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Integration of Six Sigma Methodology to Reduce Complications in a Private Hemodialysis Center

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ABSTRACT: This paper aims to evaluate the complications occurred during and after the hemodialysis sessions made in a private hemodialysis center in terms of their sigma levels and severity. Complications with sigma levels under 4.00 indicate that the sessions need improvement and corrective actions. Vital few and trivial many critical to quality (CTQ) factors are determined and some improvement suggestions are made for the process based on the vital few CTQ factors. Consequently, it is found that the hemodialysis process operates at a 3.5342 sigma level.

Keywords: Six Sigma; Hemodialysis; Complications
JEL Classifications: I20; L15

1. Introduction

With the advances in the recent hemodialysis machine technology, the clinical spectrum of complications has changed over the decades. In the pioneering days of hemodialysis, patients could develop allergic reactions to dialyzer membranes, sterilizing and reprocessing agents, coupled with machines that could not accurately control ultrafiltration rates, and chemically and bacterially contaminated dialysate (Davenport, 2006). Today, complications encountered include hypotension, hemolysis, air embolism, infections, hypertension, cardiac arrythmia, first use syndrome, disequilibrium syndrome, itching, hyperphosphataemia, hypernatremia, hyperkalemia, hypercalcemia, hypermagnesemia, hypoglycemia, haemorrhage, headache, neusea, muscle cramps, dialysis demantia, and cardiac arrest – being the most risky complication among all (Yoon et al., 2014; Yu and Levy, 1997; Nassar and Ayus, 2001; Pohlmeier and Vienken, 2001; Narula et al., 2000; Mandal and Prakash, 2014; Karnik et al., 2001).

Although hemodialysis is now considered a routine procedure, it still remains as a risky process for patients with comorbid cardiovascular diseases and diabetes. At the end of 2013, approximately 3.194M patients were being treated and about 2.519M patients regularly underwent dialysis worldwide (Fresenius Medical Care, 2013). The same year, number of dialysis patients rose by around 7% worldwide (Fresenius Medical Care, 2013). About 89% of all patients were treated by hemodialysis (Fresenius Medical Care, 2013).. Demographic trends are a major factor in the growing number of dialysis patients, which is expected to rise to 3.8M patients worldwide in 2020 (Fresenius Medical Care, 2013).

As the incidence and prevalence of hemodialysis patients in the United States have grown, the age and number of comorbid diseases in patients initiating hemodialysis therapy also have increased (Himmelfarb, 2005). In the US, primary diagnoses of diabetes and hypertension together account for 72.5% of patients starting on hemodialysis (National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2007). It was also reported that poor water quality (i.e. water with low purity ratio) and temporary catheter also yield complications (Brunet and Berland, 2000; Oliver et al., 2000). On the other hand, hypotension is the most common complications (20%-30%) in the clinical practice (Zucchelli and Santoro, 1993).

As a quality improvement method, Six Sigma can be employed in order to reduce complications encountered during and after hemodialysis procedures. In this study, a Six Sigma infrastructure was developed in a dialysis centre in order to reduce the number of complications and thus, improve the outcomes of their hemodialysis processes. In addition, sigma level of each type of complication are calculated and reported.

2. Methodology

Six Sigma is a powerful performance improvement tool that is improving the outcomes of modern healthcare processes today (Taner et al., 2007). Although it was initially introduced in manufacturing processes e.g. in automative, textile and construction industries (Bilgen and Şen; 2012; Taner, 2012; Taner, 2013a), it is being implemented in cardiology (Taner et al., 2013), ophthalmology (Taner, 2013b), diagnostic imaging (Taner et al., 2012), emergency room (Miller et al., 2003), intensive care (Eldridge et al., 2006), paramedic backup (Taner and Sezen, 2009), laboratory (Nevalainen et al., 2000), radiology (Cherry and Seshadri, 2000), pharmacy (Arafeh et al., 2014) and surgical site infections (Pexton and Young, 2004) as an effective way to improve quality, performance and productivity.

