Healthcare Performance Improvement

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Marek Šturek

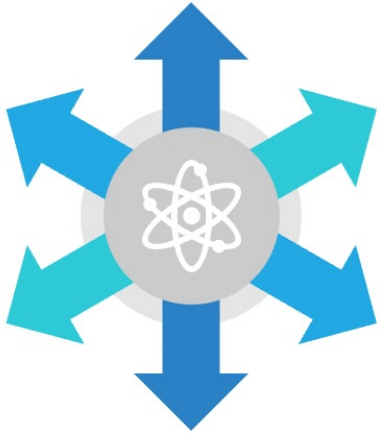
Agenda

- My journey into healthcare
- A brief overview of my healthcare work
- Connection b/w mind & heart, body & soul
- Some practical examples
- What can I do today

Crossroad

Spojená škola Tvrdošín

"Neučíme sa pre školu, ale pre život."



Timeline

YKHC

Bethel, Alaska

HNsP Trstená

Trstená, Slovakia

UPOL

Olomouc, Czechia

2007

Medtronic

Fort Worth, Texas

2014

2015

YVFWC

Yakima, Washington

2019

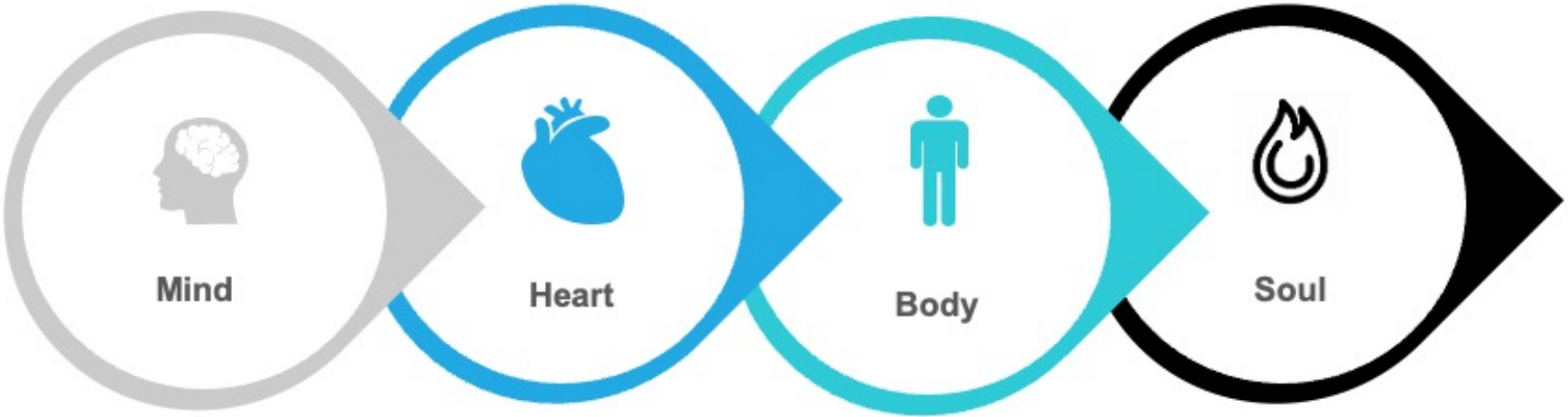
2020

SWHR

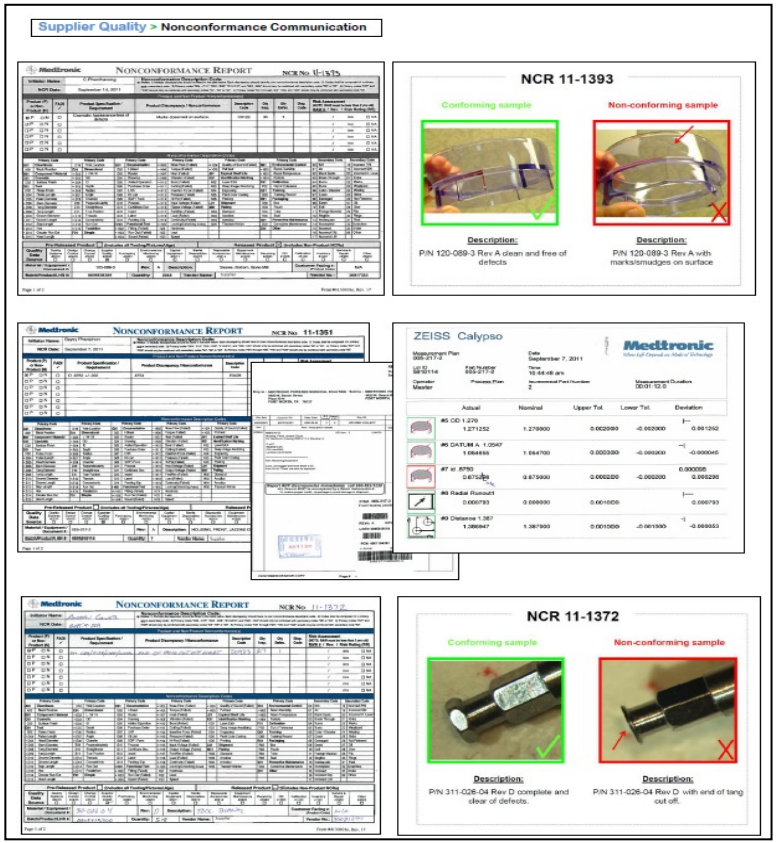
Dallas, Texas

2021

Holistic Approach



Reactive work assignments | 1/2



Medtronic

CORRECTIVE ACTION REPORT (CAR) FORM

COPY

CAR No.:	CAR 06-0092
☒ CA	☐ PA

Initiation/Background Information (CAPA Coordinator / Owner)

Product Description / Quality System	Microtec Process Capability (Length Dimension) for Part #100-580-4	**CAR Initiation Date**	10/11/06

CAR Source

- ☐ Management Review Meeting
- ☒ Quality Review Board (QRB)
- ☐ Complaint No. -
- ☐ NCR No. -
- ☐ CAPA System Review
- ☐ Investigation (Inv. No. -)
- ☐ Department Management
- ☐ Other:

Initial Risk Assessment

RAW #: NA-
(Attach copy of risk assessment)

- ☐ R1
- ☐ R2
- ☐ R3
- ☐ R4

Root or Probable Cause (If CAR source is not an Investigation)

☐ N/A (if CAR source is an Investigation)

CAR #06-0012 was issued to Microtec after MPSS received two lots of Part #100-580-4 and one lot failed incoming inspection because the overall length on 17 parts fell below the lower specification limit of .314". The initial implementation plan to perform 100% inspection on all subsequent parts for this dimension was not successful. The capability of Microtec's manufacturing process to provide parts with a proper length has not been determined or required by Medtronic.

CAR Owner	Chris Fussell	**Responsible Department**	Quality Assurance

CAR Implementation Plan (Owner)

Description of Corrective/ Preventive Action to be implemented:

☐ OR Attach a CAR Plan if the activities required are complex.

Microtec will begin capturing the data that is currently obtained during their in-process inspection procedures for the length dimension on the 100-580-4 part. The capability of the process will be determined from the data and appropriate actions will be taken to improve the capability as necessary. The current MPSS inventory levels for the 100-580-4 part will be sufficient for 3 to 4 months of production. Once Microtec begins manufacturing the 100-580-4 parts again, they will be required by MPSS Supplier Quality to provide in-process inspection data and capability measures for the length dimension of the 100-580-4 part.

