Clinical Safety & Effectiveness

Autologous Bone Flap Cranioplasty Handling Process

CENTER FOR PATIENT SAFETY & HEALTH POLICY

UT HEALTH SCIENCE CENTER™

SAN ANTONIO

The Team

- CS&E Participants
  - Izabela Tarasiewicz, MD
    - » Associate Professor, Department of Neurosurgery
  - Colin Son, MD
    - » Resident, Department of Neurosurgery
- Other Participants
  - Bryant Huang
  - Lisa Colburn, RN
- Mentor
  - Abbie Aburizik, MBA
- Sponsor
  - David Jimenez, MD
    - » Chairman, Department of Neurosurgery

AIM Statement

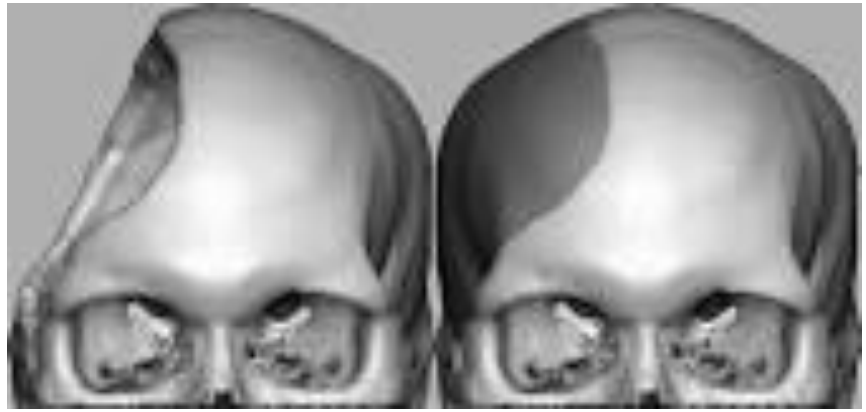
The aim of this project is to reduce surgical site infections for autologous cranioplasties (tumor, stroke, trauma) by 50% by May 30, 2016.

Background- Decompressive Craniotomies

- Medical conditions creating a state of increased intracranial pressure such as :
- Stroke
- Trauma
- Tumors
- hemorrhages

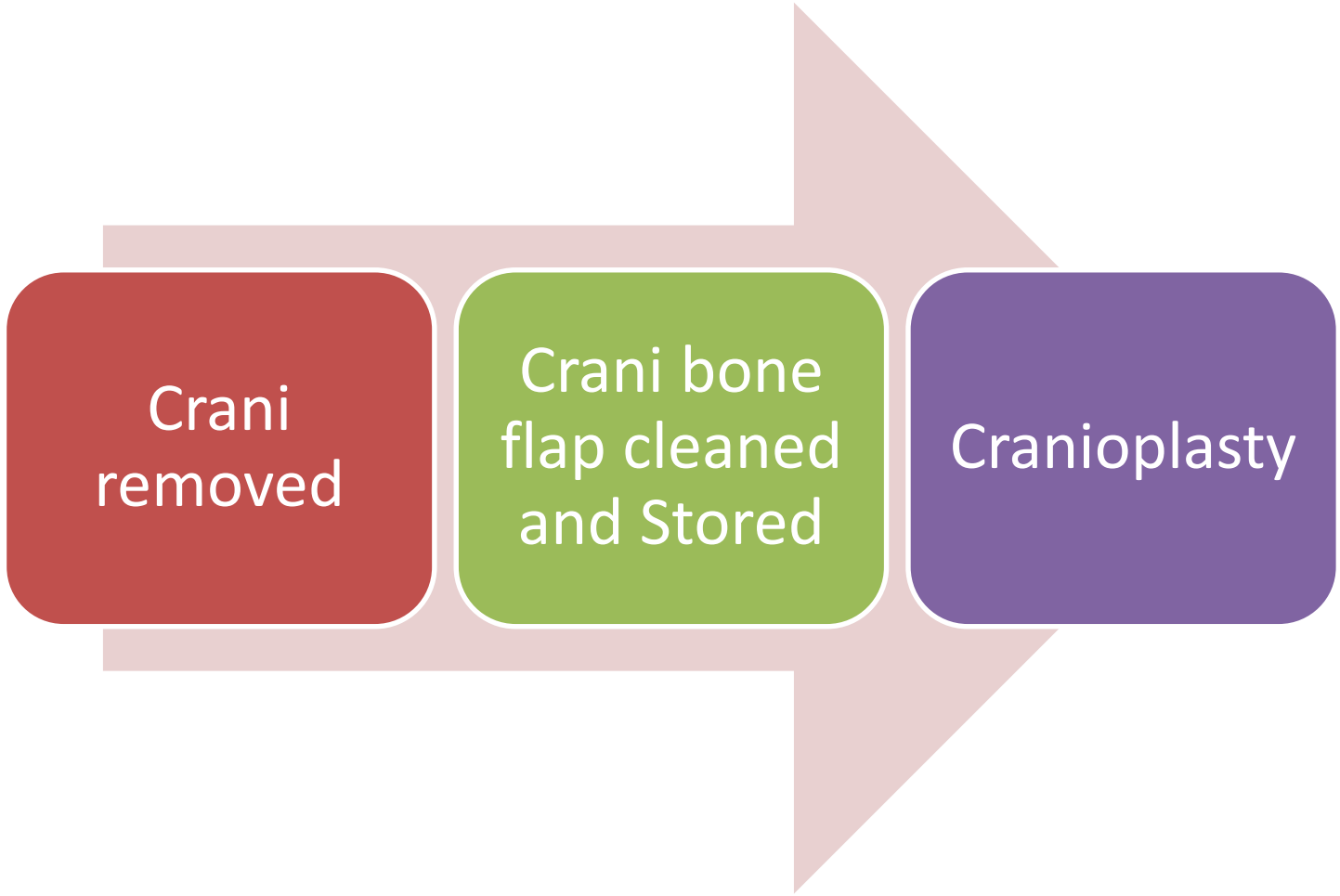
- Require sometimes an emergency intervention to remove skull/bone flap
- Decompressive craniotomy is performed to allow the brain to expand beyond the original skull contour and with time get back to its normal size.

