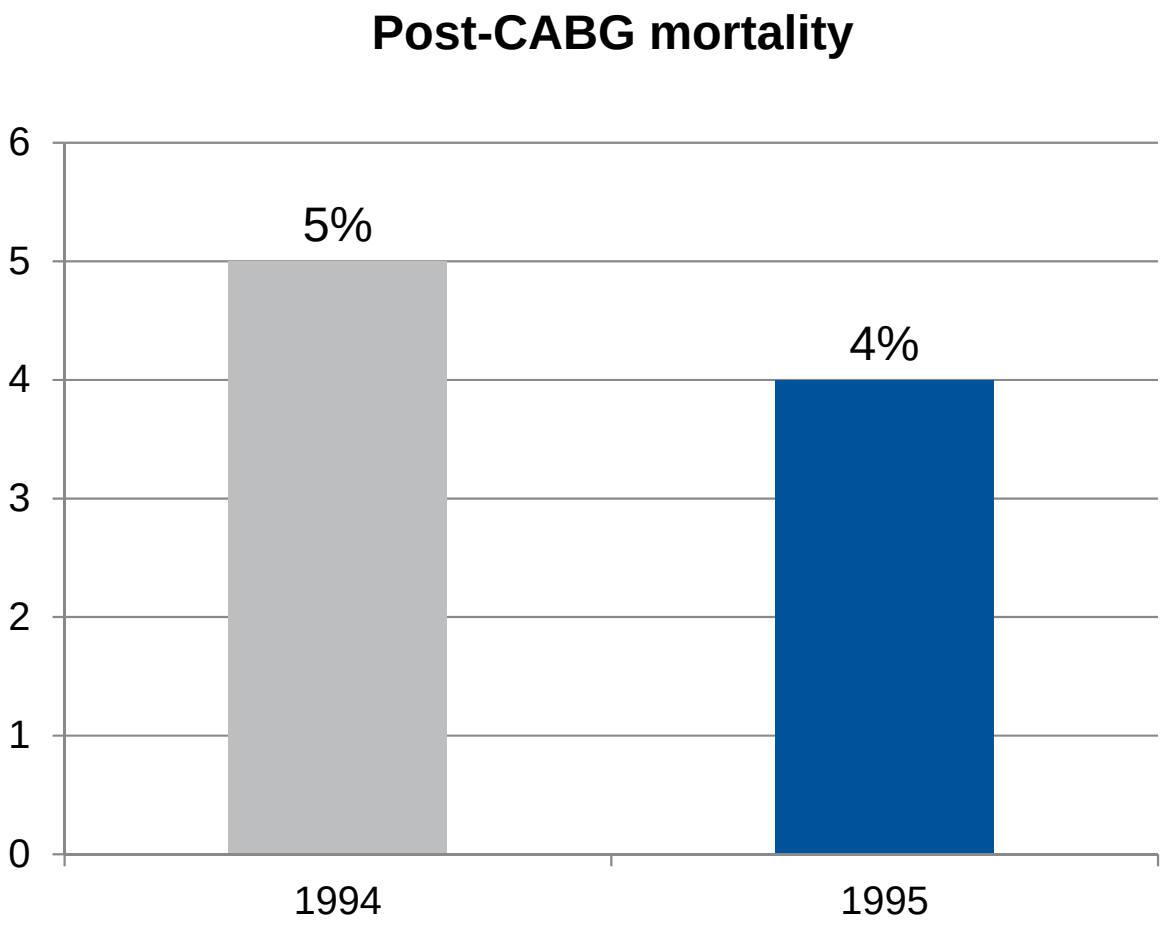
Traditional Statistical Surveillance

Table. Stratified SSI data for Hospital A compared to DICON hospitals with greater than 4,000 total procedures.

