Conceptualization of a Patient Safety Management Model as Practical Approach toward Benchmarking and Improving Healthcare Outcomes

Bahjat Al-Awa[1], Isabelle Devreux[2], Agnes Jacquerye[3], Abeer Alhazmi[1], Hussam AlBaz[1], Hamed Habib[4] and Osama Rayes[4]

[1]King Abdulaziz University Hospital, Jeddah
[2]Faculty of Applied Medical Sciences, King Abdul Aziz University
[3] Ecole de Santé Publique, Université Libre de Bruxelles
[4]Faculty of Medicine, King Abdul Aziz University
alawabahjat@gmail.com

Abstract: Introduction: Patient safety is a major concern in the Kingdom of Saudi Arabia. Organizations and investigators are alike in searching for ways to improve delivery and safety of patient care. Many have reported that the existence of a patient safety and risk management system will have an effective impact on the overall patients' outcomes. **Aims:** To study the effectiveness of a patient safety model on patient safety indicators when implemented in a university hospital. **Methods:** A task force constituted by various patient safety experts was established to design a practical concept of patient safety management based on a nine steps model and applied by all hospital departments. Patient safety indicators (780) were monitored over a four years period and the model's effectiveness was analyzed on 40 selected indicators. **Results:** A statistical significant improvement by 67.5% (27/40) of initially measured patient safety indicators was evidenced mainly in the domains of peri-operative mortalities, neonatal mortality, return to surgeries, healthcare associated infections, safety and medication use, blood transfusion reactions, cardio pulmonary resuscitations, patient adverse events, and occurrence variance reporting. However, 12.5% (5/40) of the indicators of hospital standardized mortality and specific mortality were not improved by the model's implementation while others, 20% (8/40) of the patients safety indicators were maintained as their initial baselines were satisfactory. **Conclusions:** The implementation of a patient safety management model was found to be effective in improving patient safety practices (PSP) as well as patient safety indicators (PSIs) and finally patient outcomes.
[Bahjat Al-Awa, Isabelle Devreux, Agnes Jacquerye, Abeer Alhazmi, Hussam AlBaz, Hamed Habib and Osama Rayes. **Conceptualization of a Patient Safety Management Model as Practical Approach toward Benchmarking and Improving Healthcare Outcomes**. Life Science Journal 2012; 9(3):774-780]. (ISSN: 1097-8135). http://www.lifesciencesite.com. 110

Key words: patient safety indicators, patient safety model, risk management, health care associated infection, patient's adverse events.

1. Introduction

Patients' safety continues to concern consumers, health professionals, policymakers, insurers, and researchers, as well as the general public in the Kingdom of Saudi Arabia. These common interests have been fuelled, in a part by news which was related to individuals who were victims of serious medical errors and which were originated from both private and public hospitals. To err is human[1,2], especially in hospitals where patients could consult various health care providers in multiple settings and no one might have complete information about their condition. Many types of "process errors" have been attributed to this "non-system," including medication errors, administrative mistakes, treatment delivery problems, and miscommunication.[3,4] In this situation, both patient safety and quality of healthcare might be affected.

Organizations and investigators are alike in searching for ways to improve delivery and safety of patient care. Many are intent on embedding patient safety practices into healthcare. A patient safety practice is defined as "a type of process whose application reduces the probability of an adverse event", however, evidence for the incorporation of various safety practices, including incident reporting, root cause analysis, and the promise of promoting a "culture of safety," are still in their theoretical approach. [5-7]

Monitoring the impact of its own patient safety initiatives and available outcomes using selected patient safety indicators (PSIs) require close attention. [8,9] Additionally, the complexity of patient care is still a major concern and the challenge for the patient safety practices. [3,10] The prevention of accidental harm through analysis and redesign of vulnerable patient systems such as ordering, preparation and dispensing of medications, infection control, falls, patient identification, accidents or incidents involving injury, sentinel events etc., should also be closely monitored.

