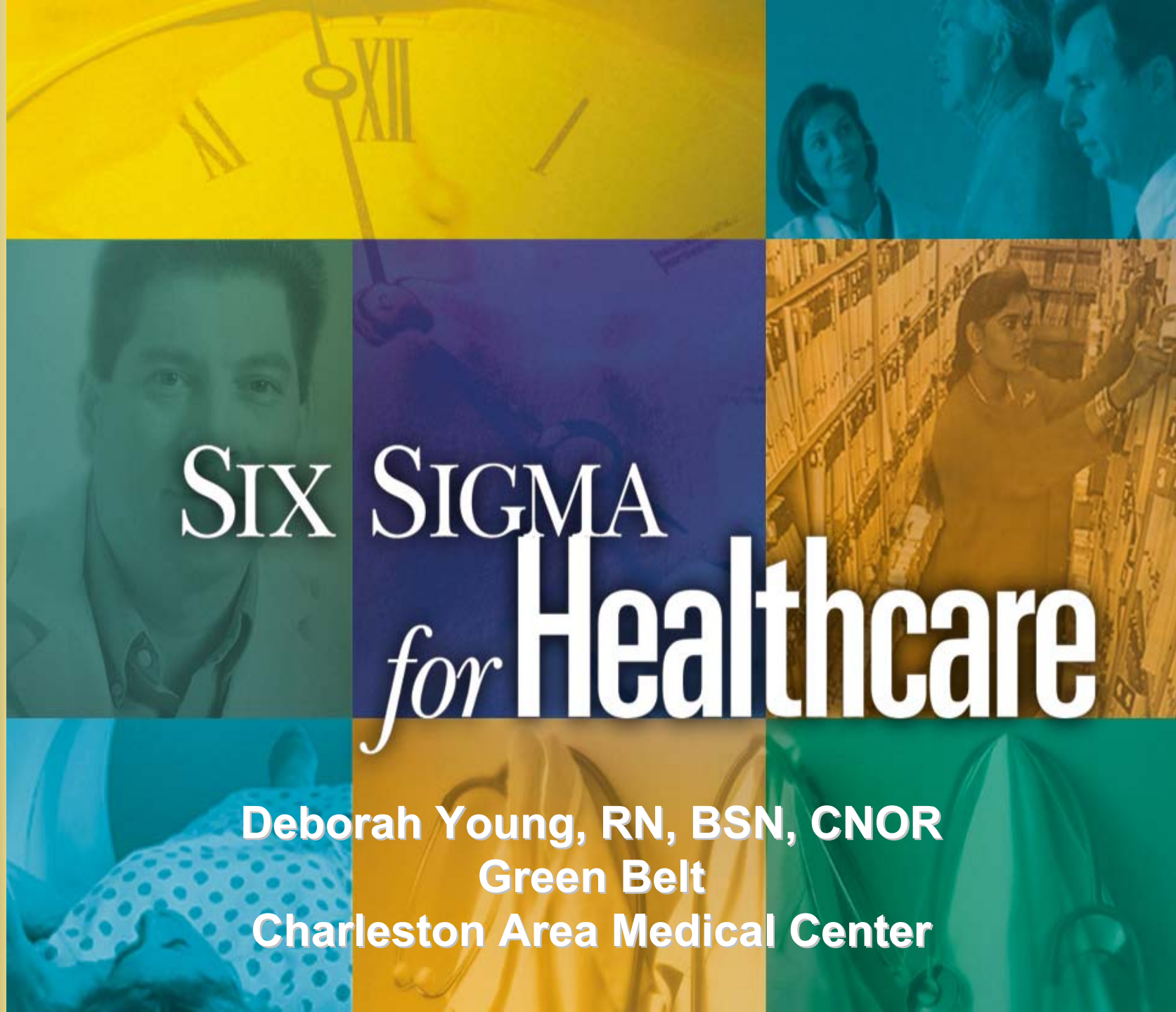


Six Sigma for Healthcare

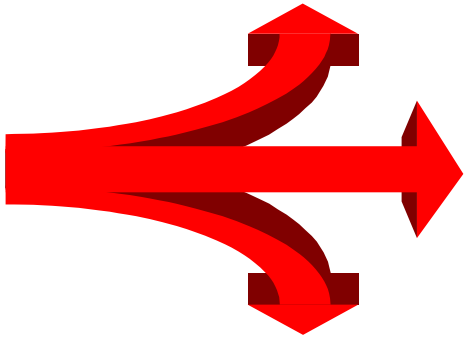
Deborah Young, RN, BSN, CNOR
Green Belt
Charleston Area Medical Center

CAMC Health System

Our mission: to improve the total health of our communities, working in partnership with the people we serve.

