

Permanently Solving A Long Term Complex Problem



Bev Daniels



Lean Six Sigma Conference
Session H1

January 4, 2009

1

Bev Daniels
IDEXX Laboratories, *Inc.*

Learning Objectives

- How to truly solve complex, multi layered problems
- A structured approach to managing a high performance, cross functional problem solving team.
- Statistical techniques for rare categorical events

January 4, 2009

2

Bev Daniels
IDEXX Laboratories, *Inc.*

Initial Problem Statement

Veterinary Practices are reporting a high incidence of “Spot Fails” with their VetTest chemistry analyzer.

The failure rate had always been relatively high (the number one chronic problem for IDEXX) but was now at the highest level ever.

- Customers were beginning to defect to a competitor's analyzer
- The Sales force was complaining that they were spending so much time dealing with this failure mode, that it was impeding their ability to sell new products.
- Customer Support was having difficulty handling the call volume
- Service was having difficulty handling the service volume; turnaround times and unrepaired inventory was climbing.

January 4, 2009

3

Bev Daniels
IDEXX Laboratories, Inc.

Customer Reported Failure Rates

The Customer call rate rose from **2% in 2004** to **4% in 2006**
~1200 calls per month from an install base of **~30500 instruments.**

The service rate rose from **0.25% in 2004** to **0.6% in 2006**
~160 service events per month

January 4, 2009

4

Bev Daniels
IDEXX Laboratories, Inc.

The VetTest Instrument

The VetTest Chemistry Analyzer is designed for Dogs, Cats and Horses.

A single blood specimen is analyzed at a time; up to 12 different chemistries can be tested.

The instrument holds up to 12 chemistry slides in a rotor.

January 4, 2009

5

Bev Daniels
IDEXX Laboratories, Inc.

Specimen Dispense Function

Measure pre spot slide values

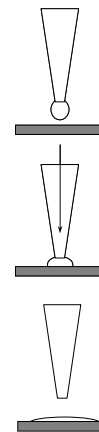
The slide rotor transports a slide under a pipette tip that dispenses either plasma or serum.

The dispense function pushes a drop out of the pipette tip

A cam action lowers the tip to the slide.

The drop diffuses into the slide

The slide values are measured after spotting to determine chemistry value.



January 4, 2009

6

Bev Daniels
IDEXX Laboratories, Inc.

What is a “Spot Fail” and Why is it Bad?

A “spot fail” occurs when the instrument software determines that no sample was dispensed onto one or more slides.

The instrument will not report any results if it detects a spot fail.

The Vet Tech must rerun the specimen and in some cases (Cats) may have to redraw the specimen.

A spot fail causes the practice workflow to ‘backup’ delaying surgery and treatment.

January 4, 2009

7

Bev Daniels
IDEXX Laboratories, Inc.



Team Selection

The ideal size for a Six Sigma team is between 3 and 4 people.

Team members must have diverse skills: practical knowledge of the situation, scientific knowledge and strong practical statistical diagnostic skills

The team members must be highly motivated to solve the problem: endurance is often one of the most important skill

January 4, 2009

8

Bev Daniels
IDEXX Laboratories, Inc.

The Spot Fail Team

Since the Spot Fail problem was so complex the team size was larger than normal and it was packed with strong individuals.

- **Jason Aguiar**, Black Belt, data analyst, supervised testing
- **Tim Cowie**, Black Belt, Product Support Engineer
- **Jeff Phelps**, Black Belt, R&D reliability
- **Jeremy Hammond**, Black Belt, Manager Product Support
- **Jennifer Mazjanis**, Manager Vet Test Marketing, Vet Tech
- **Bev Daniels**, Master Black Belt, Senior Manager FIVEX
- **Ken Taylor**, Director Product Support
- **Donalee Santoro**, Black Belt, Uber Champion, DVP Customer Support,

January 4, 2009

9

Bev Daniels
IDEXX Laboratories, Inc.

Success Factors for a Highly Functioning Team

Each member was passionately committed to solving the Problem

No team member cared about personal recognition; egos were checked at the door.