Background- Cranioplasty

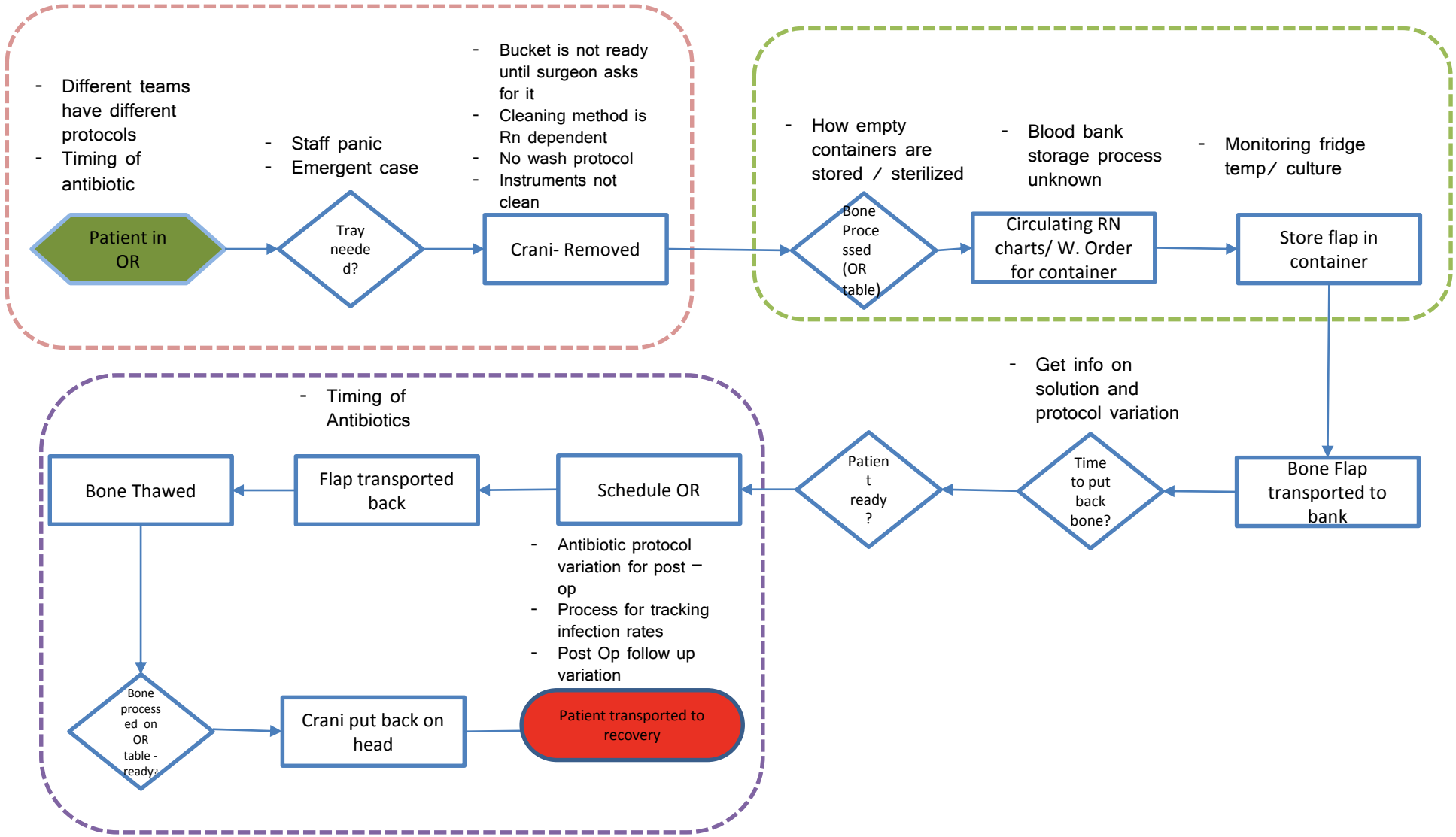


- Repair of skull defect created by the first life saving procedure
- Needed to protect brain and as matter of cosmesis
- Auto vs allograft (titanium, PMMA, hydroxyapatite, etc)
- Infections higher with autografts (especially versus titanium)
- Infection rate reported as low as 7.86% (varies 7-20%)