Charleston Area Medical Center
Charleston, West Virginia

5,818 Employees



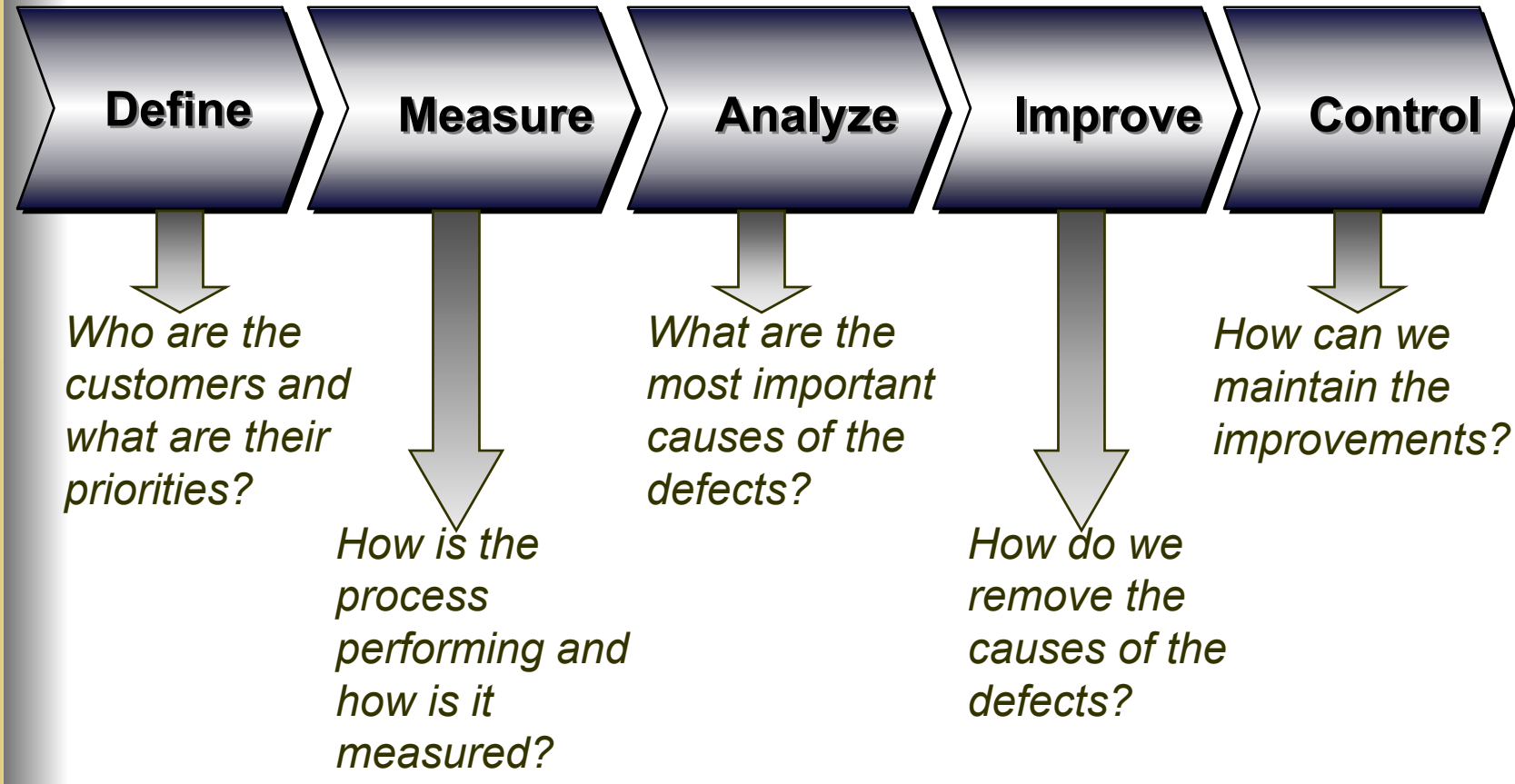
684 Members of the Medical Staff

913 Licensed Beds

392 General Hospital
375 Memorial Hospital
146 Women & Children's Hospital

Six Sigma Methodology

DMAIC: To improve any existing service or process

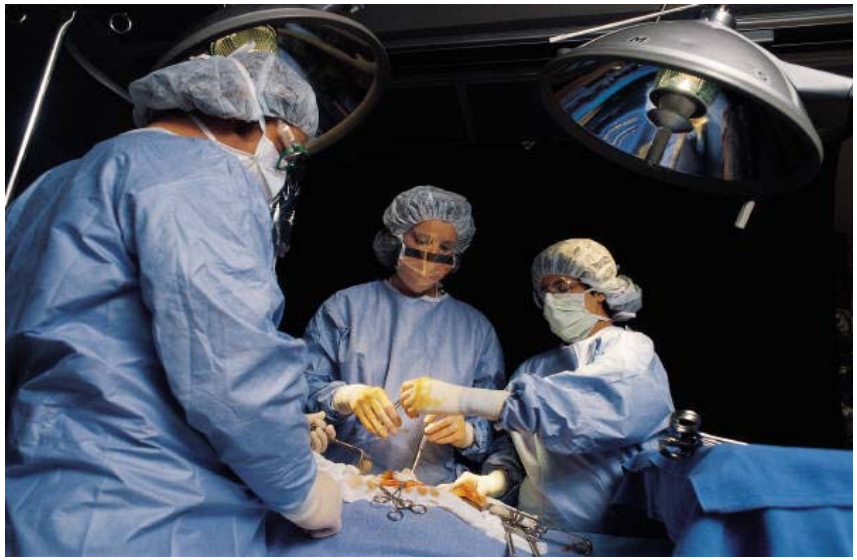


Challenges

- System and Structure Changes
- Level of Employee Computer Skills
- Multiple Information Systems
- Acquiring Raw Data
- Communication Across System
- Roles and Accountabilities
- Education
- Utilization of Trained Employee Resources
- Electronic Project Tracking
- Transition to Six Sigma Methodology
- Number of Surveys for VOC

Performance Improvement
The Six Sigma Way

Application of Six Sigma in a Surgical Infection Prevention Project



Six Sigma in Quality Initiatives

- Participation in Surgical Site Infection Prevention 2002 National Collaborative
- Literature synthesis by a panel of experts resulted in recommendations for specific indicator measurements to prevent surgical site infection
- The following resources were used in the development of indicators
  - American Society of Health-System Pharmacists
  - Infections Diseases Society Quality Standards Subcommittee
  - Centers for Disease Control and Prevention
  - Surgical Infection Society Antimicrobial Agents Committee

Collaborative Quality Indicators

- Antibiotic given between 0-60 min. prior to incision (except Vancomycin 60-120)
- Patient given appropriate antibiotic
- Patient given appropriate antibiotic dose
- Perioperative temperature $\geq 36^0$ C
- $FIO_2 \geq 80\%$ intraoperatively
- Blood Glucose < 200mg intraoperatively
- Blood Glucose < 200mg postoperatively for 48 hours
- Discontinuation of antibiotic within 24 hours of surgery stop time

Surgical Site Infection (SSI)

- Account for 14-16% of all hosp-acq infections
- 2-5% of surgical patients will develop SSI
  - 40 million operations annually in the U.S.
  - 0.8 - 2 million SSI's occur annually in the U.S.
- SSI increases LOS in hospital
  - average 7.5 days
- Excess cost per SSI:
  - *$2,734-26,019 (1985, US$)
  - US national costs: $130-845 million/year

**Jarvis, Infection Control Hospital Epidemiology 1996;17*

Impact of Surgical Site Infection

Case Control* Study of 255 Pairs

	Infected	Uninfected
▪Readmission	41%	7%
▪Median direct cost	$7531	$3844
▪L.O.S.	11d	6d
▪ICU Adm.	29%	18%
▪Mortality	7.8%	3.5%

