Enhancement of the compliance to the updated Egyptian mental health law, a six sigma breakthrough project

Introduction

Compliance to the updated Mental Health law is a quality concern, though primarily is a medico legal one.

In medical ethics, the principle of a patient’s self-determination obliges the physician to obtain the patient’s consent prior to medical treatment. A condition for valid informed consent is the patient’s competence, which may be impaired, particularly in patients with mental problems. In most cases, if the situation causes the physician to examine competence, he will proceed using his own subjective judgment and clinical experience and has difficulty applying standards suggested in the literature. Physicians also often evaluate competence differently. The admission for treatment should be authorized by a psychiatrist and audited from the National/local Counsel of Mental Health within one week, reporting defects.1

Definitions

I. The term competence to consent refers to an individual’s legal capacity to accept a proposed treatment, to refuse treatment, or to select among treatment options. 

II. Voluntary admission: should base on patient’s competence and free Volition to give informed written consent. The patient has the right to ask for being discharged.

III. Involuntary admission: conditioned with Presence of apparent signs and symptoms of severe mental illness, serious risky symptoms impacting the safety, health or life of the patient or the others or possibility of impending sever deterioration of the mental status.2

IV. Medical Abbreviations:
   a) BPRS: brief psychiatric rating scale measurement tool
   b) GAF: global functioning assessment tool
   c) HCR-20: history, clinical picture, risk management assessment scale

Hard benefits

I. Compliance to the law prevents legal consequences.

II. Decrease patient complaints Increasing the effective utilization of time by decreasing chances of re-do.

III. Increasing the total hospital’s revenue

IV. Save money payed in court sue and malpractice claims.

V. Minimizing ineffective services.

VI. +Minimizing defective services.

Soft benefits

i. Improve professional image within the Regional/National Counsel.

ii. Increase the public image of the hospital in the community.

iii. Increase confidence of the customers, internal and external.

iv. Increase the awareness of the employees

v. Facilitate quest for accreditation.

Situational analysis

Compliance to the mental health law project has been selected by Quality Council after identification of the internal process defects through the auditing reports by the National/regional Counsel of Mental Health Table 1.3

| Table 1 Customer segmentation |
|-------------------------------|
| Feb  | Mar  | Apr  | May | Jun  | Jul  | Aug | Oct | Nov | December | Total |
|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----------|------|
| Total Number of patients     | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 1000     |
| Schizophrenia                 | 7   | 5   | 3   | 5   | 7   | 12  | 23  | 9   | 1   | 10       | 82   |
| Bipolar                       | 1   | 2   | 2   | 6   | 2   | 7   | 9   | 1   | 0   | 6        | 36   |
| depression                    | 2   | 0   | 4   | 3   | 0   | 5   | 1   | 2   | 0   | 3        | 20   |
| Personality disorder          | 3   | 0   | 1   | 4   | 3   | 6   | 2   | 1   | 4   | 0        | 24   |
| addiction                     | 1   | 2   | 1   | 0   | 2   | 4   | 6   | 5   | 1   | 6        | 28   |
| Obsessive Compulsive Neurosis OCN | 1 | 0 | 1 | 0 | 0 | 2 | 1 | 2 | 3 | 0 | 10 |
| Total No. of reported Non Compliance | 15 | 9 | 12 | 18 | 14 | 36 | 42 | 20 | 9 | 25 | 200 |

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Sigma level calculation

According to data collected during the 01-02-2017 to 30-12-2017:

i. Total number of units = 1000 Cases

ii. Opportunities for defect per unit = 10

iii. Numbers of defects (non-compliance) = 200

iv. DPU= 200/1000 = 0.2

v. DPO = 200/1000 × 1/10 = 0.02

vi. DPMO = 20000

vii. Sigma level = 3.55 (Yield 98%).

Steps of a six sigma project

Define phase

i. Team selection

The quality council has selected a Cross Functional Team that will be comprised of the Following members:

i. Medical director

ii. Quality specialist

iii. Psychiatrist, resident

iv. Psychologist, resident

v. Nurse of the shit

vi. Administrator of the shift

vii. Forensic Psychiatrist, six sigma belt.

Project mission statement

Problem statement

It is a common concept that psychiatric patients are generally lacking the competence necessary for making treatment decision and the association with clinical and legal variables such as psychiatric illness, illness severity and involuntary admission that are usually assumed to be enough for the involuntary admission. Insight, as a conclusion from the symptoms is the strongest discriminator of competence and usually mistaken as the same concept for the competence though, this is not the matching the conditions of the Egyptian Mental Health law.

