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Preventing Surgical Site Infections and Colorectal Surgery: Creating an Interdisciplinary Culture of Safety and Excellence

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Abstract: *Background*: Surgical site infections (SSI) are an undesirable surgical complication that leads to negative patient and system outcomes. SSI risk correlates with various intrinsic (patient) and extrinsic (system) factors. Colorectal surgeries are especially susceptible. In 2013, the incidence of postoperative colorectal SSI rates was noted to be elevated at our institution with respect to national benchmarks. We developed and implemented an evidence based Colorectal Bundle (CRB) as our targeted intervention to reduce SSI. *Methods*: A multidisciplinary team was formed to develop and implement a CRB. The bundle was created using interventions established in the literature while also accounting for institutional biases. After a period of implementation, data was then analyzed using baseline and post implementation statistics. Additionally, infection rates were compared to national expected incidences using two national programs, the NSQIP and NHSN. Bundle compliance was encouraged over time to achieve sustained results. *Results*: We performed a total of 519 colorectal surgeries over a span of two and a half years and limited our infection rate to only 12 cases (2.3%). This was a significant reduction in SSI rates (RR 0.28, $p < 0.001$) and according to NSQIP, placed our system in the top decile with respect to SSI incidence. *Conclusions*: Implementation of our CRB resulted in a sustained decrease in SSI rates with respect to colorectal surgeries. We hope this manuscript can serve as a recipe for change. We highlight steps that were crucial to the success of our CRB from inception onward. We believe these key elements include the presence of a surgical champion, multi departmental buy-in, and continued compliance leading to a culture of excellence.

Keywords: Surgical Site Infection, Colorectal Surgery, Bundled Care, Culture, Surgical Champion, Compliance

1. Introduction

Surgical site infections (SSIs) are one of the leading causes of Health Care Associated Infections (HCAIs) and the most common HCAI within surgical patients [1]. The incidence of SSIs for most procedures is estimated in the range of 2% [2]. There are many risk factors that have been identified that increase SSI risks including comorbidities, surgical techniques, and operation urgency [3]. However, even with comparable risk factors present, colorectal surgeries have shown to have much higher rates of SSIs and have rates spanning as high as 15-30% [4].

The downstream effects of these infections are many. For the patient, SSIs cause increased morbidity in the form of hospital readmissions, repeat procedures, and increased hospital length of stays [3-5]. Problems with wound healing may lead to wound dehiscence and later hernia development. Additionally, they have been shown to cause an associated increased in mortality by 3%[3], with 75% of these deaths directly related to the SSI [6].

From a hospital standpoint, the cost of a single SSI has been estimated to range from $9,000 to $20,000 [6, 7]. These added costs accumulate to a substantial burden on the medical system which can be extrapolated to total $1.6 billion of additional inpatient costs and nearly 1 million excess hospital days [3]. Also, of note, the rate of SSIs has been an important

metric for measuring and comparing quality of care between institutions. Third party payers may use these types of metrics for reimbursement. These surrogates for quality also factor into hospital ranking scores.

In 2013, a combination of internal review as well as national ranking scores indicated that our hospital, Cleveland Clinic Akron General (CCAG) was underperforming compared to the national average with regards to the incidence of SSI after colorectal surgery. To combat this finding, we developed an intervention in the form of a bundle of care elements for patients undergoing colorectal surgery. The idea of bundled care has been demonstrated to improve surgical outcomes. Bundled care was first introduced by the Institute for Healthcare Improvement in 2001 to improve clinical outcomes in critical care populations [8]. They defined a bundle as the implementation of three or more evidence-based elements. Soon after, in 2003, the groundwork was laid for what would then become the Surgical Care Improvement Project (SCIP) whose goal was to reduce surgical complications [6, 7]. The work by Dellinger et. al in 2005 is noted to be one of the first large scale attempts at decreasing surgical site infections. They cited "poorly designed delivery systems" as the root cause for poor quality care [9]. This set the groundwork for many others to develop bundled delivery systems to deliver better quality care to their patients. Many bundles have been developed implementing varying types of interventions at various levels of evidence. None have been powered enough to isolate the effect of individual elements. However, the experience from bundled care is that compliance to the bundle as a whole, rather than individual elements, correlates to improved outcomes [8]. One meta-analysis estimated the use of SSI bundles may reduce the risk of SSIs in CRS by 40% [6].

