



# MD EXPO

Orlando, FL • October 29-31, 2023

# Save Time and Money

## Shift PMs from OEM to Repair-as-Needed (RAN)

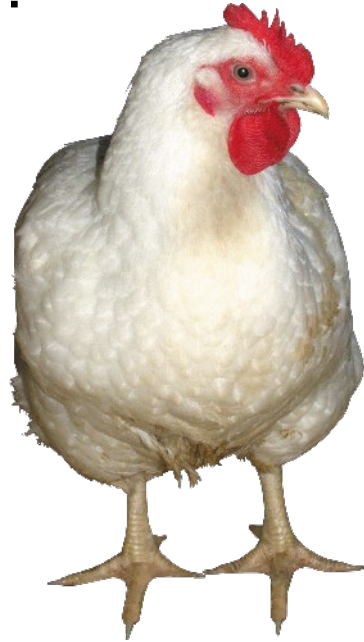
BY : MARK R. COOKSEY





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Why do PM?



PMs *prevent* downtime, right?



## The Problem.

- After state-wide COVID restrictions were lifted, patient **census skyrocketed**.
- Clinical Engineering was **denied access** to beds for PM.
- Scheduled Bed PMs became **past due**.
- A non-conformance (**NC**) was issued.
- A Corrective And Preventative Action (**CAPA**) was created.
- CE needed a **solution**.

What are the **risks** of **not** doing PM?



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# The Solution.



Use Lean 6 Sigma Tools to Solve the Problem

Let's Talk!



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## Orlando 2023



Mark Cooksey, DME Quality Engineer,  
Norton Healthcare

Save Time and Money Shifting PMs from OEM to Repair-As-Needed

**Tuesday, October 31, 8-9am**

After the COVID-19 restrictions eased, Norton Healthcare's census for its inpatient hospitals skyrocketed. With more patients in beds, clinical engineering was unable to gain access and perform PMs. During COVID, clinical engineering moved from an OEM preventative maintenance schedule to an alternative equipment maintenance (AEM) schedule but because of the rising patient census, it was missing the scheduled PM completion targets. How could biomed meet its scheduled PMs when it couldn't gain access to the beds? This question led to another question. Did the OEM schedule actually prevent failures? Could beds be put on a repair-as-needed (RAN) schedule without incurring the risk of increasing repair downtime? Learn how Norton Healthcare used statistical quality tools to validate its plan to change from an AEM to a RAN schedule for its beds freeing up valuable biomed resources without sacrificing customer service.

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**Welcome to MD Expo 2023!**



## What you will take back

- How “non-conformances” leads to **Opportunities for Improvement (OFIs)**
- Lean 6 Sigma approach to **problem solving**
- PM cost/benefit from a **risk** perspective
- Use **statistical tools / analysis** for change
- Calculate FTE **savings**

# Problem Solving

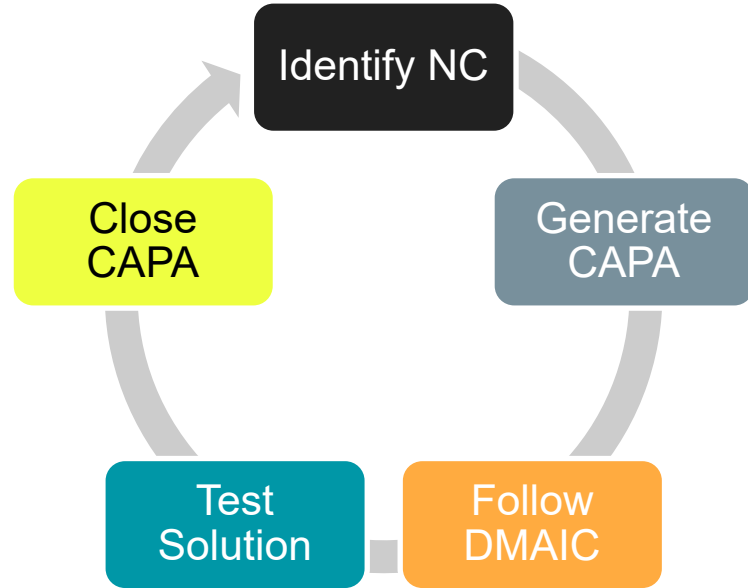


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PRE-ISO 13485



POST-ISO 13485





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# DMAIC

The Lean 6 $\sigma$  DMAIC Process



## DEFINE

Define the Problem

## MEASURE

Measure the Current State

## ANALYZE

Identify Causes

## IMPROVE

Brainstorm Solutions

## CONTROL

Monitor New Process

# Lean 6 Sigma Problem Solving





## The Problem.

- **Problem:** Current Process poses potential risk due to limited access to perform PM.
- **Root Cause:** Increased patient census prevented access to beds for maintenance.