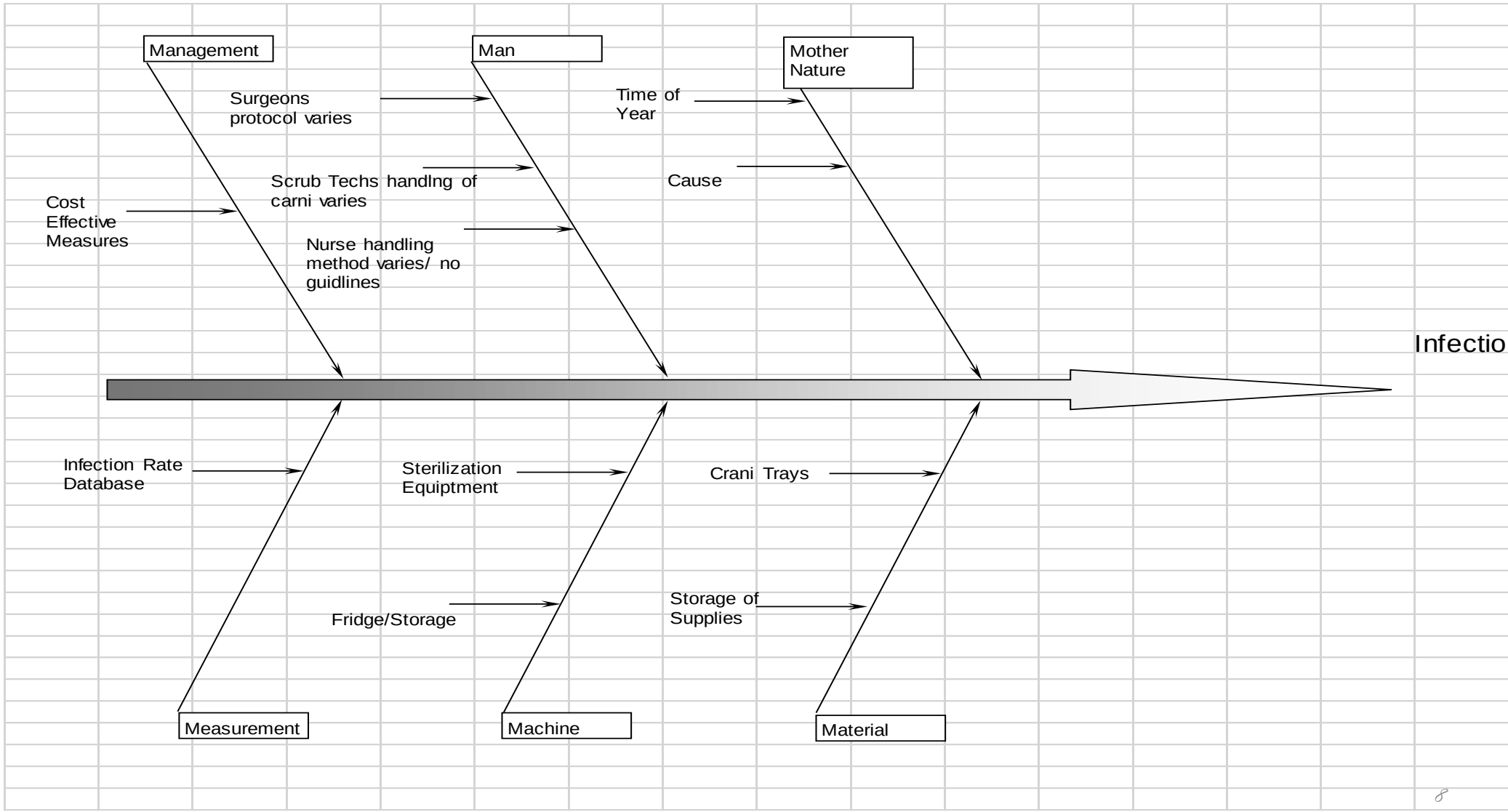
Basic Process



Flow Chart


- Different teams have different protocols
- Timing of antibiotic
- Staff panic
- Emergent case
- Bucket is not ready until surgeon asks for it
- Cleaning method is Rn dependent
- No wash protocol
- Instruments not clean
Patient in OR
Tray needed?
Crani- Removed
- How empty containers are stored / sterilized
- Blood bank storage process unknown
- Monitoring fridge temp/ culture
Bone Processed (OR table)
Circulating RN charts/ W. Order for container
Store flap in container
- Get info on solution and protocol variation
Bone Flap transported to bank
Time to put back bone?
Patient ready?
- Timing of Antibiotics
Schedule OR
Flap transported back
Bone Thawed
- Antibiotic protocol variation for post – op
- Process for tracking infection rates
- Post Op follow up variation
Patient transported to recovery
Crani put back on head
Bone processed on OR table - ready?

