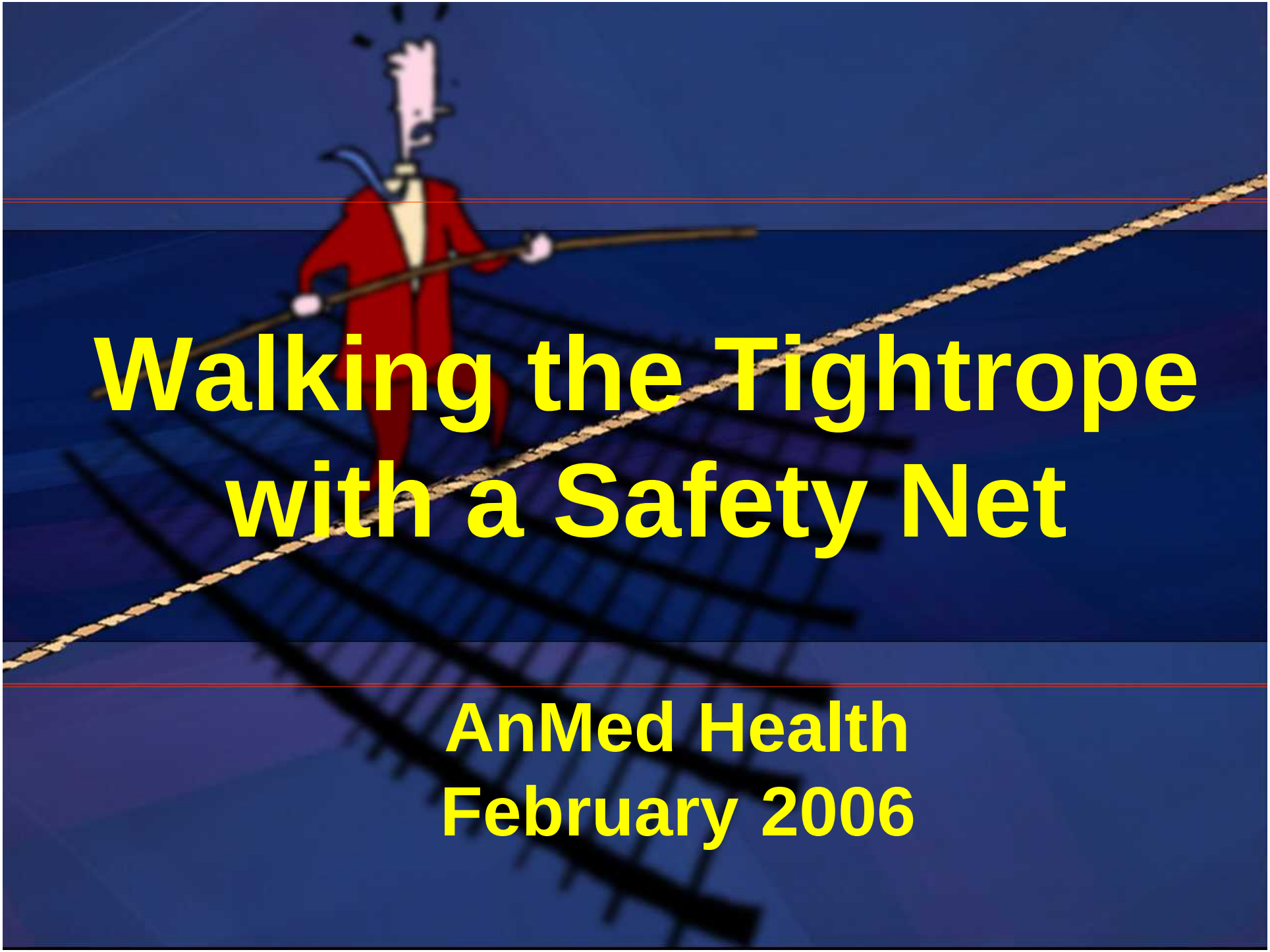


Walking the Tightrope with a Safety Net

AnMed Health
February 2006

Session Objectives

- Educate attendees on traditional FMEA model
- Examine Blood Transfusion process
- Identify and assign risk to potential failures
- Provide process controls to reduce risk in the blood transfusion process
- Critical factors to success

Failure Mode & Effects Analysis FMEA

A systematic approach used to assure that potential failures and causes have been identified, considered and addressed.