*** matched for procedure, NNIS index, age**

Kirkland. Infect Control Hosp Epidemiology 1999; 20: 725

D M A I C

Prophylactic Antibiotic Project

Executive Sponsor: Chief Operating Officer
Process Owner: Administrator for Surgical Services
Physician Champion: Clinical Director for Surgical Services
Green Belt: Surgical Research/Quality RN
Stakeholders/Team Members:
Epidemiologist
Physician Chief of Staff
Anesthesiologist
Certified Registered Nurse Anesthetist
Safety Director
Clinical Quality Specialist
Clinical Pharmacist
Registered Nurse

D M A I C

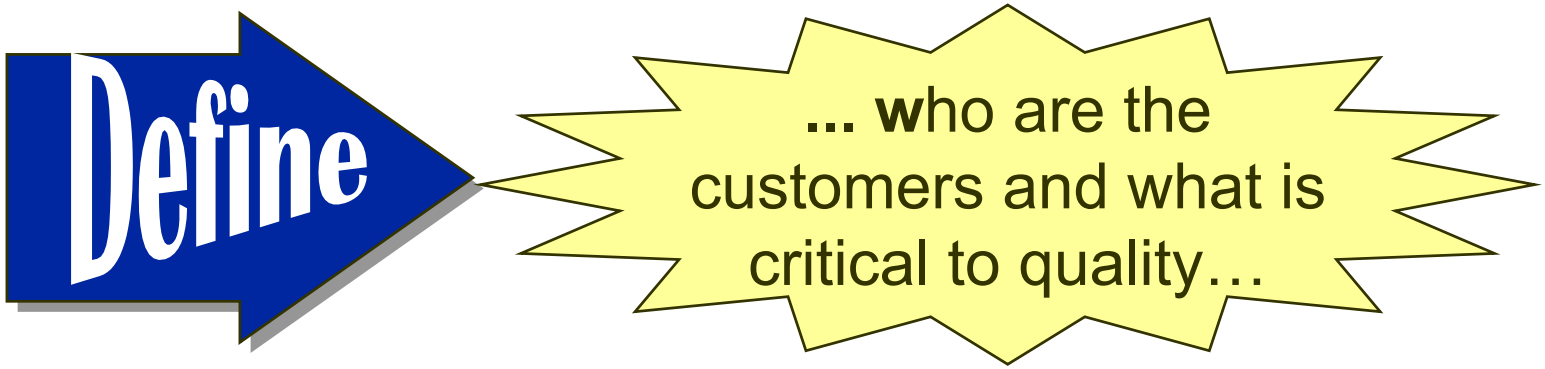
Prophylactic Antibiotic Project

Project Scope: Prophylactic antibiotics administered before and during colon and vascular surgery

Defect: < 90% compliance for each antibiotic indicator for colon and vascular surgeries

Strategic Goal 6.2: Improve indicators for the appropriate administration of prophylactic surgical antibiotics
JCAHO standard IC.6: PI plan to decrease infections

How Do You Define The Problem?



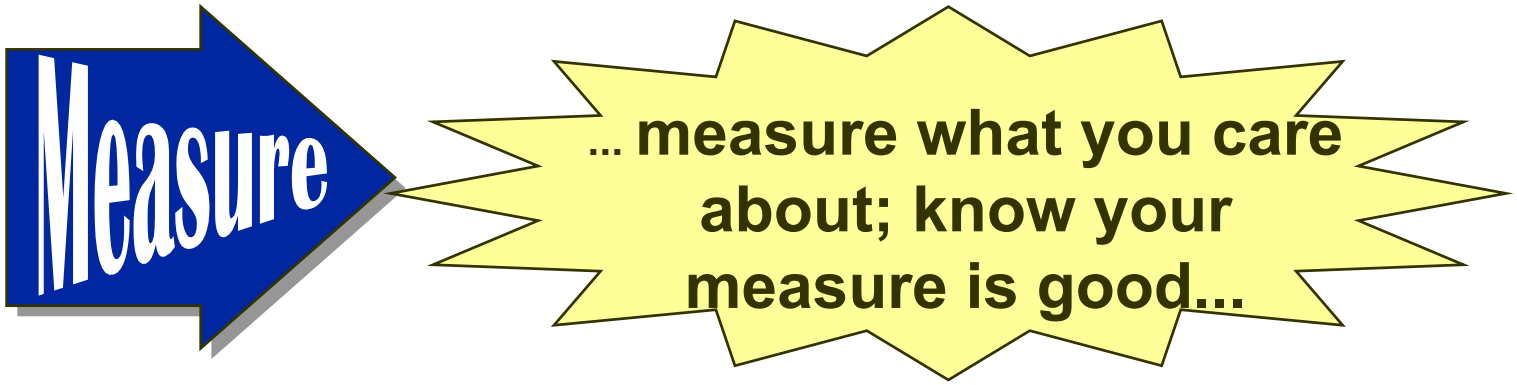
Critical To Quality Indicators

- Patient given ***antibiotic*** 0-60 minutes prior to incision (Vancomycin 0-120 minutes)
- Patient given appropriate ***antibiotic*** (based on approved list)
- Patient given appropriate *dose* of ***antibiotic*** (increased dose if > 90 kg)*
- Patient given *redose* of ***antibiotic*** if surgery greater than 4 hours*

Building Team Member Buy-In

- Identification of stakeholders and presentation of quality indicator data
- Education of team members in Six Sigma concepts with 4 days of foundations training:
  - Six Sigma methodology
  - Change Acceleration Process
  - Work-Out™

How Do You Measure The Problem?



Possible Causes for Defects

- Multiple people touch the patient prior to surgery, yet none are accountable to ensure prophylactic antibiotic administration meets the quality indicators
- Everyone feels someone else is responsible
- Lack of education regarding quality indicators by all that care for the patient
- Resistance to change processes and individual practice

Data Collection Plan

Question	Yes	No
Patient arrived in preop with antibiotic order written by surgeon/resident?		
Antibiotic ordered in preop by surgeon/resident without prompting?		
Antibiotic ordered in preop by anesthesiologist without prompting?		
CRNA prompted antibiotic order?		
Preop nurse prompted antibiotic order?		
Where was the antibiotic started?		

How Do You Analyze The Problem?

What did we want to know? Did prompting the physician for an antibiotic order improve meeting the appropriate antibiotic and dose indicators?