Fishbone


Management
Man
Mother Nature
Surgeons protocol varies
Time of Year
Scrub Techs handlng of carni varies
Cause
Cost Effective Measures
Nurse handling method varies/ no guidlines
Infectio
Infection Rate Database
Sterilization Equiptment
Crani Trays
Fridge/Storage
Storage of Supplies
Measurement
Machine
Material

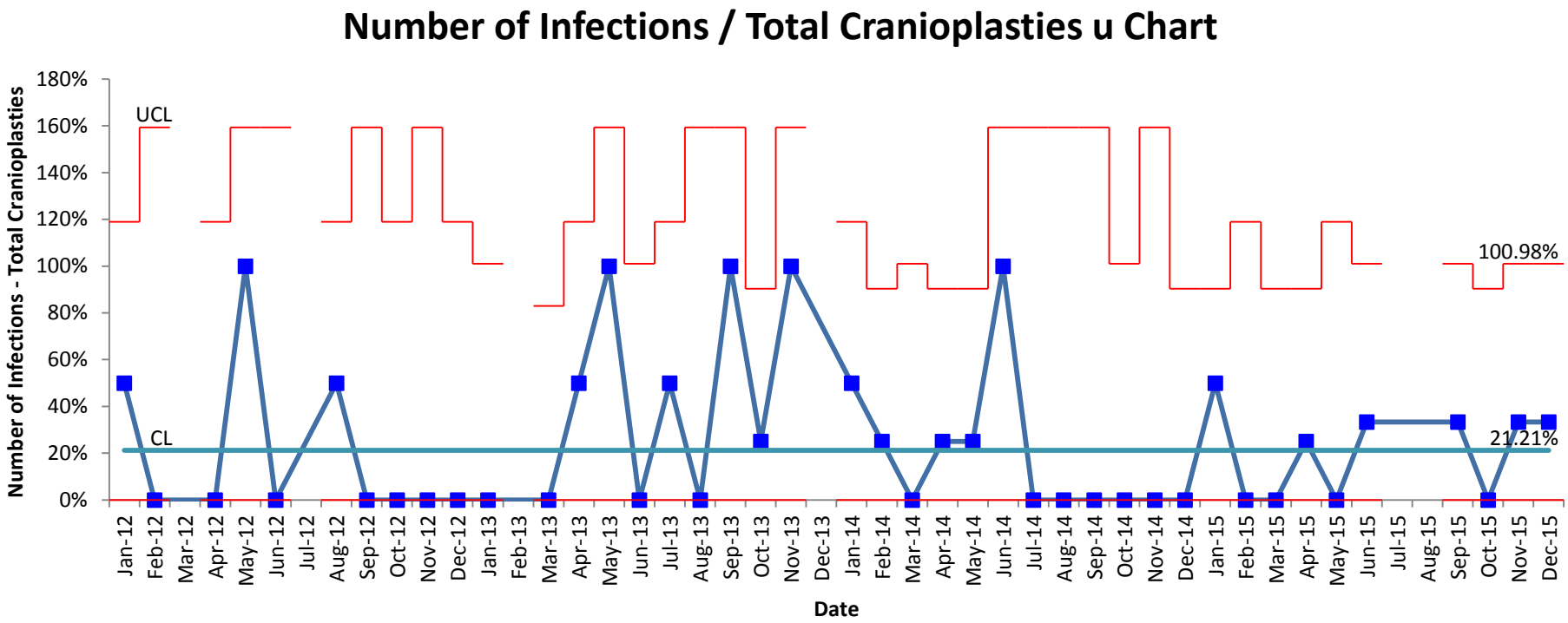
Pre-Intervention Data

- All surgeries with CPT codes 62141, 62143, 62145 or 62147 between January 1, 2012 and December 31, 2015 at all facilities for all surgeons within the Department
- By hand chart review limited to autologous cranioplasty and both surgically and non-surgically treated post operative infections identified

Pre-Intervention Data

- Pre- intervention infection rate 24/99 (24.2%)
- All but two infections treated with repeat craniectomy
- Issue: Data lapse. Won't know how well we are doing until patient comes back (Duration from flap removal to Cranioplasty is at least 3 months and up to a year.)

Pre-Intervention Data



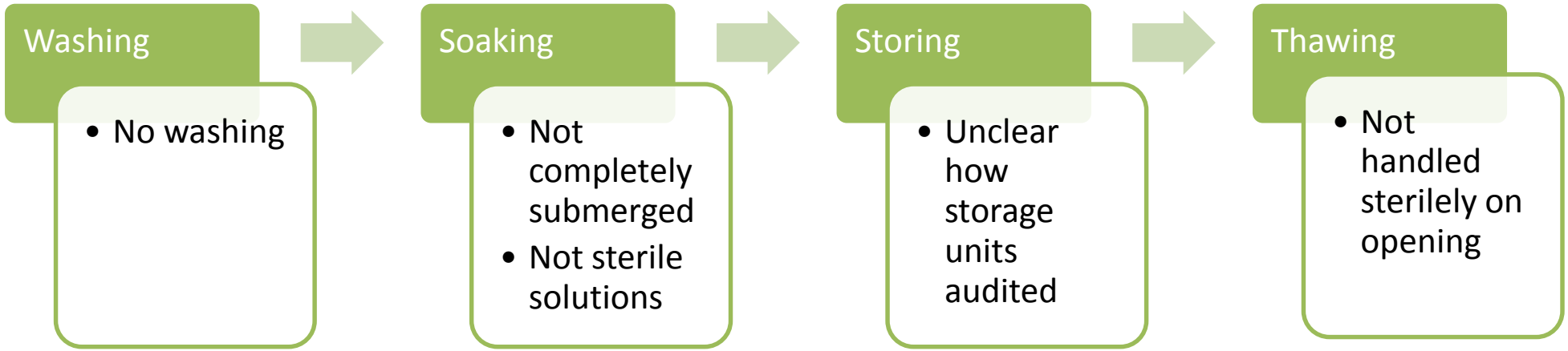
Variables

- Patient population
- Bone Handling
- Storage (regulated)
- Instruments (regulated)

The most variable process is Bone Handling.

