

**Using Lean Six Sigma to Improve the Medical Malpractice
Reporting Decision Process in the U.S. Army Medical Command**

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ACKNOWLEDGMENTS

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ABSTRACT

By Department of Defense Directive, the Army Surgeon General should determine, within 180 days of payment notification, whether to report a Health Care Provider (HCP) involved in a paid medical malpractice claim to the National Practitioner Data Bank. For malpractice cases identified from January 1, 2005 to December 23, 2008 that required his decision, the Surgeon General did not meet the 180-day standard in any of the 59 available cases. The responsible staff officer sponsored a Lean Six Sigma Black Belt project to analyze and improve the medical malpractice decision process. During the Analyze phase of the Define, Measure, Analyze, Improve, and Control (DMAIC) methodology, the team learned of a legal problem that would prevent the full analysis of the process. The author presents the abbreviated analysis and recommendations.

1.0. Introduction.

The Surgeons General of the armed services have a unique privilege regarding the reporting of HCP to the National Practitioner Data Bank (NPDB). While all civilian entities that make a payment for medical malpractice must report the involved HCP to the NPDB, the Surgeons General have a secondary review option that allows them to determine to report a HCP's name from the database if they deem it appropriate. The etiology of this privilege lies in the Federal Tort Claims Act that replaces a provider's name with that of the Federal government for all malpractice claims and suits. Department of Defense Directive (DODD) 6025.13, *Medical Quality Assurance (MQA) in the Military Health System (MHS)*, gives the Surgeon General 180 days, from receipt of claim payment notification, to make that decision.

In early 2009, COL Doreen M. Lounsbury, Chief of AMEDD Quality Management Division (QMD), suspected that the AMEDD might not be consistently meeting the 180-day standard. She sponsored a Lean Six Sigma project to examine the reporting process and recommend changes for its improvement.

2.0. Background.

Title IV of Public Law 99-660, the *Health Care Quality Improvement Act of 1986*, became law on November 14, 1986 and led to the establishment of the NPDB. The intent of the NPDB was to provide a clearinghouse for information, such as medical malpractice settlements, on the professional competence of HCPs (U.S. Department of Health and Human Services, 2001). As mentioned above, the Army Surgeon General (TSG) has the responsibility of determining whether to report a HCP to the NPDB when the US Army Claims Service or Department of Justice has made a payment on behalf of the HCP. Currently, TSG delegates the

staff analysis for the report decision to the Chief, QMD. She makes her analysis based on a process of internal and external clinical and legal review by her department's Risk Management section. If TSG does not make a determination to withhold a name within 180 days, DODD 6025.13 requires him to report the name to the NPDB.

The Chief of QM uses the Risk Management (RM) office to process all the medical malpractice cases. The Army has contracted the actual day-to-day processing of the cases to TerraHealth. The contractor has five employees that work in the RM office of MEDCOM.

3.0. Methods and Assumptions.

I enrolled in the U.S. Army's Lean Six Sigma Black Belt course and accepted this project as my Black Belt certification project. Using the full DMAIC methodology, I would study the MEDCOM's medical malpractice case process under the tutelage of my Master Black Belt mentor, COL Donna S. Whittaker, and make recommendations to the project sponsor, COL Lounsbery.

The initial project team consisted of LTC Miriam A. Spells, Chief, Risk Management section, Ms. Donna M. Wright, Risk Manager, Ms. Rosalind Gagliano, MEDCOM Judge Advocate's office, Mr. Richard Martin, Database Administrator, Mr. Miguel Esparza, Senior Systems Analyst, and Ms. Luci Coffey, Contract Team Leader. Mr. Esparza and Ms. Coffee are TerraHealth employees, while the other non-military members of the team are government employees. This distinction is significant since, during the Analyze phase, I learned that I was not supposed to involve the contract employees in the project without explicit permission from the appropriate Contracting Officer. When we requested such permission, the Contracting Officer, Mr. Miguel Gonzalez, denied the request. Without permission, I had to curtail severely

the scope of the project.

4.1 Define.

The official project initiation date was 13 Oct 08. We began with a problem statement of "The DoD expects paid case Surgeon General determination within 180 days of payment notice to TSG. MEDCOM currently averages $X \pm SD$ and has never regularly met the 180-day standard."

A Suppliers, Inputs, Process, Outputs, and Customers (SIPOC) analysis yielded the following:

Suppliers: Military Treatment Facilities (MTFs), U.S. Army Claims Service, Maximus (the external review contractor), the involved HCPs, the Office of the Surgeon General, Subject Matter Experts, and the Judge Advocate.

Inputs: Documents, Decisions, Regulations, Technology, and Experience.

Process: Receive notification, Administrative processing, Qualitative processing, External review, Internal review, Preparation for TSG decision, TSG decision.

Outputs: Letter to the HCP, Reports to the appropriate databases, Metric reports, and Reports to licensing agencies.

Customers: TSG, DoD, HCPs, MTFs, and the Armed Forces Institute of Pathology.

The team initially defined the scope as follows: Start point was receipt of notification that a claim was paid. End point was TSG determination whether to report the HCP. Specifically out of scope was the time from the actual payment to the official notification to TSG.

The team developed the swim lane process map shown in Figure 1 and identified the

significant steps in the process as: 1) gathering the medical records and results of the MTF's Standard of Care (SOC) evaluation, 2) preparing the file for the Special Review Panel (SRP), 3) preparing the file for external review (current contractor is Maximus), 4) review by Maximus, 5) HCP input, 6) Staff Judge Advocate (SJA) review, and 7) TSG review and decision. The sequence of steps 2-5 depends on the characteristics of the case rather than a standard order. If the MTF determined that all involved HCPs met the SOC, the team first prepares and sends the file for external review. The file then goes to the SRP only if the external review finds not all involved HCP met SOC. If the MTF determined that any HCP did not meet SOC, the team first prepares and sends the file to the SRP. The file then goes to external review only if the SRP finds that all involved HCPs did meet SOC. Additionally, a case may appear before the SRP multiple times, depending on whether the panel members felt the case information was complete.

4.2 Measure.

In keeping with the DMAIC methodology, we reexamined the project charter during each phase. In the Measure phase, we changed the Customers of the SIPOC analysis to eliminate all but TSG. The regulation clearly tasks TSG with the responsibility to determine reporting, and the processing team is simply his staff element responsible for preparing the decision packet. As such, we judged that the section's only customer (as defined by the Lean Six Sigma process) is TSG.

The contractor uses an Access database called the Medical Malpractice Data Tracking System to record the completion dates of the various steps in the process. However, as we began to gather data we learned that the system does not have a field for the date that the TSG makes the reporting decision. As a result, we extended the scope of our project to the date of

administrative closure in MMDTS. This closure date occurs after all appropriate notification of HCPs and the NPDB. This change would lengthen the process time and necessitate an imprecise comparison with the 180-day standard. We extracted the completion dates from MMDTS for the significant steps for all cases which had a legal notification date of 1 Jan 05 to 23 Dec 08.

