LEAP™ Analysis
SYSTEM ANALYZED: OB Ultrasound
Basic FMEA

August 27, 2003

BAC Health System - FMEA
BAC Healthcare System

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LEAP™ Analysis-Basic FMEA Explanation

The following Basic FMEA was conducted to help us determine the most significant events in our facility that would require a thorough Root Cause Analysis (RCA). This analysis was intended to look at probabilistic events. The analysis delineated which events were most critical to the system in an effort to justify a detailed RCA.

Below is a quick overview of the Basic FMEA process used to determine our facility's Significant Few events:

#	Steps	Description
1.	Define the System to Analyze	Define the scope of the analysis by describing where the process begins and ends.
2.	Define the Team Charter (Terminal Objective)	Define why this team was put together and when will they know they have been successful.
3.	Define Probability and Severity Values	Define the criteria for selecting a certain value for Probability and Severity.
4.	Define Loss	Define what is a loss in the current business environment, for the system chosen to be analyzed.
5.	Draw a Process Flow Diagram	Describe the system chosen to analyze in the form of a block diagram showing the process sub-systems.
6.	Fill Out the Basic FMEA Worksheet	Obtain the necessary event data to populate the Basic FMEA worksheet.
7.	Identify the Significant Few	Identify the events that represent 80% of the losses.
8.	Issue a report	Communicate results.
9.	Conclusion Summary	Summarize conclusions drawn from the analysis.
10.	Recommendations	Delineate the preferred path forward.

Step 1 - Define the System to Analyze

Before beginning the analysis, we defined which system we wished to analyze. This was, in essence, an effort to determine the scope of the analysis; where it began and where it ended.

In this analysis our System to Analyze was identified as:

OB Ultrasound

Step 2 - Define Team Charter (Terminal Objective)

We had to state the reason that the team was formed in a one or two paragraph statement. This served as the focal point for the team to clearly state it's purpose and objective.

This team is chartered to conduct an unbiased analysis of the proposed change in the process used to identify anomalies in OB using ultrasounds. The "Significant Few " events will be identified and recommended to management for further Root Cause Analysis (RCA). All findings and recommendations will be submitted to management for review and approval.

The data generated here will be used to determine the business case for adopting the proposed system change.

All information regarding this analysis shall remain confidential and protected under peer review statutes. This analysis format complies with the JCAHO FMEA guidelines.

Step 3 - Define Probability and Severity Values

Because the Basic FMEA is a probability analysis technique, certain assumptions had to be made with regards to the criteria for their values. Below are the tables that were chosen to reflect the criteria for selecting Probabilities and Severities in this analysis:

Level	Probability	Level	Severity
Frequent	4	Catastrophic	10
Occasional	3	Major	7
Uncommon	2	Moderate	4
Remote	1	Minor	1

Step 4 - Define Loss

What is the definition of loss in the system we have chosen to analyze? This will often vary from business to business, department to department and economic environment to economic environment. This was a necessary step to focus our efforts and develop a common understanding of what is a loss to us in this system, today.

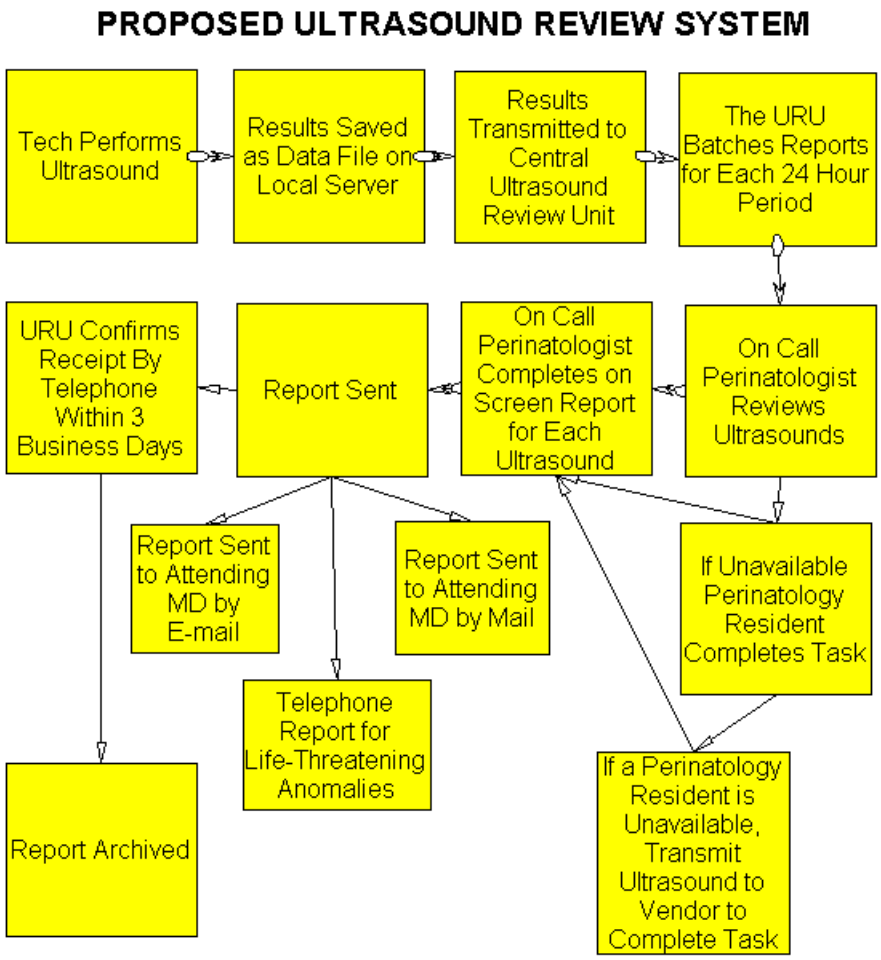
In this analysis, our Loss was defined as:

