Application of Quality Management Methods to IT Systems Development for Integrated Health Care Units

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Executive Summary

The aim of this paper is to present the current situation in healthcare institutions as regards quality standards. Avoidable error in health care is caused by a lack of standardized methods. It is a known fact that 1 in 500 people who visit a hospital requiring hospital stay, end up dying of an ailment different than what they were initially admitted for, i.e. errors on the side of the practitioners lead to their death. These errors are due not only to faulty devices, but also to miscommunication of information. Clearly, there is a need for improvement in this area, and though this may take considerable time, effort and even financial resources, one cannot deny the outcome is beneficial.

This project addressed the safety issue and the need for efficiency improvement with the aid of FMEA and Process management, cost efficiency issues (Quality Management (QM) in general) and Clinical Pathways. These processes have been proven to be successful in the manufacturing and service industry and have been introduced into the health industry, particularly in the US and in Australia, in the hope that they become standards in the next few years. Using QM tools, a set of standards have been laid out, and suitable calibration has been put in place such that the processes can be measured in terms of their severity in case of process failure or process problems alongside other criteria, and thereafter the proposed improvement methods are also measured in order to determine their efficiency. In addition, an Information Management System (IMS), a web-application has been designed to simplify the tasks of the Quality Manager. This is a tool which will assist him in organizing his data, and ensuring that the right people have access to the right information at all times. Indeed, for the Quality Manager to efficiently introduce standards into his service area, data collection and organization need to be done efficiently, thus allowing him the time and effort it will take to get the full commitment of his staff and top management.
1 Introduction

Statistics have shown that there is a dire need for improvement of healthcare with many still dying or suffering undue discomfort due to the negligence or limited knowledge of attending physicians, or even natural human error. Whatever form of improvement is adapted must lead to a reduced number of errors which in turn should lead to patient satisfaction in these institutions while keeping the cost of method implementation at a minimum. The motivation to make a change in this industry brings up the following questions which this project will strive to provide concrete answers to. How will healthcare delivery institutions be shaped in the future? What are the current trends and what transformations can be expected in the coming years? How will technology, management, and medicine be merged into a workable and economically feasible combination? What are the barriers to shaping hospitals for the future, and how will they be overcome? These are questions, which must be addressed if the management of modern healthcare enterprises is to be effective and efficient.1

In this project, the subject is taken up within the framework of a cooperation projection between Jacobs University and two local companies, Com’agere GmbH & Co. KG and WebMen Internet GmbH. While the former deals with design and sales of innovative software solutions, the latter develops websites and web-applications providing high-performance solutions. Funding is from the Bremer Investitions Gesellschaft.

With a vast number of departments in a hospital, and an even larger number of ailments, it becomes extremely complex to provide a solution which will cover all areas and yet be detailed; therefore this project will be focusing on Colorectal Cancer as a pilot project in cooperation with a practitioner in the Nordheim area. The solutions developed may very well serve as an example for other departments, and the same idea can be applied to develop a solution tailored to any other particular ailment.

As colorectal cancer is one of the most common forms of cancer, it is a good choice of ailment to begin applying the proposed methods to. Colorectal cancer refers to a combination colon cancer and rectal cancer. The normal growth and division of cells in the body may become exaggerated and if it becomes so in the colon and rectum, precancerous polyps may form in the intestinal wall. Over the years, these may become cancerous and then penetrate the walls of the colon, thus spreading to other organs and lymph nodes. If detected in its early stages, there is a very good chance of recovery. Treatment is done by Colectomy (surgery involving the removal of part of the colon), Radiation or Chemotherapy depending on just how far into the bowel wall the cancer has penetrated, and how wide into other parts of the body it has spread.

2 Statement and Motivation of Research

Industry experience shows that successful QM implementation is influenced mainly by top management. This is the subject of Total Quality Management which goes beyond my scope of influence in this project. Total Quality Management is a philosophy, associated methods and tools, and actions (leadership), which develop an entire organization, from the lowest to highest level, to excellence and

1 Matthew M. Ragsdell, D.O., Kenneth M. Ragsdell, PhD — Healthcare & The Modern Hospital: What we can learn from the factory
efficiency in personal and corporate activities. This quote is from Ragsdell & Ragsdell’s paper on “Healthcare & The Modern Hospital: What we can learn from the factory”. Though they have chosen the word “compel” in their definition of Total Quality Management, I would replace this with “encourage” as the people should be animated and heartened by informing them of the benefits of adopting this philosophy. The mindset of the top managers, e.g. doctors, influences this in a very strong way, and many at times hinder the progress of a successful QM implementation. However, where there is a will, there is a way, and therefore some hospitals have success stories to recount while others have even been praised and awarded for their successful performance strategies with national awards.