Determining the factors that are associated with the provision of safe patient care is crucial for today's healthcare environment. [11]. Researchers and

experts in patient safety and its evaluation methods have recommended the use of a theoretical and logic model and have found that the measurement, intervention and reporting contexts will improve the science of patient safety. [12]

Patient safety and risk management constitutes the main core of quality improvement, hospital performance and patient outcomes with a special focus on effectively managing and mitigating clinical and safety-related risks. Similarly, a patient safety management approach supports the organizations' understanding of an acceptable level of quality and continuum of care in health care practices. It also aims at continuously raising the bar with regards to quality improvement initiatives and serves the purpose of enhancing the end-users awareness and perception of quality care. [13,14]

A common understanding is that providing a framework which assists in the creation and implementation of systems and processes can improve operational effectiveness and enhance positive health outcomes. [13,14] Such systems can be started by the concept of understanding patient safety from theory to practice, and by improving working conditions as well as promoting the capacity building and organizational learning. It is essential to consider that patient safety practices can be only improved through the engagement of all staffs from various levels through. Therefore, the present patient safety management model is empowered by staff opinion and input, team work and expanded training that could lead to better patient outcomes. [15,16]

2. Methodology

The present research was conducted in the King Abdulaziz University Hospital (KAUH) which operates 750 beds and 200 ambulatory care beds. It has an average of 4.5 FTE employees per bed with 740 physicians and 1,250 nurses.

A task force of patient safety experts specialized and experienced the field of patient safety has been created in 2006. Team members originated from various hospital departments and included doctors, nurses, respiratory therapists, physical therapists, infection control nurses, laboratory physicians and technicians, pharmacists, as well as department chairmen. The terms of reference of the present task force were to determine the theoretical components of a patient safety model that would be followed and implemented at King Abdulaziz University Hospital (KAUH).

To that effect, the following steps were initiated:

Step 1- SWOT Analysis (strengths, weaknesses, opportunities and threats)

Meetings and brainstorming sessions have been conducted at higher level of the hospital management and quality department, and a primary SWOT analysis was made with the objective to improve healthcare and patient safety outcomes. Additionally, all departments were invited to perform their own specific SWOT analysis in terms of patient safety. Findings have been submitted to the hospital's quality department.

Step 2- Patient Risk Identification

Nursing and quality departments, in collaboration with the various task force members, identified more than 400 patient safety concerns and risks as outcomes of the SWOT analysis and information from all available sources. Preliminary patient safety concerns were identified and supported by obtaining additional information, data and input from various resources. Pertinent and interesting findings were regularly discussed in the medical board meetings to highlight and identify patients' risks in the organization.

Step 3 - Patient Risk Analysis

The analysis and review of the patient safety concerns were retained according to their impact on patients and healthcare outcomes (such as high volume, high risk, high cost, problem prone and quick win). The evaluations of patients' risks with the trending between the past and the present situations completed by the possible degree of evolution have been possible by additional ongoing assessments and the review of the updated available information.

Step 4 - Patient Safety Action Plan

The task force team created a patient safety action plan in response to issues that have been identified and assessed, and that could be prevented through a vertical and horizontal interventional plan. The plan combined strategic goals, action and tactics, performance measures, baseline, targets, responsibilities in addition to the required resources for implementation. The present patient safety action plan has therefore been limited to 40 patient safety indicators.

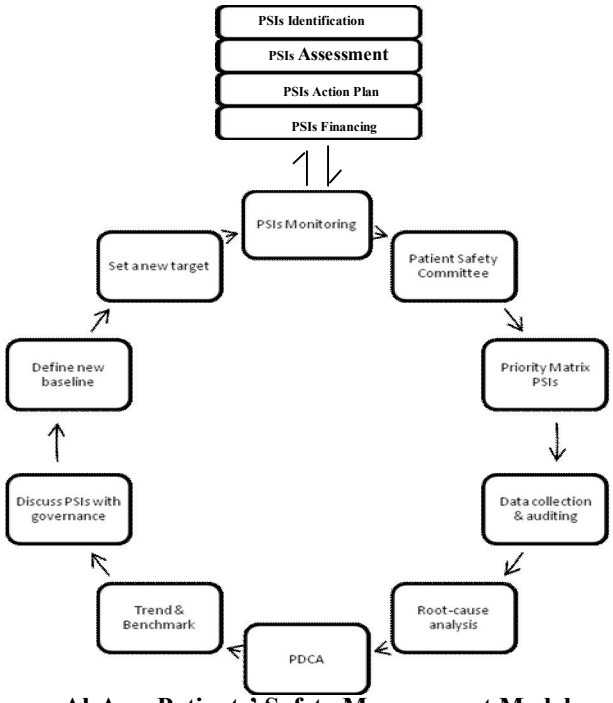
Step 5 - Patient Risk Financing

Based on the possible funds that the hospital management is willing to allocate in the risk management process, human and financial resources and benefits have been specified in the patient safety action plan.