Objectives

To establish proper policies and procedures for the compliance with the Egyptian Mental Health Law and increase the sigma level of the process up to 4.5 sigma within 10 months starting 01/02/2017.

Project goals

I. To improve the performance by more compliance to the conditions of the Egyptian Mental Health Law conditions that regulating the admission and restricting the involuntary admission to that condition.

II. To reduce the non-compliance reports from the National and Regional counsel of Mental Health by 75% within one year after finding the root cause and the remedy for improvement.

III. A six-sigma approach was used to achieve the compliance to the legal standards for competence to consent to or refuse admission.

Mission verification process

The cross functional team have verified the mission to recognize and acknowledge that it is Specific task related to the admission process outcome, Measurable as it is linked to the steps of the admission to be monitored and inspected, Attainable, as the leadership approval and support is gained with a supportive to neutral behavior of the hospital staff. This is a Reasonable one because the data is already available and the defined Time table is 10 months, from Feb 1st 2017 to December, 1st 2017. The team members have verified the mission statement with the quality council with SMART attributes. The team members shall be liable to sign the project charter devised by the sponsor under delegated authority from the council.

Voice of customer

External customers

Primary data

Drawn from the National and Regional Mental Health council reports

Secondary data

i. Direct observation and data collected from the quality department and the team members in favor of the project on the issue of not in compliance with the Egyptian Mental Health Law

ii. Data collected about number of non-compliance for the law for 10 months (From Feb, 1st 2017 to December, 1st 2017).

Internal customer

The VOC have been obtained by Table 2:

i. Direct observation through reading the counsel auditing reports (the reports include the defects and dis-satisfaction comments).

ii. Interviews with the senior psychiatrist.

iii. Focus group (Resident psychiatrist and Psychologist, the Specialized Nurse and the Administrator) (Figure 1 & Table 3).

Table 2 Internal customer

| Customer Type     | VOC (The patient’s or the counsel’s voice in-behave of the patients) |
|------------------|---------------------------------------------------------------|
| Schizophrenia    | The counsel reported non compliance                           |
| Bipolar Disorder | Patient complains                                            |
| Depression       | The counsel reported non compliance                           |
| Personality disorder | The counsel reported non compliance                        |
| Addiction        | The counsel reported non compliance                           |
| Obsessive Compulsive Neurosis OCN | The counsel reported non compliance |
Figure 1 Kano analysis.

Table 3 Project Charter

| 2. Business Case | 1. Problem Statement (opportunity) |
|------------------|-----------------------------------|
| - The reported non-compliance to admission rules in the law have had financial consequences in the form of fine penalties and official announcements declared to professional and public media. and decrease patient flow, is estimated by almost 1,000,000 LE (One Million Egyptian Pounds) annually. | The average rate The process is currently running at six sigma level = 3.55 |

| 4. Goal Statement |
|-------------------|
| 1. Reduce the Customer dissatisfaction (The patients and the counsel) and Increase sigma level up to 4.5 |
| 2. Improve the process of admission and reduce non-compliance rate |

| 5. Team Selection |
|--------------------|
| The quality council has selected a Cross Functional Team that will be compromised of the following members: |
| 1. Psychiatrist (senior and resident) |
| 2. Psychologist |
| 3. Forensic Psychiatrist (six sigma belt) |
| 4. Nurse |
| 5. Administrator |

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Measure phase

Data sampling

Data collection has been implemented by data collection sheets that have been authorized, stamped and verified by the quality department (Table 4) and (Figure 2).

Table 4 Sipoc

| Supply          | Inputs                          | Process                             | Output                                            | Customer                               |
|-----------------|---------------------------------|-------------------------------------|---------------------------------------------------|----------------------------------------|
| Family          | Assessment of symptoms severity | BBRS assessment scale               | -Voluntary admission                             | -Inpatient Department                 |
| Senior Psychiatrist |                                |                                     | -Involuntary admission                            | -Patient                              |
|                 |                                 |                                     |                                                   | -Family                                |
|                 |                                 |                                     |                                                   | -Auditing Council                     |
| Family          | Assessment of Cognitive Functions | GAF assessment scale               | Volunteer admission                               | -Inpatient Department                 |
| Psychologist    |                                 |                                     |                                                   | -Patient                              |
|                 |                                 |                                     |                                                   | -Family                                |
|                 |                                 |                                     |                                                   | -Auditing Council                     |
| Specialized Nurse | Risk Assessment               | HCR-20 Risk Assessment scale        | -Voluntary admission                               | -Inpatient Department                 |
| Family          |                                 |                                     | -Involuntary admission                            | -Patient                              |
|                 |                                 |                                     |                                                   | -Family                                |
|                 |                                 |                                     |                                                   | -Auditing Council                     |
| Administrator   | Addiction Profile assessment    |                                     | -Voluntary admission                               | -Inpatient Department                 |
| Family          |                                 |                                     | -Involuntary admission                            | -Patient                              |
|                 |                                 |                                     |                                                   | -Family                                |
|                 |                                 |                                     |                                                   | -Auditing Council                     |
| Resident Psychiatrist | Consent for admission | Direct question and answer (Y/N) | -Voluntary admission                               | -Inpatient Department                 |
| Family          |                                 |                                     | -Involuntary admission                            | -Patient                              |
|                 |                                 |                                     |                                                   | -Family                                |
|                 |                                 |                                     |                                                   | -Auditing Council                     |