The only variable we have true control over is Bone Handling.

Pre-Intervention Observations



Interventions

Protocol for bone handling	Staff Education	Early Cranioplasty	Tracking
• Washing • Sterilization • Double Soaking • Rinsing • Bagging (purchase crani storage kit - pending)	• Surgeons • OR Staff	• Agreed no early cranioplasties before 6 weeks	• CPT CODES • OR Database of cranioplasties • Audits of stored bone flaps • Check-list in EMR

Interventions

- Standardized protocol for handling of bone flap following removal and before implantation:
  - –Completely submerged in Bacitracin infused normal saline x 15 minutes
  - –Completely submerged in Betadine x 15 minutes
  - –Irrigation with 3 liters normal saline with powered irrigation debridement system (i.e. Pulsavac)
  - –Bone flap stored in sterile bag and then sterile sealed container
  - –Repeat prior to implantation

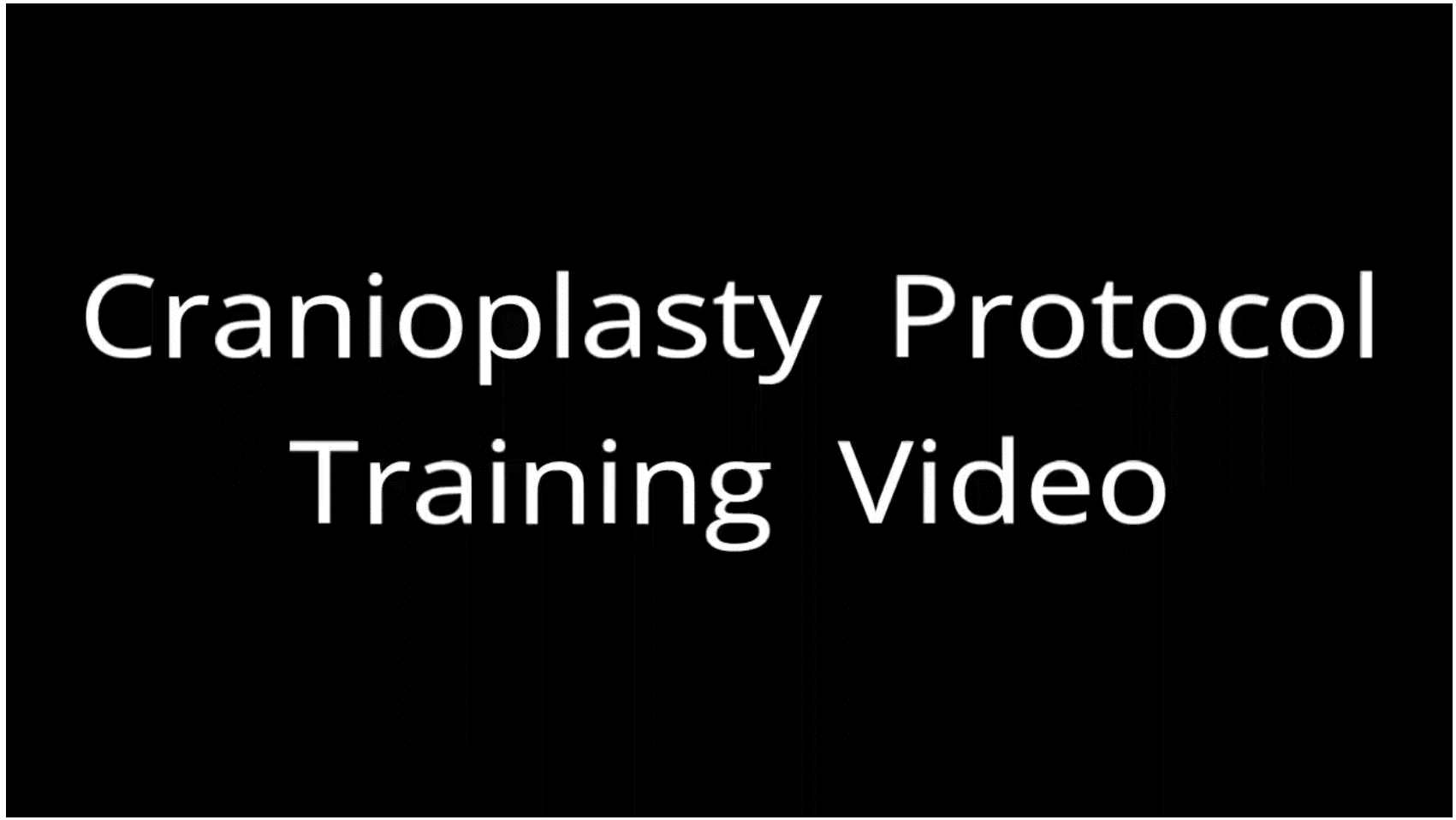
Interventions-cont.