It has been reported that more people die in any year as a result of medical errors than from car accidents, breast cancer, or aids. According to this report by the Institute of Medicine – ‘To Err is human’ – one in every 343 to 764 hospital admissions results in death from preventable medical errors. These numbers become unbelievable when compared with the aviation industry, where there is an average of one death per 8 million flights. Unbelievable but true, this shows that changes must be put in place, and a proactive and preventive rather than a reactive approach should be taken.

The goal of this project amongst others is to develop a workflow manager which will provide technological support of medical processes. This is an integrated structure which will be ported onto handheld devices allowing for direct communication and data exchange of treatment processes with the aid of data and illustrations. This will lead to a high degree of technical and organizational integration as processes will now be coordinated. As the time frame of project is an estimated 15 months, at the time of the writing on this paper, it is still in its early stages of development. This Personal Digital Assistant (PDA) will have amongst other features a questionnaire for patients which should provide feedback to their doctors, indoor guidance for patients via GPS, location-based services which will provide information about the current status of services at different locations, e.g. the length of the queue in the radiology department.

Opinion from potential clients has been sought in our locality, e.g. Detken Clinic in Nordheim. In summary, the project has been given the green light, and will most probably be very welcome into the local industry.

This research focuses in a bottom up manner first of all on how to reduce the risk of individual process steps going wrong in a proactive manner. The QM tool to do this is Failure mode and Effects analysis (FMEA), which in Germany has not been used in medicine yet to any degree (in the US and Australia, this is different). In detail, this is

- Redesigning processes to eliminate or minimize failures.
- Redefining severity, occurrence and detection criterion for FMEAs as related to the medical field
- Reanalyzing the newly adopted FMEA, thus analyzing and testing the new process
- Amalgamating the “clinical pathway” with an FMEA for every single process step
- Applying FMEA to process management
- Creating a process management framework (based on information technology) for the application of QM in the medical world

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2 Matthew M. Ragsdell, D.O., Kenneth M. Ragsdell, PhD – Healthcare & The Modern Hospital: What we can learn from the factory

3 John G. Reiling, Barbara L. Knutzen, Mike Stoecklein – FMEA – the cure for medical errors
3 Tools and Processes

To align product, process and service specifications to the customer’s requirements, a number of Quality Management tools need to be used for analysis purposes if the desired outcome is an overall improvement in quality. A number of these tools are introduced and explained here.

3.1 Clinical Pathways

Clinical Pathways is a tool to systematically plan and follow-up a patient-focused care program, rather than a staff or hospital-focused one. It is a way of identifying and defining different tasks for different team members. This is a collection of methods and tools used to guide members of a multidisciplinary team towards patient-focused collaboration for a specific patient population. These plans provide both timing and sequence of actions that should be followed in order to achieve patient goals. It also helps reduce variation in care as this way; all patients are assured of receiving the same care as the next person with the same ailment. Healthcare quality is potentially improved in this way as this will lead to a decrease in resource utilization. Clinical Pathways are used to assure a qualitative and efficient care. Though they are expensive to develop and maintain, and there is still very little evidence of their effectiveness, early reports of successful outcomes have led more and more medical institutions to eagerly implement Clinical Pathways. More research is needed to develop valid and efficient methods for evaluating the impact of these pathways in different types of hospitals.
Introducing pathways is not half as easy as it sounds this once more because of the attitudes of doctors and health professionals. It will definitely take a lot of convincing to introduce this here as quite a number of professionals find it demeaning that be ordered to follow paths when they believe they are already the most competent in their fields of expertise.

3.2 Failure Modes and Effects Analysis (FMEA)

FMEA and RCA, Root Cause Analysis are the two standard methods of modern risk management. FMEA, a proactive process known as Failure Mode and Effects Analysis, provides a way to examine the use of new products and the design of new services and processes, so that points of potential failure and their effects can be determined before any error occurs. An RCA, is a reactive process that is used after an error occurs in order to identify its underlying causes. Unlike the RCA, the FMEA is less familiar to the medical world.