The success of bundled care in improving outcomes has continued to expand in recent years, now targeting a larger breadth of patient centered outcomes with goals to "reduce perioperative stress, maintain postoperative physiologic function, and accelerate recover after surgery". These bundles are now maintained under the umbrella of the Enhanced Recovery after Surgery (ERAS) Society and target many surgical subspecialties, including colorectal surgery. The most recent iteration of an ERAS bundle for colorectal surgery was released in 2018 [10]. Similar to the bundle we created, ERAS protocols span all areas and levels of patient care and include infection prevention as a portion of its overall goals. The roll out of our bundle was done prior to instituting an ERAS program and gave us a head start on the challenges that would be expected with large scale changes.

AGMC Preventative Colorectal SSI Bundle Recommendations:

PRE-OP:

- ☐ Educate patient (office and in PST) regarding SSI preventative measures and objectives (Handout/Brochure available in Periop Director's Office)
- ☐ Standardized outpatient mechanical bowel prep w/PO ATB's (orders from surgeon)
- ☐ Shower within 12 hrs pre-op with chlorhexidine (will be provided in PST)
- ☐ Patient to have abdominal chlorhexidine wipe applied in Pre-surgery
- ☐ Antibiotics on patient chart before going to OR
- ☐ Pre-surgery pre-warming for thirty min pre-op (warm blankets/thermal cap)
- ☐ ALL colorectal patients get baseline FBS. If BS > 180, glucose management per anesthesia (Cardiac Surgery Glucose Management Guidelines as needed)

ANESTHESIA:

- ☐ IV ATB's given within 1 hour prior to incision (No re-dosing / weight adjustments)
  Ertapenem (Invanz) 1 gram - if not PCN allergic
  (Cipro 400mg + Flagyl 500mg if PCN allergic)
- ☐ Maintain active normo-thermia ***at all times > 36-38 temp*** using IV fluid warmers/table warmer / Bair hugger(s) / wrapping head as needed.
- ☐ Pre-warm room for induction / prep until patient fully draped / warmers applied
- ☐ Maintain euglycemia. Recheck BS every 2 hours diabetics and patients with pre-op BS > 180
- ☐ Administer FiO_2 80% (increased oxygenation)

OPERATING ROOM:

- ☐ Limit OR traffic - Velcro bands across main door after patient entry
- ☐ No foaming - all surgical team members "traditional" hand scrub
- ☐ Members of OR team re-education ("credentialed") for colon surgery
- ☐ Thorough and complete ChloraPrep as per directions. If stoma or perineal prep, add non-alcohol prep to these areas
- ☐ OR Team changes gown and gloves before fascial closure
- ☐ Dedicated wound closure tray / instrumentation - No change in scrub personnel from colon anastomosis until wound closed
- ☐ Use of dual ring fascial wound protector (now available)
- ☐ Post-op time-out to include team review of wound class (now posted in OR)

PACU:

- ☐ Maintain normothermia >36-38 temp. May remove thermal cap when warm.
- ☐ Diabetic patients and those with pre-op BS > 180 get FBS in PACU
- ☐ All diabetics - goal is to keep glucose < 180 glucose management per surgery (Cardiac Surgery Glucose Management Guidelines as needed)
- ☐ Supplemental oxygenation for 2 hours post-op via face mask 10l/min then wean to nasal cannula prior to transfer to floor

POST-OP FLOOR: Admit to 52A only

- ☐ Maintain normothermia; keep temp >36-38 temp x 24hrs
- ☐ Diabetic patients: every 6 hours BS monitoring to keep BS < 180
- ☐ Supplemental oxygen / pulse oximetry as needed
- ☐ Original dressing maintained for 48 hrs
- ☐ Starting on post-op day 2, daily chlorhexidine wipes of incision
- ☐ Reinforce patient and family education about SSI preventative measures