Step 1: Define the Problem



- Bed Exit Alarm System
- Intellidrive® Transport System
- Auxiliary AC Receptacle Option (120 V Version Only)
- ⊖ Navicare® System
- ⊖ Safeview® Alerts
- ⊖ Accessories
- ⊖ Safety Tips
- ⊖ Clean and Disinfect
- Preventive Maintenance**
- **Troubleshooting**
- **Bed Functions**
- The Bed Controls Do Not Work
- The Bed Does Not Lower
- The Foot Controls Do Not Work
- The Display on the Control Pod Is off
- The Display on the Control Pod Flashes When a Weight Is Taken
- The Head Section Angle Appears to be Different than the Head Angle Display Shows
- Are Flashing
- A Siderail Does Not Latch
- **Treatment/Therapy Surface Functions**
- The Surface Does Not Inflate or Does Not Inflate Correctly
- Turn Assist Does Not Work
- All Four Surface Mode Indicators Are Flashing
- Product Symbols
- Specifications



## Preventive Maintenance

### ⚠ WARNING:

Only facility-authorized personnel should service the VersaCare® Bed. Servicing performed by unauthorized personnel could result in personal injury or equipment damage.

The VersaCare® Bed requires an effective maintenance program. We recommend that you perform annual preventive maintenance (PM) and testing for The Joint Commission (formerly JCAHO). PM and testing not only meet Joint Commission requirements but will help make sure of a long, operative life for the VersaCare® Bed. PM will minimize downtime due to excessive wear. For the preventive maintenance schedule, refer to the *VersaCare® Bed Service Manual (161955)*.

Perform annual preventive maintenance procedures to make sure all VersaCare® Bed components are functioning as originally designed. Pay particular attention to safety features, including but not limited to the following:

- Siderail latching mechanisms
- Caster braking systems
- Electrical system components
- Electrical power cords for fraying, damage, and proper grounding
- All controls return to off or neutral position when released
- Controls or cabling entanglement in system mechanisms or siderails
- Proper operation of the lockout controls
- Integrity of sleep surface ticking
- Actual angle of the head section compared to the degree shown on the display (beds with the Head Angle Display option)

### VersaCare® Bed Main Battery

Replace the battery if any of the following conditions exist:

- The battery indicator does not light within 2 hours of bed connection to AC power.
- The battery indicator does not stop flashing (low condition) within 12 hours of bed connection to AC power.

# OEM Versacare Bed PM

# SERVICE MANUAL

VersaCare™  
Bed  
From Hill-Rom



Product No. P3200/P3201

For Parts or Technical Assistance  
USA 800-445-3720 Canada 800-267-2337  
International: Contact your distributor.