The data pull yielded 373 total cases. We eliminated one of the cases due to an obvious data entry error. Of the 372 remaining cases, 106 were still open and 266 were closed as of 23 Dec 08. Of the 266 closed cases, the team had closed 207 administratively (reasons may have included inability to find the HCP or medical records, obvious nuisance settlement, etc), leaving 59 cases that met the criteria for full examination.

We conducted a Measurement System Analysis of the data to determine its reliability and validity. We extracted 25 randomly sampled cases and compared the legal notification date in MMDTS with the scanned case file. Nineteen of the cases had matching dates, one had an incorrect date and five cases had unverifiable dates. We deemed this 95% concurrence acceptable.

Descriptive statistical analysis of the data (59 cases) using Minitab 15 revealed a median time of completion of 531 days, a mean of 570.8, a standard deviation of 212.2, with a range of 222 to 1268 days. Unless more than 42 days had elapsed between TSG decision and MMDTS closure of the case, TSG did not meet the 180-days standard in any of the 59 cases that the team processed and closed during this four-year period.

Control charting of the data (Figure 2) revealed multiple failures. On the Individual chart, two points (8, 12) failed by being more than three standard deviations from the mean, three points (57, 58, 59) failed by being more than nine points on the same side of the mean, one point (4) failed by having two of three points more than two standard deviations on the same side from

the mean, and three points (57, 58, 59) failed by having four of five points more than one standard deviation on the same side from the mean. On the Moving Range chart, one point (12) failed by being more than three standard deviations from the mean while four points (56, 57, 58, 59) failed by being more than nine points in a row on the same side of the mean. These strict criteria would normally lead to the conclusion that the process is not stable and not in control, but a more practical interpretation led us to conclude the control level was acceptable to proceed with our analysis.

A process capability analysis (Figure 3) compares the Voice of the Process to the Voice of the Customer. Our process revealed a Cpk (actual capability index) of -1.06, meaning that the current process was incapable of meeting the 180-day standard.

Analysis of the component steps of the process revealed the information in Tables 2 and Figure 4. If any single case had been composed of the minimum example of each of the steps, it would have met the 180-day standard, but the best overall case time of 222 days was still well short of the 180-day standard. While it is feasible that TSG made his decision by the 180-day mark and the team took 42 days to close the case in MMDTS, it is very unlikely.

As quality is one of the tenets in LSS, we examined the data for process defects or rework. We found that 39 of the cases that went to the SRP returned to the SRP, and one case returned for three reviews. A case returns to the SRP when the panel members request information that is not in the board file or when the case has followed a trail of MTF SOC non-met, SRP SOC met and external review not-met. In such a case, the SRP meets again to discuss the external review finding before making its recommendation to TSG.

The contract for the services provided by TerraHealth began with a base year of Fiscal Year 2006. During the project, the contract was in option year three of four and had a financial

value of \$608,059.56. While the introduction in the contract's Performance Work Statement does read, "...all paid malpractice cases must be resolved at the service levels within 180 days of the date of payment of the claim (goal)," it does not delineate specific performance standards for the individual steps of the process.

4.3 Analyze

Shortly after finishing the Measure phase, we learned of a legal issue that would severely curtail our project. Federal law limits the ability of representatives of the Federal government to interfere with a contractor's operations. Mr. Eugene Smith, MEDCOM Contract Law Attorney, opined that we needed the Contracting Officer's permission to proceed with our project. The Contracting Officer, Mr. Gonzalez, subsequently refused permission for us to continue interacting with the contractor's employees. As such, we were unable to continue the project as planned, and would continue with only the information we had gathered thus far.

During the analysis, we conducted Cause and Effect Analysis to determine the root cause of our process's inability to meet the 180-day target. We determined that the lack of appropriate performance metrics in the contract, irregular SRP convening, non-incentivized personnel and near total reliance on paper records all contributed to the root cause of the failure. We conducted a Failure Mode Effect Analysis to determine which root cause would lead to failure of the process if no control mechanisms were in place. We determined that irregular scheduling of the SRP was the most important root cause that would lead to process failure. Given our constraint of being unable to delve further into the process, we recommended to COL Lounsbery that she institute a regular schedule of SRPs to provide the team with a period deadline to meet. She accepted that recommendation and announced bimonthly SRPs to the team.

4.4 Improve

At the time of this writing, the Improve phase continues. COL Lounsbery announced the new SRP schedule on 28 Jan. The team has had some difficulty in responding to the new schedule. In February and March, it was able to prepare only two panels of five and six cases respectively.

5.0 Recommendations

While the project sponsor, COL Lounsbery, placed appropriate constraints on the possible changes that could arise from this project, I found it interesting to contemplate a completely reconstructed process with minimal constraints. As such, I present both the unconstrained and constrained recommendations.

5.1 Unconstrained (Figure 5.)

The purpose of the Army's quality management program is, "to continuously and objectively assess key aspects of the individual and institutional performance with the intent to improve the health and services provided to eligible DOD beneficiaries and others." (U.S. Army, 2004) Borrowing from the US Army aviation community's safety process, one can design a process that would address both the individual and institutional aspects.

When an event occurs at an MTF, the local commander would decide the severity of the incident. For simplicity sake, the MEDCOM could designate events as Class A (CMS Never Events or The Joint Commission's Sentinel Events) or Class B (all others). A Class A event would result in MEDCOM sending a two-person team (National Security Personnel Service or

Active Duty) to the MTF within a few days of the event. This team would consist of quality management experts experienced in event investigation and root cause analysis. The team would merge with a team designated by the local MTF Commander to form the event investigation team. That team would gather appropriate information and decide whether the HCPs had provided SOC. MEDCOM's two-person team would return with the team's finding, inform the Chief, QMD, and then send the report and relevant documentation to an outside organization for review. Upon receiving the external evaluation, the Chief, QMD would send the case for legal review. After receiving the legal review, the Chief, QMD would then make a staff recommendation to TSG on whether to report the involved HCPs.

For Class B events, only local personnel would conduct the investigation events, but they would have access to MEDCOM experts for consultation. The local report would follow the same process as a Class A once it reached MEDCOM.

The MEDCOM has averaged 32 sentinel events annually for the last three years (A. Bohlin, personal communication, May 6, 2009). Assuming each of those would be a Class A event, the MEDCOM would need to send 32 teams for investigations. Estimating \$4,000 per investigation (two people x \$2,000), yields an annual travel cost of \$128,000. Assuming four people available for investigations, personnel costs would be an additional \$400,000 (\$100,000/person). The personnel and travel categories would be roughly analogous to the current contract since neither involves any support costs (paper, IT support, postage, facilities, etc) costs associated with the processing of cases. Thus, the unconstrained plan would save an estimated \$80,059.56 over the current annual cost of the current contract (\$608,059.56 - 528,000). While any change in productivity is speculative at best, MEDCOM could conduct a pilot study to estimate any such changes.

