POLYPID
OPTIMIZED THERAPEUTICS

The Cost of Surgical Site Infections

PolyPid KOL Event

June 2022

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Agenda

01	**Introduction**
02	**The cost of SSI: a surgeon's view** – Dr. Kyle Cologne
03	**The cost of SSI: a hospital administration view** – Dr. Elliot Goodman
04	**Company updates**
05	**Q&A**

Surgical site infections have significant clinical and economic impact on patients and hospitals

SSI impact on patient outcomes…

7-11 days additional post-operative hospital days

2-11x increased risk of death (up to 40% mortality after deep sternal infection)

Delayed wound healing

Readmission

… has direct economic impact on hospitals

Cost of prevention and treatment of SSI

CMS penalties

Rankings and reputation

Link to 2020 KOL event on SSI impact on patient outcomes

Today’s speakers

Kyle Cologne, MD

Kyle Cologne, MD completed his general surgery training in Chicago at Rush University and Cook County Medical Centers, followed by a fellowship in Colon and Rectal Surgery at the University of Southern California, where he joined the faculty in 2012. He is the current fellowship director for the colorectal training program. Dr. Cologne is double board certified in general and colorectal surgery. He is the recipient of several awards including the Castle Connelly Pasadena and Los Angeles Top Doctor distinctions. He has performed more than 1,000 major colorectal procedures.

Dr. Cologne serves as the Vice Chair of the Quality Committee in the Department of Surgery and is the physician champion for colorectal surgical site infections and NSQIP. He serves as a section editor for the Diseases of the Colon and Rectum Journal where he is the host of a podcast and is the immediate past President of the Southern California Chapter of the American Society of Colon and Rectal Surgeons.

Dr. Cologne is a paid advisor for PolyPid

Today's speakers

Elliot Goodman, MD

Elliot Goodman, MD was born in London and educated at the University of Cambridge. After one year of postgraduate training in Cambridge and London, he moved to the United States in 1990 and trained as a general surgeon at Maimonides Medical Center in Brooklyn, New York . During this period of training, he spent two years as a research fellow at Columbia University.

After spending time as a trauma fellow at Coney Island Hospital in Brooklyn, Dr. Goodman joined the faculty of the New Jersey Medical School. After two-and-a-half years in New Jersey, Dr. Goodman moved to Montefiore Medical Center where he became Chief of Bariatric Surgery. After a successful four-and-a-half year tenure at Montefiore, Dr. Goodman was recruited by Beth Israel Medical Center to become their Chief of Bariatric Surgery in 2004. After engagements at the new Mount Sinai Beth Israel and Mount Sinai Brooklyn hospitals as Head of House Staff, Associate Chief of Surgery and Vice-Chair for Surgical Quality, he was appointed in January 2022 as Associate Director for Systems Quality and Performance in Surgery for the entire 8-hospital Mount Sinai Health System.

Dr. Goodman is on the faculty of the Icahn School of Medicine at Mount Sinai. He is a visiting professor at Ben-Gurion University, Bar Ilan University (both in Israel) and EDU (in Malta). He is the North American coordinator for the global surgical community of The Upper Gastro-intestinal Surgeons society (TUGS).

Dr. Goodman is a paid advisor for PolyPid

SURGICAL SITE INFECTIONS (SSIs): BY THE NUMBERS

KYLE G. COLOGNE, MD, FACS, FASCRS

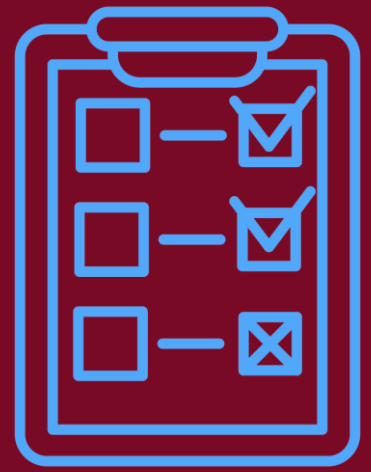
ASSOCIATE PROFESSOR OF SURGERY

VICE-CHAIR, SURGICAL QUALITY COMMITTEE

USC DIVISION OF COLORECTAL SURGERY

Learning Objectives

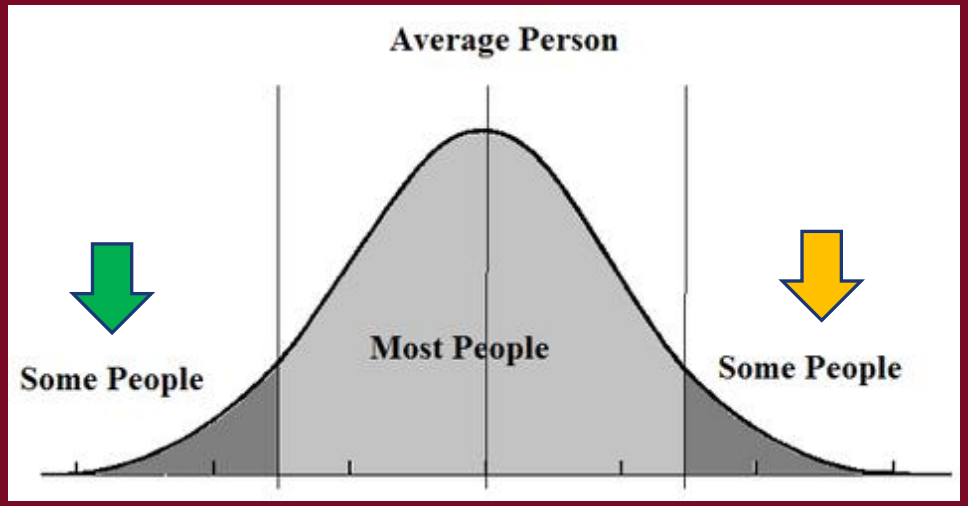
1. Understand the financial implications for SSI
2. Describe specific opportunities improvement in SSI



THE PROBLEM:

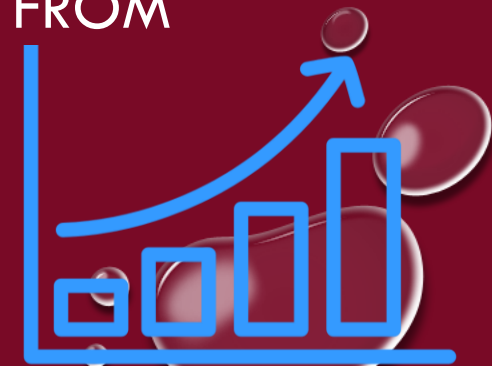
HOW BAD IS IT:

- OVERALL RATE SSI: **6-26%** (**LOW** AND **HIGH** OUTLIERS)



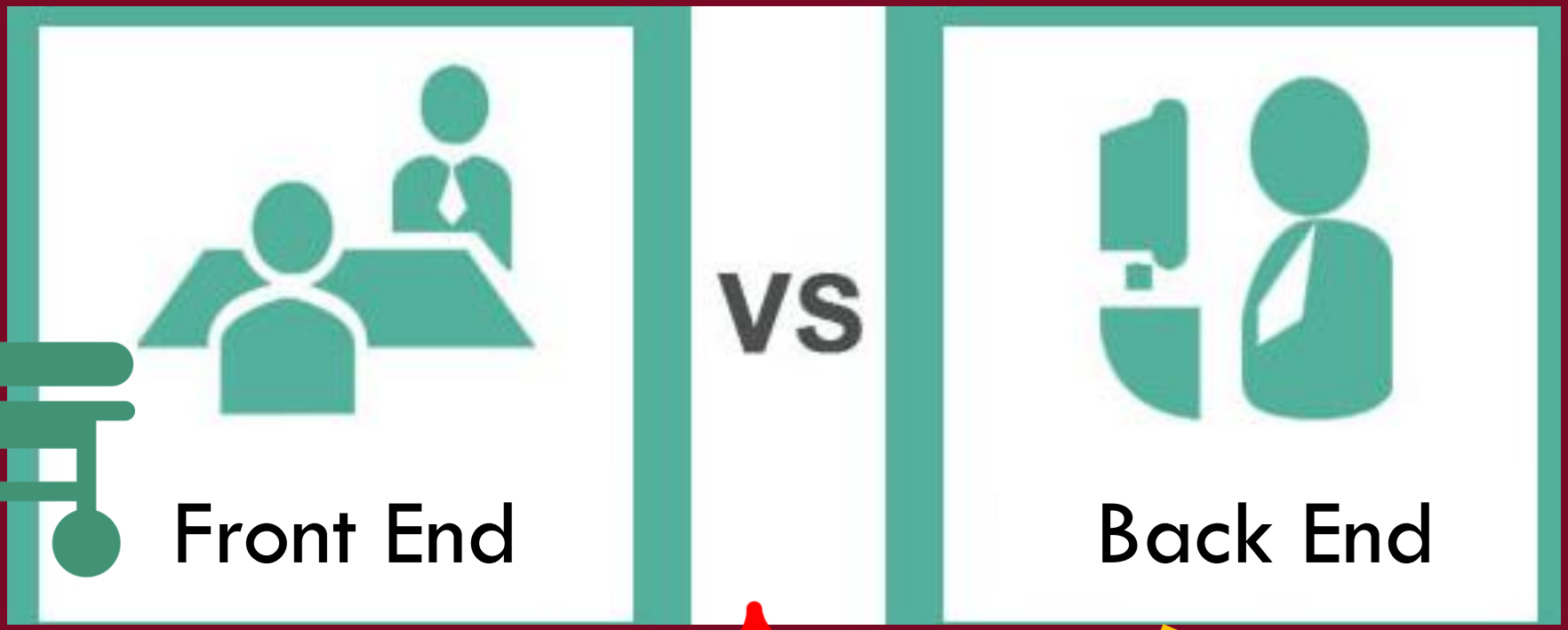
- **IT IS GETTING WORSE:**
- CALIFORNIA REPORTED A **6% INCREASE** IN COLON SURGERY SSI BETWEEN 2008 (NATIONAL BASELINE) AND 2014 AND AN **INCREASE OF 28%** FROM 2013 TO 2014