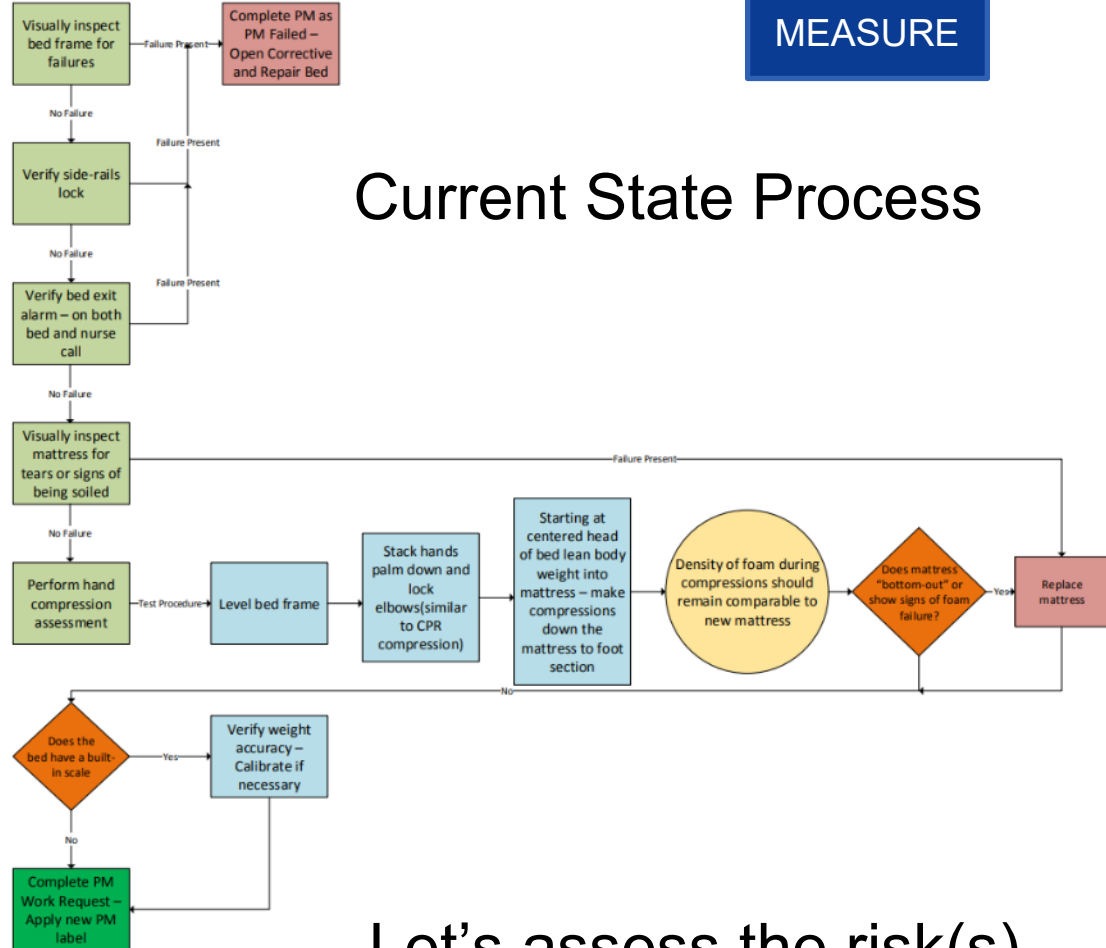
MAN333 REV 2

FRAME

ALARM

MATTRESS

WEIGHT



MEASURE

## Current State Process

Let's assess the risk(s)

What is Risk?



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MEASURE

SEVERITY

X

DETECTION

X

FREQUENCY

RISKS CAN BE EVALUATED ALONG 3 FACTORS

Risk Prioritization Number - RPN

# High Risks



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MEASURE

Traffic Safety	Distracted Driving	Using mobile devices while driving
<b>Information Security</b>	<b>Cybersecurity Threats</b>	<b>Data breaches and online security risks</b>
Healthcare	Health Neglect	Ignoring minor health issues and check-ups
Financial Security	Financial Scams	Investment and phishing fraud
Food Safety	Foodborne Illness	Contaminated food and related illnesses
Healthcare	Prescription Medication Errors	Mistakes in medication dosage and usage
Home Safety	Carbon Monoxide Poisoning	Colorless, odorless gas from faulty systems
Disaster Preparedness	Inadequate Emergency Preparedness	Lack of preparation for disasters and emergencies
Vehicle Safety	Neglecting Vehicle Maintenance	Consequences of not maintaining vehicles
Disaster Preparedness	Lack of Disaster Preparedness	Unpreparedness for natural disasters and emergencies

Bad, Hard to detect, Happens all the Time



## What is the RPN of a **Data breach**?

SEVERITY	X	DETECTION	X	FREQUENCY		
5	X	5	X	5	=	125
Real Bad If it Happens		Difficult to Detect		Daily Cyber Hacks		

RPN > 50 are **RED**

Risk Prioritization Number - RPN

# Risky Business



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- After state-wide COVID restrictions were lifted, patient census skyrocketed.
- Clinical Engineering was denied access to beds for PM.
- Bed PM completions metrics tanked.
- CE needed to evaluate the **risks**.

What are the **risks** of **not** doing PM?



- A failure of the side rail latching mechanisms can lead to
  - unintended **patient falls**
  - entrapment between the side rails,
- Severity (5):

## Side rail Latching Mechanisms





- Caster braking system failures make it difficult to secure the bed causing:
  - **impact** patient **safety and mobility**.
  - unintentional bed movement
  - patient falls
  - Difficulty securing the bed in a fixed position.
- **Severity (4):**

## Caster Braking Systems



- Electrical System Component failures can lead to
  - power outages
  - malfunctioning bed adjustments
  - unexpected movements
  - **danger** to patients or caregivers.
- Severity (5):

## Electrical System Components



- Damaged Electrical Power Cords can lead to
  - electrical shocks
  - fires
  - power loss
  - **reduced safety** and functionality of the bed.
  - **Severity (4):**

## Electrical Power Cords



- Return to Neutral Control can significantly impact bed functionality:
  - Inaccurate positioning
  - unintentional adjustments
  - patient **discomfort**
  - affect medical procedures
  - **Severity (3):**

**Return to Neutral Control**



- Controls/Cabling Entanglement can hinder adjustments
  - lead to **difficulties** in patient positioning
  - potentially affecting patient care
  - **Severity (4):**

## Controls/Cabling Entanglement



- Inadequate lockout controls may result can hinder adjustments can
  - impact bed operation and patient care.
  - create unintended adjustments
  - potentially cause **inconvenience or discomfort** for patients.
  - **Severity (3):**

## Lockout Controls



- Torn or compromised Sleep Surface can
  - significantly impact patient **comfort and hygiene**
  - result in uneven support
  - increase risk of pressure ulcers for patients
  - **Severity (3):**

**Sleep Surface**



- Incorrect head angle display, while not posing immediate safety risks can
  - create improper positioning
  - impact **patient comfort** and satisfaction
  - **Severity (3):**

## Head Angle Display





- Failure to replace the main battery can
  - lead to **power loss**,
  - affecting the bed's operation and patient care.
  - impact the bed's backup power
  - **Severity (4):**

## Bed Main Battery



Item	Severity	Detection	Frequency	RPN
Side rail Latching Mechanisms	5	1	3	15
Caster Braking Systems	4	1	3	12
Electrical System Components	5	1	3	15
Electrical Power Cords	4	1	2	8
Control Return to Neutral	3	1	3	9
Controls/Cabling Entanglement	4	1	2	8
Lockout Controls	3	1	2	6
Sleep Surface	4	1	3	12
Head Angle Display (if applicable)	3	1	2	6
VersaCare Bed Main Battery	4	1	3	12

**Key Take Aways - Risks**  
Severity may be **high**  
Detection of failure is **easy**  
Frequency of failure is **low**

**Low RPN: Evaluate PM Schedule Options**



## PROBLEM STATEMENT

Barriers to access  
prevent CE from  
following the OEM PM  
schedule

## STATISTICAL QUESTION

Is there a **statistically significant** difference in  
OEM vs. RAN for  
Versacare Beds?