Every process has steps, each of which has to be analyzed. This can be done in two different ways; a Root Cause Analysis (RCA), or a Failure Mode and Effects Analysis (FMEA).

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4 http://www.surgicaloncology.com/cpmets1.jpg
5 Mathew Grissinger, Rph - Medication Errors – Failure Mode and Effects Analysis can help guide Error-prevention efforts
6 Mathew Grissinger, Rph - Medication Errors – Failure Mode and Effects Analysis can help guide Error-prevention efforts
An RCA is used after sentinel events to determine the cause of the error. An FMEA assesses hypothetical failures, while an RCA assesses actual failures. As this project however aims to adopt a proactive approach, a focus will be placed on FMEAs, at least in stage 1.

The FMEA process was developed by and first used in the US military. Automobile, aviation, aerospace, and nuclear power industries have now adopted this method of quality management and slowly but steadily the health care industry is also now adopting it. There are reports, though few, of actual use of FMEA in medicine. Many formal quality systems, such as ISO/TS 16949 also use it.

Basically, the ways in which each individual step in a process can fail (for a process FMEA) is listed, and the consequences thereof are then rated according to risk indices of ‘Severity’, ‘Occurrence’, and ‘Detection’, each ranging from 1 (lowest risk) – 10 (highest risk). An RPN (Risk priority number) is then calculated by multiplying these three numbers.

\[ RPN = S \times O \times D \]

This RPN number is then used to prioritize the potential failure modes and then actions that can reduce the frequency of occurrence are decided upon. This usually involves finding ways to reduce the frequency of occurrence as just mentioned, and also improve the probability of detection of a particular failure mode. Achieving this leads to lower RPN numbers. An RPN is calculated before and after risk reduction which is done with the aim of achieving a high percentage of improvement in the RPN. This aim may lead one to only improving those processes that will significantly induce the overall percentage of reduction that has been achieved after the recommended actions have been carried out, and not those processes which are of most benefit to the patient. This brings us to the question, how can the quality of an FMEA be assessed?

Though FMEAs, applied as described up to now, can discover many failure modes, it is less powerful when it comes to discovering complex failures resulting from multiple failures or subsystems. A Fault tree analysis can and should be used in this case to structure the FMEA before the actual FMEA analysis is carried out.

In stage 2 of this project, the FMEA will be applied to the Key processes in integrated health care and put into the “big picture” of the overall QM systems. This part isn’t required for the current thesis, and is thus considered optional.

As a part of this project FMEA definitions have been tailored to the needs of the Health Industry for the following areas:

- IT systems
- Service + Information
- Diagnostic Systems
- Invasive Operation
Table 1: Severity, Occurrence, Detection Definitions for the Healthcare Industry

The above diagram is a part of the definitions that have been created as a part of this project. They attached in the appendix for further reference. Note however that as at publishing time, these values have yet to be reviewed by a professional in the field.

Table 2: Sample (Process) FMEA

In addition, that information about who prepared an FMEA be included on the sheet so as to allow for easy tracking and tracing.

3.3 Process Steps

These detail the sequence in which actions should be carried out. These steps are analyzed in a process FMEA and receive Severity, Occurrence and Detectability rankings, and thereafter have an RPN number assigned to them. The action required to improve the performance of the process in question is also detailed here. Process steps are used as performance measures. These are usually presented graphically, either in the form of tables or flowcharts.
### Table 3: Sample Process Steps

<table>
<thead>
<tr>
<th>Consultant</th>
<th>Doctor, Caretaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Visit, Prep for Surgery</td>
</tr>
<tr>
<td>Activity</td>
<td>Pre-Op Check</td>
</tr>
<tr>
<td>Lab</td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>Pre-Medication</td>
</tr>
<tr>
<td>Nutrition</td>
<td>Nahrungskarenz</td>
</tr>
<tr>
<td>Patient Information</td>
<td>Routine of the Day</td>
</tr>
</tbody>
</table>

The above is a very short example of a process step; these would typically be a lot more detailed than has been indicated here. This example has been kept simple however as our focus is not on the data but on its application.