CDC'S ANNUAL *INFECTIONS PROGRESS REPORT* (HAI PROGRESS REPORT) (2014 HTTP://WWW.CDC.GOV/HAI/PDFS/PROGRESS-REPORT/HAI-PROGRESS-REPORT.PDF)

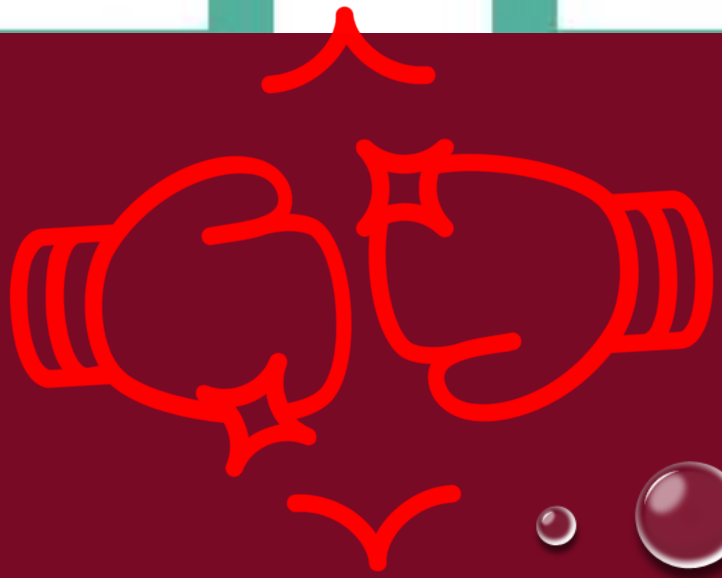


Morris SS. Ann Surg 2015
Ohman KA. J Am Coll Surg 2017
Lawson EH. JAMA 2013
Gorgun E. Dis Colon Rectum 2018

WHY IT MATTERS:



Costs more!



Reimburses Less!

WHY IT MATTERS: COSTS MORE

OVERALL: **$10 BILLION COST**

TO HEALTHCARE SYSTEM

Ban KA. J Am Coll Surg 2017
Leaper DJ. Dis Colon Rectum 2020

12-month estimated
increased cost of SSI:

$36,429-$144,809
Commercial Insurance

$17,551 - $102,280
Medicare

2 BIGGEST COST DRIVERS OF HEALTHCARE:

- **LENGTH OF STAY**
- **COMPLICATIONS**

with SSI

Keck Medical Center of USC

RESULTS:

- Reasons for prolonged (>10 day) LOS:

Factor	Odds Ratio	95% CI	p-value
American Society of Anesthesiology (ASA) score	2.152	1.245 to 3.721	0.019
Anastomotic leak	2.163	1.486 to 3.148	<0.001
Ileus	8.790	4.501 to 17.165	<0.001
Surgical site infection	**5.846**	2.764 to 12.362	**<0.001**
Cancer diagnosis	0.607	0.310 to 1.189	0.289
Transfusion required	1.193	0.889 to 1.601	<0.158

Cologne KG, Byers S, Rosen D, Hwang GS, Ortega AE, Ault GT, Lee SW. American Journal Surgery 2016

THE NUMBERS:

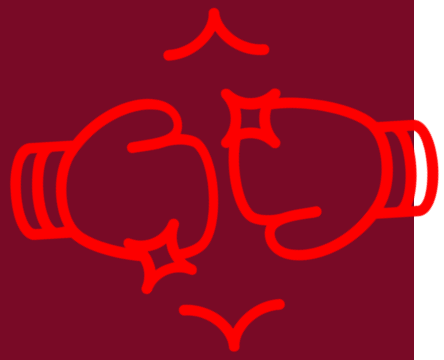
- **LOS (+$1,500 - $3,800 / DAY)**
- **COMPLICATIONS (+$ 19,000)**[1] → **(Profit Margin: $3,288**
  increased overall
  withOUT complications

vs. $755) [2]
WITH complications

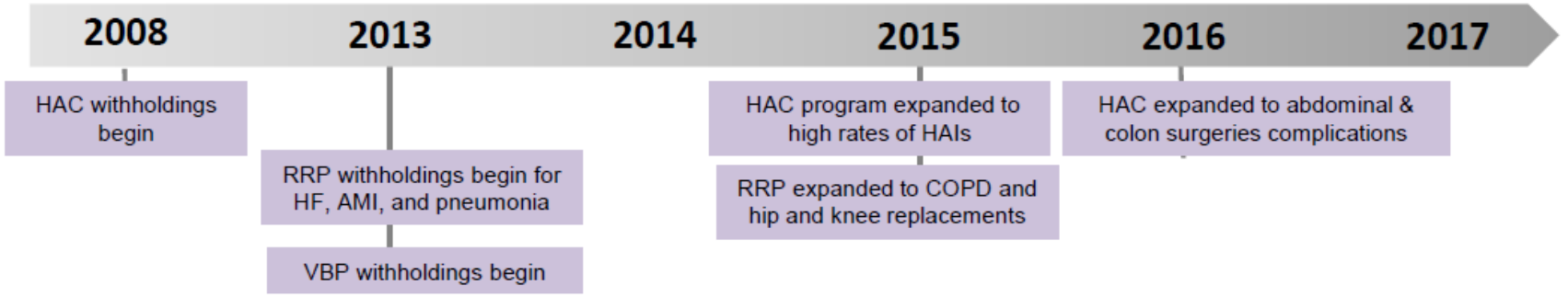
-$2,533

1) Healy MA. JAMA Surg 2016.
2) Dimick JB. J Am Coll Surg 2006.