NHSN RI	SSIs	Procedures	Rate at Hospital A	DICON Mean	P-Value	DICON Median
Colon Surgery						
Total	**7**	**300**	**2.33**	**2.78**	**0.85**	**3.21**
0	0	58	0.00	2.17	-	0.93
1	5	193	2.59	2.22	-	2.38
>=2	2	49	4.08	4.48	-	5.99
Total Knee Replacement						
Total	**4**	**610**	**0.66**	**0.41**	**0.33**	**0.43**
0	2	127	1.57	0.13	-	0.00
1	1	442	0.23	0.45	-	0.49
>=2	1	41	2.44	1.47	-	1.60
Total Hip Replacement						
Total	**2**	**356**	**0.56**	**0.76**	**1**	**0.64**
0	1	67	1.49	0.41	-	0.00
1	1	265	0.38	0.85	-	0.66
>=2	0	24	0.00	1.61	-	1.40
Vaginal Hysterectomy						
Total	**1**	**176**	**0.57**	**0.98**	**1**	**0.48**
0	0	94	0.00	0.56	-	0.00
>=1	1	82	1.22	1.56	-	0.00

Quiz #3

Was the new protocol effective in reducing deaths?



Levett JM., et al. The Annals of thoracic surgery. 1999;68(2):353-8

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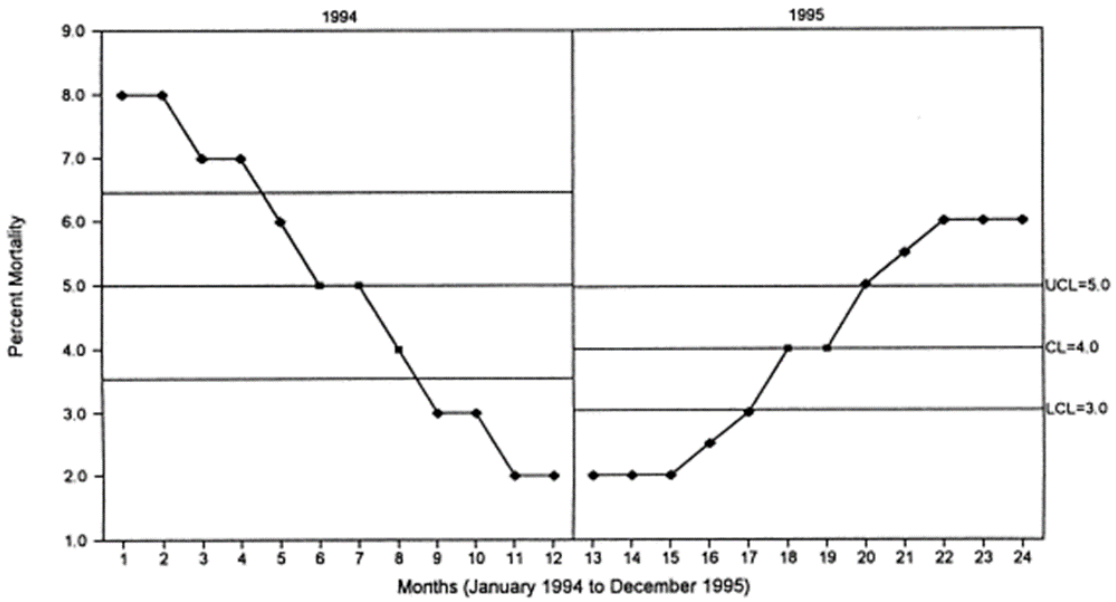
Limitations of Standard Surveillance



Post-CABG mortality

- Requires aggregation
  - Trends often missed
  - Dilution of increases
- Delay in detection of increases
- SSI increases identified by
  - Surgeon
  - IP
  - ID or other physician
  - Micro lab

Levett JM., et al. The Annals of thoracic surgery. 1999;68(2):353-8

STRATEGY 3 – STATISTICAL PROCESS CONTROL (SPC) CHARTS

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SPC Approach

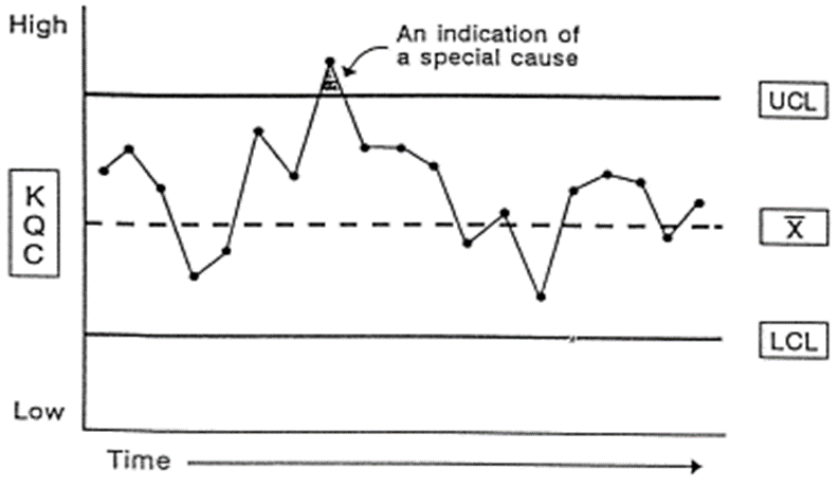
Branch of statistics that uses time series analysis