Figure 2 Detailed flow chart before improvement.

Objective was to use the sample group for

i. Extracting possible root causes of the noncompliance to the law and use the current data as a base for improvement.

ii. Using the improved data derived from the improved process as a base for the control to be plotted on the control chart (Table 5) & (Table 6).

Table 5 Data collection forms

| Project Name | Six sigma breakthrough project to enhance compliance to the updated Egyptian Mental Health Law. |
|--------------|-------------------------------------------------------------------------------------------------|
| Process Name | Increase the compliance to the mental health law in the hospital admission process through the proper application of the objective tools. |
| Data Plan prepared by | Quality Improvement Unit, Quality Management Department |
| Time interval | From 1st Feb 2017 to 1st December 2017 |
| Potential error | Operational definition |
| Senior Psychiatrist | Assessment of symptoms severity -The medical director -A copy sent to counsel |
| Psychologist | Assessment of Cognitive Functions -The medical director -A copy sent to counsel |
| Specialized Nurse | Assessment of Risk Probability -The medical director -A copy sent to counsel |
| Administrator | Addiction questionnaire -The medical director -A copy sent to counsel |
| Resident Psychiatrist | Asking for the consent for admission (Y/N) -The medical director -A copy sent to counsel |
| Responsible person for data recording | -Medical Records | -Copy to the counsel |
| When to collect data | Emergency reception room |
| How data is recorded | BPRS assessment scale form |
| Where data is recorded | Medical Records | -Copy to the counsel |
| Pre-Admission room | GAF assessment scale form |
| Pre-Admission room 2 | Addiction Questionnaire scale form |
| Pre-Admission room 3 | Written Consent form (Y/N) |
| Pre-Admission room 1 | -Medical Records | -Copy to the counsel |
| Pre-Admission room | -Medical Records | -Copy to the counsel |

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Table 6 Check sheet

| Month   | Frequency of defects | Tally |
|---------|----------------------|-------|
| Feb 2017| 15                   | /// /// /// /// /// |
| Mar 2017| 9                    | /// /// |
| Apr 2017| 12                   | /// /// /// /// /// |
| May 2017| 18                   | /// /// /// /// /// |
| Jun 2017| 14                   | /// /// /// /// /// |
| Jul 2017| 36                   | /// /// /// /// /// |
| Aug 2017| 42                   | /// /// /// /// /// /// /// /// |
| Sep 2017| 20                   | /// /// /// /// /// |
| Oct 2017| 9                    | /// /// /// /// /// |
| Nov 2017| 25                   | /// /// /// /// /// /// /// |

Individual X- Chart before Improvement

i. The process is stable as, there is no outlier point in the control chart.

ii. The process has variation and questioned for capability Figure 3.

Analyze phase
(Figures 4‒6) & (Table 7)

Figure 4 Brain storming.

Improve phase

The Root causes analysis revealed that, Schizophrenia is the most prevalent diagnosis with the reported defects as regards the type of admission (Involuntary admission). The factors related to the defect in admission of such a diagnostic group are the misinterpretation of the concept of the insight, usually lacking in those patients with the other different concept, the Competence. The remedy of this problem needs either an objective instrument for the assessment of the competence to consent for admission or the assessment by the presence of a more expert psychiatrist, a consultant level.

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Remedy selection matrix

i. The selected solution is a forensic instrument named MacArthur competence assessment toll for objective evaluation of competence according to the requirements of the Egyptian Mental Health law (Table 8).

ii. The instrument is a scale would be available in a printed form with the resident psychiatrist for the objective competence assessment and examining the patient’s ability to give an informed consent for the admission to the mental ill hospital (Figures 7–10).