- Track all future cranioplasties
  - Established required EMR documentation checklist for OR nursing to document protocol was followed during all cranioctomies and autologous cranioplasties
  - Will audit all stored bone flaps every 6 months
- Agreed with no early cranioplasties before 6 weeks

Implementation

- Researched best practices and devised a standardized protocol for the handling of the bone flap after removal and prior to replacement
- Got buy in from all surgeons regarding implementation of the protocol
- Met with OR staff and got approval from OR committee for protocol
- Filmed instructional in service video for all OR staff regarding protocol
- Created Check-list in EMR

Educational Video



Protocol Poster

CRANIAL BONE FLAP

SOAKING PROTOCOL

FOR ALL EMERGENCY CRANIOTOMIES, CRANIOTOMY FOR ANEURYSM, AND CRANIOPLASTIES

Bone flap is soaked before leaving the field, and upon return from Blood Bank for Cranioplasty)

First Soak: 50,000Units Bacitracin/1 liter Normal Saline x 15 minutes. Make sure flap is completely submerged the entire 15 minutes.

Second Soak: Betadine Paint/Solution (6-8 bottles or 24-32 oz) x 15 minutes. Make sure flap is completely submerged the entire 15 minutes.

Step 3: Pulse Evac with 3 liters Normal Saline (without antibiotics.)

EMR Checklist

Cultures?

Culture Count

Culture Note

Specimen?

Specimen Count

Specimen Note

Do you have a Large extremity specimen?

1st place extremity in plastic bag:

Place plastic bag in Red Biohazard bag and label:

Was Specimen Double Bagged Appropriately?

Was Specimen Hand Carried to Histology?

Name of attendant taking specimen to lab:

Page Histology supervisor 203-0670: to accept specimen

CRANIAL BONE FLAP:

Was a Cranial Bone Flap Lifted From the Patient?	Which Side Was Lifted?	Disposition of Cranial Bone Flap	Was Cranial Bone Flap Hand Carried to Blood Bank?	Name of Attendant taking Bone Flap to Lab

Cranial Bone Flap Washed Using Soaking Protocol?

Specimen fields updated May 2016

Project Cycle

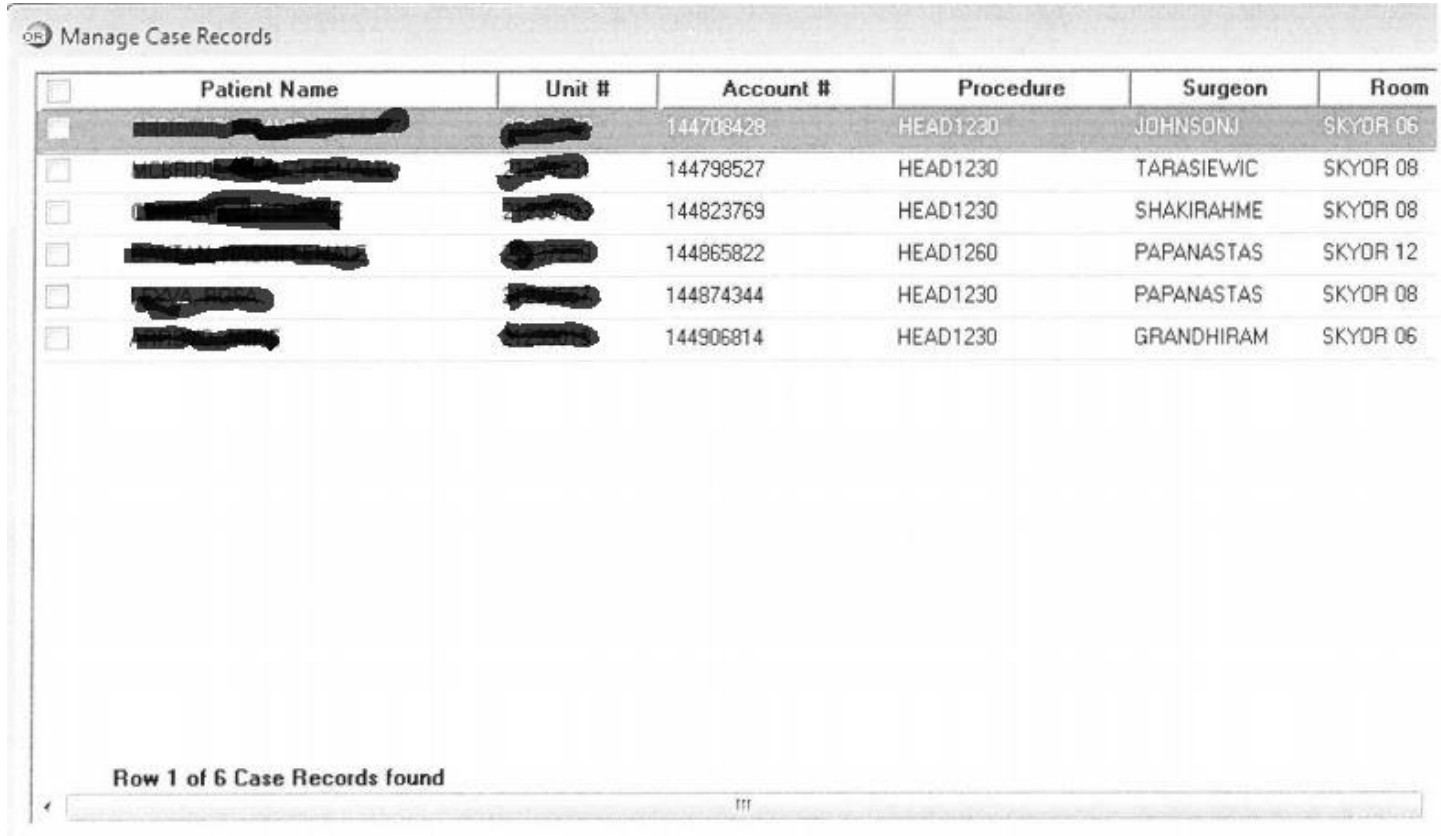
Results

- Short term data consists of compliance data via face to face surveys with OR team members following all craniectomies and cranioplasties
- Long term data will consist of compliance data in EMR and prospective cranioplasty infection tracking