FMEA Applications

- Formally introduced in the Late 1940's
- Safety Issues Worldwide

  Aviation
  Nuclear
  Aerospace
  Chemical process industries
  ……Healthcare

- Goal of FMEA is to identify, prioritize & help prevent failures or to minimize the effects
- FMEA does not replace Root Cause Analysis

RCA vs. FMEA

Root Cause Analysis (RCA)	**Failure Mode & Effects Analysis (FMEA)**
Reactive	Proactive
Focuses on Event	Focuses on Complete process
Hindsight Bias	Unbiased
Fear, Resistance	Openness
Asks, Why?	Asks, What if?

Source: Joint Commission on the Accreditation of Healthcare Organizations

Mixed Reactions to FMEA's

.....FMEAs may be a good tool but, they are time consuming. They were made for manufacturing systems not healthcare.

Which FMEA model???

Failure Mode ranking system……

- **Severity (1- 10)**

X Occurrence (1-10)

X Detection (10-1)

= Risk Priority Number (RPN)

	Process Name:				FMEA Type						**Rev. Level**
	Item No. and Rev. Level:										
					Design						
					Process						
	FMEA Team Members:										
Process Number	Process Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) of Failure	OCCUR	Current Process Controls	DETEC	RPN	Recommended Action(s)	
10											
				1		**1**		**1**	**1**		
				10		**10**		**10**	**1000**		
20											

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	Potential Effect (s) of Failure	S E V	Potential Cause (s) of Failure	O C C U R	Current Process Controls	D E T E C T	R. P. N.	Recommended Actions

…. A systematic approach

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	Potential Effect (s) of Failure	S E V	Potential Cause (s) of Failure	O C C U R	Current Process Controls	D E T E C T	R. P. N.	Recommended Actions

- Process Function
  - Determine FMEA scope by defining starting and ending points
  - Develop high-level process flowchart
  - Steps within the selected process

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

Process Function	**Potential Failure Mode**	Potential Effect (s) of Failure	S E V	Potential Cause (s) of Failure	O C C U R	Current Process Controls	D E T E C T	R. P. N.	Recommended Actions

- ***Potential*** Failure Mode
  - How a particular process step could fail?
  - Brainstorming with team is good technique to uncover potential failures

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	**Potential Effect (s) of Failure**	S E V	Potential Cause (s) of Failure	O C C U R	Current Process Controls	D E T E C T	R. P. N.	Recommended Actions

- ***Potential*** Effect (s) of Failure
  - What are the possible outcomes if the failure occurred?
  - How could the patient or other customers be impacted?
  - How can the potential failure effect the downstream process?

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	Potential Effect (s) of Failure	**S E V**	Potential Cause (s) of Failure	O C C U R	Current Process Controls	D E T E C T	R. P. N.	Recommended Actions

- Severity
  - Ranking assigned to each potential failure (1-10 scale)
  - How serious is the effect of the potential failure?
  - Applies to the ***Effect*** only

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

SEVERITY	DESCRIPTION	RANKING
Hazardous	•**Category I**: An error occurred that may have contributed to or resulted in the patient's death	**10**
	•**Category H**: An error occurred that required intervention necessary to sustain life	**9**
Very High	•**Category G**: An error occurred that may have contributed to or resulted in permanent patient harm	**8**
	•**Category F**: An error occurred that may have contributed to or resulted in the temporary harm to patient and required initial or prolonged hospitalization	**7**
High	•**Category E**: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	**6**
	•**Category D**: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm and/or intervention to preclude harm	**5**

Failure Mode & Effects Analysis FMEA

SEVERITY	DESCRIPTION	RANKING
Moderate	•**Category C**: An error occurred that reached the patient but did not cause patient harm	4
		3
Low	•**Category B**: An error occurred but the error did not reach the patient (An "error or omission" does reach the patient)	2
	•**Category A**: Circumstances or events that have the capacity to cause error	1

National Coordinating Council for Medication Error Reporting and Prevention

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	Potential Effect (s) of Failure	S E V	**Potential Cause (s) of Failure**	O C C U R	Current Process Controls	D E T E C T	R. P. N.	Recommended Actions

- ***Potential*** Cause (s) of Failure
  - What are all of the reasons that a failure may occur?
  - List all conceivable potential causes for the failure

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	Potential Effect (s) of Failure	S E V	Potential Cause (s) of Failure	**O C C U R**	Current Process Controls	D E T E C T	R. P. N.	Recommended Actions