Implementation Due Date 05/31/07 *(Provide date to CAPA Coordinator within 14 days of CAR initiation)*

☐ CAR Implementation Due Date Extended *(Attach Form 4141104 for each extension)*

Additional Team Members Requested? ☐ Yes ☒ No
(The Addition of Team Members Requires QRB Approval)

Name	Department	Name	Department

Proposed Criteria to Determine CAR Effectiveness

The in-process inspection data and process capability for the length dimension must be provided by Microtec for each of the next three production lots of the 100-580-4 parts that are manufactured for MPSS. The next three production lots must not fail for a non-conforming length dimension.

Initial Plan Approval (Owner, Owner's Supervisor, & CAPA Coordinator unless resources added)

	Signature	Date
Owner		10/25/2006
R&D		
Manufacturing		
Quality		10/25/06
Other		
RA *		
CAPA Coordinator		10/25/06

Provide Original to CAPA Coordinator After Approval

Reactive work assignments | 2/2

Project Charter **Date:** 31-January-2011 | **Project Name/QTRAK Number:** LSPR00020375

Problem Statement

Diamond coating yields at diamond coater, Di-Coat Corp., are below 96% causing shortages, affecting MPSS' ability to meet customer demands

Project Y	Path Y's (If needed)
Production yield (PY>97%)	Rolled Throughput Yield

Project Goal

Increase diamond coating yields at Di-Coat Corp. to greater than 97 % by August 2011

Scope

Scope includes: Diamond coating process through receiving inspection at Medtronic

Scope excludes: Transit, stem material, Medtronic packaging

Do not harm: Dimension of the product, durability of diamond coating

Resources

Project Team
- Julie Mouzakis
- Richard Castellanos
- Glenn Nolley
- Marek Šturek

Support Team:
- Kristin Hughes (MBB)
- Ross Smith (PO, SSBB)

Stakeholders:
- Tony Knight (CH)
- Dan Robinson (VSM)
- Dan Cleary (F)
- Humacao PR (C,S)
- Di-Coat Corp. (S)

Business Impact and Benefits

Schedule:
- Project start date: January, 2011
- Estimated project completion date: August, 2011
- Estimated date when benefits will begin: June, 2011

Benefits:

Hard savings: Estimated MPSS's scrap cost of $41K, Di-Coat's cost $31K. NCR scrap cost of $5K.
Soft savings: Reduce non-conformances, reduce rework
Other benefits: Strengthen partnership, Documented process controls

LEAN SIGMA SOLUTIONS™ -

Lean Six Sigma Di-Coat Corp. Production Project

		January-May 2011 (Prior Improve Phase)		June - August 2011 (Current State)	
I. NCR Reduction	1	Quantity (No.)	Cost ($)	Quantity (No.)	Cost ($)
		4	3485	0	0
		January-May 2011 (Prior Improve Phase)		June - August 2011 (Current State)	
II. Scrap Reduction	2	Quantity (pcs)	Average Srap (%)	Quantity (pcs)	Average Scrap (%)
		1868	4.684	1305	2.087%
		January-May 2011 (Prior Improve Phase)		June - August 2011 (Current State)	
III. Component Quantity	3	Quantity (pcs)	Average monthy receipts (pcs)	Quantity (pcs)	Average monthy receipts (pcs)
		49327	9865	61284	20428
IV. Savings	4	Di-Coat Corp. Savings		Medtronic Inc. Saving	
		400 pcs X $6 > $2400 per month		400 pcs X $10 > $4000 per month	
V. Other	-	-		-	
> MPSS Inspection time	5	Receiving inspection for curve burrs the same		Receiving inspection for curve burrs improved (Ultrasonic cleaning process removed)	
> Di-Coat Corp. Rework process	6	AVG Feb-May 2011 (Overplated, Sparse) 9.08%		AVG June-August 2011 (Overplated, Sparse) 2.47%	
> Inspection method variation	7	No visual methods of inspection established between MPSS & Di-Coat		Visual methods of inspection established & alligned	
> Di-Coat Corp. Operational & process metrics	8	Operational & process metrics the same		Weekly meetings / Data collection / Data analysis established	
What's next?		Complete drawing revisions	Drive excellence to improve Op. 40	Continue focus on XOMED curve burrs	Complete transfer to Plant No. 3