Criteria	Non-Prompted	Prompted
ABX Ordered	45%	55%
Right ABX	71%	97%

What did we learn? All patients received a prophylactic antibiotic. The right antibiotic and dose was administered 97% of the time when surgeons and residents were prompted

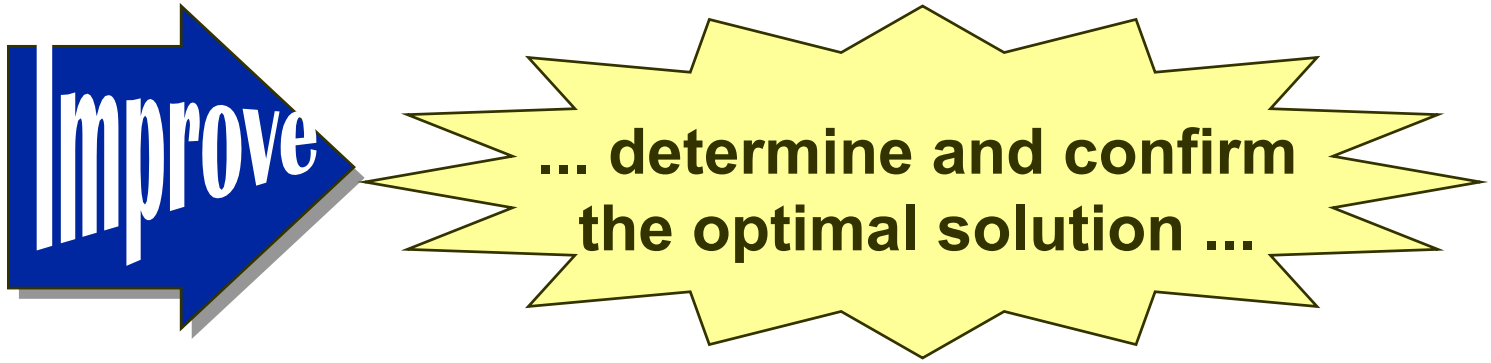
Action Plan: Building Stakeholder Buy-In

- Presentation of data with feedback for improvement solutions:
  - Sponsor and physician champion
  - Surgical Quality Improvement Council
  - Performance Improvement Council
  - Surgeons and surgical residents
  - Anesthesia staff

Summary of Causal Variables

- Right antibiotic:
  - no physician prompting for antibiotic on approved list and formulary
- Right Dose:
  - no physician prompting for patients weighing > 90kg
- Right Time:
  - antibiotics given too early if started in nursing department or the preoperative holding area

How Do You Improve The Problem?



Root Cause Analysis

Variable	*Root Cause*	*Solution*
Appropriate antibiotic and dosage	Current order set did not have physician prompts	Revise surgical order set to include appropriate antibiotic and dose
	Physicians, CRNAs and nurses unaware of antibiotic indicators	Education with supporting literature and CAMC indicator data
Timing of antibiotic administration	Antibiotic started in nursing dept or preoperative holding area	Revise surgical order set to include appropriate antibiotic timing

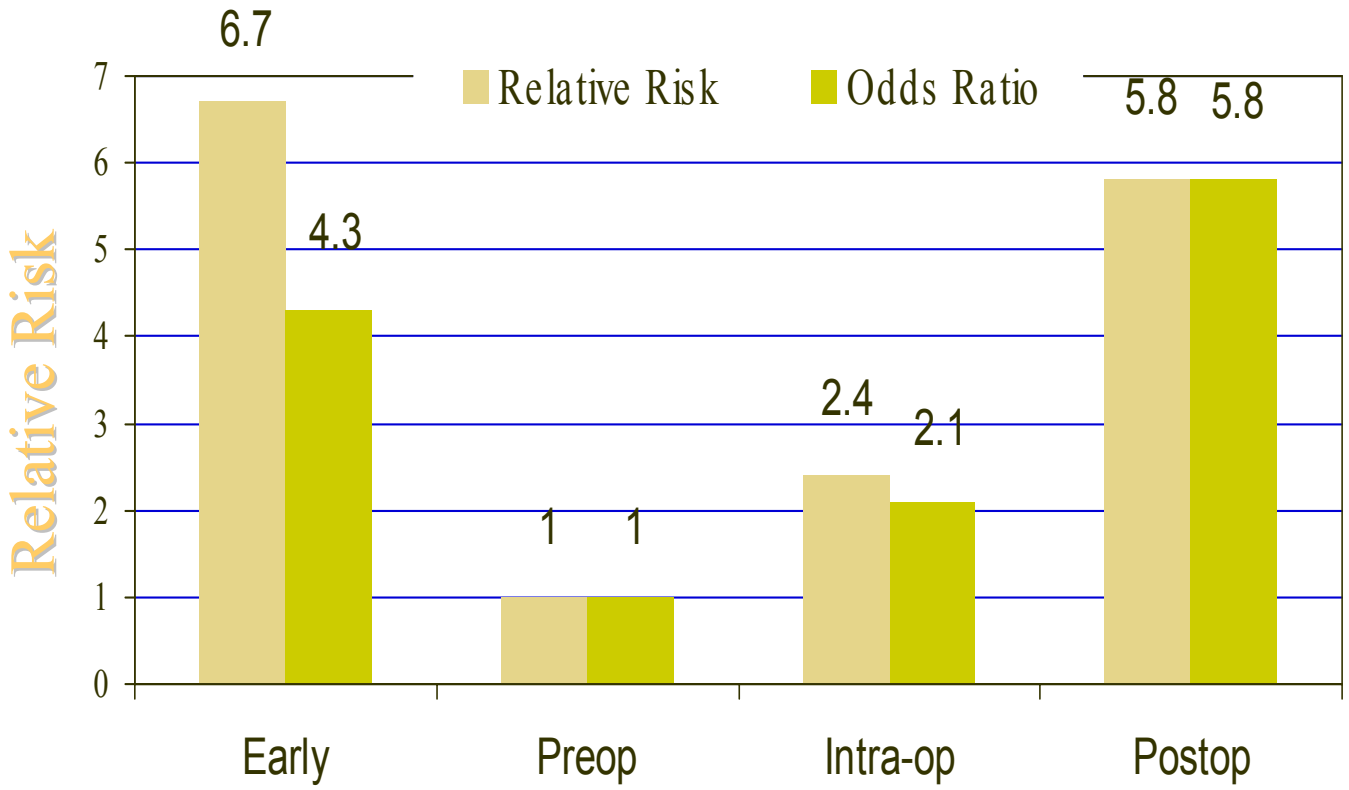
Action Plan: Building Systems and Structure