Figure 1. *Colorectal Bundle (CRB).*

2. Methods

The data used to analyze our intervention was sampled from a data set which was continuously maintained via retrospective chart review. Our infection control department diligently compiled information from surgical cases including patient demographics and clinical details in order to analyze outcome data. This chart review and documentation was in part guided by direction from the National Healthcare Safety Network (NHSN) and the National Surgical Quality Improvement Program (NSQIP). Respectively, these organizations are a national infection tracking system developed by the Center for Disease Control (CDC) and a surgical outcome tracker developed by the American College of Surgeons. They both offer a structured and standard approach to this data collection to then allow for comparisons of incidence across the nation in both raw and risk adjusted formats. Thusly, SSI incidence was monitored through this structured process of retrospective chart review. Data collection relied on a combination of documented exam findings, laboratory data, culture data, imaging data, and narrative from the clinical course to identify SSI. These infections were then further categorized based on definitions by the CDC and NHSN [11]. Briefly, the CDC subdivides infections into superficial, deep, organ space. These events were evaluated over the denominator of all surgical large bowel procedures performed at our institution as identified by then ICD-9 and subsequently ICD-10 codes. In addition to all planned operations, our data set included emergency and trauma cases as well those from patients with any ASA status.

The time span evaluated extended from 2013 through the second quarter of 2017. Bundle implantation occurred during the last quarter of 2014. Most of the recorded cases were performed by general surgeons; there were not any fellowship trained colorectal surgeons practicing at CCAG during the time frame of this project. A small number of the cases in our data set were performed by additional specialties such as Gynecology and Urology.

The intervention measured is a Colorectal Bundle (CRB) developed for the use in all colorectal surgeries. The bundle was developed with multi-departmental input incorporating evidence-based practices, as well as institutional practice elements that may not have supporting or refuting literature. The entirety of the CRB was accepted between multiple departments. The individual elements of our CRB are listed in Figure 1. This manuscript is not designed to defend or even provide the levels of evidence of any specific elements contained in the bundle.

The design of our study is to evaluate the efficacy of that intervention as a whole. The practices prior to implementation of our CRB were independent to each practicing surgeon. We did not measure how similar prior practices were pre and post and as we did not expect to have the power to evaluate those individual differences. The compliance of the individual elements were tracked internally, but will not be reported within this manuscript.

Data comparison of post-bundle implementation statistics versus baseline data was done with a chi-squared test. A p value of 0.05 was used for a level of significance. Additionally, the incidence was compared to the number of events that would be predicted to occur given a standard population. This value is set according to baseline data from the NHSN. By using demographic data which is presented within Table 1, the NHSN calculates an expected infection rate. The ratio between the incidence and number of events predicted calculates the Standard Infection Ratio (SIR). A SIR of 1 then would indicate a rate that is in line with the number of expected infections. A SIR greater than 1 would indicate a greater number of infections than expected, and a value below 1 indicates fewer infections than expected. The SIR is a powerful way to quickly evaluate a surgical departments outcomes with respect to infection rates. Using an expected distribution, the SIR is then able to stratify performers against each other. This helps to compare between institutions as well as follow rates over time. We similarly applied our data to the NSQIP database for national comparison of risk adjusted outcomes.

Table 1. *Comparison of Demographic Data.*

Variable		Pre-Bundle (n = 311)	Post-Bundle (n = 519)	p - value
Age (years)		65 (22)	62 (20)	0.030*
Male		126 (40.5%)	239 (46.1%)	0.12
ASA				0.981
1		1 (0.3%)	4 (0.8%)	
2		85 (27.3%)	158 (30.4%)	
3		183 (58.8%)	263 (50.7%)	
4		38 (12.2%)	87 (16.8%)	
5		4 (1.3%)	7 (1.3%)	
BMI		27.3 (9.9)	28.5 (9.3)	0.161
DM		23 (17.6%)˚	96 (18.5%)	0.804
Emergency		86 (27.7%)	159 (30.6%)	0.362
Trauma		14 (4.5%)	20 (3.9%)	0.648
Wound Class				<0.001*
C	0 (0.0%)		0 (0.0%)	
CC	235 (75.6%)		259 (49.9%)	
CO	26 (8.4%)		101 (19.5%)	
D	50 (16.1%)		159 (30.6%)	

Continuous data reported as median (interquartile range); percentages for categorical data do no reflect missing values; *statistical significance; ˚ n = 131 (data set incomplete); SSI: surgical site infection; ASA: American Society of Anesthesiology score; BMI: body mass index; DM: diabetes mellitus; C: clean; CC: clean contaminated; CO: contaminated; D: dirty