- Occurrence
  - How frequently the failure is projected to occur?
  - Use actual failure/occurrence data if known
  - Ranking assigned to each potential failure (1-10 scale)

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

Likelihood of Occurrence		RANKING
•More than once per day		10
•Once every 3-4 days		9
•Once per week		8
•Once per month		7
•Once every 3 months		6
•Once every 6 months		5
•Once per year		4
•Once every 1-3 years		3
•Once every 3-6 years		2
•Once every +6 years		1

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	Potential Effect (s) of Failure	S E V	Potential Cause (s) of Failure	O C C U R	**Current Process Controls**	D E T E C T	R. P. N.	Recommended Actions

- Current Process Controls
  - Activities in your current process that help prevent, stop or mitigate the potential failure
    - Examples – Visual inspections, policies & procedures, alarms, double checking

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	Potential Effect (s) of Failure	S E V	Potential Cause (s) of Failure	O C C U R	Current Process Controls	**D E T E C T**	R. P. N.	Recommended Actions

- Detection
  - Assume the failure has occurred…
  - How good are the current process controls in detecting a failure?
  - Ranking assigned to each potential failure (10-1 scale)

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

Probability	Detection	RANKING
Detection not possible at any point in system	0 of 10	10
Remote		9
Low	1 of 10	8
Low likelihood that error will be detected before error reaches patient	2 of 10	7
Moderate		
Moderate likelihood of detection before error reaches patient	4 of 10	6
	5 of 10	5
		4
High		
Error likely to be detected before error reaches patient	7 of 10	3
		2
Very High		
System will always detect error	9 of 10	1

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	Potential Effect (s) of Failure	S E V	Potential Cause (s) of Failure	O C C U R	Current Process Controls	D E T E C T	**R. P. N.**	Recommended Actions

- Risk Priority Number (RPN)
  - Is the product of Severity x Occurrence x Detection
  - Has values ranging from 1- 1000
  - Should be used to rank order potential failures
  - Special attention should be given when severity is high

Source: Automotive Industry Action Group (AIAG)

Failure Mode & Effects Analysis FMEA

Process Function	Potential Failure Mode	Potential Effect (s) of Failure	S E V	Potential Cause (s) of Failure	O C C U R	Current Process Controls	D E T E C T	R. P. N.	**Recommended Actions**

- Recommended Actions
  - Corrective actions developed for highest RPN's
  - Corrective actions can be aimed at reducing risk associated with either the severity, occurrence and/or detection ranking
  - Should be reviewed on a regular basis to stay on track

Source: Automotive Industry Action Group (AIAG)

Why the Blood Transfusion process?