5.2 Constrained

The potential changes to this system are constrained by a number of factors, the most restricting of which are current contract, legal and regulatory requirements. The unconstrained recommendation above would require significant revision of many laws and regulations - a long and tedious process. Realistically, a number of smaller recommendations would leave the current process in place, but improve its efficiency. While we were unable to fully examine the process because of the Contracting Officer limitations, we did see enough of the process to make the following recommendations (in no particular order).

1. Institute a paperless system. The current process expends significant resources transferring, shipping and copying paper. If the individual MTFs could scan appropriate documents, or ideally, create only electronic documents, the team could store all information on the secure, password accessed system they currently use. Presently, however, the team uses the server primarily to store information on closed cases. The team ships boxes of paper documents to a contractor that scans the documents onto a DVD and then destroys the documents. Team members then load the .pdf files onto the server and store the DVD as a backup.

2. Utilize team members to their capacity in their specialty fields. The nurse team member responsible for abstracting the case and making qualitative decisions about it also does a significant amount of scanning rather than utilizing the administrative support personnel for that task.

3. Conduct regular SRPs. Currently, SRPs are ad hoc and occur only when the team has a file ready and has been able to schedule the appropriate Subject Matter Experts (SMEs). This lack of periodic deadline seems to allow cases to languish in the process.

4. Institute a tasking system for SMEs. Anecdotally, team members stated that it was often difficult to schedule SMEs. The Army has a well-established mechanism for tasking personnel that could easily apply to SMEs for an SRP.

5. Institute command support for the access of medical records. Anecdotally, MTFs often take an extended period to provide the appropriate medical records and documents to the team. Again, the Army has a well-established mechanism for a staff officer to request command support. After a reasonable amount of time awaiting records, the team should submit a request for command support through the Chief, QMD to TSG. TSG should then provide the local MTF commander with appropriate motivation.

6. Conduct regular reviews of cases in progress. Currently, no regularly convened management review of cases in progress exists. MMDTS has a field for the last time an action occurred on a case. For the 106 open cases, the descriptive statistics for that time was a mean of 61.2 days, median of 39, standard deviation of 88.1, and a maximum of 602 days. I believe that if management conducted a weekly review of the status and progress of all open cases with the team and held members accountable for their steps, the times since action occurred would decrease dramatically.

7. Eliminate the third database. While MMDTS has served as the tracking database for some time, CCQAS should eventually replace it. Despite those two databases, at least two of the team members access and track data on a third database which contains no information not in the other two.

8. Consolidate the case into one file. Currently, a different file goes to the external review contractor than goes to the SRP. The external review company receives the information on DVD while the SRP receives its information in paper format. Additionally, the team often delays SRP

preparation while awaiting the HCP response. The external reviewer does not receive the HCP's additional input. This duplication of effort to prepare different files results in increased time and variability as the reviewers receive different information in different formats for the same case.

9. Revise the contract. The current contract has no performance standards concerning the time required to process cases. Revise the contract and add performance standards to assist in complying with the 180-day. Alternatively, consider converting the positions to GS/NSPS so the Chief, QMD would have greater operational and tactical control over the process.

5.3 Comparison

Either the unconstrained or the constrained course of action would constitute an improvement over the current process. While the unconstrained COA should save a significant amount of money over the constrained COA, the main source of this savings is in personnel costs. As such, the risk exists that personnel costs could rise. If successful execution of the COA required more than four people or a higher total compensation package, the projected savings would decrease or disappear. The COA could potentially cost more money if the personnel costs rose enough.

Either COA would address the current significant problem of lack of control of the process. Due to the legal constraints of federal contract work, the Chief, QM has little control over the process design or the day-to-day operations of the section. The increase in governmental control inherent in either COA has the potential to significantly improve the process and its responsiveness to the MEDCOM leadership.

Given the bureaucratic essence of the MEDCOM, the constrained course of action would be the easiest to implement. The unconstrained COA would require a radical change in business

processes and culture in this small portion of the MEDCOM. Such a radical change is fraught with difficulty in an organization as bureaucratic as the US government. Since a moderate improvement implemented is better than a complete improvement not implemented, the constrained course of action is the best possibility to improve the process.

Since the government serves many purposes in addition to the efficient conduct of its citizens' protection, the constrained course of action may be preferable to retain jobs and economic contribution. This is especially true given the economic climate in 2009 and the government's chosen strategy of response. It may seem paradoxical to institute a change that may result in the reduction of government spending and indirect employment in a climate of massive governmental stimulus and intentional deficit spending. An additional consideration should be the administrative burden of responding to any Congressional or legal procedures that result from the current or prospective contractors' dissatisfaction with such a shift from contract to governmental work.

Either of the courses of actions, in whole or in part, would be better than the current process. Not only does the current process fail to meet the regulatory standard, it fails to serve the Surgeon General, the providers of the US Army, or the citizens of the United States.

6.0 Conclusion

The current MEDCOM process for advising TSG on whether to report HCPs to the NPDB fails to meet its time standard. In its present form, it cannot meet the regulatory requirement of 180 days from time of legal notification to time of decision. The Chief, QMD should institute the recommendations outlined above to streamline the process, reduce waste, and provide better stewardship of the taxpayers' dollars.