Commonly utilized in manufacturing

Analyzes variation in a process, i.e., separates “signal from noise”
- “Common cause” natural variation
- “Special cause” unnatural variation

Detects when process is “out of control” or is demonstrating improved control

Prior studies demonstrate can identify important increases prior to standard surveillance

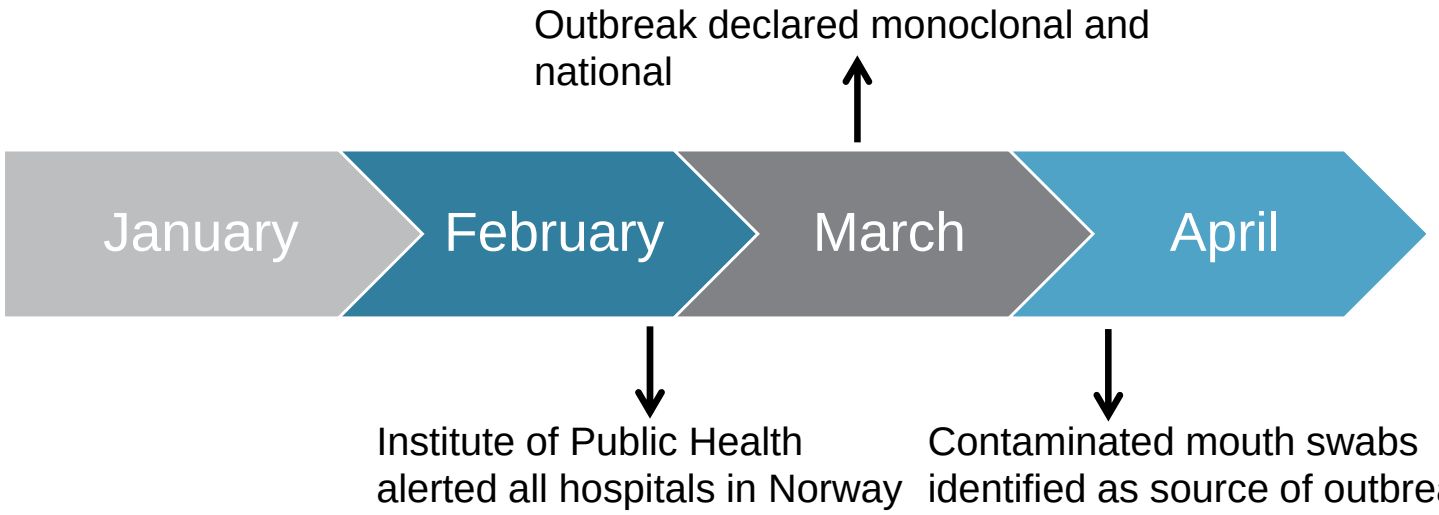


KQC = Key Quality Characteristic
UCL = Upper Control Limit
LCL = Lower Control Limit
$\bar{X}$ = Mean Score

Outbreak of PA in Norway (2002)