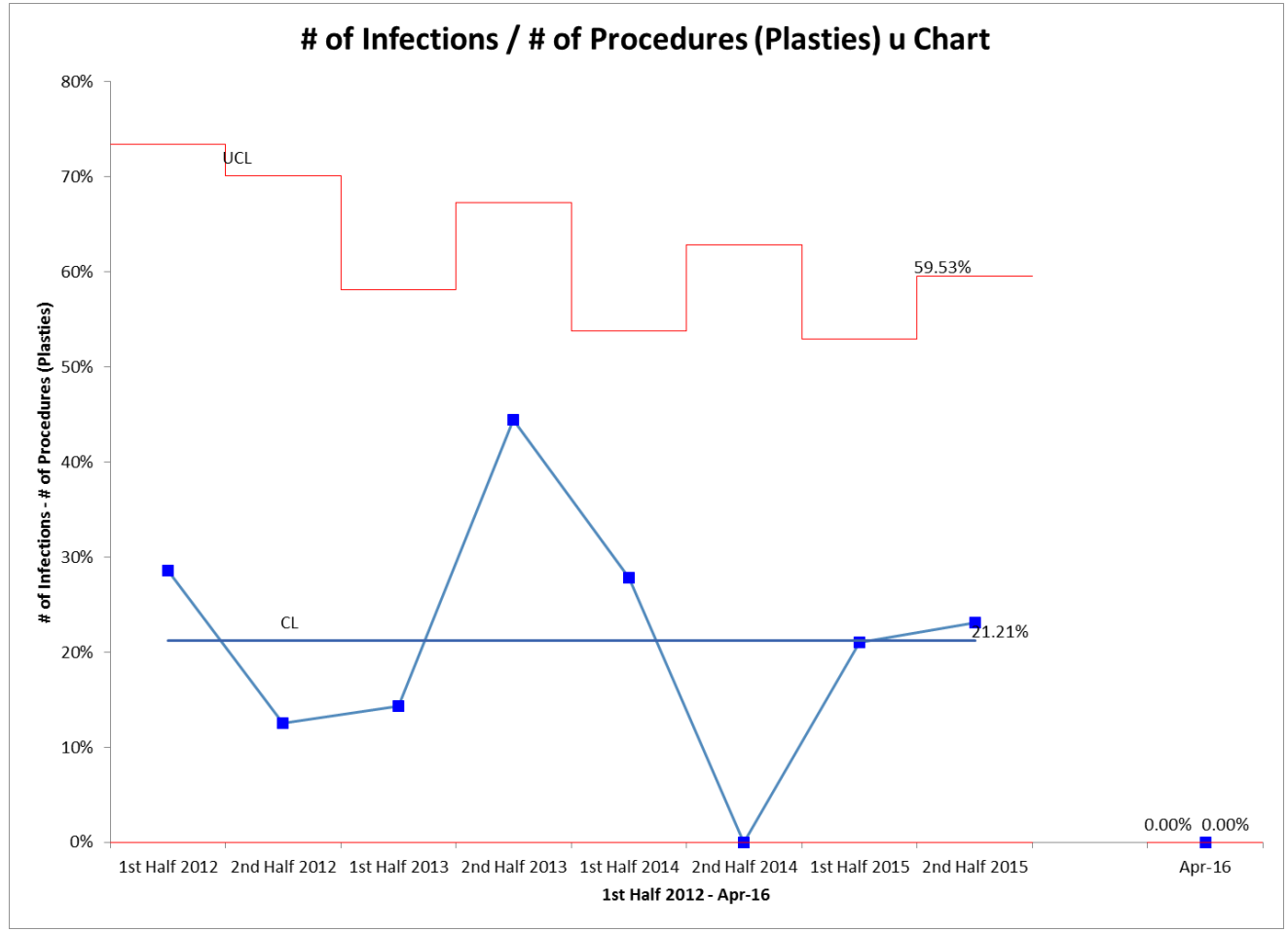
Results

- From April 1 to April 30, 2016
  - First full month following implementation
  - 6 autologous cranioplasties
    - 100% compliance with new cranioplasty soaking protocol
  - 5 emergency craniectomies
    - 100% compliance with new cranioplasty soaking protocol
  - No early infections
  - No early cranioplasties