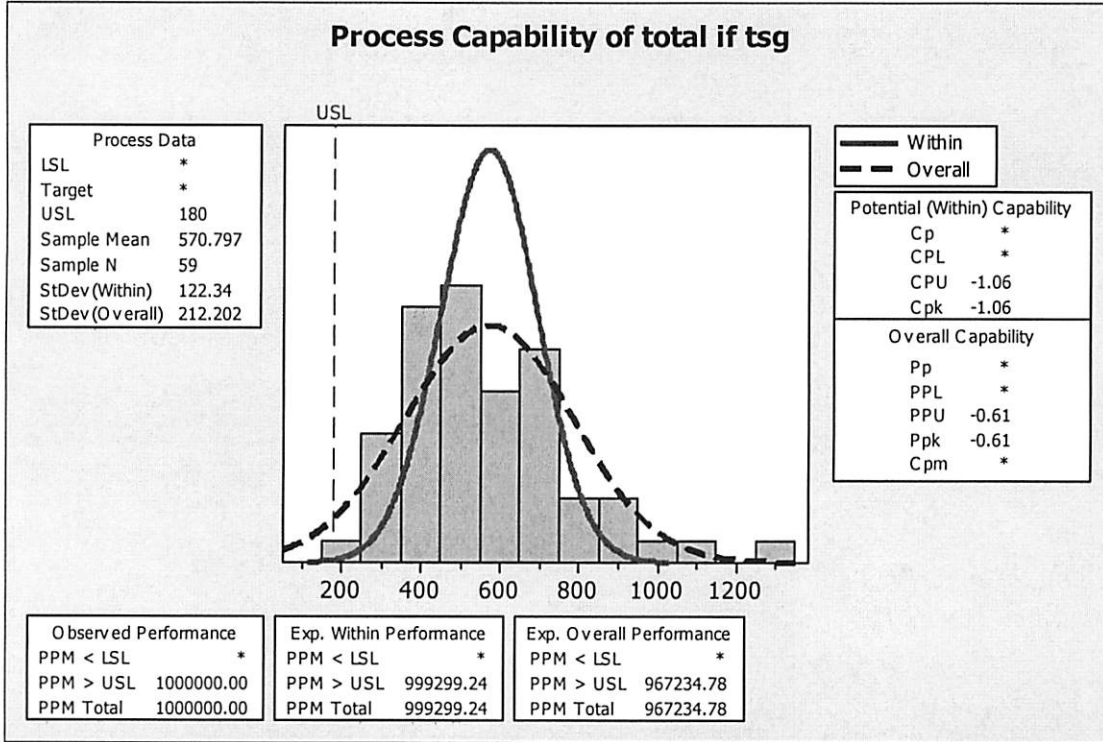


Figure 3. Process capability for the 59 cases.

Table 1. Definition of component steps.

	Start date	End date
Prepare for SRP if SRP occurs before ER	Notification of payment	SRP
Prepare for SRP if SRP occurs after ER	File returned from ER	SRP
Prepare for ER if ER occurs before SRP	Notification of payment	File sent to ER
Prepare for ER if ER occurs after SRP	SRP	File sent to ER
External review (ER)	File sent to ER	Report received from ER
HCP response	Request sent to HCP	Response received from HCP
SJA review	File sent to SJA	Response received from SJA
Office of TSG	Case sent to OTSG	Response received from OTSG

Table 2. Number of days for component steps.

Step	N	Median	Mean	SD	Min	Max
Prepare for SRP if SRP occurs before ER	43	224	267.5	165.6	59	787
Prepare for SRP if SRP occurs after ER	15	127	141.3	92.2	50	424
Prepare for ER if ER occurs before SRP	15	47	81.3	93.8	2	288
Prepare for ER if ER occurs after SRP	14	8	46.8	79.5	5	256
External review (ER)	29	31	30.2	4.2	14	36
HCP response	41	21	26.8	19.3	8	109
SJA review	57	51	65.7	50.8	4	226
Office of TSG	59	87	90.1	60.8	1	260