**Convert Practical Problem to Statistical Quest**



**Warning:** **Statistical Analysis** may cause

Confusion

Nausea

Vomiting

Headaches

Diarrhea

Loss of Appetite

Numbness

Tingling

Fatigue

Night Sweats

**Statistics: will this hurt?**

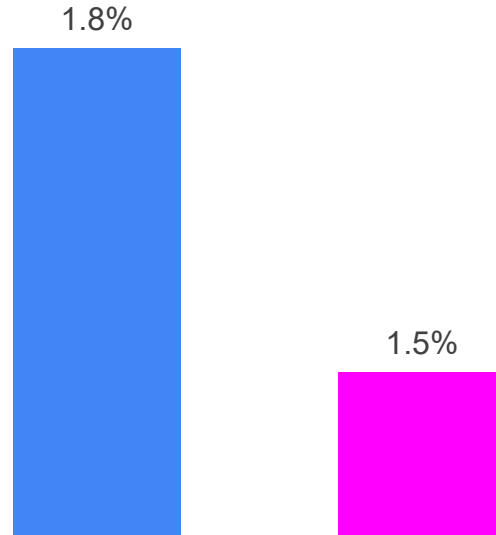


In one year,  
500,000 patients  
with COVID died

Men died at a *higher* rate than  
women.

Is the difference **statistically  
significant?**

COVID DEATH RATE



**How can we test this hypothesis?**



Chi-Square is a statistical tool used to determine if a **relationship** exists among categorical (**discrete**) variables and specific outcomes

It tests **count data** among discrete groups:

Democrat, Republican, Independent  
Male, Female  
Drug, Placebo

$\chi^2$

**What is Chi Square?**

**Chi-Square Test using p-value <.05**

**OBSERVED COUNTS (ACTUAL) in 1000s**



**EXPECTED COUNTS (CALCULATED)**



p-calculate

5. Analyze



**Chi-Square Test using p-value <.05**

**OBSERVED COUNTS (ACTUAL) in 1000s**

	DIED	SURVIVED	Row Total
MEN	273	14616	14889
WOMEN	228	15155	15383
Column Total	501	29771	30272 =< Grand total

**EXPECTED COUNTS (CALCULATED)**

	DIED	SURVIVED	Row Total
MEN	247	14642	14889
WOMEN	255	15128	15383
Column Total	501	29771	30272 =< Grand total

I want to be 95% confident so my p criteria value is  $1 - .95 = 0.05$

if p(calculated) < p(criteria), reject Null Hypothesis DIFFERENCE  
 if p(calculated) > p(criteria), fail to reject Null (cannot see a difference). NO DIFFERENCE

p-calculated = `=CHITEST(D8:E9,D15:E16)` or `=CHISQ.TEST(D8:E9,D15:E16)`

p-value calculated = 0.015

Is p(calculated) < p(criteria) Yes

5. Analyze Result Difference is Statistically Significant

# Chi Square: Gender Links to Death Rate



## Baseline

2019  
Prior to COVID



## Hypothesis

Do PMs  
Impact  
CMs?