- Development of database by Information Center for indicator data entry and analysis
- Revision of preoperative orders set to include antibiotic indicators for physician prompting
- Addition of preoperative antibiotic indicators to existing pre-induction timeout
- Quarterly surgeon and anesthesiologist letter with individual data on indicator compliance
- Monthly CRNA letter with individual data on indicator compliance

Action Plan: Building Stakeholder Buy-In

- Education of CRNA's, anesthesiologists, surgeons, residents, OR staff, and nursing staff
  - Surgery department staff meetings
  - Surgery resident conferences
  - CRNA staff meetings
  - Nurse manager meetings
  - Tri-hospital surgery administration meetings
- Education for physician office staff to use new order sets
  - Office manager luncheon and provision of new order sets

Education: Antibiotic Timing Infection Risk

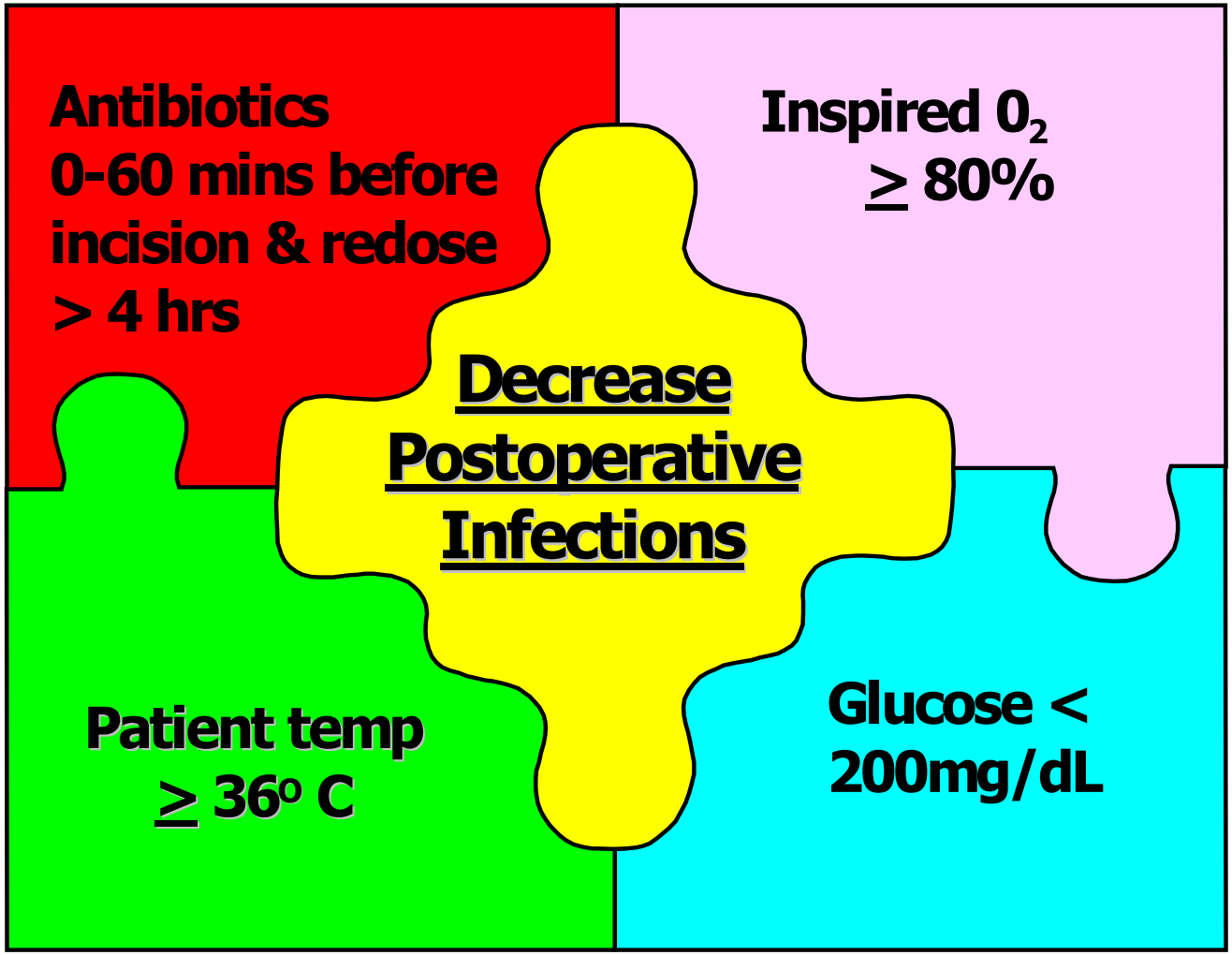


Classen. NEJM. 1992;328:281.

Physician Report Card

Indicator	*# MD Cases (date)*	*% MD cases met indicator*	*# CAMC cases (date)*	*% CAMC cases met indicator*
Antibiotic 0-60 minutes prior to incision (Vanc. 0-120 minutes)				
Right antibiotic				
Right weight based dose				
Redose if surgery > 4 hrs				

Anesthesia Education



Physician and Anesthesia Challenges

- **Surgeon focus on individual infection rates instead of quality indicators**
- **Practice Changes**
  - **Surgeon agreement and responsibility for ordering appropriate antibiotic and dose**
  - **Anesthesia agreement and responsibility to administer antibiotic 0-60 minutes prior to incision and and repeating dose if surgery > 240 minutes**

So How Did We Address These Issues?

Prophylactic Antibiotic Preoperative Order Set

ANESTHESIA TO ADMINISTER PREOPERATIVE PROPHYLACTIC ANTIBIOTIC 0-60 MINUTES (VANCOMYCIN 0-120 MINUTES) PRIOR TO INCISION. BOX CHECKED FOR ORDERED ANTIBIOTIC.