Proactive work assignments | 1/2

Medtronic MIDAS REX

RISK ANALYSIS WORKSHEET

RISK ANALYSIS TRACKING NO: RAW07-0013 | Rev.NEW

NCR / COMPLAINT# / OTHER: 07-0178

INITIATOR: JAMES ELLSWOTH — DATE INITIATED: 2/8/07

Primary Event Description (Include how the event was discovered and the facts surrounding the event.): Operator did not follow work instructions 4093800-10. 1. O-Ring was not coated with Midas Rex Lubricant prior to installation. 2. Also, step 4 of work instruction, inserting collet housing into compression nut was performed in the middle of step 3 before inserting collet carrier into collet housing.

Primary Event Source: (select one)

☒ Internal Source ☐ External Source

State Failure Effects:	☐ See Attached 1. O-Ring could become damaged during installation. 2. No failure effect is associated to this particular sequence.
State Potential Clinical Effects:	☐ See Attached There is no clinical effect of either situation 1 or 2. The risk is completely transparent to the doctor and patient.
State Potential Event Cause(s):	☐ See Attached Operator error - not following work instructions.

SEVERITY	Rationale:
☐ 4-Critical ☐ 3-Major ☐ 2-Minor ☒ 1-Negligible	1. The purpose of the O-Ring on the collet carrier is to minimize vibration. Even if the O-Ring is cut, it will still serve its purpose. There is no risk to the doctor or patient. 2. Inserting the collet housing into the compression nut prior to inserting collet carrier into collet housing has NO effect on the collet performance. Neither step is dependant on the other being performed in sequence.

FREQUENCY	Rationale:
☐ 4-Frequent ☒ 3-Occasional ☐ 2-Remote ☐ 1-Improbable	Work instructions are provided for operator at every work station, but human error is occasional.

DETECTABILITY	Rationale:
☒ 3-Not Detectable ☐ 2-May be Detectable ☐ 1-Readily Detectable	1. If the O-Ring is cut, it may not be detectable to the operator. 2. Performing assembly steps out of order would not be detectable unless found during an audit.

Calculate RPN

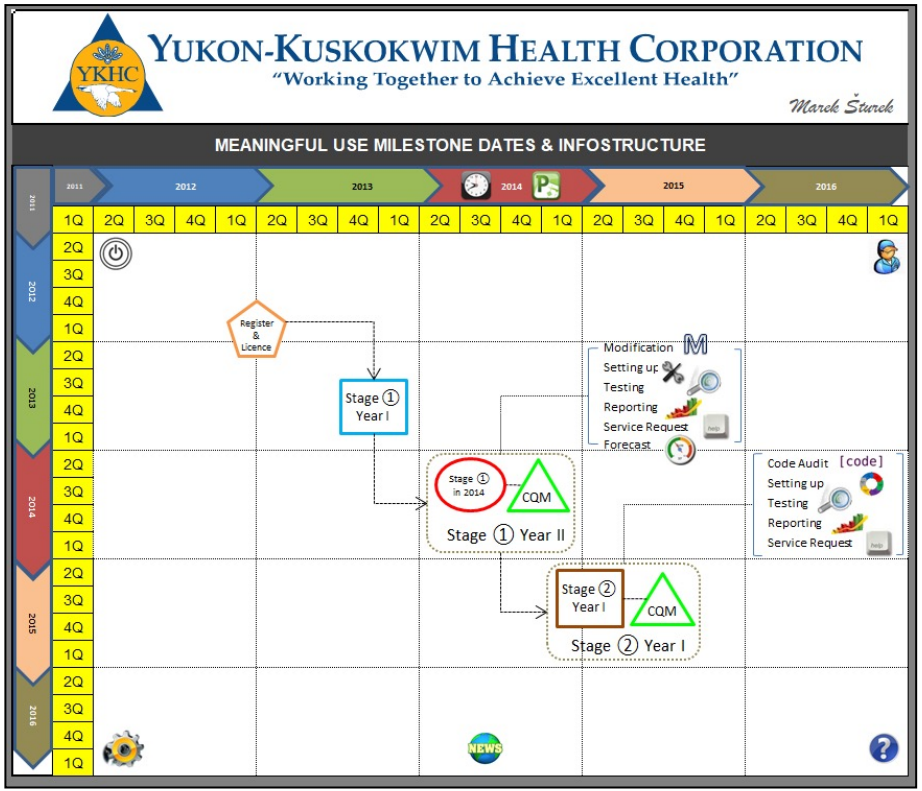
Severity X Frequency X Detectability = RPN