231 patients from 24 hospitals had outbreak strain

- 39 patients had BSI
- 71 died

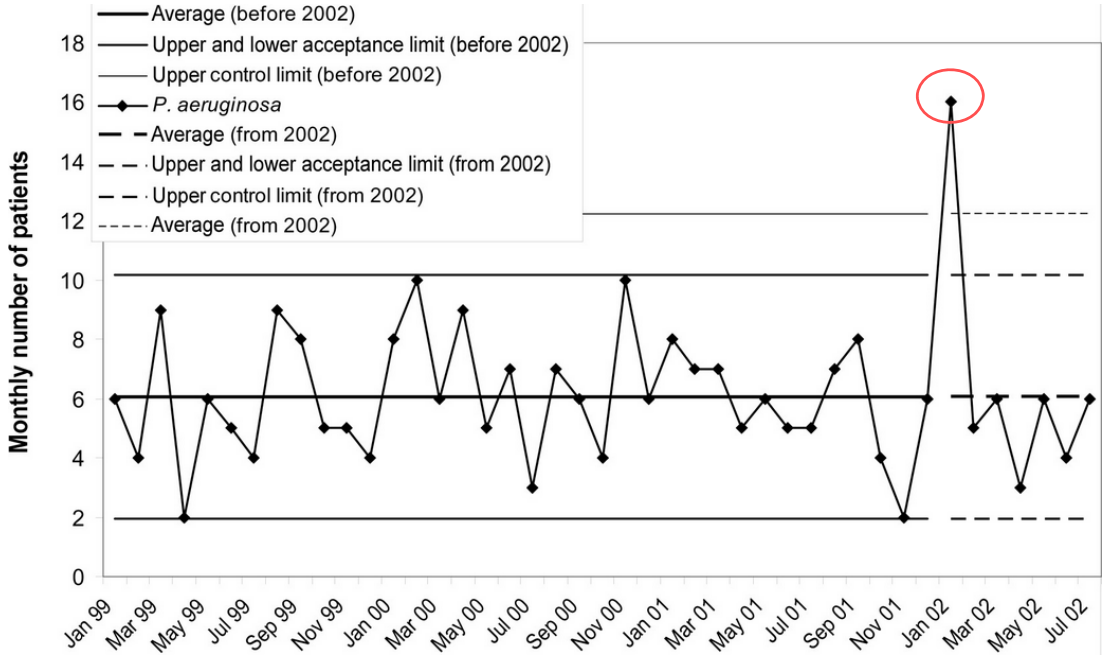


Walberg M.,et al. ICHE. 2008;29(7):635-41.

Shewhart Control Chart

February 2011: Out of control signal

1 signal above UCL



Walberg M.,et al. ICHE. 2008;29(7):635-41.

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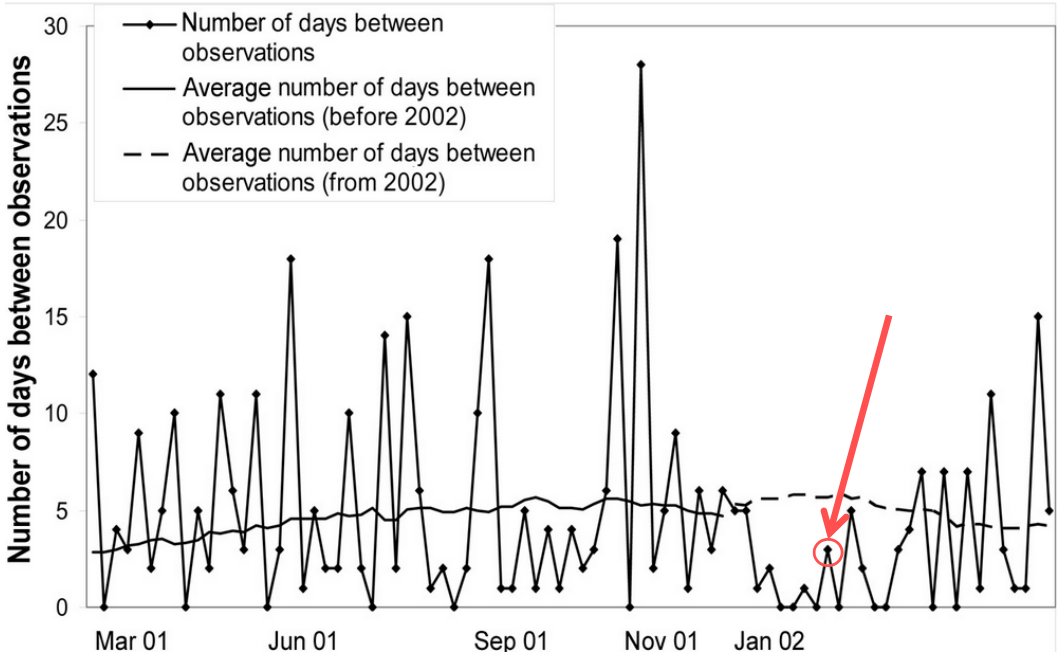
G-type Control Chart