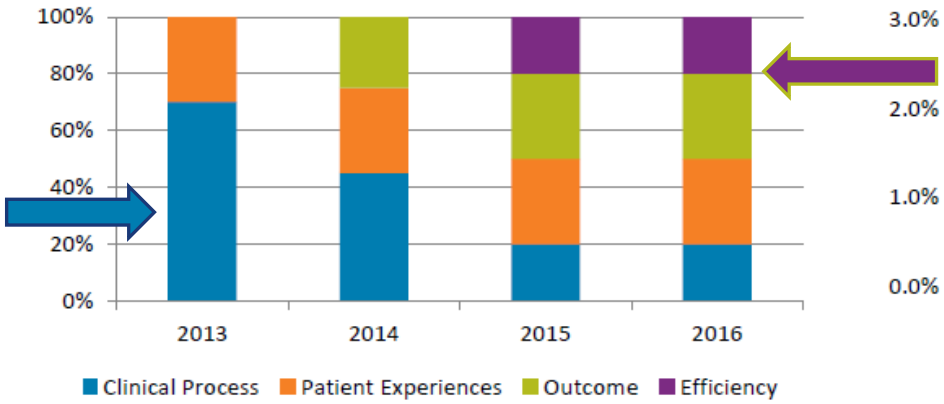
WHY IT MATTERS: REIMBURSES LESS



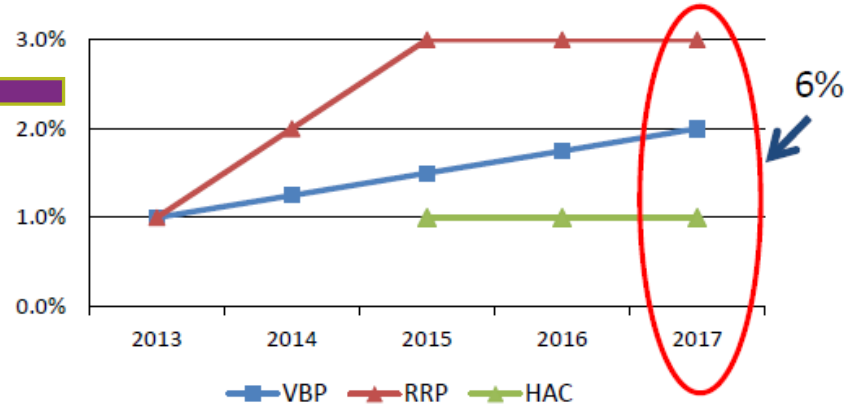
Increasing Financial Penalty for HAIs



VBP Domain Weights



Reimbursement Penalties



AMI = acute myocardial infarction; HAC = hospital-acquired condition; HF = heart failure; RRP = Readmission Reduction Program; VBP = Value-Based Purchasing Program.

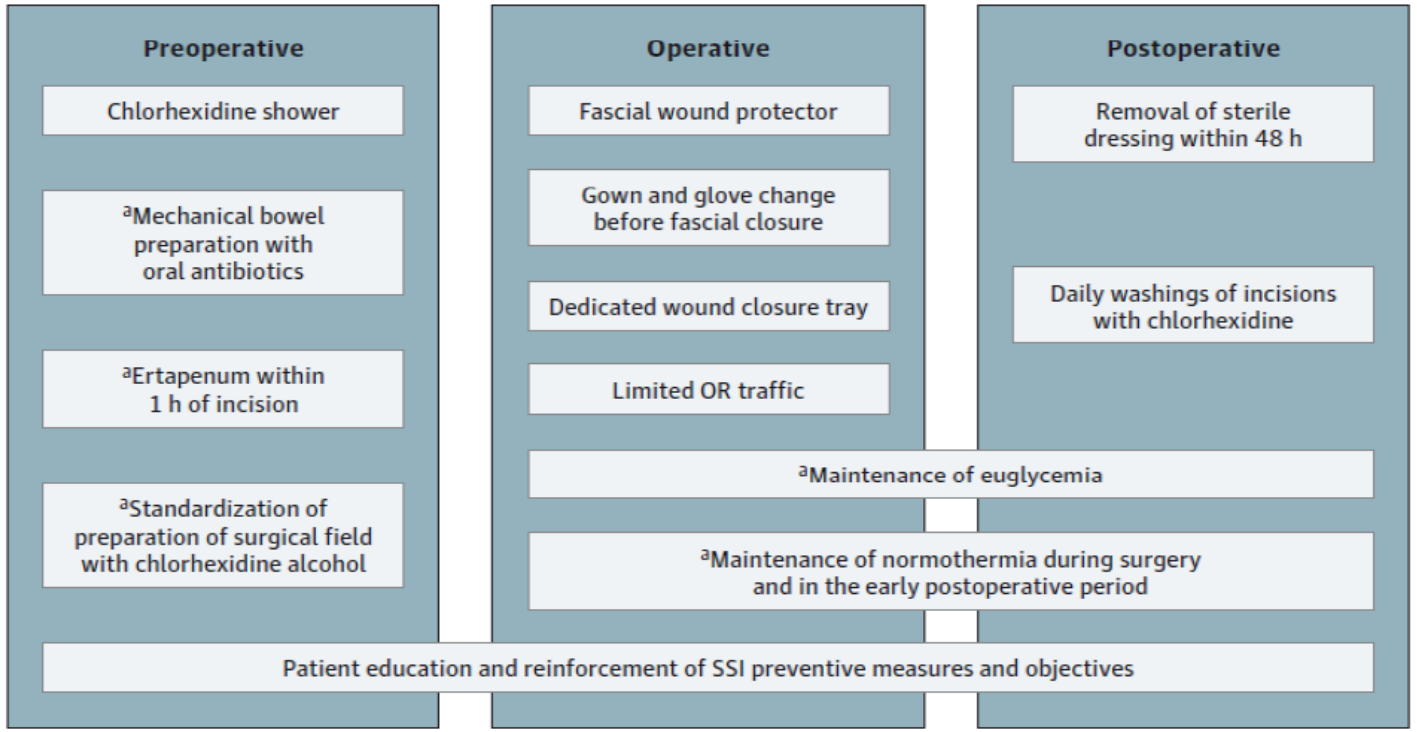
1. CMS. Hospital-Acquired Conditions. Available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html. Accessed July 21, 2014. 2. CMS. Hospital Value-Based Purchasing Program Fact Sheet. Available at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital_VBPurchasing_Fact_Sheet_ICN907664.pdf. Accessed August 4, 2014. 3. CMS. Readmissions Reduction Program. Available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html. Accessed August 4, 2014. 4. Arkansas Foundation for Medical Care, Quality Improvements Organization. Available at: http://qio.afmc.org/LinkClick.aspx?fileticket=8PsE9YwcHy0%3D. Accessed August 20, 2014.

SO WHAT ARE WE DOING ABOUT IT?

The Preventive Surgical Site Infection Bundle in Colorectal Surgery

An Effective Approach to Surgical Site Infection Reduction and Health Care Cost Savings

Figure 1. The Preventive Surgical Site Infection (SSI) Bundle in Colorectal Surgery



JAMA Surg. doi:10.1001/jamasurg.2014.3
Published online August 27, 2014.

Preop:

Mechanical + Oral bowel prep

CHG wipes + shower

Periop:

Skin prep

IV antibiotics

Wound protectors

Glove, sleeve, suction tip change

Postop:

Dressing removal after 48h

Observe for SSI

DOES IT WORK?

Monte-Carlo simulation of using **antimicrobial sutures** suggests *(based on RCTs showing RR for SSI of 0.61 [0.52-0.73])*:

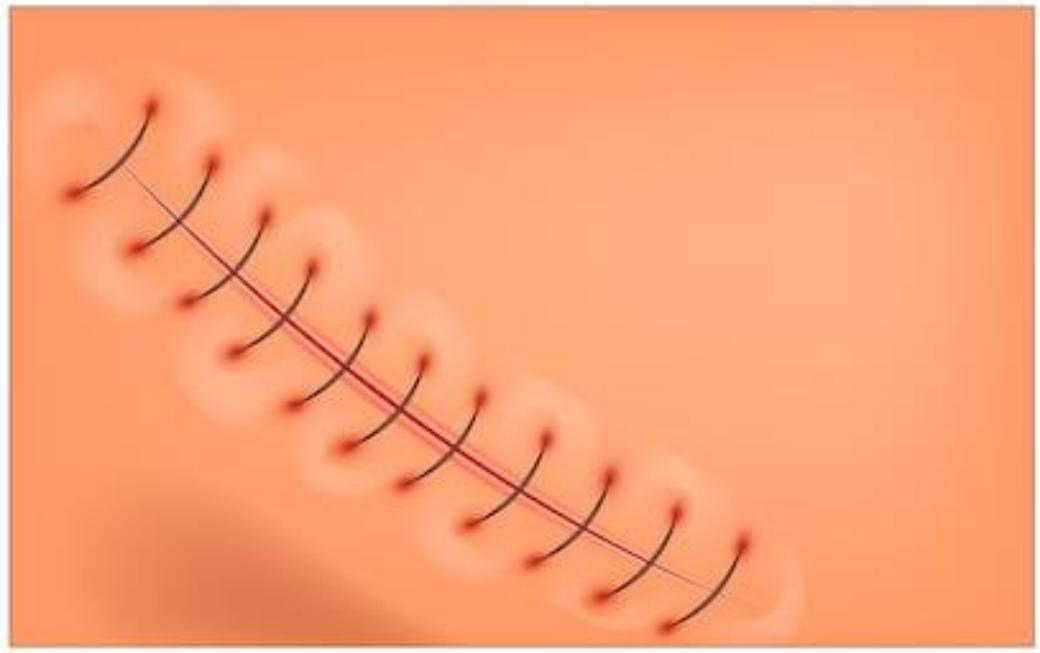
Cost Savings of **$809-1,170 / pt**

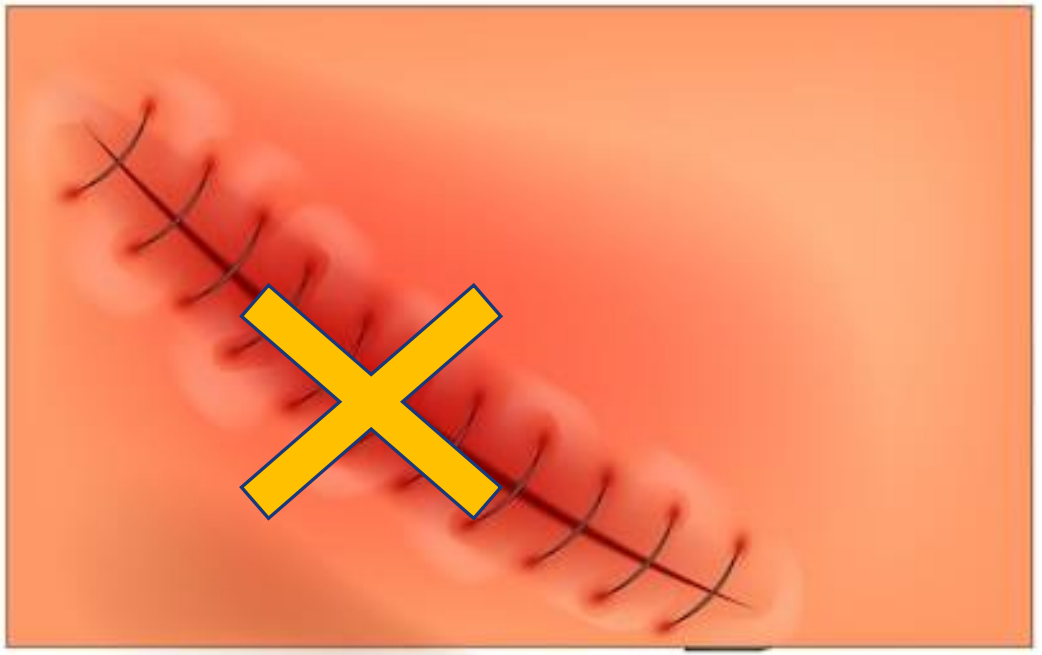
by avoiding SSI

DISEASES OF THE COLON & RECTUM

Leaper DJ. Dis Colon Rectum 2020

POTENTIAL FOR COST SAVINGS:





by avoiding SSI

$10 BILLION COST

TO HEALTHCARE SYSTEM

kyle.cologne@med.usc.edu

The economics of SSIs after colorectal surgery:

Elliot R Goodman MD,
Associate Director for Surgical Quality,
Mount Sinai Health System.

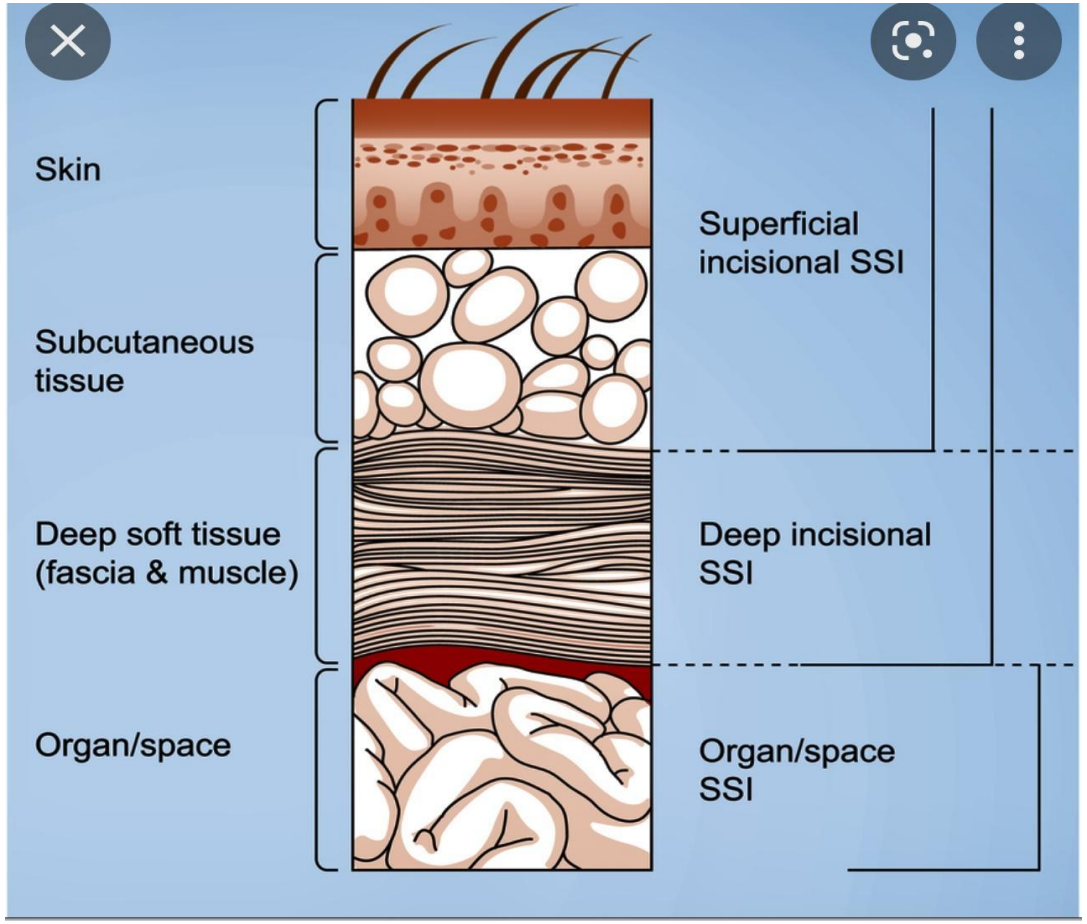
Mount Sinai

Few basic facts:

- 158,000 patients get SSIs after all surgical procedures in USA each year (ASCRS data, 2019).
- Total cost of treating these SSIs - $3.1B (approx. $20,000/patient)
- Approximately 300,000 colorectal procedures performed in USA each year (Leaper, 2020)
- Range of reported incidence of SSI after CRS - 9-41% (Leaper, 2020).
- SSI after colorectal surgery (CRS) increases total length of stay (LOS), ICU LOS, readmission rates and total cost of care (Leaper, 2020)

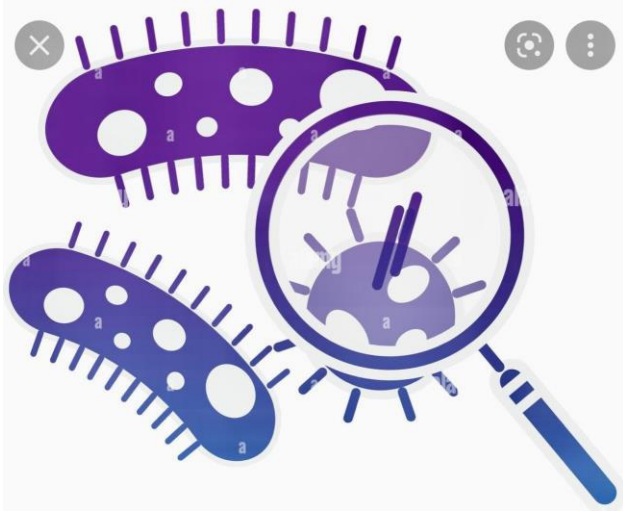
Definition of SSI in CRS (as per CDC and NHSN):

- Superficial incisional SSI
- Deep incisional SSI
- Organ/space SSI



Who monitors SSIs after CRS?

- Rate of SSI is a KPI of hospital surgical services
- Publicly available data
- May be tracked, reported and publicized by hospitals themselves, by State DoHs, payers inc. CMS, third-party watch dogs (e.g. Leapfrog, Healthgrades)



Who monitors SSIs after CRS?