Step 6 - Concept of Patient Safety Management Model

The patient safety task force team has thereafter designed a practical concept of patient safety management to be followed by all departments which started by monitoring and assessing patient safety indicators as per specifically defined criteria. The following steps were implemented and were summarized as follows: It is at first required to create a patient safety committee composed of experts in the field. This task force will prioritize

patient safety indicators as per a feasibility matrix, create tools for data collection and auditing, and conduct effective root cause analyses. These tasks are completed by the actions of trending and benchmarking aiming at improving benchmarks through a process of PDCA (Plan-Do-Check-Act). Whenever necessary, it appears essential to discuss benchmarks with the concerned departments, and discuss the results of patient safety indicators with governance. In addition, it is advised over time to define new baselines and new targets to reach, and finally to continue monitoring or defining new patient safety indicators for improvement



Al-Awa Patients' Safety Management Model

Step 7 - Patient Safety Indicators (PSIs) Classifications and Benchmarks

The monitored patient safety indicators have been grouped in various categories such as standardized mortality, surgery/invasive procedures, healthcare associated infections, medication safety, blood product, codes, patient adverse events, and occurrence variance reporting as quality indicators.

Step 8- Statistical Analysis

Patient safety indicators were collected on a monthly basis over the period of four years and comparative analysis was made using a One-way Anova test and a global *P*-value was calculated for each indicator using the Statistical Package for Social Sciences.

Step 9 - Study of the Model's Impact

Results sensitive to the model's implementation and non-sensitive results have been classified into two groups with average benchmarks for the four years of data collection.

3. Results

The results are based on data collected during the period 2006 to 2009. Patients' safety indicators and identified risks were collected through various methods and monitored on a monthly basis manually or through the hospital information system (HIS). The following results are classified as patient safety indicators (PSIs) sensitive to model implementation and resumed in the tables (1) and (2).

Table 1: Patient Safety & Quality Indicators Sensitive to Model Implementation

No.	Patient Safety Indicators	2006	2007	2008	2009	Average & Benchmark	*P*-Value
Hospital Standardized Mortality Rates							
1	Perioperative deaths/month	1.08	0.42	0.25	0.17	0.48	.002
2	Perioperative mortality/1000 surgeries	1.81	0.61	0.4	0.22	0.76	.003
3	Perioperative mortality/1000 total deaths	22.28	7.29	4.10	2.38	9.01	.001
4	Neonatal mortality/100 NICU admissions	46.14	20.24	23.83	18.32	27.13	.001
Surgery/Invasive Procedures							

1	Average unplanned returns to surgery ≤ 48 hours	2.33	0.83	0.58	1.67	1.35	.009
2	Unplanned returns to surgery / 100 operations	0.37	0.13	0.10	0.19	0.20	.013
Health Care Associated Infections (HAIs) & Hand Hygiene							
1	HAIs targeted infections / 1000 hospital day	4.18	3.00	2.15	2.27	2.9	.001
2	Clean surgical site infections per 1000 operations	7.12	4.52	1.81	4.30	4.44	.001
3	Neonatal HAIs /1000 patient days	11.40	9.22	7.87	4.79	8.32	.008
4	Blood stream infections per 1000 patient days	1.17	0.78	0.17	0.52	0.66	.001
5	Central line BSIs / 1000 device days in Adult ICU	15.18	6.98	6.29	4.21	8.17	.000
6	Central line BSIs / 1000 device days in NICU	17.34	30.04	40.17	12.81	25.09	.008
7	Urinary tract HAIs / 1000 patient days.	1.34	0.90	0.28	0.88	0.85	.001
8	UTIs / 1000 device days in Adult ICU	12.68	6.88	2.45	2.79	6.20	.001
9	Respiratory tract HAIs / 1000 patient days	0.27	0.26	0.04	0.31	0.22	.022
10	VAP infections / 1000 device days in Adult ICU	23.78	8.53	7.35	8.12	11.95	.001
11	Skin and soft tissue HAIs / 1000 patient days.	0.62	0.62	0.49	0.16	0.47	.003
12	Average use of alcohol hand disinfectant in liter / bed	0.45	0.63	1.23	1.72	1.00	.000