This example is from the operation day for a patient due suffering from Colorectal Cancer. Day 0 represents the day of the operation. Days before will be assigned negative numbers, and days afterwards positive numbers. The Number is a unique identifier, and this represents the process in the FMEA. The Location describes where the activity in question is to take place. The success criteria field describes the expected result if the process has been successfully carried out. The Consultant refers to the professionals involved in this step of action. The Description field contains a description as detailed as possible of the step in question. The Activity refers to the action being carried out. Should any labs be involved in this process, they would be indicated here. The Diagnosis field describes the ailment. Medication lists all medicines that should be administered at this step of the treatment. What food is consumed before and after surgery is important and is detailed in the Nutrition field. At different steps, certain information should be given to the patient or his guardians to make sure they are up to date with the current situation. The fields here may vary depending on the ailment.

This task is certainly time-consuming as a lot of detail is required for every action that is to be carried out. However, it is by being very specific and very detailed that one can hope to achieve total quality management in this industry.

### 3.4 Process Capability (Cp) -Values

Cp, with the aid of capability indices controls the output of the process in-control to the specification limits. If almost all measurements fall within the specification limits, we say that this process is capable. This comparison is made thus:

\[
C_p = \frac{USL - LSL}{6\sigma}
\]

Where USL = Upper Specification Limit and LSL = Lower Specification Limit, and these form the boundaries of acceptable levels of variation in the process. The difference USL – LSL represents the engineering tolerance while 6\(\sigma\) represents the natural tolerance, where \(\sigma\) represents the standard deviation.

As Cp values do not take into account where the process is centered, it is advisable that these be used in conjunction with Cpk values (Process Capability index). While the Cp value is a measure of how much of the specification limits is being used, the Cpk value is a measure of just how close to the expected value the process is. Therefore adjusting the centering of a process will affect the Cpk value while only a change in the process itself will affect the Cp value. Combining these two, to attain Six Sigma, a
process should have a Cp value of 2.0 which will guarantee a Cpk value of 1.5 even if the process is not centered.\textsuperscript{7}

Taking into account the Cp value alone, a value greater than 1.0 indicates that the process in question is capable. i.e. the measured process requirements fall between/within the customer’s USL and LSL. The diagram below should provide a visual idea of what is meant by the varying Cp values.

\textsuperscript{7} http://www.isotemp.com/docs/146-008.pdf
\textsuperscript{8} http://www.itl.nist.gov/div898/handbook/pmc/section1/gifs/cpi1.gif
\textsuperscript{9} http://www.itl.nist.gov/div898/handbook/pmc/section1/gifs/cpi2.gif
Should one need to improve the Cpk values of a process (in the case that this is less than the Cp value), one should center the process in the specification.

3.5 Six Sigma

Six Sigma is a measure of quality that strives for near perfection. It is a disciplined, data-driven approach and methodology for eliminating defects (driving towards six standard deviations between the mean and the nearest specification limit) in any process. This gives a quantitative measure of how a process is performing. A Six Sigma defect is anything outside the customer's specifications. This method is focused on improving process performance and reducing process variation. The frequency of any error can be converted to a sigma value which is derived from how the actual distribution of process results. The idea here is to convert the percentage number of errors into a "virtual" sigma. This is straightforward since in business and service processes, the outcome is simply right or wrong avoiding any fuzzy result. One of the key concepts on Six Sigma is Process Capability, which as mentioned above, is a measure of what a process can deliver. At its best, a process should result in only 3.4 defects per million to achieve perfection as the term Six Sigma indicates. If one can fit six standard deviations between the mean of a process and the nearest specification limit (both ways, the USL and also the LSL), the process will result in almost no productions exceeding the specified limits.

The 1.5 standard deviation used in the above illustration is the drift of a process mean. It is generally assumed that this drift occurs in all processes.

<table>
<thead>
<tr>
<th>USL – LSL</th>
<th>6σ</th>
<th>8σ</th>
<th>10σ</th>
<th>12σ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cp</td>
<td>1.00</td>
<td>1.33</td>
<td>1.67</td>
<td>2.00</td>
</tr>
<tr>
<td>% of spec used</td>
<td>100</td>
<td>75</td>
<td>60</td>
<td>50</td>
</tr>
</tbody>
</table>

Table 4: Numerical description of Fig. 110

Fig. 5: Six Sigma "Sigma Values"12

The 1.5 standard deviation used in the above illustration is the drift of a process mean. It is generally assumed that this drift occurs in all processes.