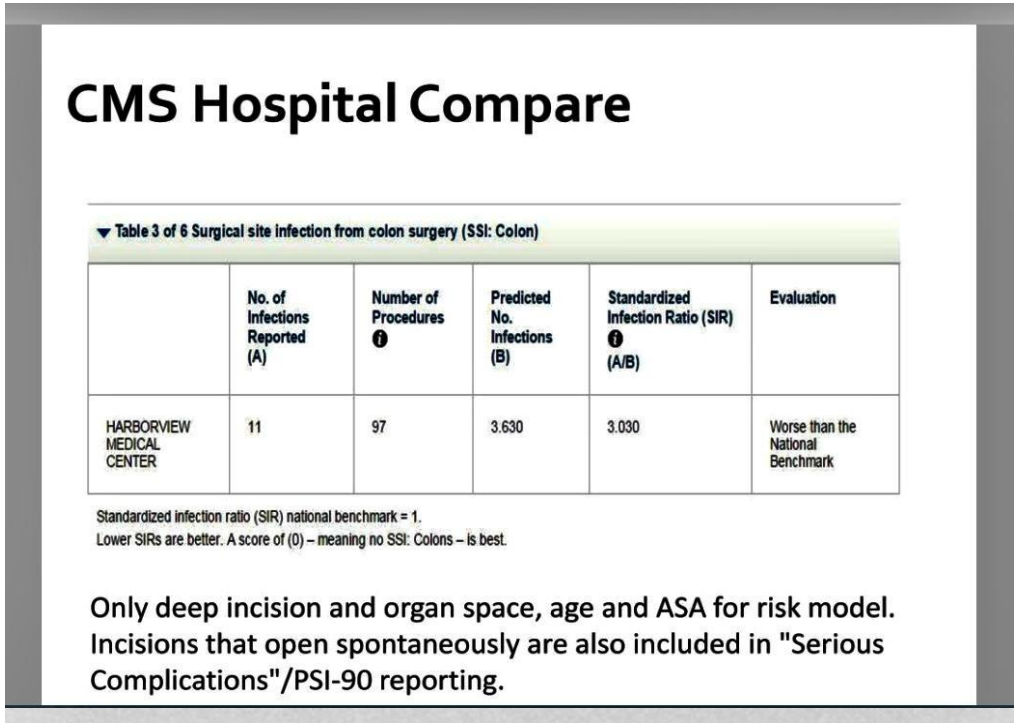
- Hospitals themselves for internal quality improvement - from ICD-10/DRG codes and billing data
- Govt agencies such as National Healthcare Safety Network [NHSN] and Agency for Healthcare Research and Quality [AHRQ] gather data from hospitals and report SSIs to CMS (may use data for VBP decisions)
- Third-party patient safety watch dogs such as Leapfrog and Healthgrades who grade hospitals using CMS data
- NSQIP - ACS program involving 700+ hospitals in USA and overseas

Leapfrog/Hospital Safety Score

Includes deep incisional and organ space SSI - developed by ACS-CDC group

Who monitors SSIs after CRS?

- NHSN and AHRQ data - not risk adjusted, only report in-patient SSIs (missing 50% of SSIs diagnosed post-discharge) and do not include superficial incisional SSIs
- NSQIP - risk adjusted for patient acuity/comorbidities, includes in- and out-patient diagnoses of SSI but data capture is labor intensive and misses 60-80% of all surgical cases



CMS Hospital Compare

Table 3 of 6 Surgical site infection from colon surgery (SSI: Colon)

	No. of Infections Reported (A)	Number of Procedures	Predicted No. Infections (B)	Standardized Infection Ratio (SIR) (A/B)	Evaluation
HARBORVIEW MEDICAL CENTER	11	97	3.630	3.030	Worse than the National Benchmark

Standardized infection ratio (SIR) national benchmark = 1.
Lower SIRs are better. A score of (0) – meaning no SSI: Colons – is best.

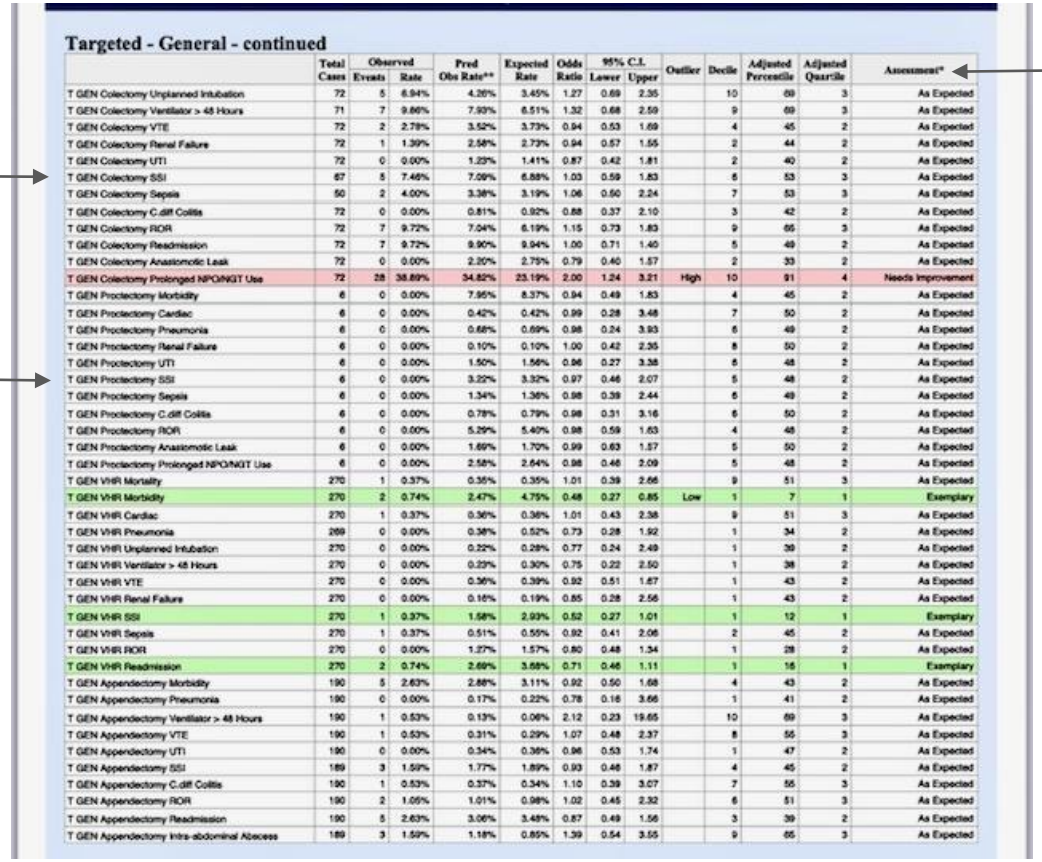
Only deep incision and organ space, age and ASA for risk model. Incisions that open spontaneously are also included in "Serious Complications"/PSI-90 reporting.

CMS data accrued by NHSN

Who monitors SSIs after CRS?