A Six Sigma process produces only 3.4 defects per 1,000,000 opportunities (DPMO) [Buck, 2001]. To eliminate defects, Six Sigma makes use of a structured methodology called DMAIC to find the root causes behind problems and to reach near perfect processes [Park and Antony, 2008]. DMAIC can analyse and modify complicated time-sensitive healthcare processes involving multiple specialists and treatment areas by identifying and eliminating root causes of defects, errors or complications and thus minimizing healthcare process variability [Taner et al., 2007)].

To achieve this, normal distribution underlies Six Sigma's statistical assumptions [Taner et al., 2012]. An empirically-based 1.5 sigma shift is introduced into the calculation [Taner et al., 2012]. DPMO is calculated from Equation (1) as follows:

$$\text{DPMO} = 1{,}000{,}000 \times (\text{TNS}/\text{TNC}) \quad (1)$$

where TNS is the total number of hemodialysis sessions performed and TNC is the total number of complications occurred. The, the level of sigma is calculated directly from DPMO by simple arithmetics. The higher level of sigma indicates a lower rate of complications and a more efficient process (Taner et al., 2013).

3. Analysis

When the top management of the hemodialysis centre had decided that Six Sigma was the best way to achieve their goals, a Six Sigma team had been assembled from a nephrologist, head nurse and dialysis technician, and was trained in the methodology. Committed and consistent leadership to overcome the complications was assured by this team. They firstly generated a SIPOC (Supplier, Input, Process, Output and Customer) Table for the hemodialysis process (Table 1). Then, they determined the metrics to measure existing process.

The metrics to be chosen for a Six Sigma study were:

1. Total number of hemodialysis sessions performed in the dialysis center,
2. Total count of complications occurred by type.

The Six Sigma team defined the successful outcome after hemodialysis process as patients having an urea reduction ratio of 70% to 80% and having balanced biochemical parameters of sodium, potassium, phosphate, bicarbonate, magnesium and calcium. In general, these elements are said to have a "balance" after hemodialysis when their concentration level in patient's blood are stabilized within an acceptable range given in Table 1.

Therefore, the objective is the optimization of urea reduction ratio, sodium balance, potassium balance, phosphate balance, bicarbonate balance, magnesium balance and calcium balance that can be denoted by y_1,y_2,y_3,y_4,y_5,$y_6$and y_7, respectively. Figure 1 summarizes the hemodialysis process.