Table 2. *Comparison of SSI rates before and after implementation of the CRB bundle.*

	Pre-Bundle (n = 311)	Post-Bundle (n = 519)	p - value
Number of Reportable SSIs	25 (8.0%)	12 (2.3%)	p < 0.001*

* statistical significance; SSI: surgical site infection

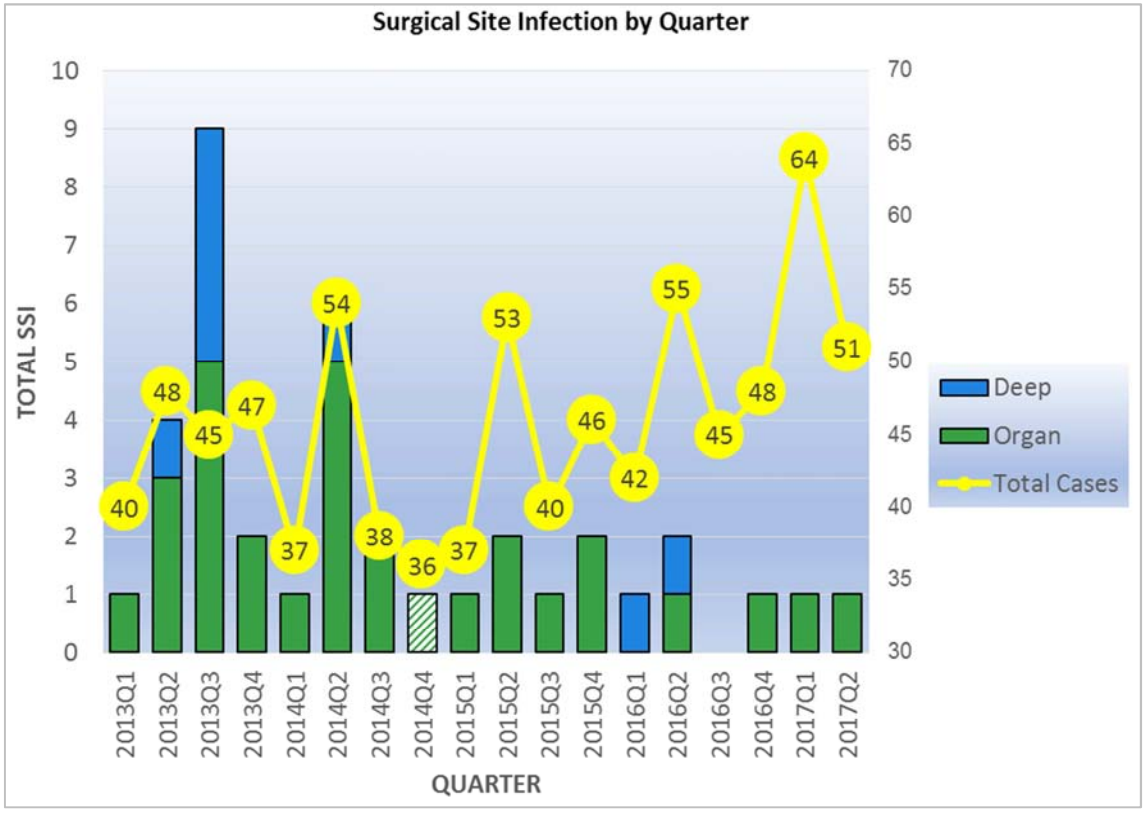

Figure 2. *SSIs per quarter and total colorectal surgery cases. First quarter of CRB implementation in 2014Q4 noted by diagonal fill.*

3. Results

In the time frame evaluated before bundle implementation, 311 colorectal surgeries were performed out of which there were a total of 25 SSI reported (8%). After our intervention, we performed a total of 519 colorectal surgeries and limited our infection rate to only 12 cases (2.3%) (Table 2). The groups compared were similar (Table 1). There was a statistical difference noted with a pre-implementation group that was slightly older (65 vs 62 p = 0.03) and a post-implementation group that had a higher level of wound class (p = <0.001).