Colectomy SSI

Proctectomy SSI



Targeted - General - continued

	Total Cases	Observed Events	Observed Rate	Pred Obs Rate**	Expected Rate	Odds Ratio	95% C.I. Lower	95% C.I. Upper	Outlier	Decile	Adjusted Percentile	Adjusted Quartile	Assessment*
T GEN Colectomy Unplanned Intubation	72	5	6.94%	4.26%	3.45%	1.27	0.69	2.35		10	69	3	As Expected
T GEN Colectomy Ventilator > 48 Hours	71	7	9.86%	7.93%	6.51%	1.32	0.68	2.59		9	69	3	As Expected
T GEN Colectomy VTE	72	2	2.78%	3.52%	3.73%	0.94	0.53	1.69		4	45	2	As Expected
T GEN Colectomy Renal Failure	72	1	1.39%	2.58%	2.73%	0.94	0.57	1.55		2	44	2	As Expected
T GEN Colectomy UTI	72	0	0.00%	1.23%	1.41%	0.87	0.42	1.81		2	40	2	As Expected
T GEN Colectomy SSI	67	5	7.46%	7.09%	6.88%	1.03	0.59	1.83		6	53	3	As Expected
T GEN Colectomy Sepsis	50	2	4.00%	3.38%	3.19%	1.06	0.50	2.24		7	53	3	As Expected
T GEN Colectomy C.diff Colitis	72	0	0.00%	0.81%	0.92%	0.88	0.37	2.10		3	42	2	As Expected
T GEN Colectomy ROR	72	7	9.72%	7.04%	6.19%	1.15	0.73	1.83		9	66	3	As Expected
T GEN Colectomy Readmission	72	7	9.72%	9.90%	9.94%	1.00	0.71	1.40		5	49	2	As Expected
T GEN Colectomy Anastomotic Leak	72	0	0.00%	2.20%	2.75%	0.79	0.40	1.57		2	33	2	As Expected
T GEN Colectomy Prolonged NPO/NGT Use	72	28	38.89%	34.82%	23.19%	2.00	1.24	3.21	High	10	91	4	Needs Improvement
T GEN Proctectomy Morbidity	6	0	0.00%	7.95%	8.37%	0.94	0.49	1.83		4	45	2	As Expected
T GEN Proctectomy Cardiac	6	0	0.00%	0.42%	0.42%	0.99	0.28	3.48		7	50	2	As Expected
T GEN Proctectomy Pneumonia	6	0	0.00%	0.68%	0.69%	0.98	0.24	3.93		6	49	2	As Expected
T GEN Proctectomy Renal Failure	6	0	0.00%	0.10%	0.10%	1.00	0.42	2.35		8	50	2	As Expected
T GEN Proctectomy UTI	6	0	0.00%	1.50%	1.56%	0.96	0.27	3.38		6	48	2	As Expected
T GEN Proctectomy SSI	6	0	0.00%	3.22%	3.32%	0.97	0.46	2.07		5	48	2	As Expected
T GEN Proctectomy Sepsis	6	0	0.00%	1.34%	1.36%	0.98	0.39	2.44		6	49	2	As Expected
T GEN Proctectomy C.diff Colitis	6	0	0.00%	0.78%	0.79%	0.98	0.31	3.16		6	50	2	As Expected
T GEN Proctectomy ROR	6	0	0.00%	5.29%	5.40%	0.98	0.59	1.63		4	46	2	As Expected
T GEN Proctectomy Anastomotic Leak	6	0	0.00%	1.69%	1.70%	0.99	0.63	1.57		5	50	2	As Expected
T GEN Proctectomy Prolonged NPO/NGT Use	6	0	0.00%	2.58%	2.64%	0.98	0.46	2.09		5	48	2	As Expected
T GEN VHR Mortality	270	1	0.37%	0.35%	0.35%	1.01	0.39	2.66		9	51	3	As Expected
T GEN VHR Morbidity	270	2	0.74%	2.47%	4.75%	0.48	0.27	0.85	Low	1	7	1	Exemplary
T GEN VHR Cardiac	270	1	0.37%	0.36%	0.36%	1.01	0.43	2.38		9	51	3	As Expected
T GEN VHR Pneumonia	269	0	0.00%	0.38%	0.52%	0.73	0.28	1.92		1	34	2	As Expected
T GEN VHR Unplanned Intubation	270	0	0.00%	0.22%	0.28%	0.77	0.24	2.49		1	39	2	As Expected
T GEN VHR Ventilator > 48 Hours	270	0	0.00%	0.23%	0.30%	0.75	0.22	2.50		1	38	2	As Expected
T GEN VHR VTE	270	0	0.00%	0.36%	0.39%	0.92	0.51	1.67		1	43	2	As Expected
T GEN VHR Renal Failure	270	0	0.00%	0.16%	0.19%	0.85	0.28	2.56		1	43	2	As Expected
T GEN VHR SSI	270	1	0.37%	1.58%	2.93%	0.52	0.27	1.01		1	12	1	Exemplary
T GEN VHR Sepsis	270	1	0.37%	0.51%	0.55%	0.92	0.41	2.06		2	45	2	As Expected
T GEN VHR ROR	270	0	0.00%	1.27%	1.57%	0.80	0.48	1.34		1	28	2	As Expected
T GEN VHR Readmission	270	2	0.74%	2.69%	3.58%	0.71	0.46	1.11		1	16	1	Exemplary
T GEN Appendectomy Morbidity	190	5	2.63%	2.88%	3.11%	0.92	0.50	1.68		4	43	2	As Expected
T GEN Appendectomy Pneumonia	190	0	0.00%	0.17%	0.22%	0.78	0.16	3.66		1	41	2	As Expected
T GEN Appendectomy Ventilator > 48 Hours	190	1	0.53%	0.13%	0.06%	2.12	0.23	19.65		10	69	3	As Expected
T GEN Appendectomy VTE	190	1	0.53%	0.31%	0.29%	1.07	0.48	2.37		8	55	3	As Expected
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T GEN Appendectomy SSI	189	3	1.59%	1.77%	1.89%	0.93	0.46	1.87		4	45	2	As Expected
T GEN Appendectomy C.diff Colitis	190	1	0.53%	0.37%	0.34%	1.10	0.39	3.07		7	55	3	As Expected
T GEN Appendectomy ROR	190	2	1.05%	1.01%	0.98%	1.02	0.45	2.32		6	51	3	As Expected
T GEN Appendectomy Readmission	190	5	2.63%	3.06%	3.48%	0.87	0.49	1.56		3	39	2	As Expected
T GEN Appendectomy Intra-abdominal Abscess	189	3	1.59%	1.18%	0.85%	1.39	0.54	3.55		9	66	3	As Expected

Assessment:
needs improvement, as expected, exemplary

ACS NSQIP
semi-annual report 2020

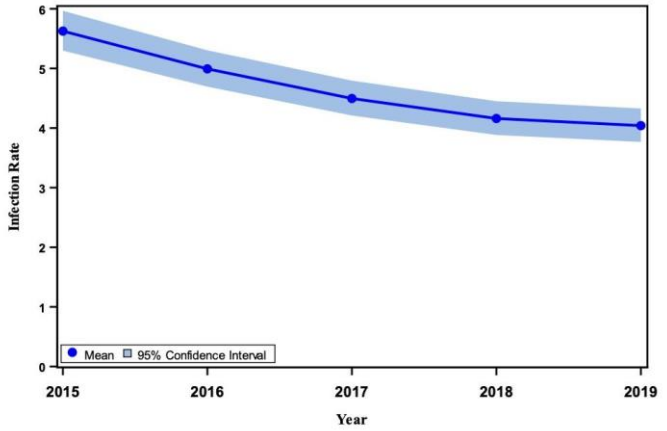
Who monitors SSIs after CRS? NYS Department of Health [DoH] HAI surveillance program (since 2007):

Table 2. Method of detection of colon surgical site infection by depth of infection, New York State 2019

Extent (Row%) (Column%)	When Detected				
	Initial Hospitalization	Readmitted to the Same Hospital	Readmitted to Another Hospital	Post-Discharge Surveillance Not Readmitted	Total
Superficial Incisional	165 (44.5%) (37.4%)	106 (28.6%) (35.3%)	7 (1.9%) (20.0%)	93 (25.1%) (93.0%)	371 (42.4%)
Deep Incisional	25 (52.1%) (5.7%)	19 (39.6%) (6.3%)	2 (4.2%) (5.7%)	2 (4.2%) (2.0%)	48 (5.5%)
Organ/Space	251 (54.9%) (56.9%)	175 (38.3%) (58.3%)	26 (5.7%) (74.3%)	5 (1.1%) (5.0%)	457 (52.2%)
Total	441 (50.0%)	300 (34.2%)	35 (4.0%)	100 (11.4%)	876

New York State data reported as of December 8, 2020. Excludes infections present at time of surgery.