Leadership was truly situational: the lowest grade level individual was just as likely to assign tasks and make decisions as the highest grade level on the team.

No decisions were made outside the team; we were always available to each other.

Team meetings were constant. Twice weekly planned meetings and multiple informal daily working meetings.

January 4, 2009

10

Bev Daniels
IDEXX Laboratories, Inc.



Steering Team

High impact, complex projects that span multiple functions are assigned a senior management steering team to oversee the project

- Sponsors the team members and ensures that resources have adequate time to work on the project.
- Ensures alignment and cooperation across functions
- Provides financial, space and instrumentation resources
- Makes all business decisions regarding implementation of containment and solution deployment.

It is critical that senior management provide visible consistent support and leadership to ensure that complex projects are successful.

January 4, 2009

11

Bev Daniels
IDEXX Laboratories, Inc.

The Problem Solving Approach

There are two basic strategies to solving a Problem:

- Working from the cause side and testing to determine if one or more suspect causes create the Problem. “Cause to Effect”
- Working from the Problem side “backwards” to isolate the Cause. “Effect to Cause”

The primary strategy utilized by IDEXX is Effect to Cause.

The Problem was broken down into all possible causal categories based on system function.

January 4, 2009

12

Bev Daniels
IDEXX Laboratories, Inc.

Balance, Structure & Discipline

The biggest mistakes in formal or informal Problem Solving are a lack of balance, discipline and/or structure

BALANCE: testing all levels that are relevant

STRUCTURE: create statistical significance and practical importance

DISCIPLINE: execute the test protocol as designed

Balance

High and Low levels of the X (suspected cause)

Old and New: current method or part vs. the proposed solution to the method or part.

Sample sizes for each level must be equivalent; a ratio of no more than 3:4 is recommended if equal sample sizes can't be obtained.

Ensure that your data spans the full range of variation in The Y

Structure

Sample size and independent replicates

Simultaneous testing of all alternative theories

- Use of appropriate experimental controls: ensure that external extraneous changes are not missed or misinterpreted.
- Inclusion of changes in “experimentally uncontrolled” factors
- Randomization

Protocol:

- ensuring that the test conditions replicate normal operating conditions
- Ensuring that worst case conditions are correlated to normal conditions and are not beyond actual worst case conditions

Discipline

Don't alter the test plan to chase an “observation” (aka the shiny object) that may well be an isolated anomaly or coincidence.

Don't alter the test plan to be quicker or easier midstream or without consultation

BE THERE – It's amazing the things you can see if you look

Don't throw out data you don't like. If the data is a confirmed typo or experimental error you can remove from the statistics (annotate its' existence). If it's an extreme value without assignable error cause, leave it in.

Previous Problem Solving Approaches

There were many opinions about the cause of this problem.

One commonly held belief was that the operator didn't use proper protocol in sample prep and testing: It was believed that the tip required special wiping after aspirating the sample into the pipette.

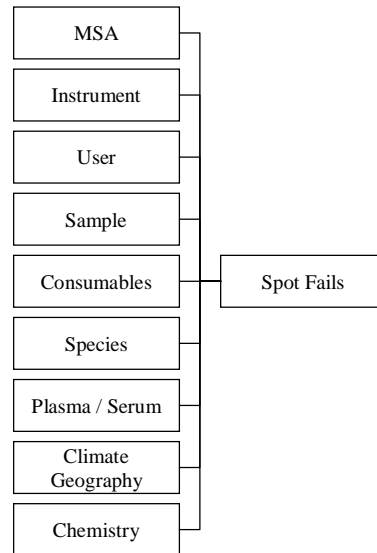
Previous problem solving efforts were tests of suspect Xs without knowledge of the failure rate. Sample sizes were not statistically determined and test conditions were not representative of actual veterinary practice.

Most tests lacked balance, structure and discipline.