Unacceptable delay

Step 5 – Draw a Process Flow Diagram

At this point we needed to map out the sub-systems of the process we chose to analyze. We used the typical flow charting symbols to develop a simple block diagram to depict the process flow.

In this analysis, our Process Flow Diagram was represented as:



Step 6 – Fill Out the Basic FMEA Worksheet

We now determined where the data would come from to fill out our Basic FMEA worksheet. Several sources were available such as interviews, existing databases, logs, etc. We used the most reliable data source at our disposal.

Once the data was collected and formatted into our worksheet, we did a simple calculation to generate our total loss, for each event in the analysis. The calculation was done automatically in the LEAP™ software as follows:

Severity x Probability = Rank Prioritization Number (RPN)

In this analysis, our Basic FMEA Spreadsheet resulted in the following:

Sub System	Event	Mode	Probability	Severity	RPN
Vendor reads	Delay	Transmission line problem	4	10	40
Report by telephone	Delay	Attending unavailable (off hours)	3	10	30
URU Confirmation	Delay	Other priorities	4	7	28
Resident reads	Delay	Emergencies	4	7	28
Report Archived	Delay	Server Crash	4	7	28
Vendor reads	Delay	Quality of data transmission requires re-read	3	7	21
Vendor reads	Misinterpretation	Clinical competency	3	7	21
Report sent by mail	Delay	Post office problem	3	7	21
Report sent by email	Delay	Server problem	3	7	21
Report by telephone	Delay	Manpower	3	7	21
Resident reads	Misinterpretation	Clinical competency	3	7	21

Sub System	Event	Mode	Probability	Severity	RPN
Prenatologist interprets	Delay	Emergency	3	4	12
Batching results	Delay	Emergencies	2	4	8
Onscreen report completed	Delay	System Crash	2	4	8
Report sent	Delay	System crash	2	4	8
Tech Performs Ultrasound	Delay	Overbooking	4	1	4
Results transmitted	Delay	System Capacity	3	1	3
Results saved on server	Delay	System Capacity	2	1	2

Step 7 - Identify the Significant Few

The concept of the Significant Few was derived from a famous Italian Economist named Vilfredo Pareto. Pareto stated that 'In any set or collection of objects, ideas, people and events, a FEW within the sets or collections are MORE SIGNIFICANT than the remaining majority'. Consider these examples:

- 80% of a banks assets are representative of 20% or less of its customers

- 80% of the care given in a hospital is received by 20% or less of its patients

- 80% of the losses in a manufacturing plant are caused by 20% or less of the events

This means that we only have to perform RCA on 20% or less of our events to reduce or eliminate 80% of our facilities losses.