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10 More on Cp values can be found here: http://www.itl.nist.gov/div898/handbook/pmc/section1/pmc16.htm
12 www.micquality.com
Application of Six Sigma in the healthcare industry, though still new, has helped reduce waste and variation and this has led to improved patient care and better processes among others. It should be noted however that while the number of defects of 3.4 per million is acceptable in other applications, this may not be satisfactory in the healthcare industry, e.g. the fabrication on pacemakers, one would expect even more perfection. Nevertheless, hospitals, mostly in the USA who have tried and tested this methodology can now boast of

- Increased Patient Satisfaction
- Increased Physician Satisfaction
- Reduced Costs / Costs savings
- Stronger Growth (elimination of bottlenecks)\(^{14}\)

Research shows that it is advantageous to introduce this methodology in health institutions, and this is now a strategy that we will introduce health institutions to in the later stages of this project. An example of success is Saint Luke’s Hospital (SLH) in Missouri, which received the Malcolm Baldridge National Quality Award in 2003 for quality performance.\(^{15}\)

## 4 Development of Web-Application

Healthcare Quality Management, HQM is a tool designed to simplify the tasks of the Quality Manager. This helps him keep his data organized and ensures that his team and other staff always have access to the most updated data. The traditional ways of storing this data is with text files and excel sheets. This method, though it has been in use for years and in many different industries, is definitely not the most efficient way of proceeding. What has been developed here is a web-application with an underlying database which stores the following information:

- Clinical Pathways
- Process Steps
- Process FMEA

<table>
<thead>
<tr>
<th>Distribution</th>
<th>Cp</th>
<th>Centered</th>
<th>Cpk</th>
<th>Expected Defects</th>
</tr>
</thead>
<tbody>
<tr>
<td>±3.0 sigma</td>
<td>1.00</td>
<td>NO</td>
<td>0.50</td>
<td>66,810 ppm</td>
</tr>
<tr>
<td>±3.0 sigma</td>
<td>1.00</td>
<td>YES</td>
<td>1.00</td>
<td>2,700 ppm</td>
</tr>
<tr>
<td>±4.5 sigma</td>
<td>1.50</td>
<td>NO</td>
<td>1.00</td>
<td>2,700 ppm</td>
</tr>
<tr>
<td>±4.5 sigma</td>
<td>1.50</td>
<td>YES</td>
<td>1.50</td>
<td>3.4 ppm</td>
</tr>
<tr>
<td>±6.0 sigma</td>
<td>2.00</td>
<td>NO</td>
<td>1.50</td>
<td>3.4 ppm</td>
</tr>
<tr>
<td>±6.0 sigma</td>
<td>2.00</td>
<td>YES</td>
<td>2.00</td>
<td>0.002 ppm</td>
</tr>
</tbody>
</table>

\(^{13}\) [http://www.isotemp.com/docs/146-008.pdf](http://www.isotemp.com/docs/146-008.pdf)


\(^{15}\) The Malcolm Baldridge National Quality Award (MBNQA) was established by the U.S. Congress in 1987 to promote quality awareness, to recognize quality and business achievements of U.S. organizations, and to publicize these organization’s successful performance strategies. This award has become America’s highest honor for performance excellence, and is presented annually to U.S. organizations by the nation’s President. Awards are given to different types of organizations including health care.
CP-Values as related to the case of Colorectal Cancer.

The site has homogeneity in its layout, and keeps the same familiar colour on all pages. There isn't only consistency in the sense that operations are always performed in the same way, but it is also very easy to navigate. One could describe the overall look and feel of the application as minimalist and simple, to reflect the idea that navigation and task completion through the site will be an easy process as is intended by this application.

The system is designed such that no data can be accessed without logging in, thus ensuring data security. All registered members are assigned access levels which determine what permissions they have in the application. The lowest of these levels is the “User level” which allows members to log in and view data only. Higher in rank is the “Admin level”. This member is allowed to edit data stored in the database, and also the settings of all registered users but not that of other Admin members. The master of all levels is the “Super Admin level”. This member has all the above-mentioned permissions and also the right to edit the settings of other Members at the Admin level, including his own settings. In essence, the application ensures constant access to the required and most updated version of data at all times.

The application is currently located at:

http://tlab060.clamv.iu-bremen.de/~spapantona/Monsurat/HQM/

As the database is running on one of computer lab machines, the application can only be accessed on the Jacobs University campus.