Figure 1. Trend in colon surgical site infection rates, New York State 2015-2019
Excluding infections present at time of surgery or detected in outpatient settings without readmission



Data obtained directly [by mandate] from hospitals and indirectly from Federal sources (NHSN/CDC)

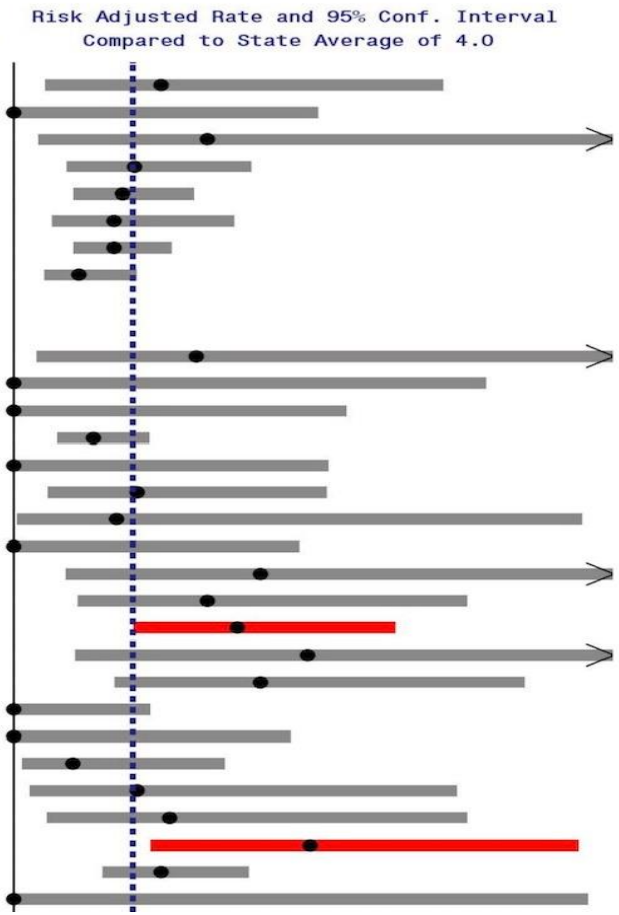
2019 NYS DoH data

NYS DoH HAI surveillance program:

2019 data

Figure 2. Colon surgical site infection rates, New York 2019 (page 3 of 4)

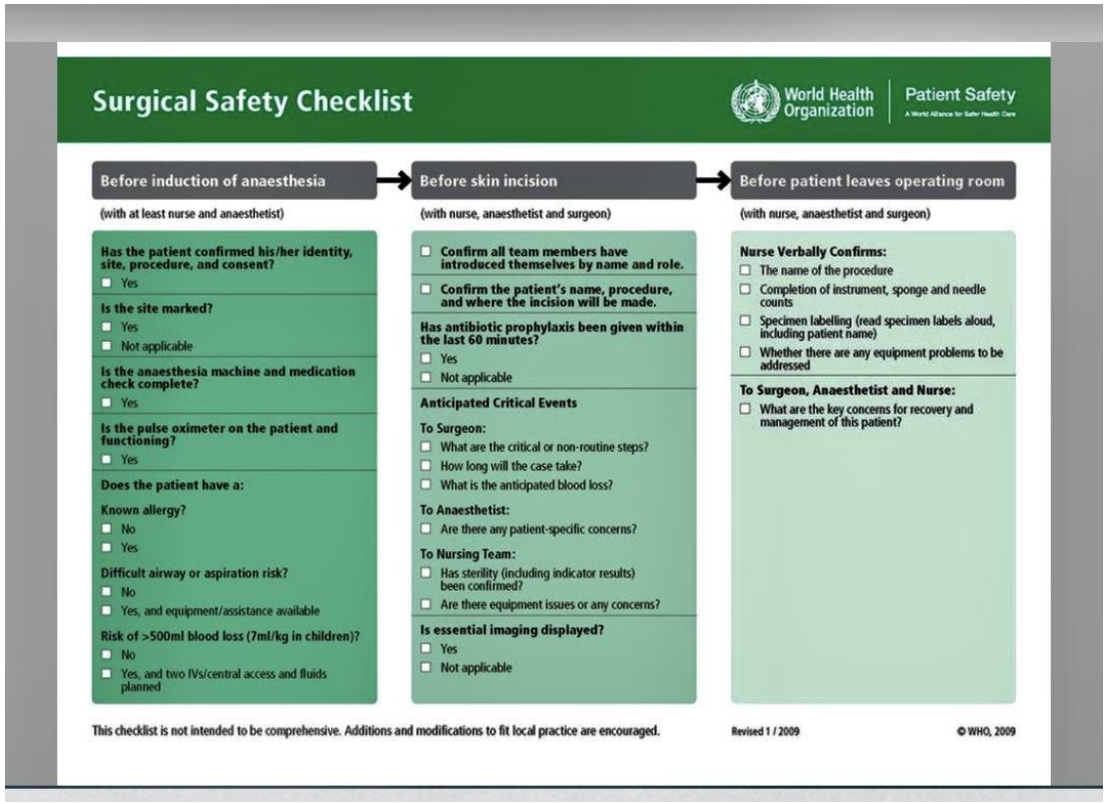
Hospital	# SSI	#PATOS excl.	#PDS excl.	# Procs	Raw Rate	Adj Rate
NYP-Lawrence	3	0	0	63	4.8	5.0
NYP-Lower Manhattan	0	0	0	35	0.0	0.0
NYP-Morgan Stanley	2	0	0	30	6.7	6.6
NYP-Queens	8	6	0	197	4.1	4.1
NYP-Weill Cornell	14	6	0	440	3.2	3.7
NYU Langone Brooklyn	6	3	0	158	3.8	3.4
NYU Tisch	18	5	2	536	3.4	3.4
NYU Winthrop	9	9	0	366	2.5	2.2
Nassau University	NA	NA	NA	NA	NA	NA
Nathan Littauer	NA	NA	NA	NA	NA	NA
Newark Wayne	2	1	0	37	5.4	6.2
Niagara Falls	0	0	0	22	0.0	0.0
North Central Bronx	0	0	0	22	0.0	0.0
North Shore	13	16	0	454	2.9	2.7
Northern Dutchess	0	2	0	27	0.0	0.0
Northern Westchester	4	3	0	123	3.3	4.2
Noyes Memorial	1	0	0	23	4.3	3.5
Oishei Childrens	0	0	0	31	0.0	0.0
Olean General	3	0	1	34	8.8	8.4
Oneida Healthcare	5	4	1	95	5.3	6.6
Orange Regional^	13	2	0	178	7.3	7.6
Oswego Hospital	3	1	2	29	10.3	10.0
Our Lady of Lourdes	7	2	1	103	6.8	8.4
Peconic Bay Medical	0	2	0	58	0.0	0.0
Phelps Memorial	0	0	0	41	0.0	0.0
Plainview Hospital	2	0	0	98	2.0	2.0
Putnam Hospital	2	0	0	63	3.2	4.2
Queens Hospital	3	0	1	49	6.1	5.3
Richmond Univ MC^	9	1	2	91	9.9	10.1
Rochester General	18	4	1	395	4.6	5.0
Rome Memorial	0	0	0	21	0.0	0.0



What have we done to reduce risk of CRS SSIs?

- CMS Surgical care improvement program (SCIP, 2002) - single perioperative checklist designed by CMS to align surgical quality to reimbursement
- Evidence-based surgical care bundles (antibiotics, skin prep, maintenance of normothermia and good glycemic control)
- Perioperative surgical checklists (first developed by WHO)
- These measures have reduced SSI rates by 40-55% in various meta-analyses (Turner and Migaly, 2019)
- Cost of admission reduced from mean of $32,000/pt to $22,000/pt (50% SSIs diagnosed pre-discharge)

What have we done to reduce risk of CRS SSIs?



Surgical Safety Checklist

World Health Organization | Patient Safety

Before induction of anaesthesia (with at least nurse and anaesthetist)

- **Has the patient confirmed his/her identity, site, procedure, and consent?**
  - ☐ Yes
- **Is the site marked?**
  - ☐ Yes
  - ☐ Not applicable
- **Is the anaesthesia machine and medication check complete?**
  - ☐ Yes
- **Is the pulse oximeter on the patient and functioning?**
  - ☐ Yes
- **Does the patient have a:**

  Known allergy?
  - ☐ No
  - ☐ Yes

  Difficult airway or aspiration risk?
  - ☐ No
  - ☐ Yes, and equipment/assistance available

  Risk of >500ml blood loss (7ml/kg in children)?
  - ☐ No
  - ☐ Yes, and two IVs/central access and fluids planned

Before skin incision (with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**
- **Has antibiotic prophylaxis been given within the last 60 minutes?**
  - ☐ Yes
  - ☐ Not applicable
- **Anticipated Critical Events**

  To Surgeon:
  - ☐ What are the critical or non-routine steps?
  - ☐ How long will the case take?
  - ☐ What is the anticipated blood loss?

  To Anaesthetist:
  - ☐ Are there any patient-specific concerns?