Figure 1. The Hemodialysis System

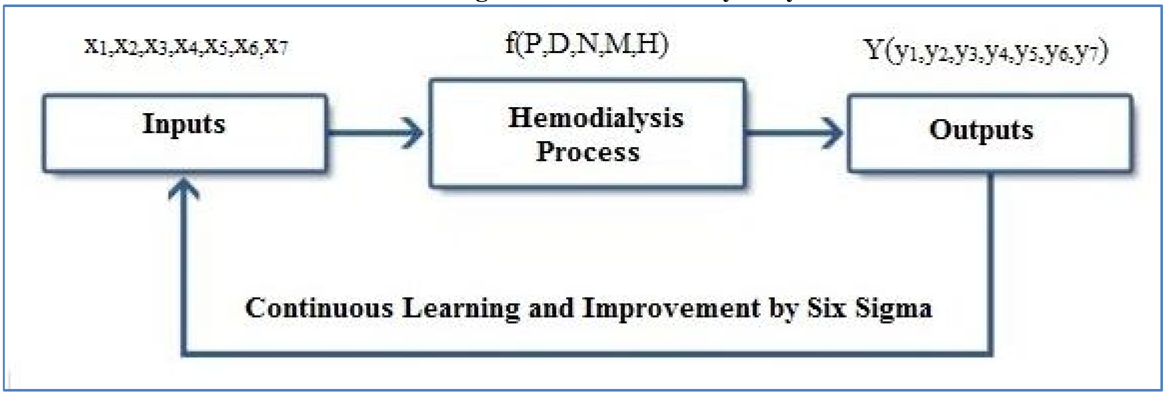

Table 1. SIPOC Table for Hemodialysis Process

SUPPLIERS	INPUTS (x)	PROCESS	OUTPUTS (y)	CUSTOMER
Nephrologist	Patient		Urea Reduction Ratio (70%-80%)	
Dialysis Nurse	Hemodialysis Hemodialysis machine		Sodium balance (135-145 mEq/L)	
Dialysis Technician	Dialyzer		Potassium balance (3.5-5 mEq/L)	
	Bicarbonate Concentrate	Hemodialysis	Phosphate balance (3-4.5 mEq/L)	Patient
	Purified Water		Bicarbonate balance (22-26 mEq/L)	
	Acid Concentrate		Magnesium balance (1.5-2.5 mEq/L)	
	Dialysis Catheter		Calcium Balance (4.2-5.2 mEq/L)	
	AV fistule needle			

The incidence of complications depended on multiple sources of variables. Patient variables (P), nephrologist variables (D), nurse variables (N), material variables (M) and machine variables (H). Thus, the process function can be written in Equations 2 as follows:

$$Y(y_1,y_2,y_3,y_4,y_5,y_6,y_7) = f(P,D,N,M,H) \quad (2)$$

In addition, there exists the following relationships in the system: f(P) = f(C,Z); f(D) = f(E); f(M) = f(R, S, T); f(N) = f(G), and f(H) = f(W, S, K), where experience of nephrologist (E) type of dialyzer material (T), sterilization and hygiene (S), type of acid solution (S), type of catheter (K), purity of water system (W) and patient's nutrition habit (Z).

The team also defined a "complication" as any unwanted outcome that inhibits the patient from being cured and stable (Taner, 2012). Then, they determined by brainstorming the CTQ factors, i.e. the factors that may have an influence on the occurrence of complications. The team followed the patients for 12-months (Table 2). They collected the complications' data during and after an annual of 12,208 hemodialysis sessions. As a result, the team identified fourteen types of complications and classified them as how soon they occur, i.e. acute and/or sub-acute and/or chronic (Table 3). Sources (Table 4) and root-causes (Table 5) of these complications were tabulated by type.

The variables were all evaluated when attempting to assess the root-cause of a complication (Table 5 and Table 6). The Six Sigma team analysed the occurrence frequency of each complication (Table 6) and related them with these root-causes. The analysis revealed that hypotension, hypertension and hyperphosphataemia were the three most frequently occurring complications in the hemodialysis sessions. Then, the CTQs are classified as "vital few factors" and "trivial many factors" according to how frequent they caused the complications. The "vital few" factors, i.e. the factors that had the most impact on the success of hemodialysis procedure were determined to be patient's nutritional habit and presence of comorbid diseases (e.g. diabetes and cardiac problems) in patient's history. The other factors, i.e. experience of nephrologist, sterilization and hygiene, performance of hemodialysis machine, type of dialyzer material, type of acid solution (i.e. w/glucose or w/o glucose), type of catheter (i.e. permanent or temporary) and purity of water system were found to be the "trivial many" factors.

Table 2. Number of Hemodialysis Patients and Sessions (2014)

Month	Count	
	Patient	Session
January	99	1,097
February	93	990
March	97	1,074
April	99	1,075
May	99	1,110
June	93	985
July	85	943
August	81	889
September	93	932
October	99	1,052
November	92	991
December	97	1,070
Total	1,127	12,208

Table 3. Complications Experienced

	Complication	Acute	Sub-Acute	Chronic
Type I	Hypotension	X		
Type II	Hyperglicemia	X		
Type III	Hyperpotassemia	X		
Type IV	Infection		X	X
Type V	Bradycardia	X	X	
Type VI	Tachycardia	X	X	
Type VII	Itching		X	X
Type VIII	Cardiac Arrest	X		
Type IX	Pericarditis		X	
Type X	Formation of Trombosis		X	
Type XI	Hypertension	X		
Type XII	Hypernatraemia		X	X
Type XIII	Hyperparathyroidism		X	X
Type XIV	Hyperphosphataemia		X	X