January 11, 2002: Out of control signal

7th consecutive observation below the mean



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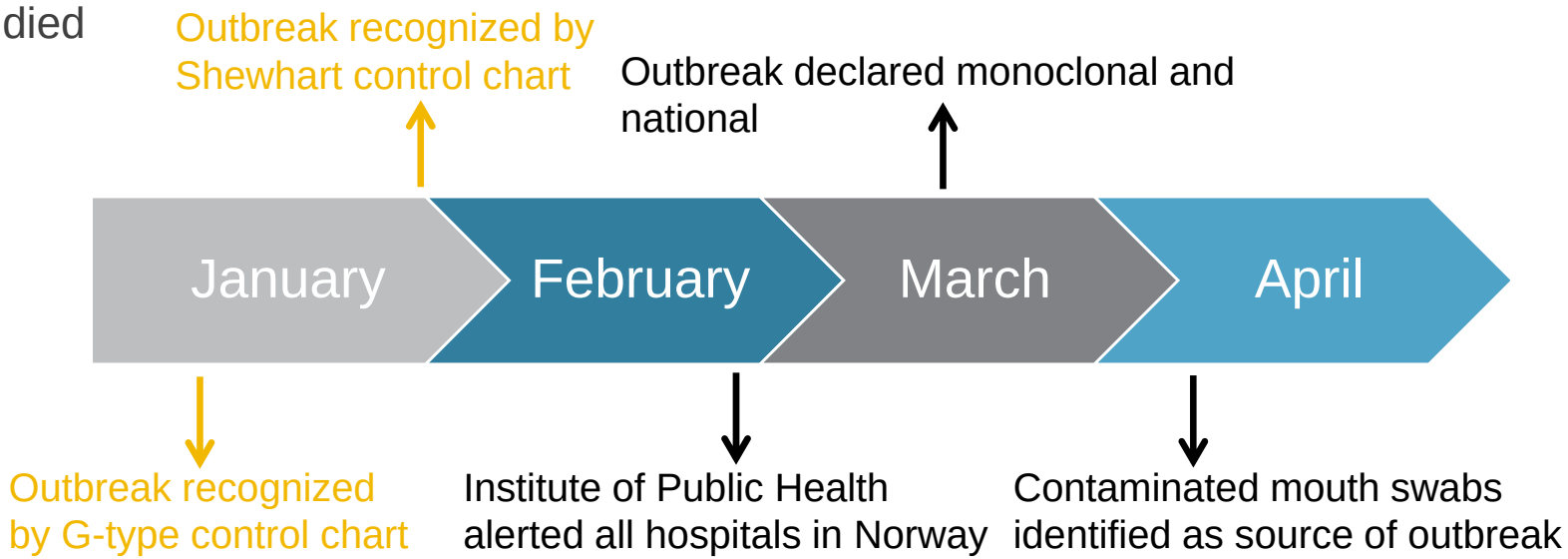