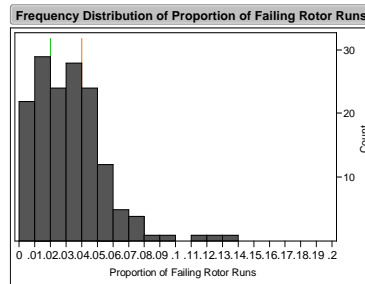
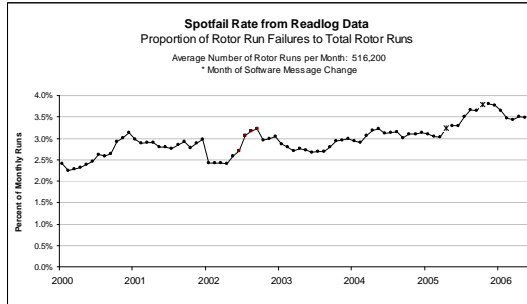
The Investigative Structure

All possible causes are included in the causal categories.

Data Mining of the on board data logs, rapidly resulted in the elimination of Consumables, Species, Plasma/Serum, Climate, Geography and Chemistry type.



Actual Failure Rate Baselines



All instruments experience spot fails: Failure rates range from less than 1% of rotor runs to a few instruments experiencing 14%.

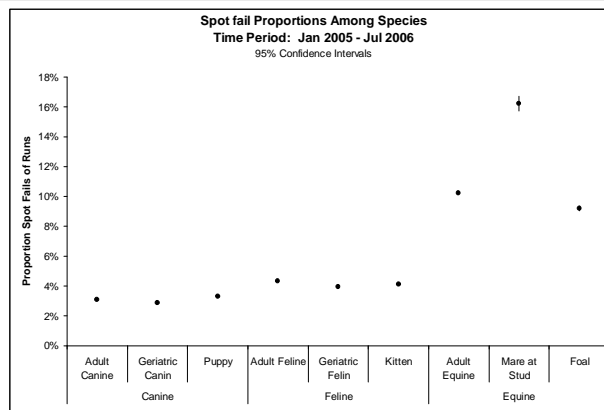
High failure rate instruments were from Equine practices...

January 4, 2009

19

Bev Daniels
IDEXX Laboratories, Inc.

Species



Although there is a difference between species, the difference is not large enough to explain a significant portion of the variation in The Y. Some property of the fluid (Species) may be a secondary or interacting cause

January 4, 2009

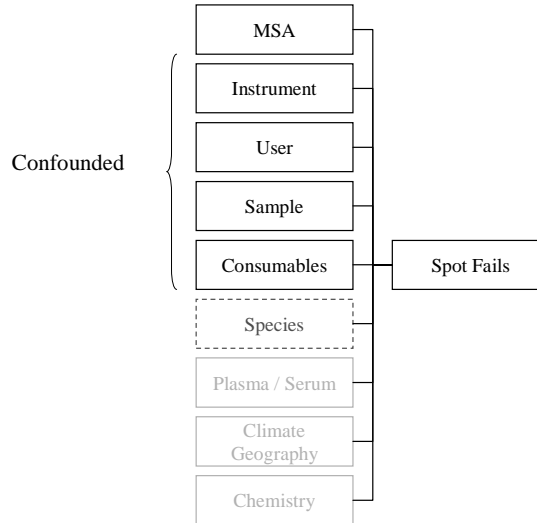
20

Bev Daniels
IDEXX Laboratories, Inc.

Confounded

The remaining causal categories are confounded at the practices.

The next step for the team was to select instruments from the field and perform diagnostic testing at IDEXX.



January 4, 2009

21

Bev Daniels
IDEXX Laboratories, Inc.

Rare Events Require Special Handling

Baseline analysis included time series charts of spot fail events for individual instruments.

Since the failure rate is fairly low, special approaches must be used.

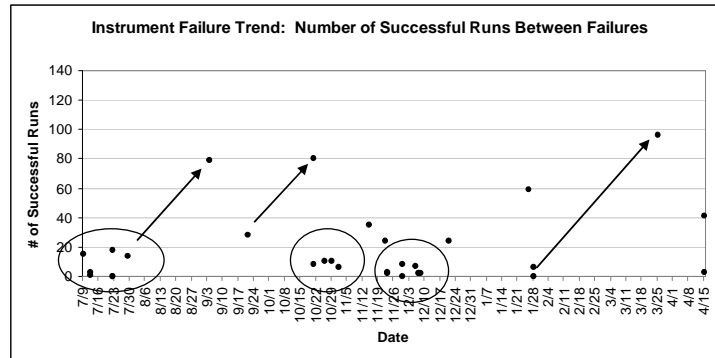
Spot fail trending within an instrument is done by plotting the **number of successful rotor runs between failures**

January 4, 2009

22

Bev Daniels
IDEXX Laboratories, Inc.