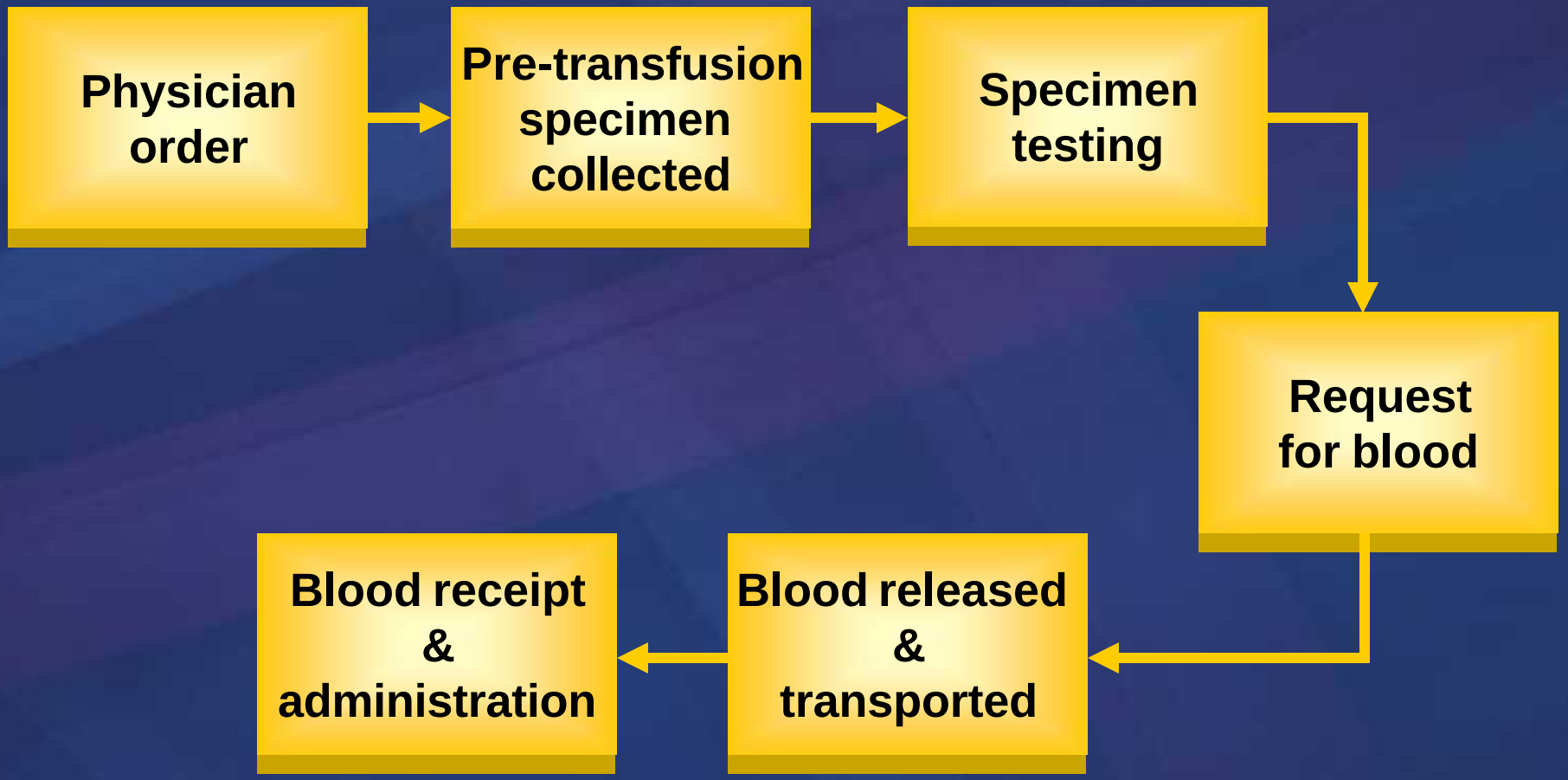
- High risk, high volume process
- JCAHO Sentinel Event Alert
- Multiple hand-offs
- Interested & engaged staff