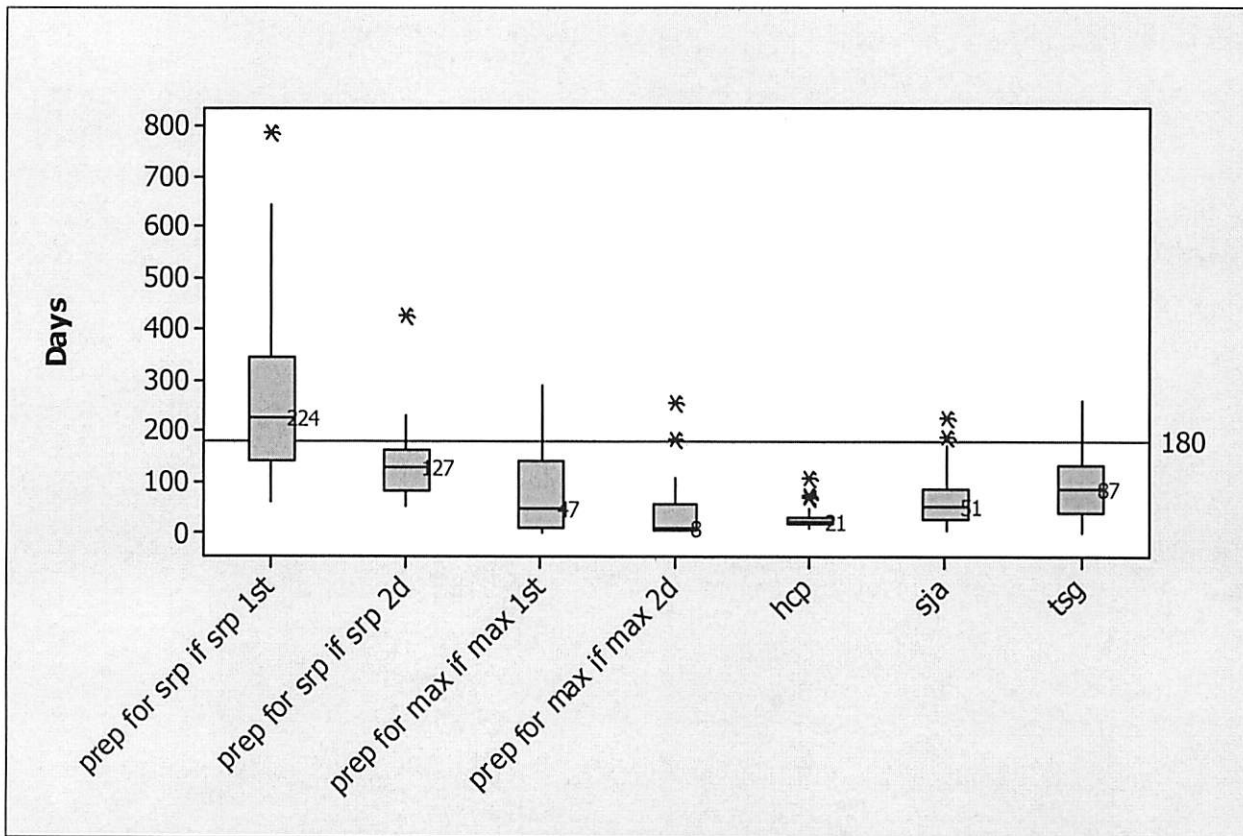


Figure 4. Boxplot of number of days of component steps

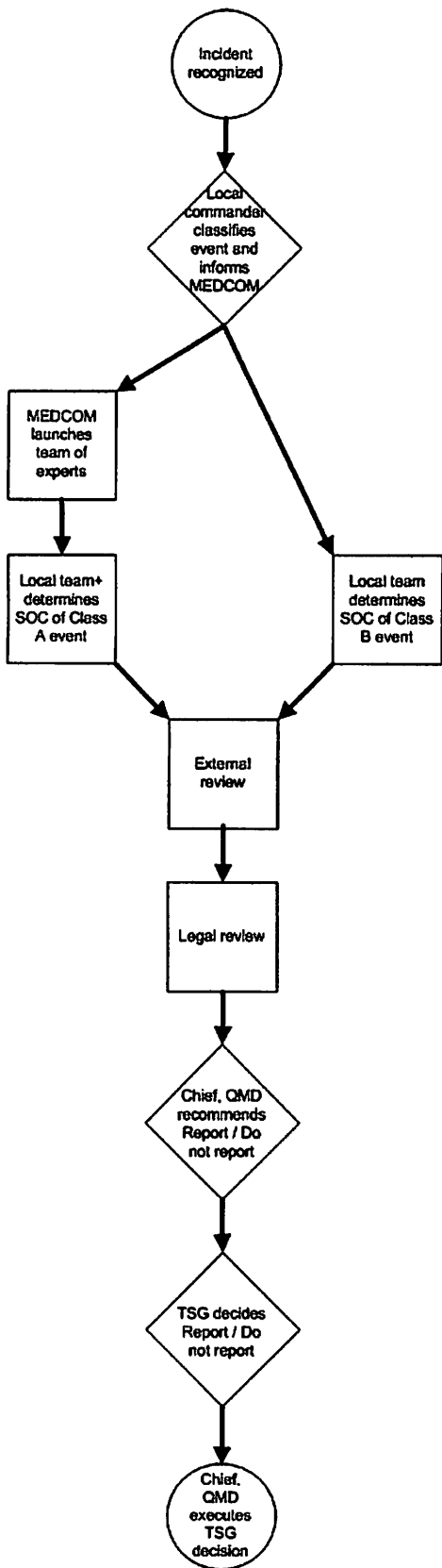


Figure 5. Non-constrained recommendation

REFERENCES

Department of Defense. (2004). *Medical Quality Assurance (MQA) in the Military Health System (MHS)* (6025.13). Washington D.C.

U.S. Army. (2004). *Clinical quality management (AR 40-68)*. Washington D.C.: Department of the Army.

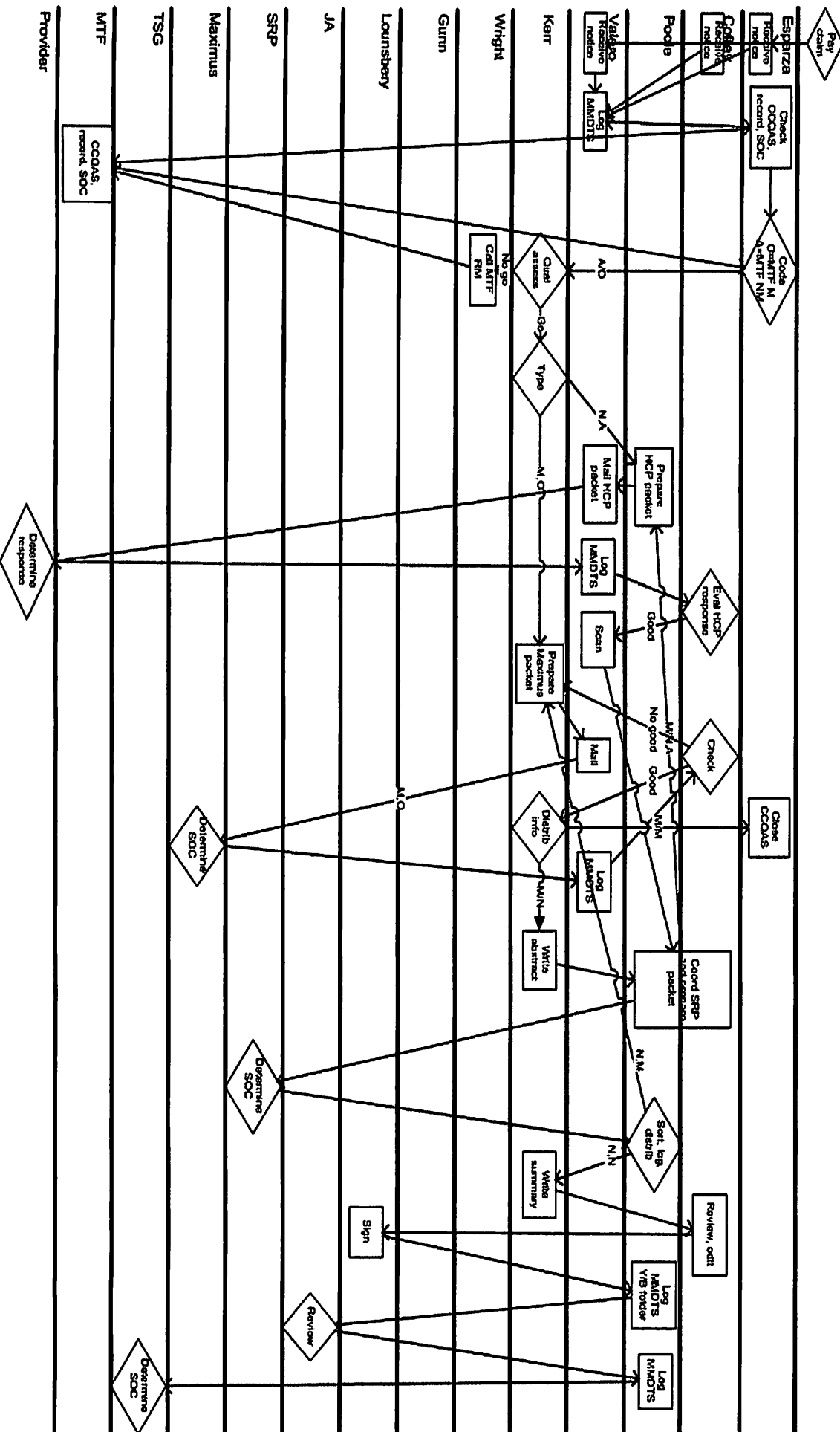
U.S. Department of Health and Human Services. (2001). *National Practitioner Data Bank GUIDEBOOK* (HRSA-95-255). Rockville, MD: Division of Quality Assurance.