Spot Fails Cluster



There can be relatively long periods of no failures and then several failures will occur within a relatively short time frame. This made the “quick experiments” that had been performed in the past inconclusive and misleading.

January 4, 2009

23

Bev Daniels
IDEXX Laboratories, Inc.

The Power of the Observational Study

The Scientific Process begins with Observation!

Understanding of the full range of variation in The Y

Understanding of any non-homogeneous variation which will drive sampling schemes for any invasive experiments.

- Largest components of variation such as run to run, time to time, vendor lot to lot, etc.
- Clustering of failures (a common occurrence with rare events, defect rate < 5%)

Understanding of Normal Operating Conditions including best and worst case.

Identification and separation of existing failure modes

The causal factor or many clues may actually be visible...

January 4, 2009

24

Bev Daniels
IDEXX Laboratories, Inc.

Practice Visits

In order to ensure that we were performing appropriate tests, two team members visited 10 local practices to observe their workflow, protocol and work environment.

Practices were selected based on spot fail rate: 5 practices with low rates (<2%) and 5 with high rates (>4%) were visited.

The visits yielded no obvious clues – although the practice with the best spot fail rate had the worst protocol.

The visits enabled the team to establish best and worst case protocols for diagnostic testing.



The Customer Comes First

The team was committed to making the customer experience as painless as possible.

Rule #1: NEVER blame your Customer; ALWAYS take care of them

The first action was to establish a “Do Not Troubleshoot” policy when the Customer called in with a spot fail complaint.

We acknowledged the existence of the Problem and told the customer that we were working on it.

The Customer was provided with free consumables to replace the wasted ones from the spot fail event. They were asked to continue to call in after any spot fail and they would receive free consumable replacements without question.

The Customers who called in were put on a list in order to receive the solution as soon as it was available.



Confidence Intervals for Rare Events

Rare categorical events cannot be assessed with standard statistical analyses. All statistical analysis was performed using the Exact Binomial confidence intervals.

An Alternative to using the exact Binomial equations is to use the Inverse Beta function:

Lower Confidence Limit: $BETAINV(\alpha/2, d+1, n-d+1)$

Upper Confidence Limit: $BETAINV(1-\alpha/2, d+1, n-d+1)$

(Where d = the number of defective events in sample size, n)



Determining Sample Size

Rare events do not follow standard Normal approximations to the Binomial or even Poisson distribution. Rare events can be modeled with the Geometric Distribution.

The sample size can then be calculated as the maximum expected number of runs between failures for any alpha rate:

$$\text{Max Expected Successful Runs} = -\overline{\text{Run}} \times \ln\left(\frac{\alpha}{2}\right)$$

This provides the minimum sample size required...

(where $\overline{\text{Run}}$ is the mathematical average number of successful runs between failures = $1/\bar{p}$)

The Observational DOE

The initial DOE was established to identify significance of user protocol, run rate, and instrument

- Two protocol levels: “preferred” and “non-preferred”
- Run Rate for our DOE at low level of 5 runs per day, and high level of 20 runs per day (average practice run rate = 3 per day)
- Obtained 8 instruments from the field: 4 with a relatively high spot fail rate and 4 with relatively low spot fail rates.

A high speed camera was randomly inserted into one of the instruments each day to observe any failures.

		Instruments			
		SF Lo		SF Hi	
Protocol -	Runs -	(1)	n=4	a	n=4
	Runs +	b	n=4	ab	n=4
Protocol +	Runs -	c	n=4	ac	n=4
	Runs +	bc	n=4	abc	n=4

January 4, 2009

29

Bev Daniels
IDEXX Laboratories, Inc.