Wanted to make a safe process, Safer

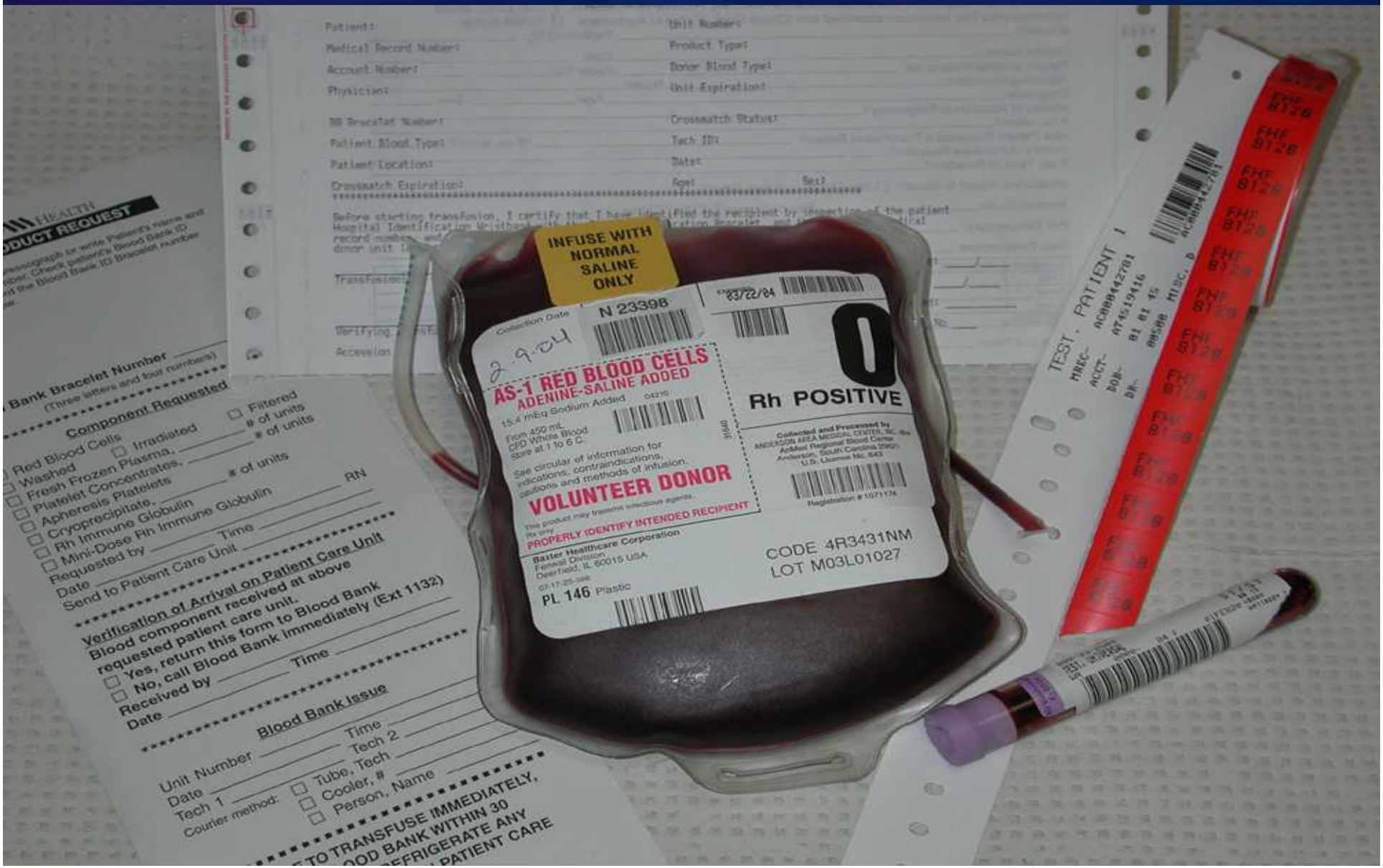
Blood Transfusion FMEA Team

- Medical Director of Laboratory
- Laboratory Director
- Laboratory QA Manager
- Blood Bank Manager
- Nurse Manager - Women's Services
- Nurse Manager- Intensive Care Unit
- Nursing – Special Projects and Research
- Staff Nurses
- Quality and Process Improvement

Blood Transfusion FMEA Scope



Process Controls



Blood Transfusion
FMEA Summary

- 30 Potential Failure Modes identified
- 26 Causes of Failure
- 3 Failure Modes had Risk Priority Number (RPN) greater than threshold of 200
- Average Risk Priority Number (RPN) = 76

Blood Transfusion FMEA
Prioritized Areas of Focus

1. Specimen drawn on wrong patient
2. Wrong patient label placed on specimen
3. Transfusion started with patient receiving dextrose

Worst Case Scenario...

- Pre-transfusion specimen drawn from wrong patient, however, specimen was labeled with the intended patient's label
- The intended patient has no prior testing history in the healthcare facility
- The specimen from the wrong patient & the intended patient have different blood types

Blood Transfusion
Recommendations/Issues/Actions

- Patient Identification & Specimen Labeling
  - Policy & Procedures reviewed & revised
    - Labeling in patient care room or area
  - Rejection of specimens
    - Recollection of specimens
    - Scripting for staff
  - Staff Accountability
    - Consistent policy enforcement throughout organization

Blood Transfusion
Recommendations/Issues/Actions

- Patients with No Prior Testing History
  - Policy & Procedures developed & approved
  - Validation typing conducted in Blood Bank
  - Currently, 40% of patients have no prior testing history in facility
  - Of all the patients with no prior history, only 8% have to incur another stick
  - Scripts developed for staff to use

Blood Transfusion
Recommendations/Issues/Actions

- Label printer Technology
  - Label printer at bedside (mobile printing technology)

Blood Transfusion
Recommendations/Issues/Actions

- Awareness label placed on units of blood
  - Infuse with Normal Saline only

- Staff education & support
  - Train-the-trainer sessions
    - Specimen Labeling Procedures
    - Staff accountability process

Blood Transfusion
Physician Awareness

- Medical Executive Committee approval
- Re-sampling of patients who have no prior testing history at AnMed Health
- Specimens will be rejected & recollected when not labeled according to policy
- Staff will be held accountable

Impact of Recommended Actions

- RPN reduction in identified failure modes by over 43%
- No adverse outcomes to date in the Blood Transfusion process
- No reported occurrences related blood transfusions being started on a patient receiving dextrose products