CPR: Cardio Pulmonary Resuscitation HAIs: Healthcare Associated Infections VAP: Ventilated Associated Pneumonia BSIs: Blood Stream Infections UTI: Urinary Tract Infection

Table 2: Patient Safety & Quality Indicators Sensitive to Model Implementation

No.	Patient Safety Indicators	2006	2007	2008	2009	Average & Benchmark	*P*-Value
Safety of using medications							
1	Average numbers of medication errors reported	0.58	1.42	1.00	2.17	1.29	.039
2	Reported medication errors / 100 admissions	0.02	0.05	0.03	0.07	0.04	.050
3	Reported medication errors / 100 hospital beds	0.10	0.21	0.15	0.33	0.20	.050
Blood Products Use							
1	Numbers of blood transfusion reactions	3.25	1.33	1.25	3.17	2.25	.002
2	Rates of blood transfusion reactions / 100 transfusions.	0.37	0.32	0.15	0.29	0.27	.018
Codes: Cardiopulmonary Resuscitations							
1	Average patients survival post first CPR.	21.08	23.08	33.08	38.08	28.83	.001
Patient Adverse Events							
1	Pressure ulcers developed / 1000 admissions.	2.83	1.74	1.95	1.56	2.02	.020
2	Average Length of Stay	4.10	3.47	3.31	3.28	3.54	.000
OVRs Reporting as Quality Indicators							
1	Numbers of occurrence variance reports	186.08	257.25	320.08	247.50	252.73	.000

CPR: Cardio Pulmonary Resuscitation HAIs: Healthcare Associated Infections VAP: Ventilated Associated Pneumonia BSIs: Blood Stream Infections UTI: Urinary Tract Infection

4. Discussion

The implementation of the designed management model of patient safety was resumed in monthly reports to the management. The reported indicators were signed on a format of data collection by the concerned department heads which emphasized increased staff awareness and allowed the management to review the departments' performance, bench marking and patient safety practices. In addition, patient safety practices and benchmarks were discussed in the medical board meetings and in the quality and nursing departments' management which largely contributed to the creation of a system process. This process encouraged each department to improve their data to meet acceptable international standards.

It is to note that the improvement which was observed in the peri-operative mortality was certainly due to the opening of pre-anesthesia clinic and the increased team effort that took place to reduce the operating room cancellation rate. This last was based on the improvement of operating room booking process using the Hospital Information System (HIS) in addition to the credentialing and privileging of surgeons, better hospital bed bookings for surgical cases, and the support of the hospital leadership. This also was certainly impacted positively on the peri-operative deaths which were reduced by 238%. In the contrary, there was no improvement identified in the standardized hospital mortality rate of 1.98% of admissions. However, it was noticed that the average unplanned returned to surgery were significantly reduced by ($P \leq .009$) which was positively correlated with the peri-operative mortality. Also, the mortality of neonates has been decreased by 170% as compared to 2006, and as confirmed by other surveys, this is mainly explained by enhanced teamwork to control and reduce the cross infections and the implementation of strict environmental and hand hygiene. [5,17,18]

Results analysis identified that the healthcare associated infections (HAIs) in general have significantly improved. The implemented policies and the dissemination of information regarding the

importance of controlling nosocomial infections through education, posters, news letter, and the increased availability of hand disinfectant dispensers have in our opinion contributed to this excellent result. For instance, the average utilization of hand disinfectant was multiplied by 3.82 as compared to 2006. Additionally, it is worth to mention that the significant ($P\leq$ 000) reduction of length of stay (LOS) which was our focus by 0.82 days per admission have contributed positively to less acquired infections. [19,20,21] Similarly, the implementation of evidence based policies that central line insertions are to be inserted in the operating room rather than in the acute care wards, has significantly improved the central line blood stream infections (*P*,000).[5,22,23] Additionally, the implementation of the bundle for the prevention of ventilator associated pneumonia has significantly reduced the VAP ($P\leq$.001). The present findings were also supported by the international literature. [24-26]