4.1 Entity-Relationship Diagram

An Entity-Relationship Diagram (ER – Diagram), is an illustration of the relationships between entities in a database. Entities, Attributes and Relationships are represented by a box, an oval and a diamond, respectively. This diagram details what information is stored about every entity, which can be otherwise described as a unit of existence, e.g. a Member. The underlined attribute of every entity is that entity’s primary key. A primary key is a unique identifier, i.e. the value of this key is unique to the entry in that row. This diagram is available in the documentation folder of the application for further reference. The Logical Database Schema provides a literal description of the illustration presented here.

http://tlab060.clamv.iu-bremen.de/~spapantona/Monsurat/HQM/_doc

4.2 Justification of Data Model

The reasons for designing the database in the way it has been designed is justified in this document located at

http://tlab060.clamv.iu-bremen.de/~spapantona/Monsurat/HQM/_doc

4.3 Logical Database Schema

The tables in the database are described in this file which is in the “_doc” folder located here:

http://tlab060.clamv.iu-bremen.de/~spapantona/Monsurat/HQM/_doc

The logical database schema describes the database structure under this application. Each table’s attributes are defined here. This will provide an administrator with information detailed information
about the tables, such as the type and size of each attribute. The document should be read by all administrators of the site, as it will help them understand the fields they’ll be presented with should they wish to edit the content of any tables.

5 Project Outcome

FMEA method is established so that with other QM tools in a QM system, the following long term goals for the Integrated Health Care units can be achieved. These are the basics for the IT systems to support practical QM.

- Better quality and more pleasant clinical outcomes
- Safer environment for patients, families and employees
- Greater efficiency and reduced costs
- Stronger leadership capabilities of people in charge leading to higher employee motivation
- Increased revenue and market share
- Optimized technology and workflow

QM systematic methods facilitate the smooth and efficient operation of the Integrated Health care unit through:

- Good information flows
- Built-in efficiency in the process
- Built-in continuous improvement
- Pro-active error prevention

6 Recommendations and Conclusions

Clearly, this project is still in its early stages, but with such a solid foundation already laid out, it is no doubt that this will end a huge success.

There evidently is a need for an efficient, reliable and fast method for impacting patient safety and the technique that should be utilized here is definitely the Failure mode and effects analysis, FMEA, whose purpose is to prevent failures that have never occurred, and prevent errors. A way of assessing the quality of an FMEA needs to be put in place. There isn’t an easy way to measure this, as this is measuring and quantifying something else. It has been suggested though, that an analysis of near-miss data may be helpful in assessing the quality of this model.

When assigning Risk Priority Numbers (RPN), to process steps, one should be mindful of the fact that in a hospital setting, failure modes aren’t limited to only one variable as is common in the engineering field. E.g. a Patient’s death should always rank higher on the scale even if the frequency of occurrence

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16 [http://healthcare.isixsigma.com/library/content/c040317a.asp](http://healthcare.isixsigma.com/library/content/c040317a.asp) - 18/02/07

17 Jan S. Krouwer, PhF, FACB – An Improved Failure Mode Effects Analysis for Hospitals
is low. A multi-disciplinary team is necessary to reduce the potential for bias in designing FMEAs, as what one may consider very severe, another might consider otherwise. All guiding principles need to be balanced. The outcome of this will be a design with both a patient and a staff focus which will only lead to increased efficiency which in turn leads to a healing environment. This requires teamwork.

Although designing and applying FMEAs is time-consuming and arduous, it is without a doubt, a valuable tool in the healthcare industry as it focuses primarily on the safety of patients. It is only with great efforts, determination and dedication that Total Quality Management can be achieved in this industry.


Understanding how Cp and Cpk values are used to ensure quality. (n.d.). Retrieved 05 13, 2006, from Isotemp: http://www.isotemp.com/docs/146-008.pdf