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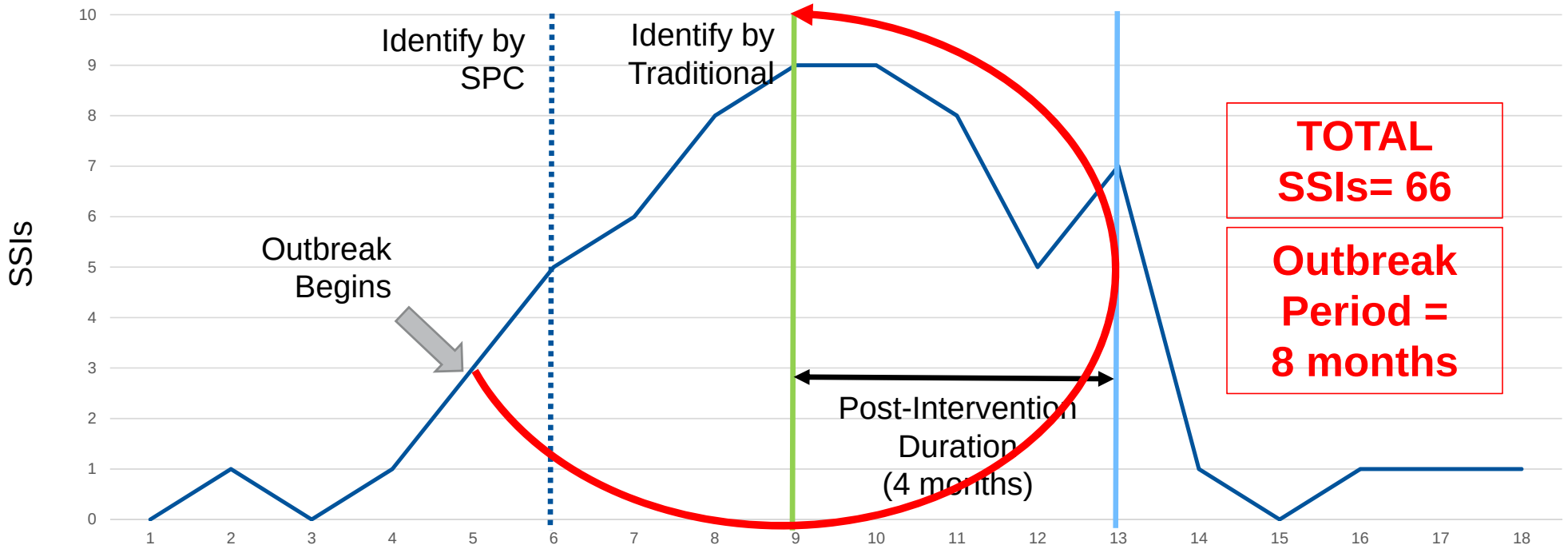
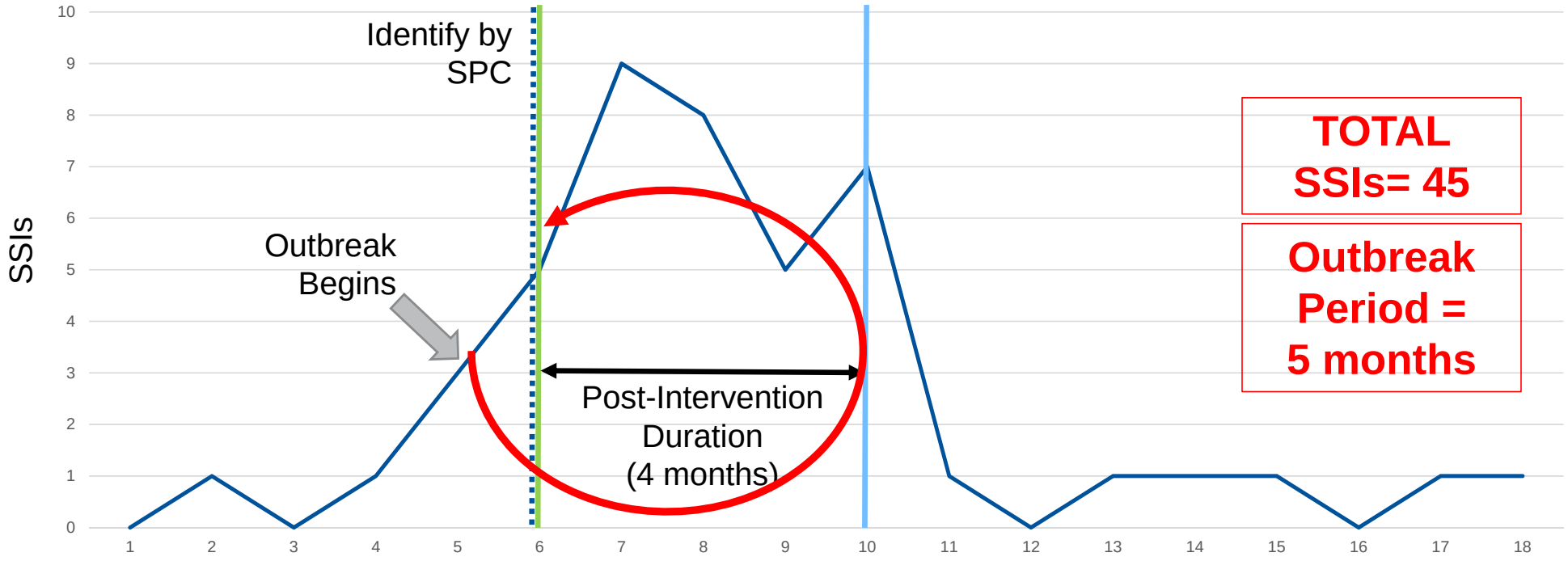
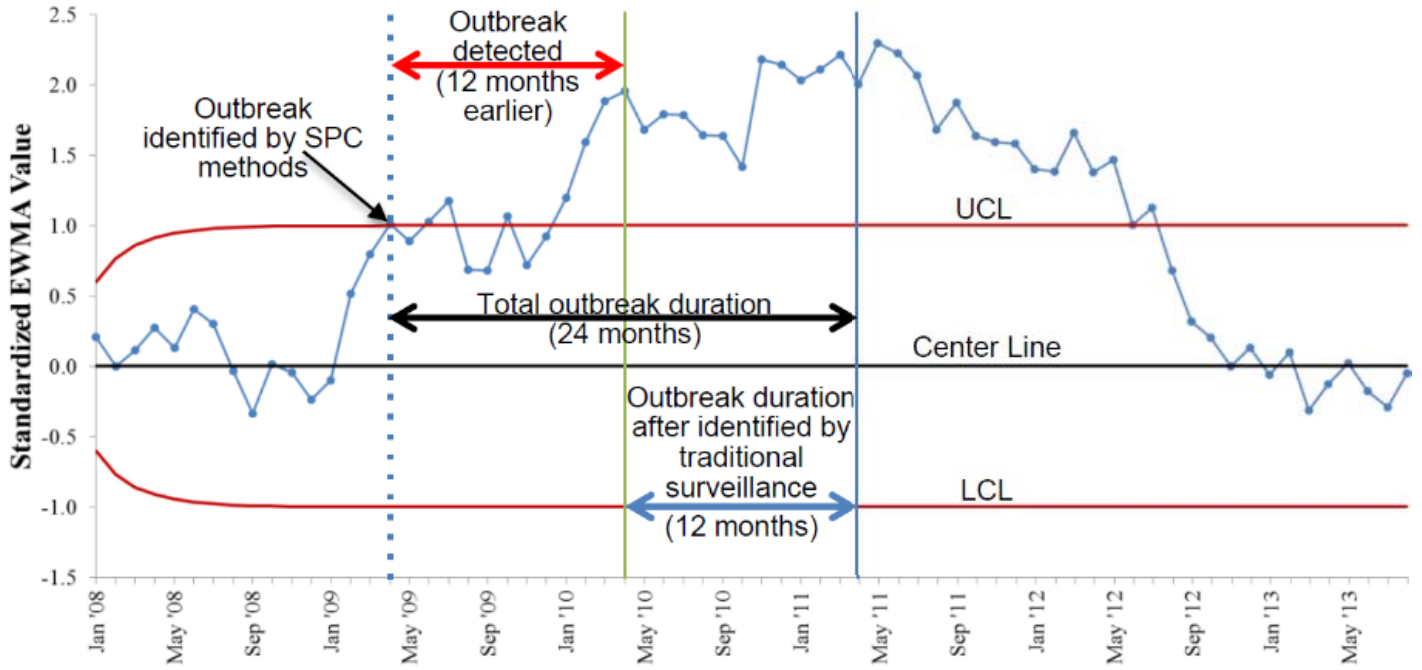
Outbreak Response