1 X 3 X 3 = 9

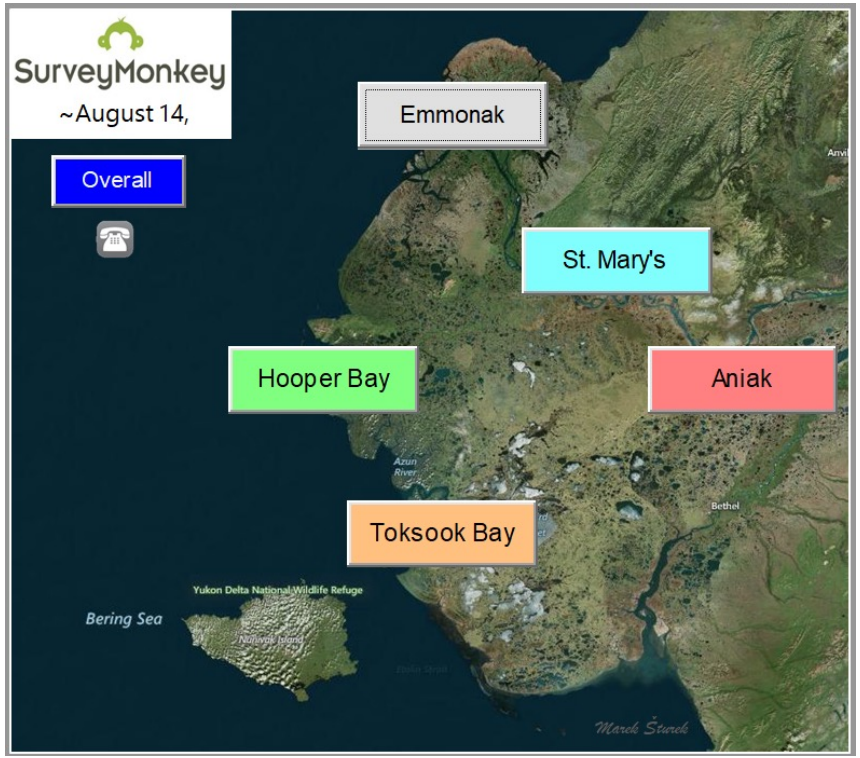
☐	≥ 24	R1	Intolerable Risk; must be mitigated
☐	12-23	R2	Unacceptable risk; must be mitigated per Table 4
☒	5-11	R3	Marginally acceptable; may require mitigation
☐	1-4	R4	Acceptable; mitigation not required