SURGERIES *WITHOUT* ANAEROBES PRESENT (i.e. anaerobes include Bacteroides)

1. No known allergy to Penicillin (or known tolerance of cephalosporins):

IV REGIMEN	TRADE NAME	wt. < 90 kg.	wt. 90-199 kg.	wt. ≥ 200 kg.	Redose in OR (normal renal function)
Cefazolin	Ancef , Kefzol	1gm	2gm	3gm	3 hours post incision

2. Severe allergy to Penicillin:

IV REGIMEN	TRADE NAME	wt. < 90 kg.	wt. 90-199 kg.	wt. ≥ 200 kg.	Redose in OR (normal renal function)
Vancomycin	Vancocin , Vancoled	1gm	1.5gm	2gm	6 hours post incision

SURGERIES *WITH* ANAEROBES PRESENT (i.e. Bacteroides)

1. No known allergy to Penicillin (or known tolerance of cephalosporins):

IV REGIMEN	TRADE NAME	wt. < 90 kg.	wt. 90-199 kg.	wt. ≥ 200 kg.	Redose in OR (normal renal function)
Cefotetan	Cefotan	1gm	2gm	3gm	6 hours post incision

2. Severe allergy to Penicillin:

	IV REGIMEN	TRADE NAME	wt. < 90 kg.	wt. 90-199 kg.	wt. ≥ 200 kg.	Redose in OR (normal renal function)
	Clindamycin	Cleocin	600mg	900mg	900mg	3 hours post incision
PLUS	Ciprofloxacin	Cipro	400mg	400mg	400mg	3 hours post incision

Spreading Success

- 2003 strategic goal to spread improvements from GI and vascular surgeries to hysterectomy, total hip and knee replacement, coronary artery bypass graft, and other cardiac surgeries
- Some of the cardiovascular surgeons had already implemented these quality measures for all surgeries they perform as a result of their vascular surgery education

Strategic Goal By Quarter 2003

QTR 1	QTR2	Qtr 3	QTR 4
Improvement in colon and vascular surgery antibiotic indicators	90% achieved for indicators in colon and vascular surgeries	Diffuse to all appropriate surgeries	90% compliance with ABX indicators achieved in one additional procedure

System and Structure Challenges

- Reviewing the 250 existing order sets to identify preoperative order sets
- Revising the preoperative order sets and gaining physician specialty approval
- Breaking the current structure for moving the order sets through the system for printing
- Aligning surgical prophylactic antibiotic quality goals into executive, director, and clinical physician responsibility and incentives
- Educating 183 surgeons and residents on quality indicators

How Do You Control The Problem?

…be sure the problem doesn't come back...

Control Plan: Building Systems and Structure

- Executive sponsor letter to surgeons delineating prophylactic quality indicators, Internet site to access additional information, and sample of data they will receive on a quarterly basis
- Flowchart of antibiotic process with Intranet link to existing policy for new preoperative order set development
- Clinical Quality Specialist responsibility for monthly data collection and reporting on indicators and critical variables
- Clinical physician director accountability for physician outliers
- Surgical Quality Improvement Council oversight of continued improvements

Next Step: *Discontinuation of Prophylactic Antibiotics Project*

Project Start Date: 2/7/03
Team: Same administrative/executive team, RN from 3 hospitals, Clinical pharmacist

Project Scope:
Discontinuation of prophylactic antibiotic 24 hours from surgery stop time

Defect: < 90% compliance for colon and vascular surgeries

Strategic Goal 6.2: Improve appropriate administration of prophylactic antibiotics
JCAHO standard IC.6: Decrease infection risk

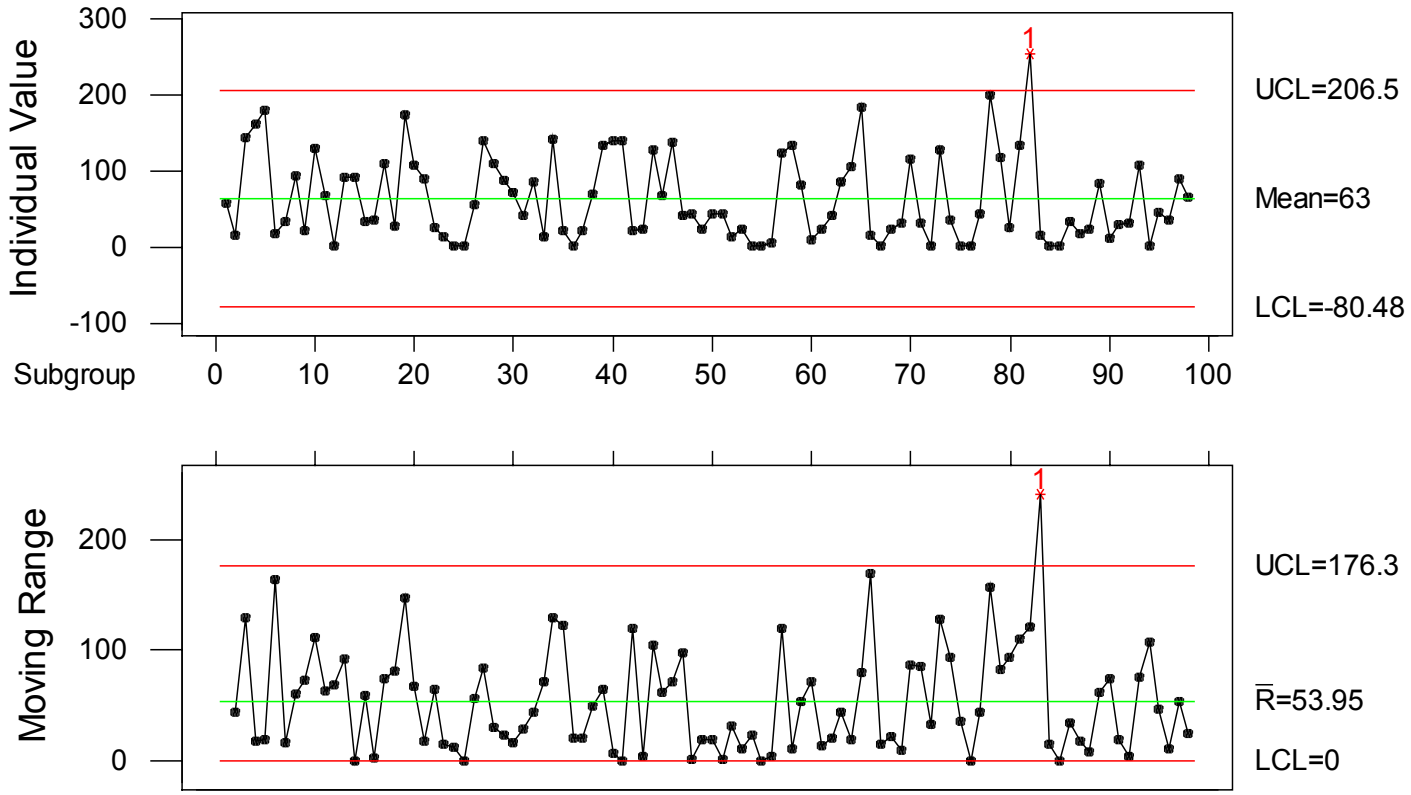
Determine Potential Causes

- Team members and stakeholders identified 44 possible causes for antibiotics to be continued > 24 hours, and 24 of these causes were measurable