## Results

PM vs Non-  
PM beds  
had same  
CM rate

## Analysis

2019 vs. 2020  
Trend  
Chi Square



## Corrective and Preventive Action Record

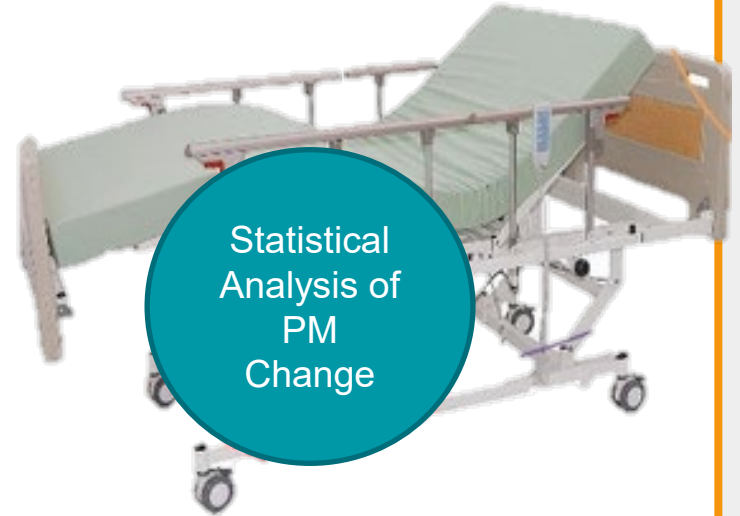
PART A: CAPA Information			
<b>CAPA #:</b> CAPA22-010	<b>Date Initiated:</b> 7/12/2022	<b>Initiated By:</b> Mark Cooksey	<b>Source Document #:</b> CR22-002
<b>CAPA Initiated From:</b> <input type="checkbox"/> Audit Finding <input type="checkbox"/> Supplier <input type="checkbox"/> Complaint <input checked="" type="checkbox"/> Nonconforming Product/Process  <input type="checkbox"/> Improvement Idea/Good Catch/Safe Moment <input type="checkbox"/> Other: (specify)			<b>Corrective Action</b> <input checked="" type="checkbox"/> <b>Preventive Action</b> <input type="checkbox"/> <b>OFI Suggestion</b> <input type="checkbox"/>
<b>Description of CAPA/Improvement Idea:</b> During a random sweep with Biomed Supervisor and Director, a number of bed PM stickers were found past due. Since July 2022, Bed PMs following an AEM schedule have been replace with a RAN (Repair as Needed)			
<b>Category of the CAPA:</b>	<input type="checkbox"/> Major 5 days	<input checked="" type="checkbox"/> Minor 15 days	<input type="checkbox"/> Opportunity for Improvement 20 days (Response Due Date per QSP)
<b>Risk Assessment of CAPA:</b>	<input type="checkbox"/> Critical	<input checked="" type="checkbox"/> Significant	<input type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Minimal (See Appendix)
<b>Further Investigation Required?</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<b>Present to Standing Committee(s)</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>Due Date for Response:</b> 7/19/2022		<b>Investigator Assigned:</b> Kara Fautz/Mark Cooksey	

# Use CAPA to document improvement



# Can we use statistics to validate our PM change?

Analysis to Close Out  
CAPA22-010



## Statistical Validation



- Situation: Non-Conformance identified when Bed PMs were found **past due**.
- Background: Beginning in 2020, Bed PMs were changed from OEM-defined PMs to **AEM**.
- Assessment: After the COVID shutdown, patients census increased **restricting access** to perform the AEM PMs.
- Recommendation: Transition to a “repair as needed” (**RAN**) for beds and evaluate the impact on the rate of repairs.