In order to determine the 'Significant Few', we performed a few simple steps (with the help of the LEAP™ software):

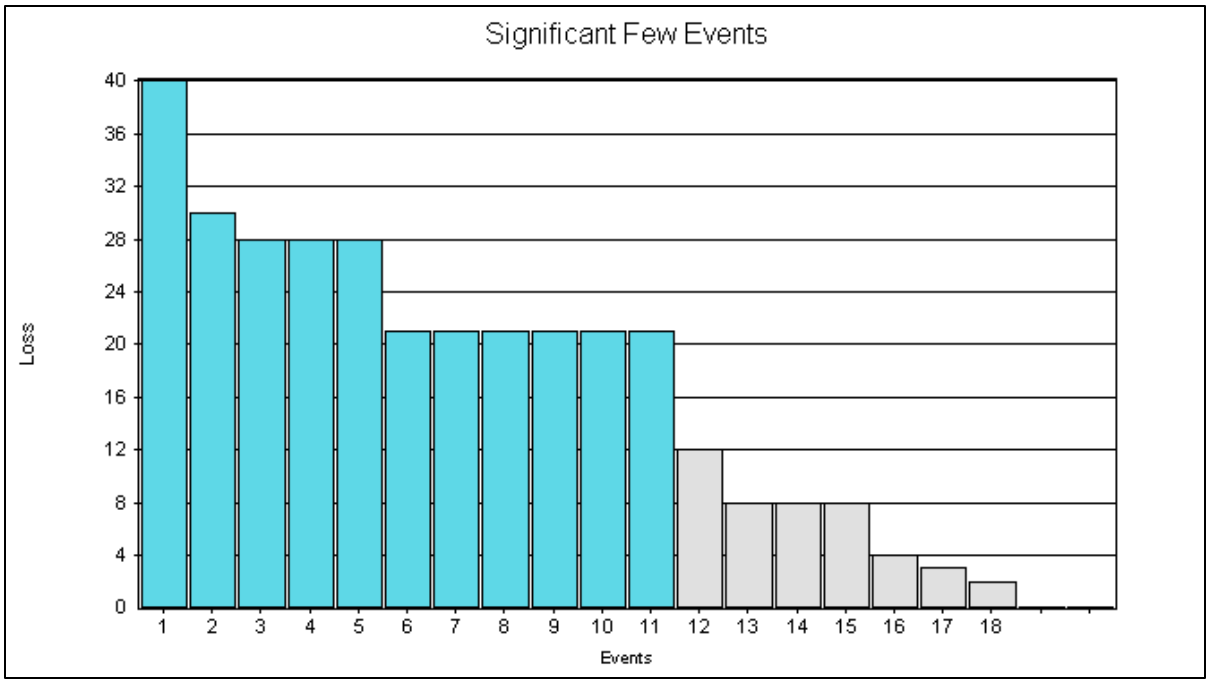
- Totaled all of the events in the analysis to create a global total loss.

- Sorted the total loss column in descending order (i.e. highest to lowest)

- Multiplied the global total loss column by 80% or .80. This gave us the 'Significant Few' loss figure that we will need to determine what the 'Significant Few' events are in our facility.

- We went to the top of the total loss column and begin adding the top events from top to bottom. When the sum of these losses is equal to or greater than the 'Significant Few' loss figure then those events are your 'Significant Few' events.

In this analysis, our Significant Few events were identified as:



ID	Event	Mode	RPN
1	Delay	Transmission line problem	40
2	Delay	Attending unavailable (off hours)	30
3	Delay	Other priorities	28
4	Delay	Emergencies	28
5	Delay	Server Crash	28
6	Delay	Quality of data transmission requires re-read	21
7	Misinterpretation	Clinical competency	21
8	Delay	Post office problem	21
9	Delay	Server problem	21
10	Delay	Manpower	21
11	Misinterpretation	Clinical competency	21

Step 8 – Issue a Report

As with any analysis, it was important to communicate our findings to all interested parties. Our report includes the following items:

- An explanation of the analysis technique.

- The event definition that was utilized.

- The process flow diagram that was utilized.

- The results displayed graphically as well as the supporting spreadsheet lists.

- Recommendations of which events are candidates for Root Cause Analysis.

In summary, Basic FMEA is a fantastic tool for limiting our analysis work to only those things that are of significant importance to the facility. We cannot perform Root Cause Analysis on everything. However, we can use this tool to help narrow our focus to what is 'most' important.

Step 9 – Conclusion Summary

A number of challenges and systems failures were identified in the proposed re-design of perinatal interpretation of ultrasounds. Dr. Welper's proposal was intended to stream line the current system. As reflected in this Basic FMEA the proposed re-design generated additional steps in the process with identified risk for delay in diagnosis, misdiagnosis, compliance issues and quality of care considerations.

Step 10 – Recommendations

The recommendation is to refer the proposed process re-design to the team, with the view to eliminate identified risks and quality of care considerations. The revamped proposal should include data to help demonstrate that it will enhance patient care and maximize available resources.

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