DOE Results

The DOE yielded several interesting results:

Protocol mattered. It was the primary driver of spot fails
Run rate had a small but real influence; high run rates resulted in slightly higher spot fail rates.

There was NO contribution from the instrument itself.

Although protocol was the primary driver, it did not provide a viable solution.

January 4, 2009

30

Bev Daniels
IDEXX Laboratories, Inc.

Why We Can't Fix Protocol

It is difficult to control the operator

- Training is not effective
- Training is difficult to maintain as staff turns over
- An IDEXX instrument should be easy to use and not dependent on operator technique

Even with the preferred protocols, the spot fail rate was not 0.

- Common anecdote is that Field Technical Support reps (our most competent users) have spot fails as they are training the users on the correct technique

A more viable corrective action is to robust the system against user protocol

January 4, 2009

31

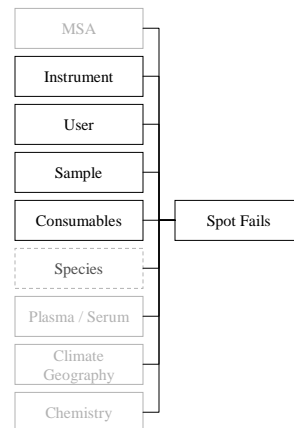
Bev Daniels
IDEXX Laboratories, Inc.

The Measurement Systems Analysis

400 rotor runs were video taped and the video was compared to the reported spot fail rate for each rotor run.

	Instrument Reported	Video Actual
Spot Fails	45	42
No Spot Fail	355	358

Kappa = .93



January 4, 2009

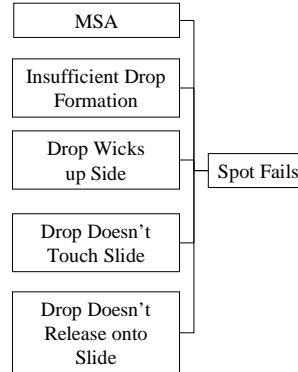
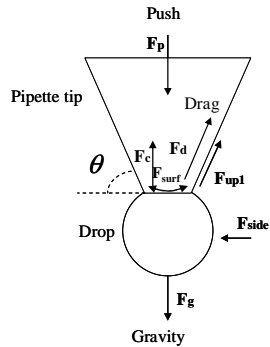
32

Bev Daniels
IDEXX Laboratories, Inc.

An Alternative Approach

Instead of the broad causal categories of the original approach, we refined the strategy to one of pure physics and function, concentrating at the exact point of the failure – the tip to drop interface:

Drop Free Body Diagram



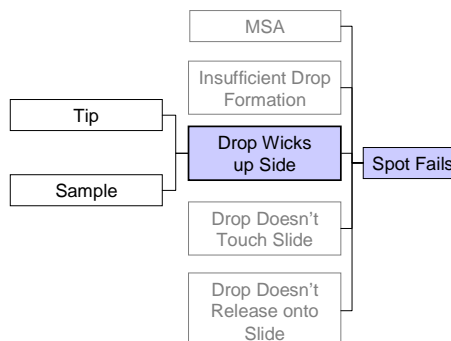
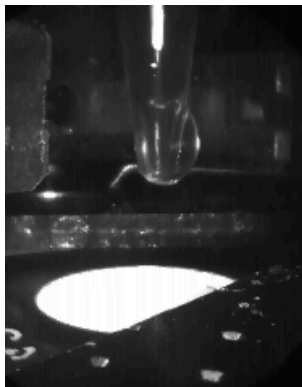
January 4, 2009

33

Bev Daniels
IDEXX Laboratories, Inc.

The Primary Failure Mode

The camera revealed that the primary failure mode was wicking up the side of the tip...



January 4, 2009

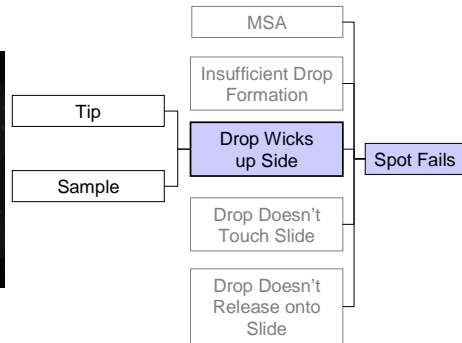
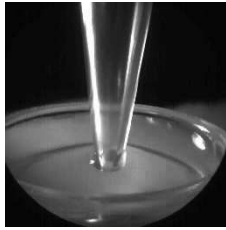
34

Bev Daniels
IDEXX Laboratories, Inc.