Table 4. Sources of Complications

	Nephrologist (D)	Nurse (N)	Patient (P)	Hemodialysis machine (H)	Type/Quality of Materials (M)
Type I			X	X	X
Type II			X		X
Type III	X		X		X
Type IV		X	X		X
Type V			X		
Type VI			X	X	
Type VII			X		
Type VIII			X		
Type IX	X	X	X	X	
Type X	X		X		
Type XI			X		
Type XII			X		
Type XIII			X		
Type XIV			X		

Table 5. Root-causes of Complications

	Experience of Nephrologist (E)	Type of Dialyzer Material (T)	Sterilization and Hygiene (G)	Presence of a Comorbid Disease (C)	Performance of Hemodialysis Machine (R)	Type of Acid Solution (S)	Type of Catheter (K)	Purity of Water System (W)	Patient's Nutrition Habit (Z)
Type I		X			X			X	X
Type II						X			X
Type III	X					X			X
Type IV			X	X			X		
Type V				X					
Type VI				X	X				
Type VII				X					
Type VIII				X					X
Type IX	X	X		X	X				
Type X	X			X					
Type XI									X
Type XII									X
Type XIII									X
Type XIV									X

The surgical team calculated the current DPMO and sigma levels for each complication type (Table 6). The process sigma level, calculated as the arithmetic average of fourteen complications, was found to be 3.5342.

Table 6. Cumulative frequency, DPMO and Sigma Levels

	Count	Frequency (%)	DPMO	Sigma Level
Type I	2319	0.1899	189,957	2.38
Type II	330	0.0270	27,031	3.43
Type III	118	0.0096	9,666	3.84
Type IV	301	0.0246	24,656	3.47
Type V	87	0.0071	7,126	3.95
Type VI	351	0.0287	28,752	3.40
Type VII	486	0.0398	39,810	3.25
Type VIII	1	0.00008	82	5.27
Type IX	93	0.0076	7,618	3.93
Type X	384	0.0314	31,455	3.36
Type XI	595	0.0487	48,739	3.16
Type XII	32	0.0026	2,621	4.29
Type XIII	442	0.0362	36,206	3.30
Type XIV	756	0.0619	61,927	3.04

The highest sigma level was obtained for cardiac arrest. The lowest sigma level was found to be belong to hypotension. Having sigma levels lower than 4.00; the occurence frequencies of hyperglicemia, hyperpotassemia, infections, bradycardia, tachycardia, itching, pericarditis, formation of trombosis, hypertension, hyperparathyroidism and hyperphosphataemia needed to be reduced in the hemodialysis process.

Risk assessment of hemodialysis sessions was achieved by Failure, Mode and Effect Analysis (FMEA) (Ookalkar et al., 2009). Utilization of the FMEA involved break down the process into individual steps: potential failure modes (i.e. complications), severity score, probability score, hazard score, criticality and detection, so that the Six Sigma team could look at key drivers in the process based on the past experience (Taner et al., 2012).

Complication trends and their consequences over a 12-month period had been monitored and recorded. The Six Sigma team prioritized the complications according to how serious their consequences were (i.e. severity score), how frequently they occurred (i.e. probability score) and how easily they could be detected. Hazard analysis was employed in order to identify failure modes and their causes and effects. The Six Sigma team determined the severity of each complication and assigned scores for them. The severity of each complication was scored from 1 to 4 (Table 7).

Table 7. Severity Scores

Severity Score	**4**	**3**	**2**	**1**
Severity of Complication	Death	Permanent harm	Temporary harm	No harm

For each complication type, the hazard score was calculated by multiplying the severity score with the probability score. Consequently, an FMEA table was drawn (Table 8). Among the complications, hypotension yielded the highest hazard score. According to FMEA, hypernatraemia was the least hazardous complication.