## Appendix I – FMEA definitions for the Healthcare Industry

### Severity

<table>
<thead>
<tr>
<th>Rating</th>
<th>Criteria</th>
<th>Service + Information</th>
<th>Diagnostic Systems</th>
<th>Invasive Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Hazardous to Patient, irreversible</td>
<td>misdiagnosis of illness resulting in incorrect treatment in turn resulting in severe damage or death</td>
<td>incorrect machinery setup, (e.g. leaving out filters in x ray machines leading to exposure to radiation, Electrical shock from faulty or improperly grounded equipment, or equipment with faulty insulation. (hazard to patient and/or User)</td>
<td>pre/post-operation diet error (e.g. Staying away from aspirin), mistakes which can lead to death or permanent damage</td>
</tr>
<tr>
<td>9</td>
<td>Hazardous to User, complicated correction methods</td>
<td>incorrect dosis of medication with irreversible damage</td>
<td>incorrect machinery setup which may cause physical damage, parts falling onto User or patient</td>
<td>major deficiencies such as nonsterile products/tools</td>
</tr>
<tr>
<td>8</td>
<td>Hazardous to User, moderate correction methods</td>
<td>incorrect treatment recommended with no serious damage</td>
<td>faulty machinery producing seemingly correct results, incorrect gauging leading to incorrect measurements. delayed diagnosis leading to extreme worsening of condition (e.g. Inflammations, ruptures)</td>
<td>Simple mistakes in operating procedures</td>
</tr>
<tr>
<td>7</td>
<td>Hazardous to User, simple correction methods</td>
<td>medication consumption methods (e.g. Before/after meal, quantity slightly wrong)</td>
<td>outdated or marginally wrong calibration which give non-optimum diagnostic results</td>
<td>Experimental procedures/therapy resulting in repairable damage</td>
</tr>
<tr>
<td>6</td>
<td>Causes great inconvenience to User with potential hazards</td>
<td>major incorrect information leading to extensive delays or waste of time</td>
<td>incorrect machinery setup causing extreme discomfort to User, too small/tight MRI capsules</td>
<td>forgetting foreign material (tools) in patient after operation</td>
</tr>
<tr>
<td>5</td>
<td>Causes considerable inconvenience to User</td>
<td>Patient care/attention (meals, cleanliness) is strongly deficient</td>
<td>faulty machinery leading to delay of testing</td>
<td>forgetting foreign material (gauzes/tissues) in patient after operation without damaging effects. (biodegradable foreign materials)</td>
</tr>
<tr>
<td>4</td>
<td>Causes great dissatisfaction to User</td>
<td>insufficient information provided about medication (e.g. Adverse effects not mentioned), Waiting times &gt;1h, wrong information on place and time of appointments</td>
<td>faulty machinery producing obviously incorrect results (spurious events), incorrect gauging leading to absurd values (causes dissatisfaction as tests will need to be repeated)</td>
<td>negligent conduct that does not cause damage, (e.g. incorrect/insufficient dose of anaesthesia leading to too much pain/ side effects)</td>
</tr>
<tr>
<td>3</td>
<td>Causes some dissatisfaction to User</td>
<td>Waiting times &lt;1h</td>
<td>cold machinery on skin, uncomfortable positions</td>
<td>inadequate and improper post-operation therapy which causes unnecessary pain/irritation, with serious effects</td>
</tr>
<tr>
<td>2</td>
<td>Causes discomfort to User</td>
<td>insufficient facilities (access to phone, TV, refrigerator...), inadequate of supply of aid machinery leading to waiting/sharing of these (e.g wheelchairs)</td>
<td>inadequate of supply of aid machinery leading to waiting/sharing of these (e.g. wheelchairs)</td>
<td>Bandages applied to tight (if not pointed out early, made lead to increased blood pressure)</td>
</tr>
<tr>
<td>1</td>
<td>Not hazardous but should be avoided</td>
<td>untidy office and other appearance issues</td>
<td>noisy machinery</td>
<td></td>
</tr>
</tbody>
</table>

---

### Example

- **Example for Service + Information**
  - Incorrect dosis of medication with irreversible damage
  - Incorrect machinery setup leading to exposure to radiation
- **Example for Diagnostic Systems**
  - Faulty machinery producing seemingly correct results
  - Incorrect gauging leading to incorrect measurements
- **Example for Invasive Operation**
  - Pre/post-operation diet error
  - Staying away from aspirin
## Appendix I – FMEA definitions for the Healthcare Industry