The Causal Mechanism

Experimentation with water, serum and plasma revealed:

- The tip is hydrophobic (it repels water)
- **The tip is Hemophilic** (it attracts blood serum and plasma)



The attractive force of the tip is powerful enough to overcome the surface tension of the drop and gravity:

Spot Fails are all Fup!

January 4, 2009

35

Bev Daniels
IDEXX Laboratories, Inc.

The Solution

At this point the solution was to either change the material of the tip to make it hemophobic or to physically prevent the drop from wicking up the side.

The approach taken was to create a mechanical barrier for the attractive force of the tip. It was faster and posed less risk to altering chemistry performance.



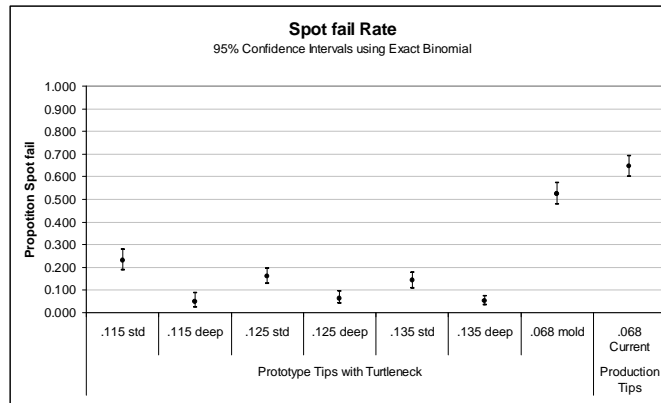
January 4, 2009

36

Bev Daniels
IDEXX Laboratories, Inc.

Tip Optimization

Several tip designs were tested under worst case protocols to amplify the failure rates and ensure that the selected design would be very robust to wicking.



January 4, 2009

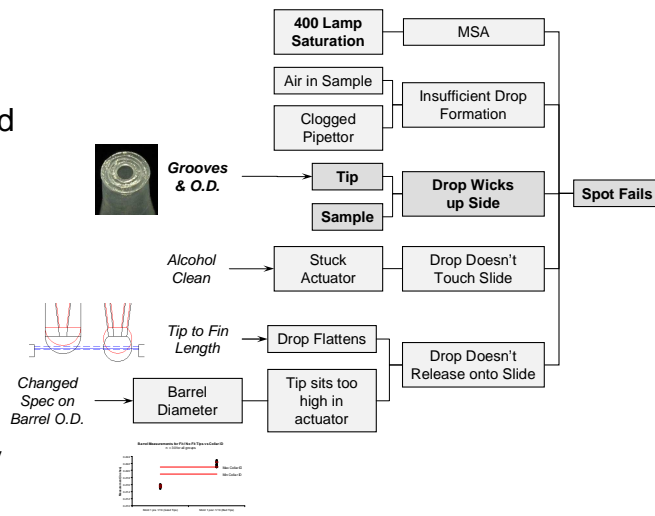
37

Bev Daniels
IDEXX Laboratories, Inc.

Endurance

Eventually every possible failure mode was detected and corrected except for insufficient drop formation

Failure rates today are less than 1%



January 4, 2009

38

Bev Daniels
IDEXX Laboratories, Inc.

Summary: Success Factors

- **Strong, committed passionate teams that have been well trained**
- Senior management oversight that provides guidance, leadership and resources for the project teams
- Senior leadership must recognize and reward success and provide opportunities for everyone to contribute
- PRIORITIZED project selection
- Effective diagnostic methodologies that are well taught and mentored: **Balance, Structure and Discipline**
- **Keep the Customer as your number one priority**
- Endurance: determining root cause is fun, seeing it thru to the end is a grind...