  To Nursing Team:
  - ☐ Has sterility (including indicator results) been confirmed?
  - ☐ Are there equipment issues or any concerns?
- **Is essential imaging displayed?**
  - ☐ Yes
  - ☐ Not applicable

Before patient leaves operating room (with nurse, anaesthetist and surgeon)

- **Nurse Verbally Confirms:**
  - ☐ The name of the procedure
  - ☐ Completion of instrument, sponge and needle counts
  - ☐ Specimen labelling (read specimen labels aloud, including patient name)
  - ☐ Whether there are any equipment problems to be addressed
- **To Surgeon, Anaesthetist and Nurse:**
  - ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009 © WHO, 2009

Checklist and Complications

	Before n=3773	After n=3955
•SSI	6.2%	3.4%
•Unplan Return-O.R.	2.4%	1.8%
•Any Complic	11.0%	7.0%
•Death	1.5%	0.8%

Haynes. NEJM 2009; 360: 491-9

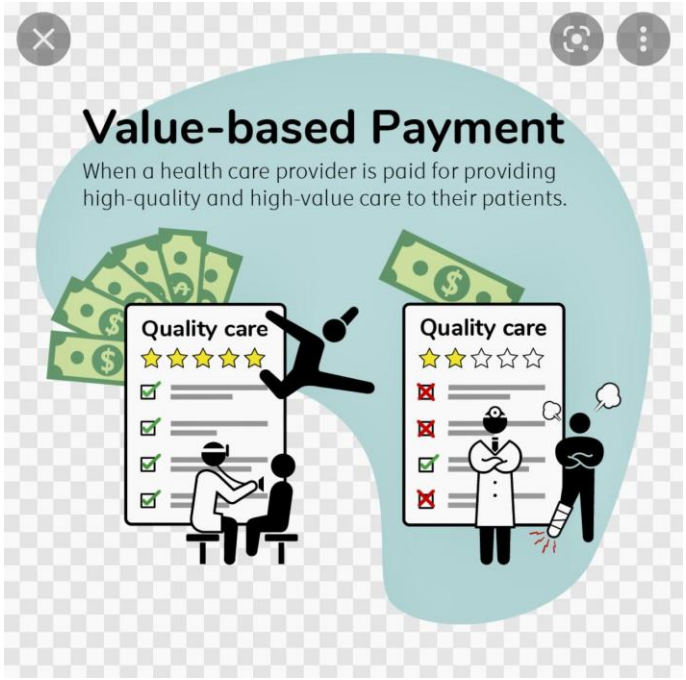
The economic cost of SSI after CRS:

- Leaper 2020 study: retrospective observational cohort analysis of 108,000 patients undergoing CRS in USA 2014-2018
- Followed patients for 24 months after surgery
- 4% incidence of superficial incisional SSI
- 20% incidence of deep incisional or organ space SSI
- SSI added $36-144,000/pt to cost of care for commercial payer cases and $18-102,000/pt for Medicare cases
- Cost depended on severity of SSI
- Extra cost of care due to SSI seen over full 24 months of study

The economic cost of SSI after CRS:

- Leaper study: large, long-duration (24 months) longitudinal study
- Better assessment of incidence and cost of SSI after CRS than previous smaller and shorter-duration studies which probably underestimated both incidence and economic cost of SSI (7-10%, $12-42,000/pt)
- Caveats: data capture of Leaper study not perfect and some differences in cost data due to recent increases in overall cost of healthcare

The economic cost of SSI after CRS - value based purchasing (VBP):



The economic cost of SSI after CRS - value based purchasing:

- Payers such as CMS now use KPIs such as rate of SSIs and other hospital-acquired infections (HAIs) to make VBP decisions
- CMS can reduce payment by up to 6% if best practice guidelines are not met e.g. hospital is in lowest quartile for HAIs
- Loss of reimbursement can be incentive to improve quality of care by reducing HAI rates

Conclusions:

- SSI after CRS is common and causes significant postoperative morbidity
- SSI adds greatly to the cost and length of care and can reduce payer reimbursement to hospitals
- Rates of SSI after CRS are reportable events and can become publicly available data points
- Hospital reputations can be damaged when SSI rates are higher than the benchmark range
- Anything we can do to reduce SSI after CRS will have significant clinical, economic and reputational benefits for hospitals and surgeons alike
- Hospital c-suites are acutely aware of clinical, economic and reputational implications of SSIs and hold providers and clinical managers accountable for their occurrence

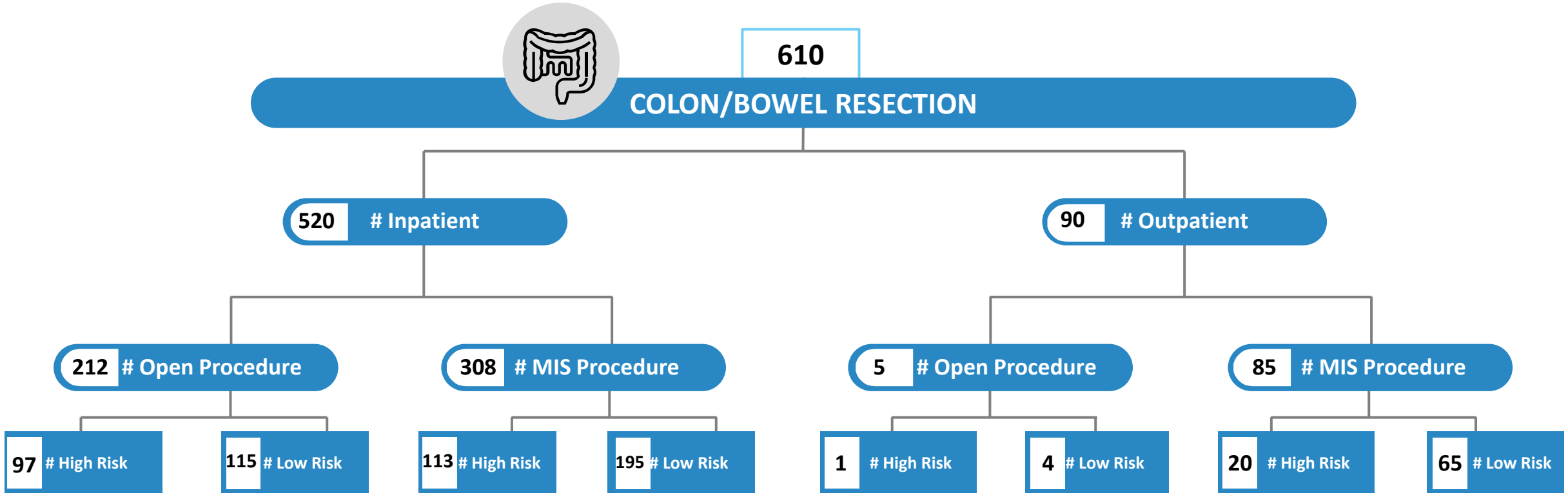
References:

- **Leaper, D. et al (2020): *Assessment of the Risk and Economic Burden of Surgical Site Infection Following Colorectal Surgery Using a US Longitudinal Database: Is There a Role for Innovative Antimicrobial Wound Closure Technology to Reduce the Risk of Infection?* Diseases of the Colon & Rectum: 63;1628-1638**
- **ASCRS Guidelines (2019): *Reducing Surgical Site Infection: Where Do I Look?* https://fascrs.org/my-ascrs/news/quality-assessment-and-safety-committee-initiative/special-edition-from-the-qas-committee-reducing-su**
- **Hospital-Acquired Infections in New York State, 2019 Part 2: Technical Report https://www.health.ny.gov/statistics/facilities/hospital/hospital_acquired_infections/2019/docs/hospital_acquired_infection_p2.pdf**
- **Turner, M. and Migaly, J. (2019): *Surgical Site Infection: The Clinical and Economic Impact* Clin Colon Rectal Surg 32;157-165.**

Company updates

Recent market research suggest that 40% of all in-patient colorectal resection procedures are performed on high-risk patients

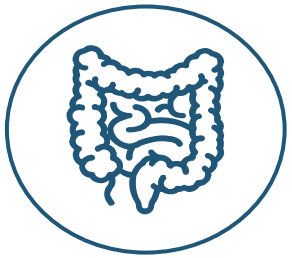
Number of patients split by type of surgery and patient risk



Source: MarketVision market research, June 2022

Recent and upcoming milestones

- Data Safety Monitoring Board recently **recommended concluding study at 950 patients**, the minimum number of patients targeted
- **Last-patient-in** was announced on May 31
- A total of 977 patients enrolled in the trial - the largest trial in colorectal surgery infection prevention in over a decade



- **Topline Results** expected by the end of Q3 2022

- Potential **NDA submission** targeted for H1 2023

Q&A