Table 8. FMEA Table

Complication Type	**Hazard Analysis**			**Decision Tree Analysis**	
	Severity Score	**Probability Score**	**Hazard Score**	**Critical?**	**Detectable?**
Type I	1	0.1899	0.1899	Yes	Yes
Type II	1	0.0270	0.0270	Yes	Yes
Type III	1	0.0096	0.0096	Yes	Yes
Type IV	1 / 3[a]	0.0246	0.0246 / 0.0492[a]	No / Yes[a]	No / No[a]
Type V	2	0.0071	0.0142	Yes	Yes
Type VI	2	0.0287	0.0574	Yes	Yes
Type VII	1	0.0398	0.0398	No	Yes
Type VIII	4	0.00008	0.00032	Yes	Yes
Type IX	2	0.0076	0.0152	Yes	Yes
Type X	2	0.0314	0.0628	No	Yes
Type XI	2	0.0487	0.0974	No	Yes
Type XII	1	0.0026	0.0026	No	Yes
Type XIII	1	0.0362	0.0362	No	Yes
Type XIV	1	0.0619	0.0619	No	Yes

[a]Chronic infections

The Six Sigma team developed preventative measures for each type of complication in order to bring the overall process under control. They implemented a corrective action plan to reduce and/or eliminate the complications (Table 9).

Table 9. Preventative Measure(s) per Complication

Complication Type	Complication Name	Preventative Measure(s)
Type I	Hypotension	-Arrange new treatment protocols. -Start a new medication programme. If needed, change the dose of the patient's drugs. -Achieve patient's compliance with his nephrologist and dietitian. -If needed, train the patient on his new nutrition list.
Type II	Hyperglicemia	
Type III	Hyperpotassemia	
Type IV	Infection	-Start an antibacterial treatment.
Type V	Bradycardia	-Administer adrenaline and decrease beta-blocker. -Arrange new treatment protocols. -Start a new medication programme. If needed, change the dose of the patient's drugs.
Type VI	Tachycardia	-Administer atropine and increase beta-blocker. -Arrange new treatment protocols. -Start a new medication programme. If needed, change the dose of the patient's drugs.
Type VII	Itching	-Moisten patient's skin. -If necessary, use antihistamine drops.
Type VIII	Cardiac Arrest	- Restore a normal heart rhythm by cardioversion. -Use of chest compressions and artificial ventilation to maintain circulatory flow and oxygenation.
Type IX	Pericarditis	-Sustain efficient hemodialysis by increasing its frequency and duration. -Increase the surface area of dialysis.
Type X	Formation of Trombosis	-Administer heparine.
Type XI	Hypertension	-Arrange new treatment protocols. Start a new medication programme. If needed, change the dose of the patient's drugs. -Achieve patient's compliance with his nephrologist and dietitian. -If needed, train the patient on his new nutrition list.
Type XII	Hypernatraemia	
Type XIII	Hyperparathyroidism	
Type XIV	Hyperphosphataemia	

4. Conclusion

In this study, authors identified and reported fourteen types of complications encountered during and after hemodialysis sessions. Many complications were related to the patient variables. Nephrologist and dietitian were in a critical position to arrange a new nutrition list and treatment protocol for each patient. Patient's compliance with the nephrologist and dietitian was a crucial step to accomplish the reduction of the complications that had resulted from their nutrition habits. When needed, patients were educated on the root causes of their problems and how to minimize them.

Infections were significantly reduced by using permanent catheters instead of temporary ones. Nurses are given training on hygiene and sterilization. To achieve higher purity ratio of the water system, the frequency of maintenance was increased by the dialysis technician. The dialysis center started to use acid solution with glucose for patients who did not have diabetes. In addition, continuous monitoring and early detection reduced and prevented many problems and complications.

Nonetheless, the surgical team concluded that the risks associated with the hemodialysis process could be minimized by taking the necessary preventative measures with careful preoperative examination by the nephrologist and compliance with him and the dietitian by the patient.

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