Use SPC Surveillance – Close the Loop



Applied to Real Data



Optimized SPC Methods

Goal: identify charts with high sensitivity and acceptable specificity

Retrospective review of 12 years of data from 49 hospitals

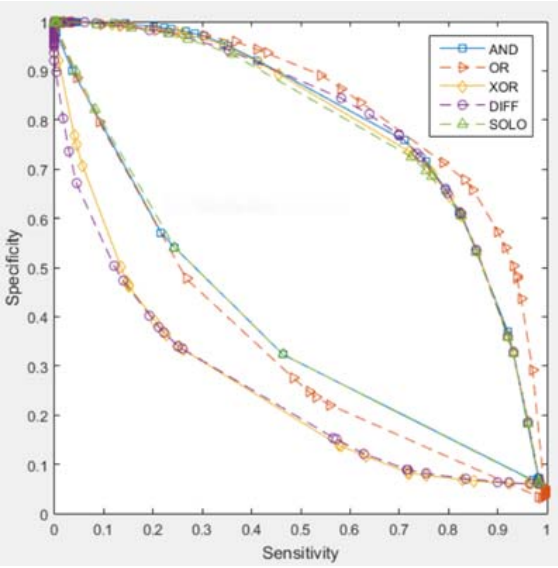
- >1.2 million procedures

Evaluated using 50 different SPC charts

- Weighted average, baseline window, lag, etc.
- 3,600 variations

Compared ability of SPC chart(s) to identify important increases in SSI compared to “gold standard” (review by epidemiologist)