We attribute the significantly reduced SSI rates (RR 0.28, p < 0.001) to the colorectal bundle and the efforts of all of the departments involved in its implementation. The changes seen were demonstrated over time, as noted in Figure 2, with 10 quarters of data measured post-implementation. With respect to nationally accepted standards, the surgical site infection rate while using our colorectal bundle was in the top 10th percentile for multiple quarters as reported by NSQIP.

4. Discussion

The efficacy of bundled care has been well supported. There are many manuscripts describing how to develop bundled interventions within one's own system [12]. With respect to colorectal surgery, many bundles exist in the literature, all with subtle differences. Individual elements are continually being analyzed in order to better design bundles [13, 14]. And many manuscripts will offer their own bundle as a formula for successful implentation [15]. However, any bundle's subsequent success is reliant not only on specific bundle elements, but a systems overall adherence to the bundle as a whole. Therefore, equal resources must be allocated to both creation and implementation of the bundle [16]. Rather than belabor the efficacy of bundled care, which has been well demonstrated, we hope to focus this discussion on the following implementation elements that we believe were crucial to our bundle's success.

1) A Surgical Champion [17]
   a) There must be a tangible force to stand for and drive progress. In our case, the catalyst for change was the chairman of the surgical department. Having a surgeon take the lead in a quality team has been shown in the literature to improve outcomes [17]. The quality world refers to this person as the Surgical Champion (SC).
   b) The burdens of the SC are two-fold. Both duties embody the definition of the word "champion" in its verbal and nominal form [18].
      i) Champion (verb): support the cause of; defend. The champion must stand as a beacon and as a symbol of reform. They must proselytize others to gain support and momentum of change. Being an advocate for quality created the impetus for improvement.
      ii) Champion (noun): a person who has defeated or surpassed all rivals in a competition. They must steadfast in their objectives, understanding that

change will undoubtedly meet resistance. Steadfastness translated to consistency in a vision from the point of creation through implementation and maintenance. "Rivals" existed in multiple forms, including those resistant to change, but also time itself, contributing to both educational lapses as well as fatigue or apathy. Keeping deligence to the cause over time was crucial in sustaining results.

2) Obtaining Multi-Departmental Buy In [19]
   a) Our SC championed for quality improvement in full awareness that it would necessitate institutional changes and inevitable resistance. Other departments were brought in early in the bundle development. Engagement of other departments allowed for contributions from different perspectives and for the ability to account for current practices and beliefs. The contributions from other departments fueled this collaborative culture and multi-departmental "buy in". Adding additional groups bolstered energy and momentum to the process. By using a consensus approach, an engaged, collaborative group formed to create the final colorectal bundle. Just as our bundled elements spanned silos of care, we involved members of all specialties and all levels of care, from pre-surgical nurses to surgical floor nurses and every caregiver in between.
   b) We must mention here that we are fortunate to practice in an institution with good working relationships between departments. We have no dissillusions that this starting point made our progress easier. We were purposeful to continue to foster that professionalism by encouraging input from all departments involved. Our goal was to create a partnership in which all caregivers worked towards the shared goal of improved patient outcomes. Objectively, this collaboration could be demonstrated by a measured overall level of bundle element compliance.
3) Compliance [8]
   a) Order sets were created within our medical record program to make the orders standardized and accessible.
   b) A printed checklist was created to follow the patient through each deparment and to facilitate individual element completion.
   c) Education was delivered proactively to teams involved to encourage understanding and buy in [20].
   d) Caregivers were encouraged to be "whistle blowers" in the name of patient care. All members of the team were comfortable encouraging bundle compliance by being aware of crucial bundled elements. We believe this is crucial in developing a sustaining system. Compliance to specific elements did not rely solely on the surgeon's direction. Instead elements are anticipated and encouraged by all members of the team.
   e) The compliance of these elements were continually audited over time to allow for early identification of problems through root cause analysis and immediate redirection. Audit and feedback is considered to be a crucial player in effecting change over time [10, 20].
4) Analysis [15, 21, 22]
   a) Although analysis of bundle effectiveness does not make a poorly planned intervention more successful, it is crucial in order to verify the desired effect was realized and make changes as necessary. It is important to analyze local data against national benchmarks in order to get true assessments of performance.
   b) In addition, national benchmark data such as NSQIP give early notification of low performance areas.
5) Creating Culture Change
   c) We believe that being consistent in our drive for improvement created an environment of compliance. Our continued efforts, on all fronts mentioned, have begun to create a habit of better quality care and an atmosphere of safety. We aim to culminate those efforts in a sustaining culture of safety and excellence.