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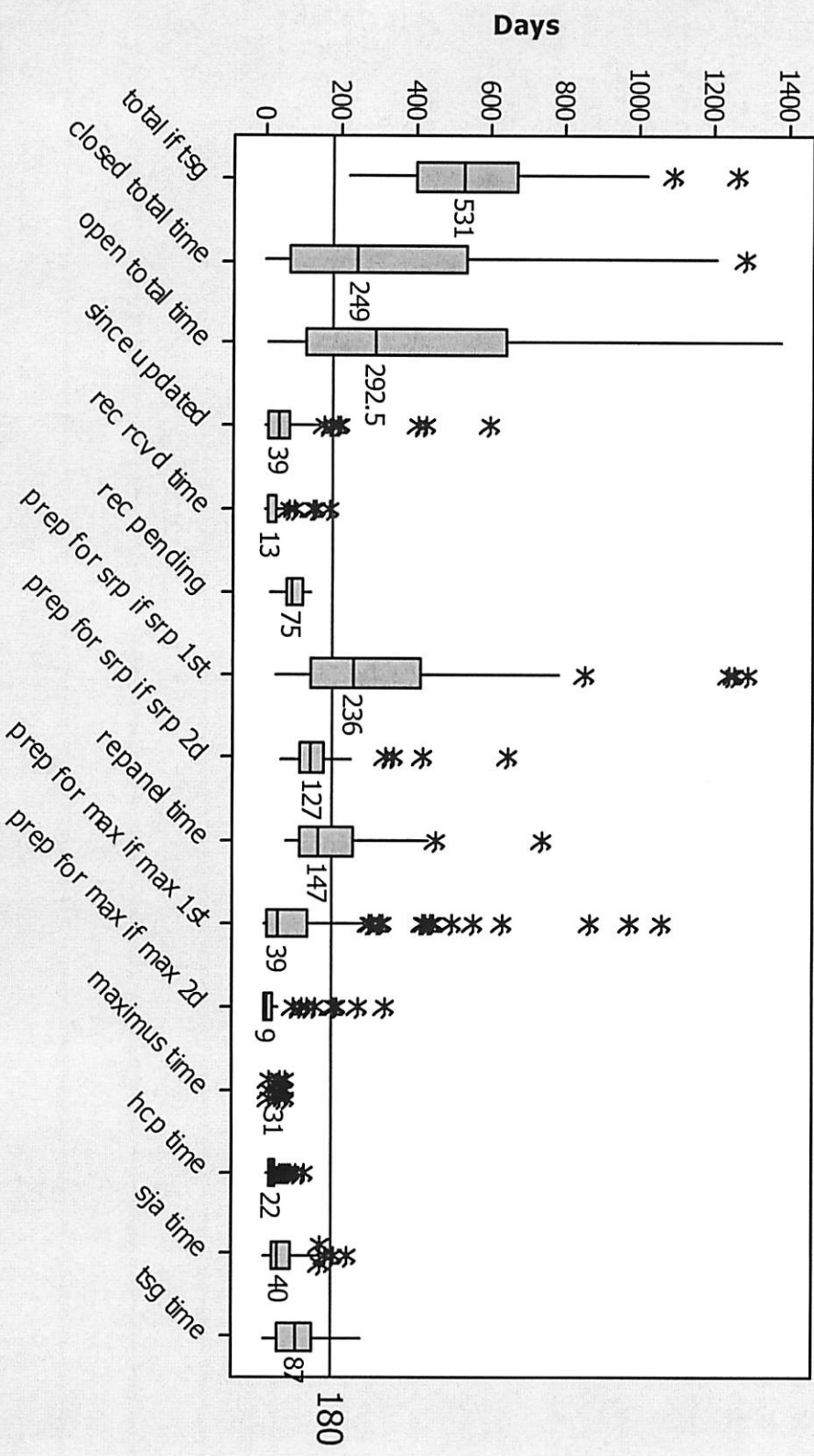
Briefing Slides

Process Map

USARCS/LD/Treas



Baseline Data



Cases that entered 1 Jan 05 to 23 Dec 08

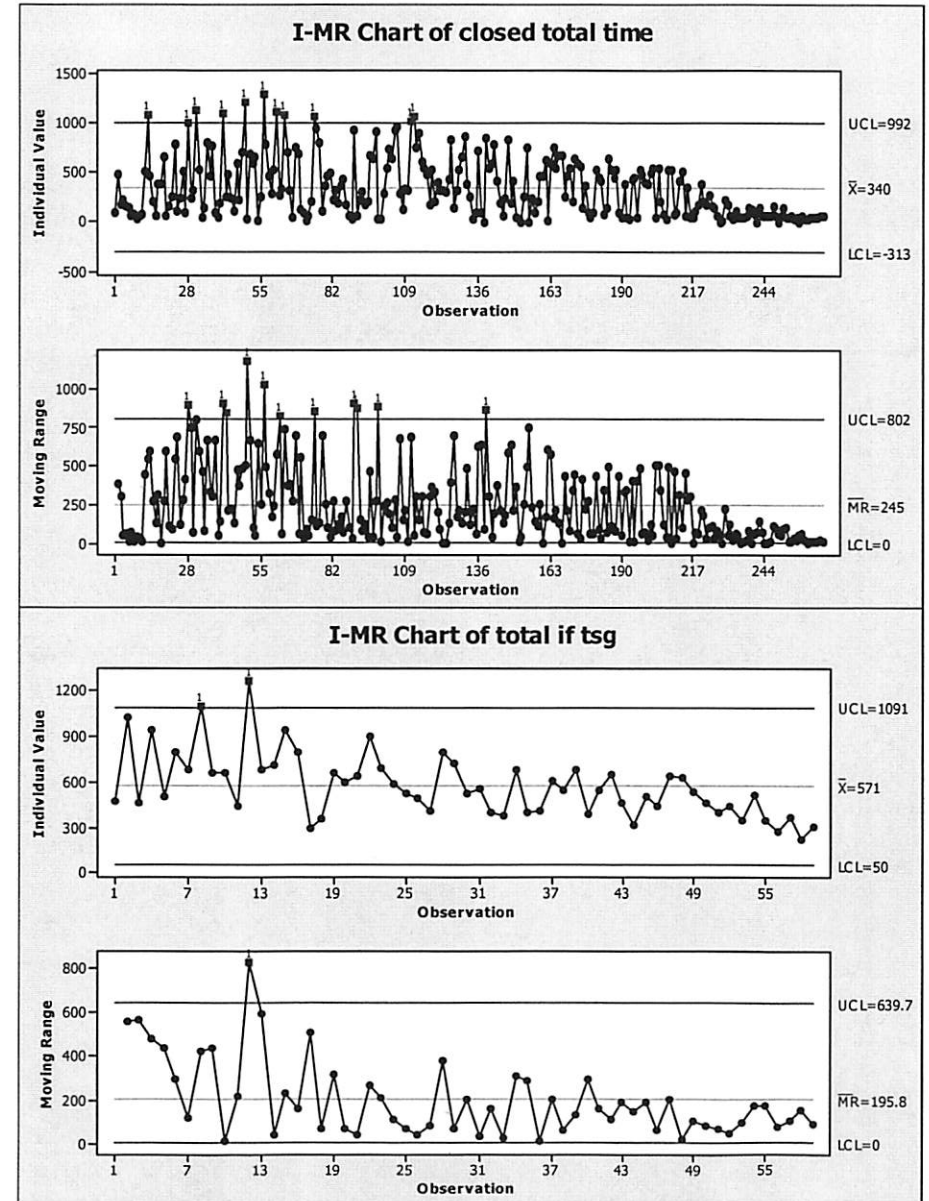
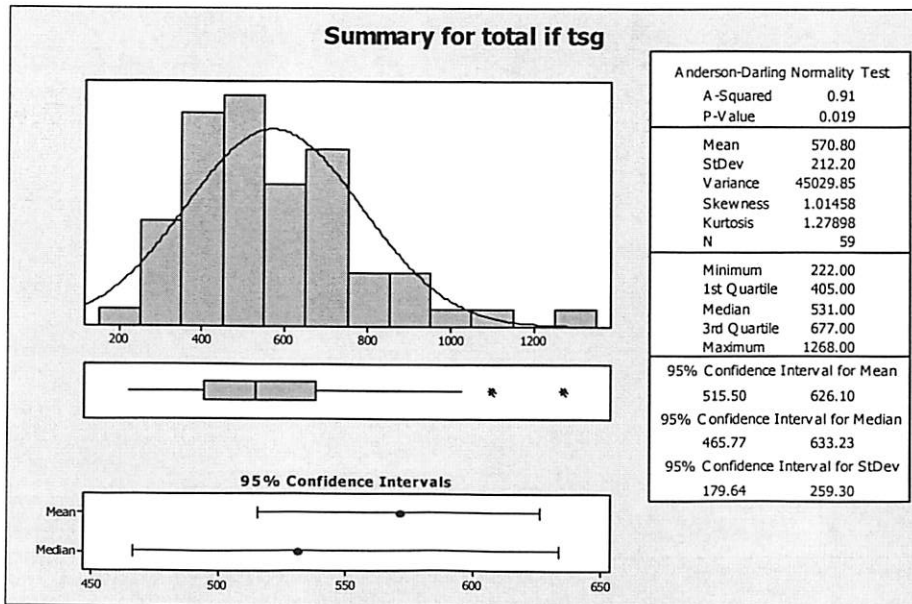
Baseline Data