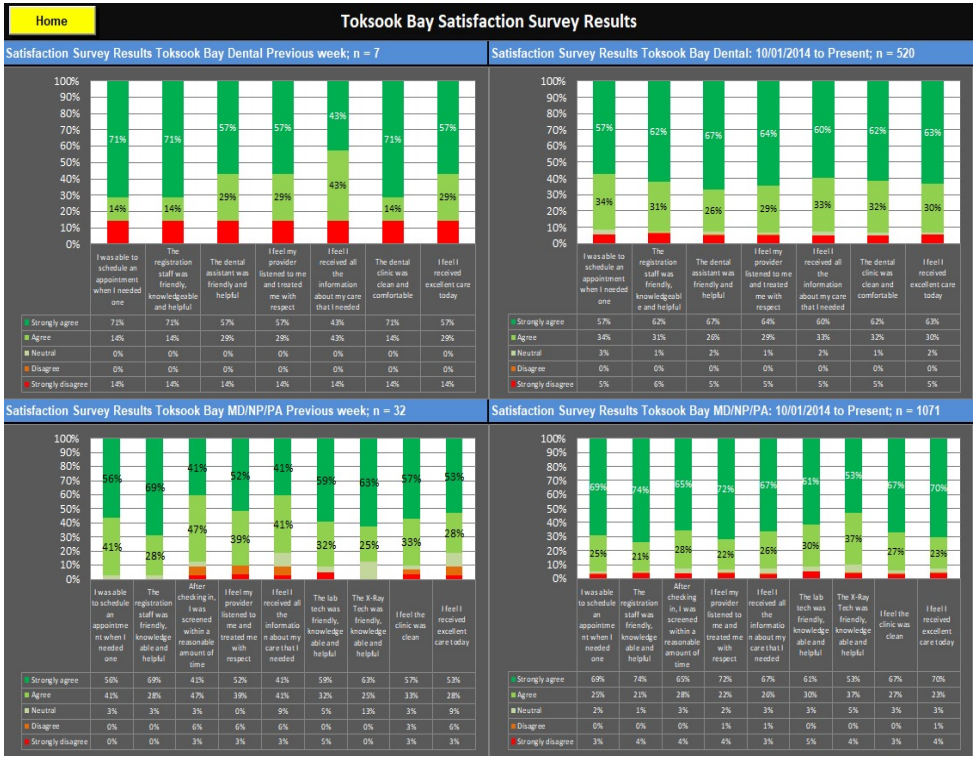
Approved By: (External Sources require Regulatory and Product Engineering Signatures, Internal Sources require Quality Engineering, Manufacturing Engineering, all product labeling and potential field impact requires Regulatory signature)

Department	Signature	Date
☒Quality Engineering	Jenn Tovar	2-22-07
☒Manufacturing Engineering	James Ellsworth	2-22-07
☐Regulatory		
☐Product Engineer (R&D)		