2019

- **OEM**
- Scheduled PMs

PRE COVID

2020

TRANSITION TO  
**AEM** PM SCHEDULE

COVID YEARS

2021

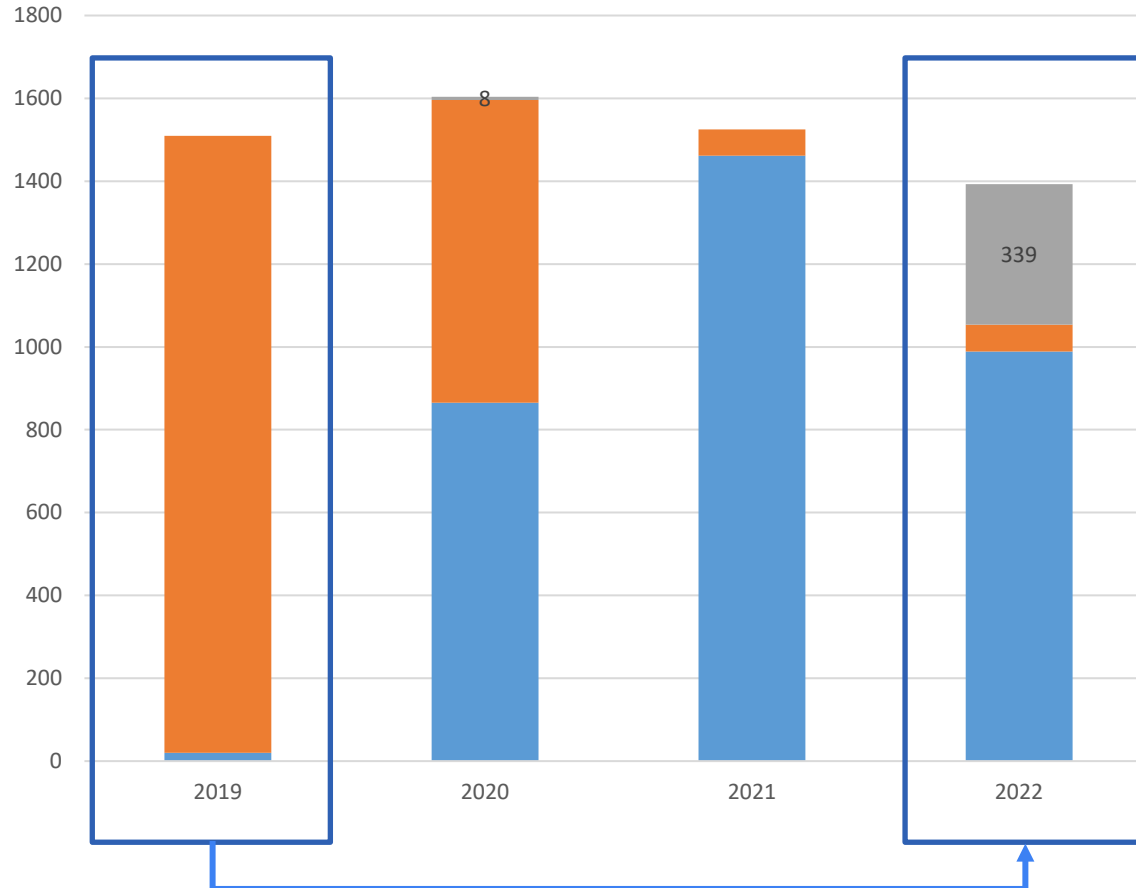
2022

- **RAN**
- **NO** scheduled PMs

POST COVID

## Timeline of PM Protocol Changes

# 4 Year PM Types: Transition from OEM AEM to RAN



**RAN**  
STARTED  
JULY 2022



<b>DEFECTS</b>	<b>D</b>	PMs past due = non conformity
<b>OVERPRODUCTION</b>	<b>O</b>	Resources spent for PM <u>and</u> CM
<b>WAITING</b>	<b>W</b>	Waiting on beds availability to do PM
<b>NOT USING TALENT</b>	<b>N</b>	Not trained in 6 Sigma tools
<b>TRANSPORT</b>	<b>T</b>	Difficult to move beds for repair
<b>INVENTORY</b>	<b>I</b>	Unused bed parts everywhere
<b>MOTION</b>	<b>M</b>	Documenting PM delays (FIUs, CNLs)
<b>EXTRA PROCESSING</b>	<b>E</b>	Do OEM PMs add value?

**Waste Eliminated = Time Saved = \$\$\$\$**



Manufacturer	Asset #	Asset Description
HILLROM	CE071752	VERSACARE PT CARE BED
HILLROM	CE071404	VERSACARE PT CARE BED
HILLROM	CE071110	VERSACARE PT CARE BED

Source: CMMS - **VERSACARE PT CARE BED**  
WORK ORDERS  
2019 - 2022

**Control Phase: Verification**





OEM PM  
Schedule

RAN  
(No PM)

The screenshot shows a data query interface with two filter panels. The 'Years' panel on the left has a list of years: 2018, 2019, 2020, 2021, 2022, <11/08/2018, >01/03/2023, and 2023. The 'Facility' panel on the right has a list of facility names: CHILDREN'S HOSPITAL FOUNDATIO..., NORTON AUDUBON HOSPITAL, NORTON BROWNSBORO HOSPITAL, NORTON CHILDREN'S HOSPITAL, NORTON HEALTHCARE SYSTEM, NORTON HOSPITAL, NORTON HOSPITAL PAVILION, and NORTON WOMEN'S and CHILDREN... Both panels have a search icon and a clear filter icon.

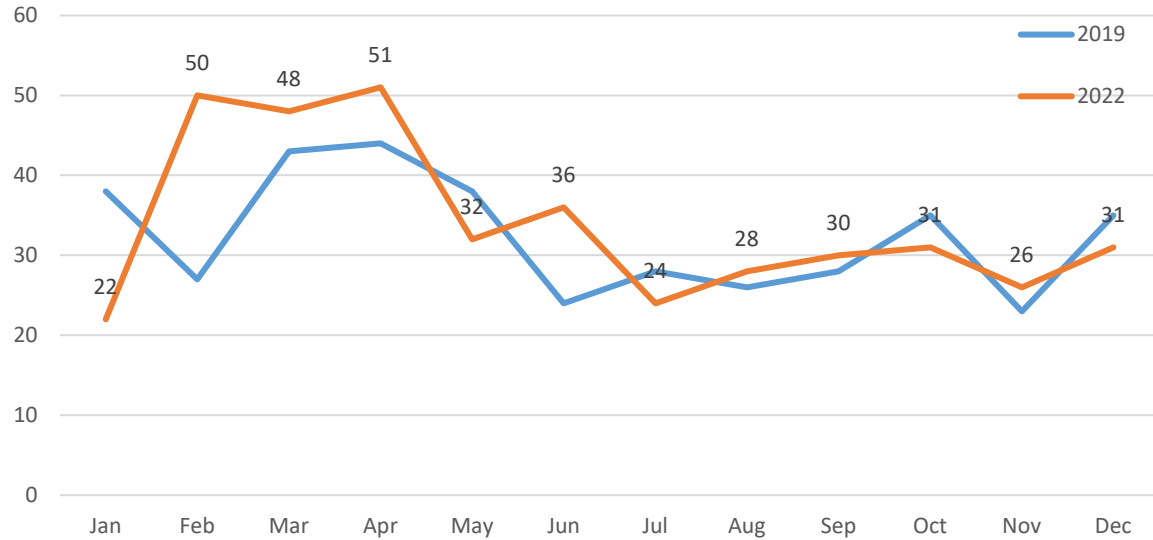
**Pull Repair Data Before and After**

# Trend Analysis



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CONTROL



Repair trends appear the same

# Chi Square Analysis



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**CONTROL**

Step	Details
Create Contingency Table	2 x 2 Outcomes vs. Inputs
Establish Hypothesis Criterion Target (CL)	95% Confidence Level (CL) for statistical significance
Establish target "p" value for Statistical Significance	5% threshold (1 - .95 = .05) target "p" value = 0.05
Calculate actual "p" Value	Using statistical software or Excel
Compare actual "p" to target "p" = .05	If "p" <b>actual &lt; 0.05</b> : assume statistical difference If "p" <b>actual &gt; 0.05</b> : do not claim a statistically significant difference
Interpretation	Since $p > 0.05$ , there is <u>no statistical difference between the two groups.</u>