Table 8 Remedy selection matrix

| Criteria of selection | Weight | Objective Competence assessment By Resident Psychiatrist Using Forensic Instrument Form | Evaluation by Consultant Psychiatrist |
|-----------------------|--------|--------------------------------------------------------------------------------------|----------------------------------------|
| Cost                  | 10     | 9                                                                                    | 1                                      |
| Effectiveness         | 10     | 9                                                                                    | 9                                      |
| Benefit               | 10     | 9                                                                                    | 9                                      |
| Risk                  | 5      | 4                                                                                    | 1                                      |
| Total Score           |        | 290                                                                                  | 195                                    |

Figure 7 New detailed flow chart after improvement.

Figure 8 Tree diagram for the remedy.

Figure 9 Planning matrix.

Failure mode and effect analysis (FMEA)

Function: a tool for objective competence assessment for consent to admission (Table 9).
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**Figure 10** Barriers and aids chart.

**Table 9**

| Process step/input                     | Potential failure mode | Potential failure effect                                      | Potential causes                      | occurrence | severity | detection | RNP | Design action                                      | Design validation                        |
|----------------------------------------|------------------------|----------------------------------------------------------------|--------------------------------------|------------|----------|-----------|-----|--------------------------------------------------|------------------------------------------|
| Objective assessment of Competence using the MacArthur form | Non proper application of MacArthur form | Risk of wrong admission categorization (Involuntary) | No full participation of team | 3          | 10       | 2         | 60  | The resident Psychiatrist has to go through the MacArthur form to assess competence based consent | -Auditing by the consultant -Auditing by the counsel |

**Proving effectiveness and pilot testing**

The project team prior to the final implementation of the new improved process decided to test its effectiveness in order to unmask the following:

i. Feasibility for implementation of the new improved process decided in the reality context

ii. Explore resources that might be needed for the full implementation of the process.

iii. The acceptance of the users for the new process and the level of commitment needed by each user to reach full implementation.

iv. The barriers identified as to the full implementation of the process.

v. The effectiveness of the new process to meet its desired improved outcomes

vi. The team selected the pilot testing in view of its accuracy and realistic features.

**Implementation**

After the pilot testing the project team is ready to begin full scale implementation. Before implementation of the new improved process the project team addressed the following issues leaned from the pilot study:

i. Barriers determined.

ii. Countermeasures addressed.

iii. Process prove efficacy under ideal performance conditions.

iv. Leadership and commitment for the full implementation phase in order to define the accountability.

**Changes inflicted by implementation requires**

i. Clear plans for deployment and Empowerment.

ii. Change management plan.

iii. Clearly written and documented procedures.

**Preparations**

i. Involvement of process owners (Admission team)

ii. Training for the end users (Resident Psychiatrists) to obtain the desired outcome.

Change in processes that involve:

1. Change in the working methodologies.

2. Roles plays are essential (Table 10 & Figure 11).

**The control chart is displaying that**

i. The process is Stable after the improvement

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ii. The process gets more capable and the variation is minimized (Figure 12).

**New Sigma Level to be calculated**

I. According to data collected in the pilot testing and early implementation:
II. Total number of units = 100
III. Opportunities for defect per unit = 4

**Table 10 Control Phase**

| Control variable | How measured | Where measured | Standard | Who analyze | Who acts | What done |
|------------------|--------------|----------------|----------|-------------|---------|-----------|
| During admission process; the Clinical versus the objective assessment of competence | MacArthur objective assessment form | Preadmission room 3 | relevant Score is written to explain the type of admission | Resident Psychologist | Resident Psychologist | Systematic questions and filling the form and calculating a score |

Figure 11 Individual X-Control chart after improvement.

Figure 12 Audit the control feedback loop.

**Summary and conclusion**

I. After legalization of the Egyptian Law of the Care of the Mentally Ill Patient, this is the first effort to measure competence of making admission’s decision in Egypt with the use of standard and objective assessment tools.

II. The current project is aiming for improvement the compliance to the new Egyptian law by objective assessment of the competence.

III. The project improved the performance of the psychiatrists in taking consent for the admission to the mental ill hospitals.

**Recommendations**

The compliance to the conditions of the Updated Egyptian Mental Health Law through an objective assessment tools though proved it effectiveness to improve the performance and reduce the money leak in the mental health facilities, yet it requires more training and continuous improvement using this new tool (MacArthur assessment tool) and to search for more types of improvements in the process of admission.

**Acknowledgments**

None

**Conflicts of interest**

The author declares that there are no conflicts of interest.

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