- Reviewed 2,711 signals in derivation and validation phases



Final Optimized Approach

Combination of two charts – look for signal generated by EITHER ("OR") chart

Chart	DICON baseline	Window size	Window lag	Avg param	Control limits	Chart type	Sens	Spec
A	Yes	12	12	12	1	MA	0.90	0.57
B	No	3	6	0.4	1	MA		

In preliminary application to retrospective data, found 80% of "important increases" prior to standard surveillance

As of March 2017, we began a RCT with stepped-wedge design in 29 DICON hospitals

How Translate to SSI Elimination?

CLOSE THE LOOP

- Identify important increases earlier = Start improvement processes earlier = Decrease in SSI

Some technical challenges, but not many

- SPC alerts can be automated

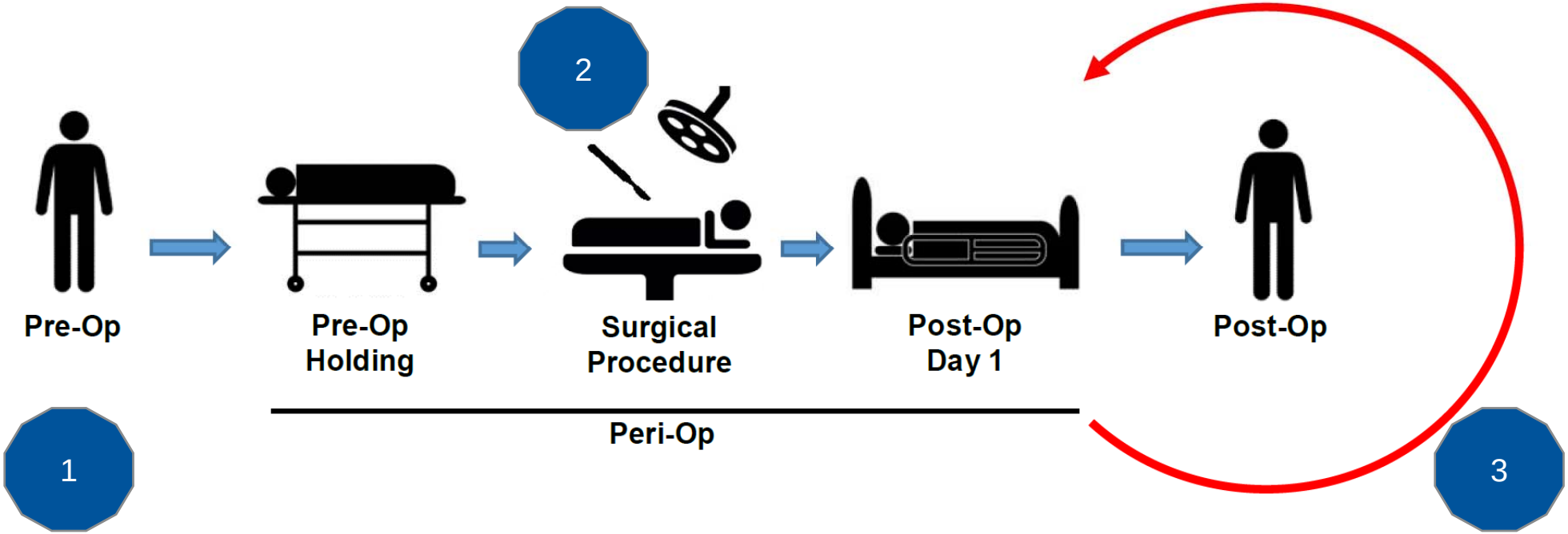
Uncertain of “acceptable” rate of false positive signals

- Time and effort required to investigate signals

Can be coupled with other strategies to improve detection and surveillance

- Coded data
- Clinical data

Take Home Points



Take Home Points

We may have plateaued with current approaches to SSI prevention

- Perhaps rates are improved, but still too common (and not ZERO)
- Need to pursue new ideas

I believe these three novel strategies are promising and worth pursuing

- I don't know if they will pan out
  - FAIL vs. superceded
- I don't know how long it will take for them to become widespread

Regardless, it will be an interesting ride!

QUESTIONS?

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