	# of Beds Repaired	# of Beds <b>Not</b> Needing Repairs
<b>OEM PM</b> 2019	389	387
<b>RAN</b> 2022	409	367

Result: actual p value is .309  
Which is  $> .05$  target /threshold "p"

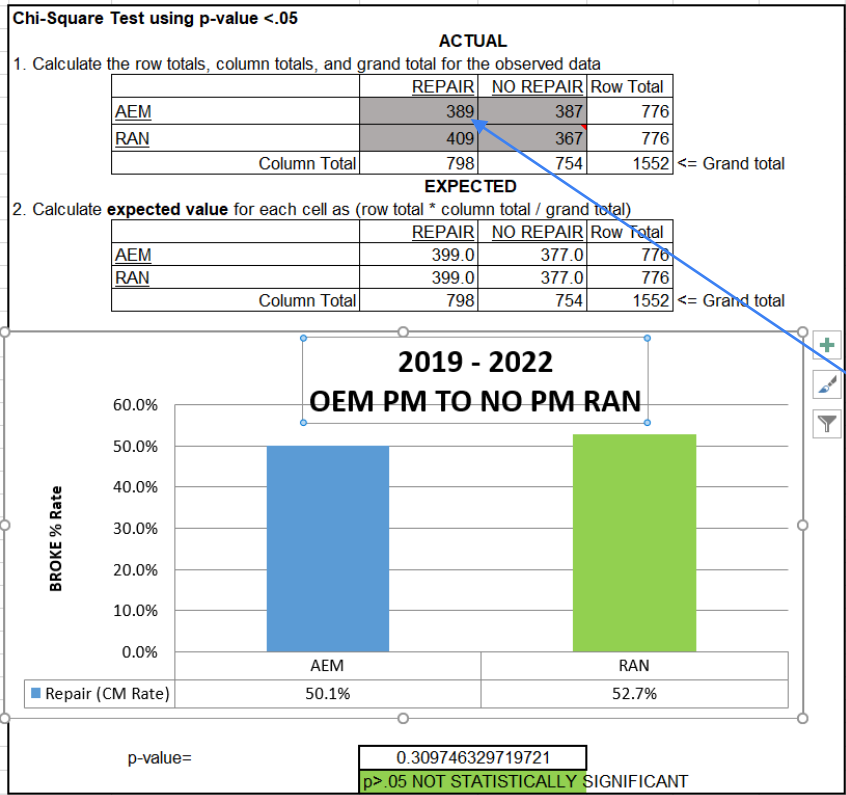
Interpretation: There is **no Statistically significant Difference** in # of Repairs OEM vs. NO PM

CLOSE OUT CAPA



## Chi Square Validates Repair Trend

# Chi Square Analysis finds **no difference** in CM rates OEM PM vs RAN (i.e. No PMs)



### Assumptions:

1. Include all type of CM repairs
2. NH Beds are **excluded** from the data set
3. Each Bed in service is an opportunity for repair.
4. There are 776 opportunities for repair

Column Labels	2022	Grand Total	
2019	38	22	60
	27	50	77
	43	48	91
	44	51	95
	38	32	70
	24	36	60
	28	24	52
	26	28	54
	28	30	58
	35	31	66
	23	26	49
	35	31	66
	<b>389</b>	<b>409</b>	<b>798</b>