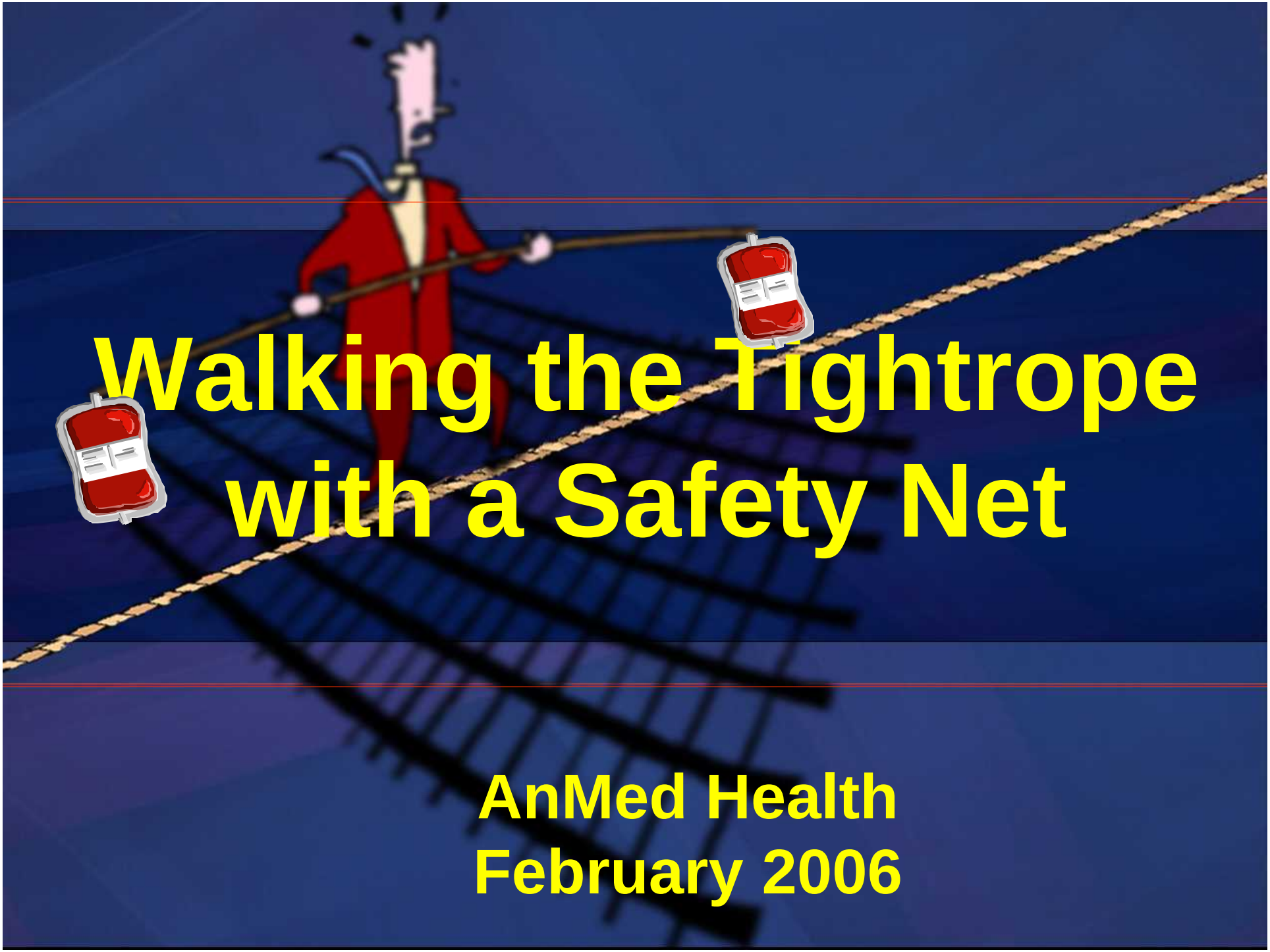
Overall Lessons Learned FMEA

Factors for Success

- Multidisciplinary team
  - Overall better understanding of processes
  - Well defined scope
- Resource commitments
  - Invest time into determining how processes can fail
- Open sharing of information
  - Team members were open to sharing potential failures
- Management support

Other FMEA Applications…

- Surgical Specimen process
- Patient Controlled Analgesic process
- Home Infusion process
- Insulin Administration process
- Reportable Conditions (Microbiology)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