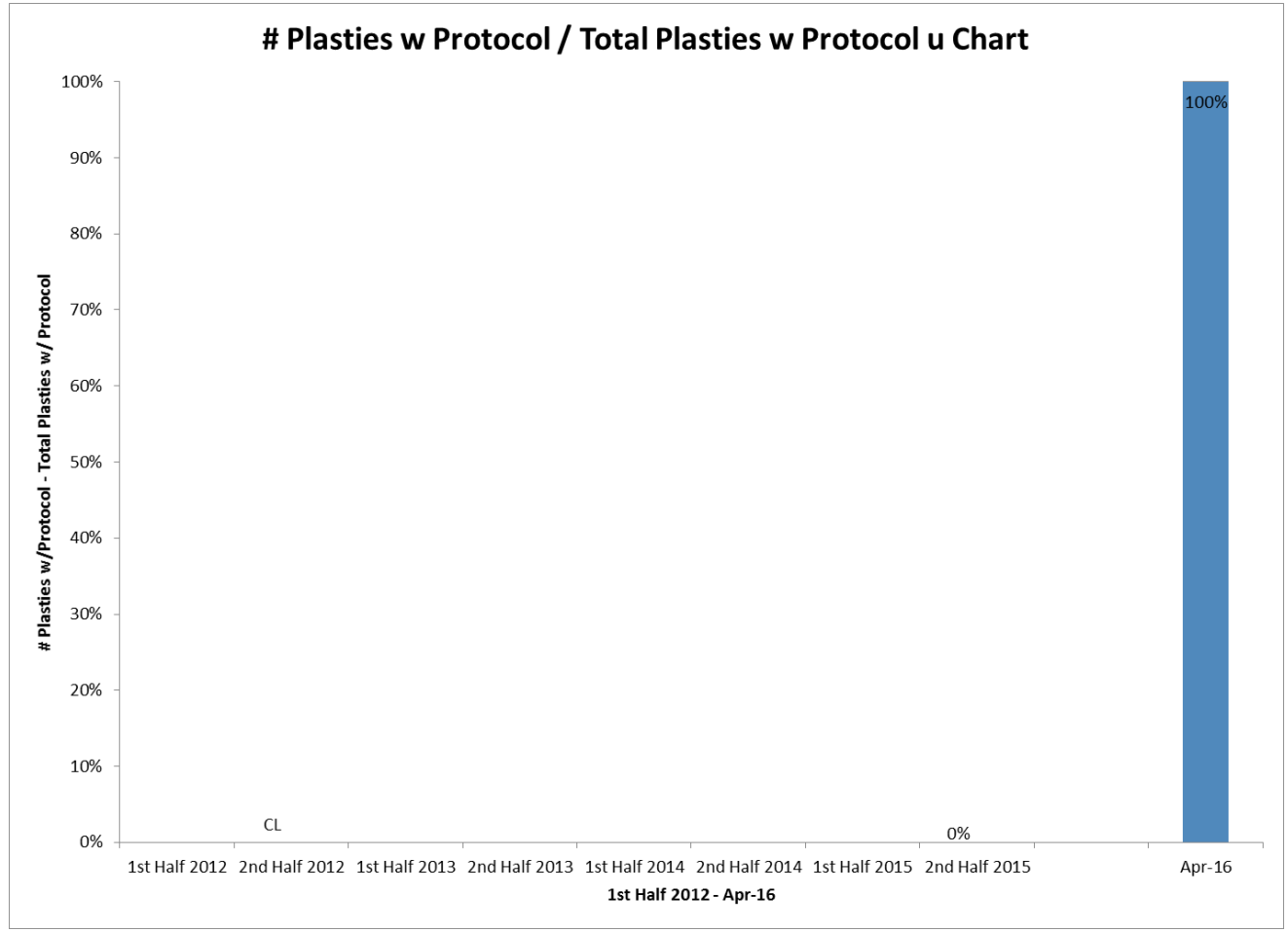
Results


Manage Case Records
Patient Name
Unit #
Account #
Procedure
Surgeon
Room
144708428 HEAD1230 JOHNSONJ SKYOR 06
144798527 HEAD1230 TARASIEWIC SKYOR 08
144823769 HEAD1230 SHAKIRAHME SKYOR 08
144865822 HEAD1260 PAPANASTAS SKYOR 12
144874344 HEAD1230 PAPANASTAS SKYOR 08
144906814 HEAD1230 GRANDHIRAM SKYOR 06
Row 1 of 6 Case Records found

Results- Infections Rate



Results- Protocol Compliance



Sustaining the Results

- Previously it was difficult to track cranioplasties and subsequent infections in real time. We have implemented tracking within nursing EMR
- We'll meet regularly with OR nursing leadership to review the data
- We will use random surgeon and OR staff audit surveys to document compliance with the protocol

Return on Investment

- Cost of Implementation of Soaking Protocol
  - Minimal additional operating room time
  - Bacitracin ~$25
  - Betadine ~$95
  - Pulsavac ~$40
  - Normal Saline Solution ~$30
  - Approximately $190/case for implementation of soaking protocol

Return on Investment

- Cost of Cranioplasty ranges from $14,500-75,000
- Cost of autologous cranioplasty infection
  - Average inpatient hospital bill for 6 surgically treated autologous cranioplasty infections from January 2015 to December 2015: $82,654
  - Does not include the eventual implantation of a synthetic cranioplasty
  - Atbx 2 weeks and hospital stay 30,000-60,000$(ssi surgical site infection vs MRSA)

Return on Investment

- A 50% reduction in autologous cranioplasty infections would likely result in yearly savings to all payers in the high seven figures

Conclusion

- Pre-intervention data confirms our anecdotal suspicion of an abnormally high rate of infection associated with autologous cranioplasty
- Following extensive participant buy in and education we have had good compliance with a new cranioplasty soaking protocol which we are hopeful will reduce our rates of infection
- A successful 50% reduction in our rate of infection has the potential to save hundreds of thousands of dollars per year

Team Picture