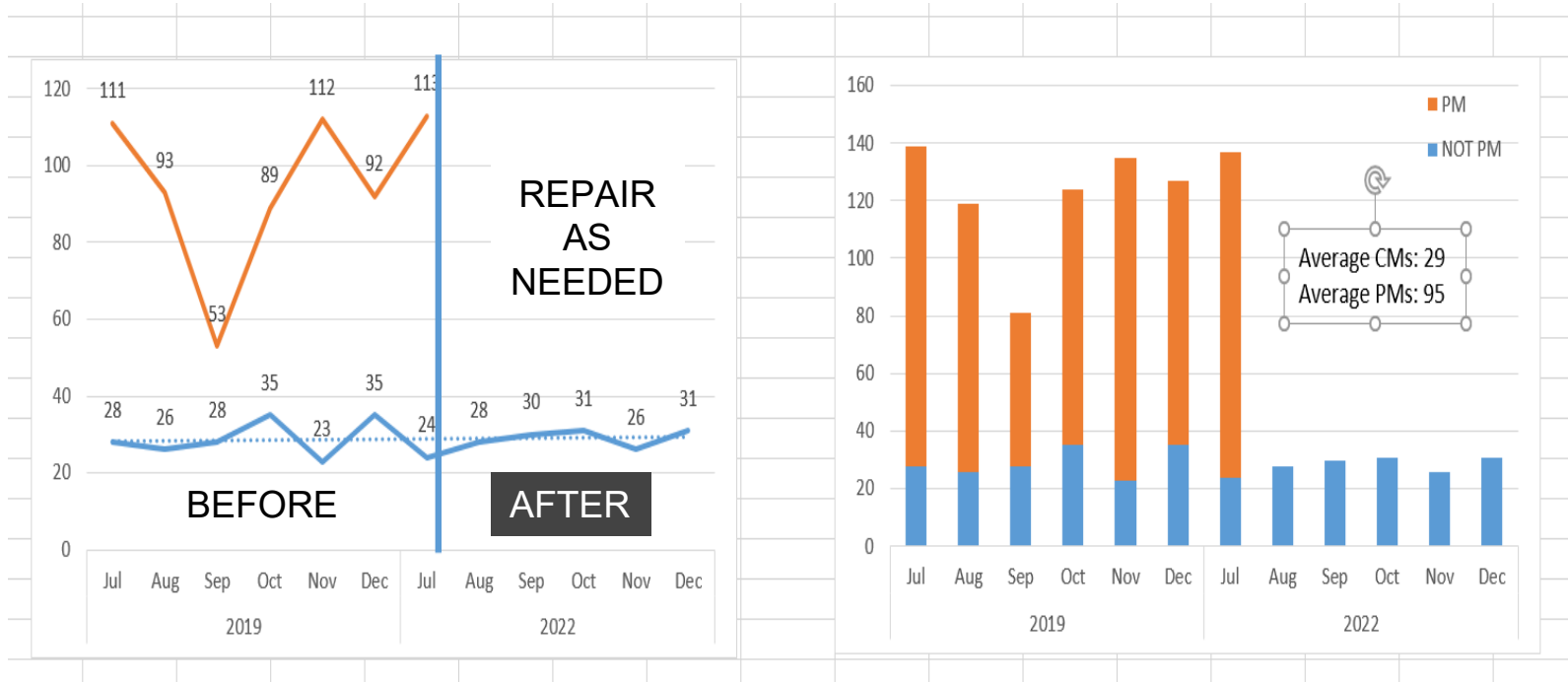
PM OR NOT  
 NOT PM  
 PM

# Close Out CAPA



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**CONTROL**



**RAN validated: Close out CAPA**



CALCULATE FTE SAVINGS FROM PM CHANGE

TOTAL PM TIME / BED

X

TOTAL # OF BEDS



TOTAL PM TIME AVAILABLE / TECH

KEY ELEMENT	DATA
TOTAL PM TIME PER BED	<u>PM HOURS</u> BED
# OF BEDS	TOTAL BEDS
TECH TIME AVAILABLE - HOURS (LESS BREAKS, MEETINGS, PTO)	<u>NET HOURS</u> YEAR

How much time was spent on PMs?



CALCULATE FTE SAVINGS FROM PM CHANGE

**3** HOURS PM TIME / BED

X

**1000** BEDS

=

**2.2** BED  
TECHS

**1352** HOURS AVAILABLE / TECH

KEY ELEMENT	DATA
TOTAL PM TIME PER BED	<u>3 HOURS</u> BED
# OF BEDS	1000 BEDS
TECH TIME AVAILABLE - HOURS (LESS BREAKS, MEETINGS, PTO)	<u>1352 HOURS</u> YEAR

**How much time was spent on PMs?**

Pay off



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CONTROL

What could *you*  
do with the extra  
capacity?



**What to do with extra capacity**





## What you will take back

- How “non-conformances” leads to **Opportunities for Improvement (OFIs)**
- Lean 6 Sigma approach to **problem solving**
- PM cost/benefit from a **risk** perspective
- Use **statistical tools / analysis** for change
- Calculate FTE **savings**



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# THANK YOU!

## CONTACT ME

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**We value your feedback!**

**Please scan the QR code to  
submit a survey for this  
session.**

**Thank You!**



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## TOTAL PM TIME / BED

## AVAILABLE TIME

Task	Minimum Time	Maximum Time
Regular Cleaning	15	30
Inspect and Tighten Fasteners	15	30
Check Electrical Components	15	30
Mattress Maintenance	15	30
Safety Checks	30	45
Inspect Casters and Wheels	15	30
Lubrication	15	30
Documentation	15	30
	135	255

### STANDARD HOURS DAY

8 HOUR

### DEDUCT

LUNCH / BREAKS

1 HOUR

MEETINGS / EMAILS

1 HOUR

PRORATED PTO ( 4 WEEKS x 8 ) / 52

WEEKS/YEAR

0.8 HOUR

NET WORK DAYS / YEAR

5.2 HOUR

52 WEEKS X 5 DAYS/ WEEK

260 DAYS

TOTAL HOURS AVAILABLE (260 X 5.2)

**1352 HOURS**