As in the present study population, 90% of our nursing staffs were foreigners and it might appear that they were less familiar with the process of reporting medication errors or were fearful of an established culture of blame.[27] It appeared thus essential in a risk management approach related to the medication use to encourage clinical workers to report with blame free. [28,29] The average medication errors reported over four years has significantly improved ($P\leq$0.039) and have been multiplied by 3.74 as well as, the reported medication errors per 100 beds has significantly improved with ($P\leq$.050). The increase in reporting medication errors was certainly one of the steps of acquiring patient safety culture. [5,30,31] In the same idea, the sentinel events reporting have decreased from 12 events per year in 2006 to 8 events in 2009. The question remains however to identify whether this progress was due to less sentinel events effectively occurring or due to a lack of reporting by the healthcare providers. The survey culture conducted in the present hospital, as compared to the United States, showed that the studied hospital was still presenting a lower percentage of feedback and communication about error with ($P\leq$.001). The communication openness sum was in average 36% as compared to 60% in the International Hospital in United States with ($P\leq$.001). The average teamwork in the unit was 68% as compared to 74% with ($P\leq$.005). Finally, regarding the organization learning and continuous improvement, the studied hospital's score was in average of 74% as compared to 71% while no significant difference was evidenced. Additional benchmark studies identified that the hospital management and the patient safety support was in average of 61% as compared to 60% with no significant difference. Additionally, the frequency of events reported in average represented 57% as compared to 52% ($P\leq$.050) and for the overall patient safety, our survey results evidenced a score of 45% as compared to 57% ($P\leq$.001) in international benchmarks.

The benchmarking of blood transfusion reactions in 2006 was initially of 0.37% and showed a decrease to 0.27% over the period of four years with a marginal gain of 0.10%. This was explained by increased evidence-based practices in the whole management of blood transfusion which included cross matching, blood storage, staff education, and the implementation of newly developed policies in the early 2006.

Many indicators of nursing care have also improved over the studied period, as well as many satisfactory indicators of patient safety and quality of care which were maintained at their initial baseline level and were judged of acceptable benchmark as compared to other institutions. [36] The implementation of patient assessment risk for falls (Waterloo Scale) and the compulsory implementation of a patient risk plan for all nursing areas have contributed to reduce the average number of developed pressure ulcers per 1000 admission from 2.83 to an average of 2.02 with ($P\leq$.020). There is no doubt that a significant reduction in the length of stay ($P\leq$ .000) as in table 2 have contributed positively to the reduction of patients' adverse events.

Such practical implementation of a patient safety management model and the policy of blame free in addition to the clinical guidelines and a performance improvement program contributed to very positive changes over the years. It also appeared that the creation of patient safety committee identifying patients' safety indicators, the utilization of a matrix PSI's, as well as organized data collection, monitoring and auditing were contributing factors to the improvements. The management model was also based on the implementation of root-cause analysis, PDCA, trends analysis and benchmarking in addition to the discussion of patient safety indicators with the hospital's governance to define new baselines of action. It also appeared that the value of establishing new targets in patient safety monitoring and risk management made people proud instead of fearful of reporting incidents and occurrences as this reporting was significantly increased over the four years of research to reach an average 252.73 occurrence variance reports per month ($P\leq$.000).

Conclusion

The conceptualization and implementation of a communicated patient safety management was

effective in improving patients' safety practices and patients' safety indicators.

As demonstrated in this research, patient's safety indicators sensitive to improvement were mainly in the domains of peri-operative and neonatal mortalities, return to surgeries, healthcare associated infections and medication use. In the same line, blood transfusion reactions, cardio-pulmonary resuscitations, patient adverse events, and occurrence variance reporting also showed significant improvements. However, it was observed that the hospital standardized and specific mortalities were not improved by the model's implementation while some patient safety indicators were maintained at their initial acceptable baseline.

The present study highlights the importance of clinical governance by developing a patient safety culture based on positive reporting and discussion with the higher authorities to create a dynamic and continuous process of patient safety improvement.

Corresponding author
Dr. Bahjat Al-Awa
King Abdulaziz University Hospital, Jeddah-KSA.
alawabahjat@gmail.com

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