Time Data Collection Plan

- Time of last perioperative antibiotic
- End of surgery time
- Time physician ordered antibiotic to be discontinued
- How physician wrote antibiotic order (q 8 hrs x 3, etc.)
- Actual time last dose of antibiotic given

Current Process



<u>What did we learn?</u> Prophylactic antibiotics are administered an average of 63 hours from the end of surgery, with a range of 54 hours

Determine Variable Correlation and Causation

- Positive correlation of 3 variables
  - Ordering physician
  - Number of doses physician orders
  - How physician writes order
- Regression validated variable causation and invalidated stakeholder perception that using standard medication administration times was a causal variable
- One-way ANOVA confirmed a statistical difference between ordering physicians with a p-value of 0.001

What did we want to know? What is the number of doses that exceed 24 hours

# Doses	Mean (Hours)	Median (Hours)	Standard Deviation (Hours)
1	11.75	9.50	8.58
2	19.11	20.0	5.49
3	25.58	26.50	8.07
4	37.90	38.50	13.67

What did we learn? Doses of antibiotic administered range from 1-24. Doses > 2 have an average over 24 hours.

Financial Savings

- 775 cases reviewed in third quarter of 2003 for CABG, Cardiac, Colon, Hysterectomy, Total hip/knees, and Vascular surgeries
  - 482 of cases (62%) were administered 3 doses or less
  - $13.75 for 1st dose
  - $8.85 for each additional dose
  - Minimum of $21,329 savings for 5 doses (based on baseline of 8 doses)
  - Estimated annual savings of $85,316 for these patient populations

Business Case

- Out of 22,126 total surgeries in 2002 15,399 surgeries were eligible for prophylactic antibiotics
- Baseline average of 8 doses of prophylactic antibiotics given postoperatively
- $118,344 savings annually for each dose of antibiotic not administered as prophylaxis
  - $14,041 pharmacy and nursing labor
  - $104,304 in antibiotic and supply cost

Root Cause Analysis

Variable	*Root Cause*	*Solution*
How physician writes order	No general surgery postoperative preprinted order set	Develop postoperative order set for MD prompting
Doses physician orders	System issues prevent antibiotic to be given < 24 hrs when ordered q8 hrs times 3 or q12 hrs times 2	Include option in order set to discontinue antibiotic < 24 hrs
Therapeutic use of antibiotic	Physician using antibiotic therapeutically without documentation	Include option in order set for therapeutic antibiotic documentation

Translating Previous Success

- Postoperative order set developed for colon & general surgeries
- Revised GYN, Ortho, CV, and Vascular postoperative order sets to include prophylactic and therapeutic antibiotics
- Development of surgical prophylactic antibiotic algorithm used for staff education and operative order set development
- Letter sent to surgeons and surgical residents delineating antibiotic quality indicator with appropriate specialty postoperative order set
- Add discontinuation of antibiotic data to existing letter/data sent to surgeons

Postoperative Physician Order Set

14. ***Prophylactic Antibiotic:***

❑ No postoperative antibiotic

❑ Discontinue after one postoperative dose

❑ Discontinue antibiotic 24 hours after surgery stop time.
PACU staff to provide times to pharmacy:

Last dose time:	Surgery stop time:

SURGERIES *WITHOUT* ANAEROBES PRESENT (i.e. anaerobes include Bacteroides)

1. No known allergy to Penicillin (or known tolerance of cephalosporins):

IV REGIMEN	TRADE NAME	wt. < 90 kg.	wt. 90-199 kg.	wt. ≥ 200 kg.	Frequency (normal renal function)
❑ Cefazolin	Ancef®, Kefzol®	❑ 1gm	❑ 2gm	❑ 3gm	❑ every 8 hours

2. Severe allergy to Penicillin:

IV REGIMEN	TRADE NAME	wt. < 90 kg.	wt. 90-199 kg.	wt. ≥ 200 kg.	Frequency (normal renal function)
❑ Vancomycin	Vancocin®, Vancoled®	❑ 1gm	❑ 1.5gm	❑ 2gm	❑ every 12 hours *unless abnormal creatinine then consult clinical pharmacist*

SURGERIES *WITH* ANAEROBES PRESENT (i.e. Bacteroides)

1. No known allergy to Penicillin (or known tolerance of cephalosporins):

IV REGIMEN	TRADE NAME	wt. < 90 kg.	wt. 90-199 kg.	wt. ≥ 200 kg.	Frequency (normal renal function)
❑ Cefotetan	Cefotan®	❑ 1gm	❑ 2gm	❑ 3gm	❑ every 12 hours

2. Severe allergy to Penicillin:

	IV REGIMEN	TRADE NAME	wt. < 90 kg.	wt. 90-199 kg.	wt. ≥ 200 kg.	Frequency (normal renal function)
	❑ Clindamycin	Cleocin®	❑ 600mg.	❑ 900mg.	❑ 900mg.	❑ every 8 hours
PLUS	❑ Ciprofloxacin	Cipro®	❑ 400mg.	❑ 400mg.	❑ 400mg.	❑ every 12 hours

15. ***Therapeutic Antibiotic:*** ❑ Contaminated wound ❑ Infected wound ❑ Preop infection ❑ Other: ***(document)***