Variable	N	Mean	StDev	Minimum	Median	Maximum
total if tsg	59	570.8	212.2	222	531.0	1268
closed total time	266	339.9	297.3	0	249.0	1290
open total time	106	420.2	366.4	12	292.5	1384
since updated	106	61.2	88.1	0	39.0	602
rec rcvd time	41	28.7	38.9	1	13.0	175
rec pending	9	77.4	32.8	14	75.0	123
prep for srp if srp 1st	126	297.7	237.1	34	236.0	1294
prep for srp if srp 2d	28	161.0	131.4	47	127.0	650
repanel time	44	189.4	138.2	57	147.0	749
prep for max if max 1st	153	103.8	171.3	1	39.0	1068
prep for max if max 2d	51	37.9	68.9	3	9.0	323
maximus time	197	31.2	6.3	14	31.0	61
hcp time	109	27.3	17.8	8	22.0	109
sja time	71	57.5	48.7	4	40.0	226
tsg time	59	90.1	60.8	1	87.0	260

Control Charts

Substantial improvement in Closed process control since 7 Feb 08

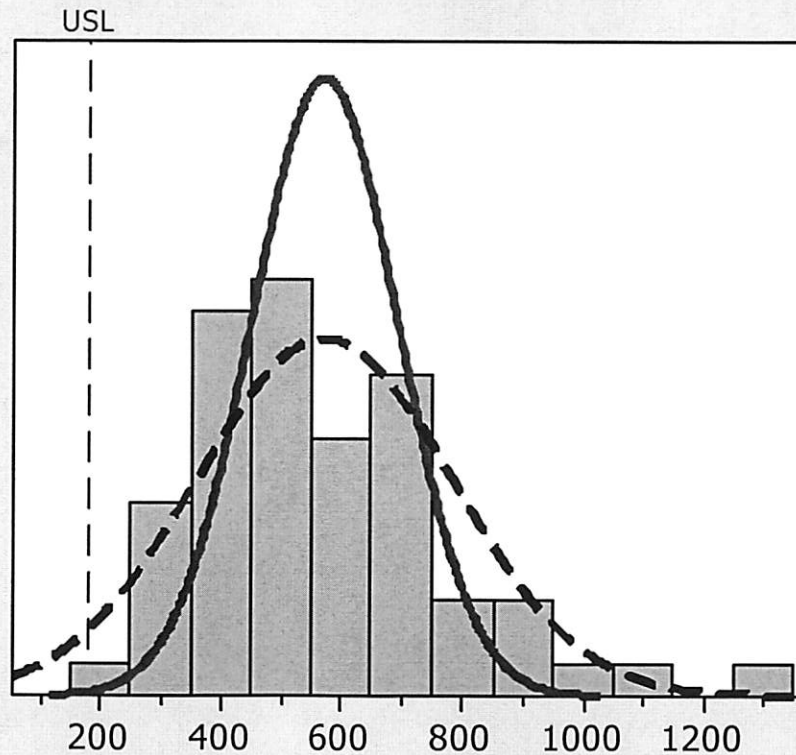
Gradual improvement in TSG process control



Cp/Cpk

Process Capability of total if tsg

Process Data	
LSL	*
Target	*
USL	180
Sample Mean	570.797
Sample N	59
StDev (Within)	122.34
StDev (Overall)	212.202



—	Within
- - -	Overall

Potential (Within) Capability	
Cp	*
CPL	*
CPU	-1.06
Cpk	-1.06

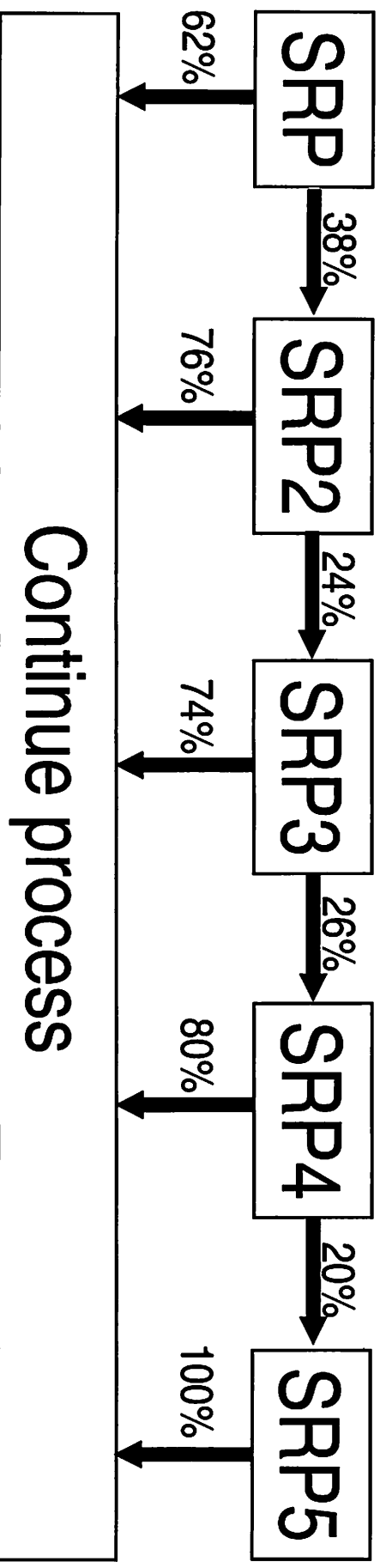
Overall Capability	
Pp	*
PPL	*
PPU	-0.61
Ppk	-0.61
Cpm	*