### Severity (IT system)

<table>
<thead>
<tr>
<th>Rating</th>
<th>Criteria</th>
<th>Example</th>
<th>Criteria for probability</th>
<th>Failure Probability</th>
<th>Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Failure prevents system operation</td>
<td>System crash, resulting in loss of considerable amount of data</td>
<td>Very High: Failure is almost inevitable</td>
<td>≥1ce a day</td>
<td>Almost impossible</td>
</tr>
<tr>
<td>9</td>
<td>Failure leads to improper system operation</td>
<td>System sporadically delivers arbitrary results. User may not realize instantly</td>
<td>Regularly</td>
<td>1ce a day</td>
<td>Very low</td>
</tr>
<tr>
<td>8</td>
<td>Failure causes loss of unrelated files</td>
<td>User may not realize instantly</td>
<td>Very Frequent: Repeated Failures</td>
<td>1ce a week</td>
<td>Low</td>
</tr>
<tr>
<td>7</td>
<td>Failure compromises integrity of data</td>
<td>Data corruption. User may realize</td>
<td>Frequent</td>
<td>1ce a month</td>
<td>Low</td>
</tr>
<tr>
<td>6</td>
<td>Failure is deterrent to operation</td>
<td>System slow due to race condition (interdependent timing of events)</td>
<td>Moderate: Occasional failures</td>
<td>1ce in 3 months</td>
<td>Moderate</td>
</tr>
<tr>
<td>5</td>
<td>Low. Mild disruption to service</td>
<td>System overload. May not recur if system is restarted</td>
<td>Some failures</td>
<td>1ce in 6 months</td>
<td>Moderately High</td>
</tr>
<tr>
<td>4</td>
<td>Very Low. Minor disruption to service</td>
<td>Error not easily reproducible, e.g. Improper display of graphics. May not recur if system is restarted</td>
<td>Few failures</td>
<td>1ce in 1yr</td>
<td>High</td>
</tr>
</tbody>
</table>

### Occurrence

<table>
<thead>
<tr>
<th>Failure Probability</th>
<th>Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥1ce a day</td>
<td>Almost impossible</td>
</tr>
<tr>
<td>1ce a day</td>
<td>Very low</td>
</tr>
<tr>
<td>1ce a week</td>
<td>Low</td>
</tr>
<tr>
<td>1ce a month</td>
<td>Low</td>
</tr>
<tr>
<td>1ce in 3 months</td>
<td>Moderate</td>
</tr>
<tr>
<td>1ce in 6 months</td>
<td>Moderately High</td>
</tr>
<tr>
<td>1ce in 1yr</td>
<td>High</td>
</tr>
</tbody>
</table>

### Detection

<table>
<thead>
<tr>
<th>Criteria: Likelihood of detection prior to product shipping</th>
<th>Range of Detection Methods (for Software)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute certainty of non-detection. No specific test pattern for detection</td>
<td>No specific method. Cannot be directly checked</td>
</tr>
<tr>
<td>Detection is most improbable &lt;1% ~30 days after occurrence</td>
<td>end-to-end testing</td>
</tr>
<tr>
<td>Very Poor chance of detection &lt;10% &lt;14 days after occurrence</td>
<td>sanity testing or smoke testing</td>
</tr>
<tr>
<td>Poor chance of detection 25% &lt;7 days after occurrence</td>
<td>.incremental integration testing</td>
</tr>
<tr>
<td>Fair chance of detection 50% &lt;24hrs</td>
<td></td>
</tr>
<tr>
<td>Good chance of detection before irreversible damage is done 80%</td>
<td></td>
</tr>
<tr>
<td>Very Good chance of detection before great damage is done 95%</td>
<td></td>
</tr>
</tbody>
</table>
Appendix I – FMEA definitions for the Healthcare Industry

<table>
<thead>
<tr>
<th></th>
<th>Minor</th>
<th>Slightly delayed system response</th>
<th>Low: Relatively Few Isolated failures</th>
<th>1ce in 3yrs</th>
<th>Very High</th>
<th>Will be detected before effects take place</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>99% &lt;2hr</td>
</tr>
<tr>
<td>2</td>
<td>Very minor. System operable with minimal interference</td>
<td>System restart will correct it</td>
<td>Rare occurrence</td>
<td>1ce in 10yrs</td>
<td>Almost Certain</td>
<td>Easy to detect through testing before effects take place 99.99%</td>
</tr>
<tr>
<td></td>
<td>None. Harmless Error</td>
<td>No effect</td>
<td>Remote: Failure is unlikely</td>
<td>1ce in 20yrs</td>
<td>Absolutely Certain</td>
<td>Will certainly be detected without any effects before detection &lt;30mins</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>White Box Testing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Black Box Testing</td>
</tr>
</tbody>
</table>