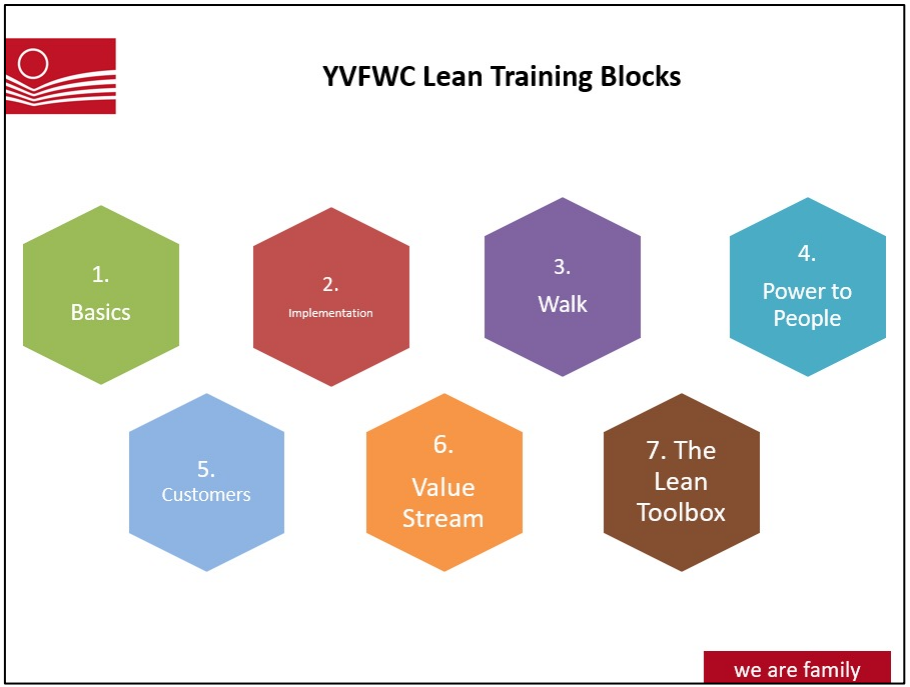


Proactive work assignments | 2/2





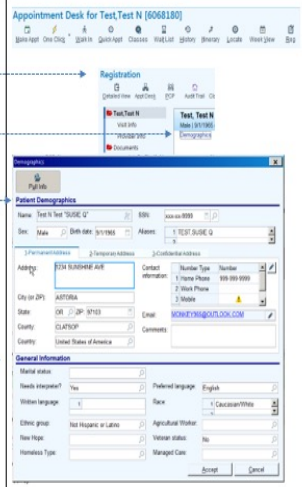
Preventive work assignments | 1/2



Preventive work assignments | 2/2

Task	Job:	Standard Work	Department:	Date:
R1	Acute Patient	YMDC Reception	Quality	12/04/2017

Task Elements Owner: Front Office Supervisor

	Description	☒ If Critical	Key Points	Visual Cue(s)
1.	Greet the patient	☒	Ask for D.O.B, First and Last Name, Introduce yourself. Let patient know who they are seeing and what time is appointment.	
2.	Demographics	☒	Click on Appointment Desk Registration Demographics Patient Demographics General Information	

HFMEA Subprocess Step Title and Number

HFMEA Step 4 - Hazard Analysis										HFMEA Step 5 - Identify Actions and Outcomes			
Failure Mode: First Evaluate failure mode before determining potential causes		Potential Causes	Scoring: Severity	Scoring: Probability	Scoring: Haz Score	Decision Tree Analysis: Single Point Weakness?	Decision Tree Analysis: Existing Control Measure ?	Decision Tree Analysis: Detectability	Decision Tree Analysis: Proceed?	Action Type (Control, Accept, Eliminate)	Actions or Rationale for Stopping	Outcome Measure	Person Responsible	Management Concurrence
Bed availability (Inpatient 3 beds, ER 2 beds)		→	Major	Frequent	12	N	N	N	Y					
	1	Gender, Age in same room	Moderate	Frequent	8	Y	N	N	Y	N/A	State and Joint Commition regulations			
	2	Hight volume of patient	Moderate	Frequent	8	N	N	N	Y	Control	Review staffing plan for North Wing and ER in order to establish more effective patient service	Effective patient service measured by Patient Satisfaction, Decreased length of stay	Carrine, Rachelle, Jeff	Barbara , Ray
	3	Staffing	Moderate	Frequent	8	N	N	N	Y	Control	> Create guidelines for addmition > Review staffing plan on North Wing > Training status			
	4	Lack of guards	Minor	Occasional	3	N	N	N	N	Accept				
	5	Intoxication (High acquity)	Major	Frequent	12	N	N	N	Y	Accept				
	6	Insufficient # of room	Major	Frequent	12	N	N	N	Y	Control				
	7	Mechanical issue	Moderate	Uncommon	4	N	N	N	Y	Control				
	8	Standardization	Moderate	Occasional	6	N	N	N	Y	Control				
	9	Waiting Judge, API Response, BH clinicial	Moderate	Frequent	8	N	N	N	Y	Accept				

Today not tomorrow

8 steps
according to
JOHN KOTTER

- Urgency of change
- Coalition supporting change
- Clear vision
- Communication of vision
- Stronger employee engagement
- Short wins
- Support of next change
- Hardwiring change

Thank you & Questions