It must be noted that during the time frame being presented for the purposes of this paper, the NHSN definitions of reportable surgical site infections changed. The specific change occurred at the beginning of 2015. Prior to 2015, all surgical sites that did not involve "closed skin" could not be counted in the numerator for surgical site infections and therefore were also excluded for the denominator. Closed skin was defined as any attempt at skin closure after an incision, including a single staple or suture only re-approximating skin edges. After 2015, this caveat was removed. At that time, there was also an amendment to exclude infections present at the time of surgery (PATOS). As they were excluded, the theoretical inclusion of this data for calculation purposes was not performed. The effects of these changes in definitions therefore cannot be fully evaluated.

In general, we believe our approach to our bundle's implementation can be used across specialties and with a wide variety of interventions. However, we understand the applicability of the specific data presented does hone into specific roll out questions. We hope to address some of these specific questions here and highlight where the limitations in our study minimize the ability to be definitive.

With respect to data collection, the demographics reported in Table 1 reflect data that the NHSN thought most important or easiest to collect when calculating risk adjusted outcome data. We believe our data set is unique in the sense that it did include emergency surgeries, which do offer unique difficulties with respect to surgical outcomes. The fact that there was little difference between study groups in this area does add further strength.

There were differences between groups with respect to age as well as wound classification. With respect to age, a slightly older population in the pre-implementation group may suggest a higher risk of poor outcomes, minimizing the subsequent raw decrease in infection rates. However, this concern we

believe is assuaged by the SIR by showing that our risk adjusted outcomes did in fact improve in addition to our raw incidence. The wound classification difference is interesting as it shows more wounds were classified as dirty in post implementation. As noted prior, this may have placed cases involving established organ space infections (PATOS) out of the numerator of infectious complications post operatively. We believe that this classification change is fair and just. Educating our surgeons in this matter only helps us better demonstrate the level of acuity of the cases being performed and better stratifying risk adjusted outcomes. Therefore, if this is a driver in the decrease, we believe when evaluating national risk adjusted outcomes, it only puts our data on more even footing.

Other data that was not reported, but may be interesting, center on case specifics. These could include pre or post op diagnosis, surgical specialty, number of surgeons involved in performing colorectal surgeries to name a few. Although interesting, we ultimately did not feel that these specifics would contribute to any clarity in the data presented and may add more confounding elements. We do however believe that bundling care elements in the setting of our wide demographic may have been even more effective by empowering our system to control key variables and not allowing individual case details from being distracting.

With respect to bundle elements, the outstanding question is "which evidence-based practices will synergize to the best result?" We were purposeful in avoiding the discussion of the level of evidence of specific elements included in our bundle. Similarly, we did not report which of these elements may have already been in use and to what degree. Therefore, we hoped to not be misleading in implying that this manuscript gives any power to discerning which elements were most influential. Further research must be done to answer this question, and would be best done with prospective, randomized trials. Although we did use an evidence-based approach to creating our final bundle, we centered our implementation strategy on two key principles: bundle compliance and interdisciplinary buy in. Ultimately, we believe our success was secondary to these principles.

5. Conclusion

After this retrospective evaluation of the effect of bundled care in colorectal surgery, we were able to demonstrate a reduction in surgical site infections. Our study further supports the collection of publications that demonstrate that bundled care improves outcomes. Concurrently, we hope to bolster the existing literature by further describing the science behind the implementation of our intervention. We believe achieving successful change is reliant on the compliance of a system to bundled practices. We believe the keys to encouraging sustained compliance is by identifying a surgical champion, obtaining multi-departmental buy in, and molding compliance over time into becoming an interdisciplinary culture of safety and excellence.

6. Highlights

1) Surgical site infections confer a heavy burden on patients and hospital systems.
2) Colorectal surgery has high rates of surgical site infections relative to other types of surgery.
3) Bundled care improves outcomes in many health care settings, including colorectal surgery.
4) Calculated implementation of bundled care can help to ensure success and create an interdisciplinary culture of safety and excellence.

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