Observed Performance	
PPM < LSL	*
PPM > USL	1000000.00
PPM Total	1000000.00

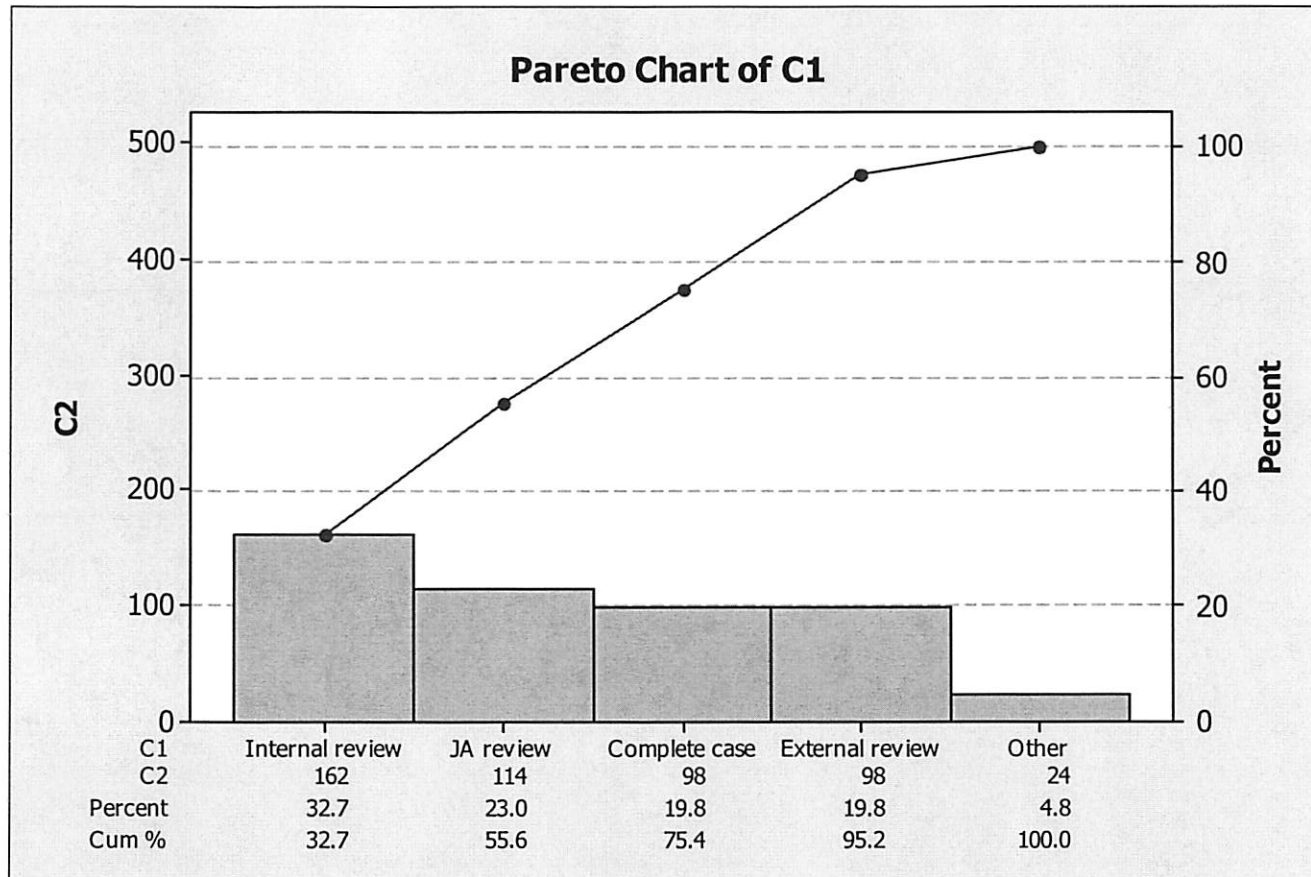
Exp. Within Performance	
PPM < LSL	*
PPM > USL	999299.24
PPM Total	999299.24

Exp. Overall Performance	
PPM < LSL	*
PPM > USL	967234.78
PPM Total	967234.78

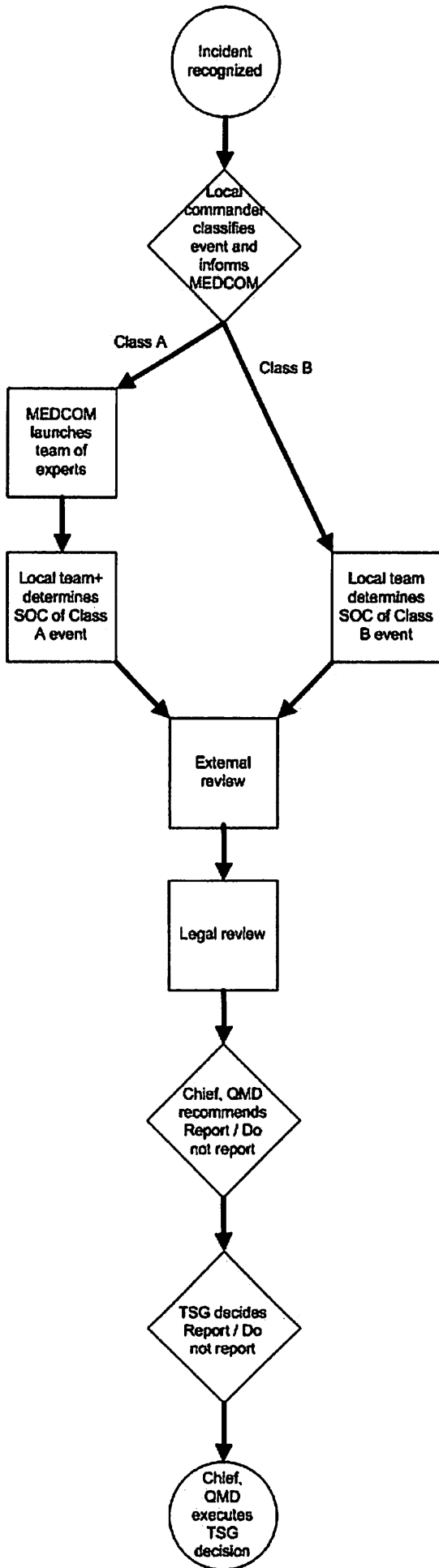
Error rates



Reducing List of Root Causes: Pareto Analysis



Unconstrained COA



Constrained COA

1. Paperless
2. Comparative advantage
3. Regularly scheduled SRPs
4. Tasking system
5. Medical records requests
6. Regularly scheduled status review
7. Eliminate extra database
8. Consolidation of review file formats
9. Contract modification

Questions?