Antibiotic:_____ Dose:_____ Frequency:_____ Route:_____

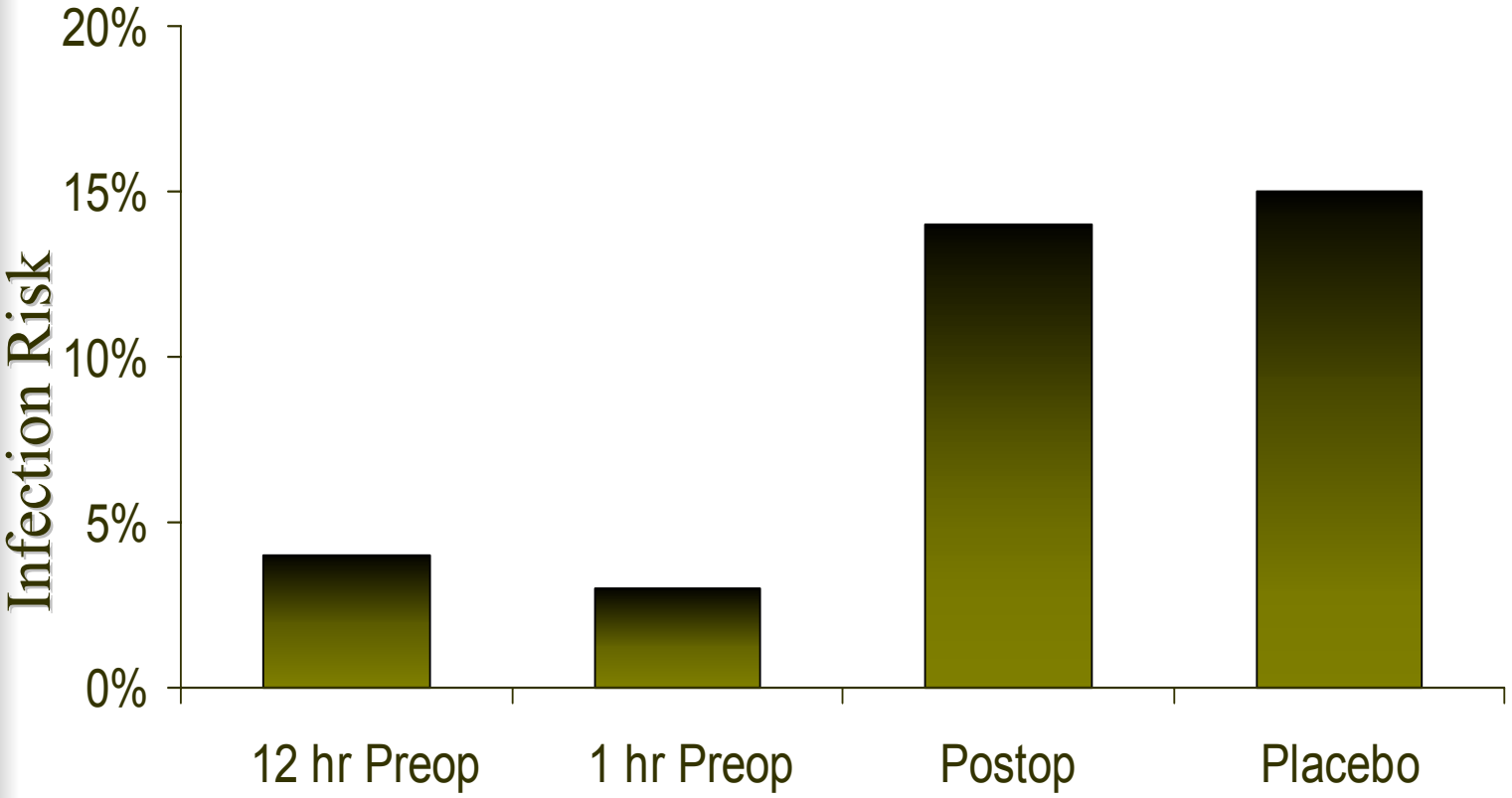
Action Plan: Building Stakeholder Buy-In

- Utilized early physician adopters as change agents
- Education of surgeons, residents, and nursing staff
  - Surgery department staff meetings
  - Surgery resident conferences
  - Nurse manager meetings
  - 1 – page staff education sheet
- Placement of the appropriate surgical preoperative and postoperative order sets on all patient charts for same day as well as inpatient surgeries for physician prompting

Medical Literature: Duration of Antibiotic Prophylaxis

Colorectal	3
Mixed GI	4
Hysterectomy	3
GYN & GI	1
Head & Neck	3
Orthopedic	4
Vascular	3
Cardiac	7
Total	28
Papers supporting longer duration	1

Education:
Antibiotic Timing Infection Risk



Stone HH et al. Ann Surg. 1976;184:443-452.

First Do No Harm

- Antibiotic prophylaxis is one of many methods for reducing the incidence of SSI
- There is a lack of evidence that antibiotics given after the end of the operation prevent SSI's
- There is evidence that increased use of antibiotics promotes antibiotic resistance

Challenges

- Orthopedist resistance to change postoperative prophylaxis from 48 hours to 24 hours for total knees and hip replacements until the American Academy of Orthopaedic Surgeons issued an official statement supporting 24 hour prophylaxis
- Educating surgeons and residents the need to write orders differently if intention is to discontinue antibiotic within 24 hours
- Surgeon and resident use of postoperative order sets

Control Plan: Translating Previous Successes

- Clinical Quality Specialist responsibility for monthly data collection and reporting on indicator and critical variables
- Sending physician specific data on indicators quarterly
- Clinical physician directors accountability for physician outliers
- Surgical Quality Improvement Council oversight for continued improvements

Critical Success Factors

- Executive sponsorship
- Respected physician champion
- Sponsor willingness to remove barriers
- Expert and well respected surgical RN Six Sigma Green Belt trained
- Administration support of time for Green Belt to work on project
- Detailed and updated WWW action plan and communication plan
- Black Belt to maintain focus on the project and mentor the Green Belt in using the Six Sigma methodology

Next Steps

- Remeasurement of indicator compliance in process
- 2004 Strategic Goals:
  - Surgical prophylactic antibiotic indicators in top 10th percentile in benchmarking group
  - 90% of one major surgical patient population maintains intraoperative temperature $\geq 36^{0}$ C
  - 90% of one major surgical patient population maintains intraoperative glucose < 200mg

Performance Improvement

The Six Sigma Way

CAMC Health System

Our mission: to improve the total health of our communities, working in partnership with the people we serve.