Factors Affecting Patient Safety Programme in Government Hospitals of Sri Lanka

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Abstract: The objective of this study is to assess the factors that affect the patient safety programme in government hospitals of Sri Lanka. Method: A hospital based cross sectional descriptive study was conducted at the selected line ministry hospitals as they have established Quality Management Units. The study population was the administrative and clinical staff at these hospitals who had been employed at the hospital for at least 6 months and they should be working on a permanent basis. A self-administered questionnaire was used to collect the data collection. It contains two parts. First part deals with the perception on patient safety programme. It consists patient safety programme as dependent variable and five independent variables (organizational safety culture, leadership, communication, team structure and work environment) with 45 questions. The second part comprised six questions on socio-economic characteristics. Results: 327 members participated in his study. Out of that, 242(74%) were female, 74(22.6%) were male and 11(3.4%) didn't mention the gender. Leadership has the highest mean value of independent variables and work environment has the second highest mean. Patient safety programme shows highest correlation with team structure (0.255), and lowest with work environment (0.200). Organizational safety culture has the correlation of 0.253 with patient safety programme which is an important factor next to team structure. Communication has the correlation of 0.231 and leadership has the value of 0.221, and both have significant correlation with patient safety programme. Conclusion**:** All assessed independent variables such as team structure, organizational safety culture, leadership, communication and work environment significantly affect the patient safety programme. Team structure and organizational safety culture have the highest correlation with patient safety programme.

Keywords: Patient Safety, Organizational Safety Culture, Leadership, Communication, Team Structure, Work Environment

1. Introduction

1.1. Background Information

Patient safety is a priority concern among the all healthcare providers. The concept of patient safety has been recognized since the time of the Great physicians of Ancient Greece and Rome – 'First, do no harm'. As it implies there is a possibility of harming the patient under the care of Physician. However, healthcare is a complex intervention and the outcome is influenced by many factors. It is inevitable that every encounter within any healthcare system patients carry fair risk of being harmed [1].

Hospital is the most important place where the patients obtain treatments for their health problems. At the same time vast number of misconducts, negligence and adverse events are recorded from the patient care institutions which can resulting in permanent injury, increased Length of Stay (LOS) in hospitals or even death. The system of health care today is so complex that the successful outcome for each patient depends on a range of factors, not just the competence of an individual health-care provider [1]. Worldwide, adverse events occur in around 10% of hospital patients. Studies have shown that 4-17% of hospital admissions undergo adverse events and 5- 21% of them leads to death [2].

Patient safety is relatively a new concept introduced to Sri

Lankan health care system. Sri Lanka is a country known for provision of free healthcare services to the patients. In Sri Lanka the numbers of adverse events related to patient safety seem to be rising. Necessity of initiating patient safety culture in health care system and a compensation mechanism has been raised [3]. In turn the organization lacks the opportunity to learn from its errors and prevent / mitigate future adverse events [4].

Patient safety can be defined as the prevention or reduction of adverse outcomes' [5], making healthcare institutions safer, reliable and trust worthy, by learning from mistakes, preventing adverse events and mitigating possible adverse outcomes. Patient safety is not only for the benefit of the patient but it is also for the healthcare providers. Institution will have reliable patient safety mechanisms, reliable services, patient satisfaction and credibility. Health institutions in the world have developed various systems and indicators to introduce and sustain safety practices. Indicators will monitor complications and adverse events following all procedures. The Patient Safety Indicators (PSIs) can be used to help hospitals identify potential adverse events that might need further study; provide the opportunity to assess the incidence of adverse events using administrative data. Patient safety is identified as a part of health care quality; in turn it is a significant criterion in hospital accreditation. One of the key methods to develop and strengthen patient safety is to build a patient safety culture within the health institution [5].

1.2. Patient Safety Culture

Patient safety culture is defined as values, beliefs and assumptions within the members of an organization towards patient safety. Patient safety culture emphasizes the reporting, analysis and prevention of errors that lead to adverse health care events [5].

Patient safety culture is an important discipline in health care. To improve patient safety culture, we have to improve the attitudes, values and beliefs of staff. Introducing patient safety thinking patterns to health care system can achieve a patient safety culture within the system. One of the important theories is *system thinking* where the providers take the health care service as a single system not as different units. Eg; whole hospital works as a health team not as different wards or departments. This promotes unity, teamwork, high productivity, teaching and learning from errors, new methods identification, reliable preventive methods and most of all sustainable patient safety culture. However much the system is prepared there will always be unpredictable situations. Higher the reliability, more resilient is the organization for these unpredictable situations. When improving safety in a health care system the level of safety leaps from one level to another [6].

Hierarchy of safety culture starts with *safety attitude* that is perception of safety by the personal or at unit level. Collection of safety attitudes builds *safety climate*. It is the group level perception of safety or the shared perception regarding the events, practices and procedures as well as kind of behavior that gets rewarded, supported and expected in a particular organizational setting. This is the measurable aspect of the culture. These terms can be interchanged with each other when necessary [7].

1.3. Importance of Patient Safety

Millions of patients receive high-quality healthcare every year. Unfortunately, preventable medical errors occur, and they occur fairly often. For example, a surgeon in a Florida hospital amputated the wrong leg of a patient. In the state of Washington, a heart transplant patient received a heart with the wrong blood type. In a Boston hospital, one doctor simultaneously was overseeing blood transfusions for two patients undergoing operations and switched the different blood types. In another instance, an anaesthesiologist forgot to turn the anaesthesia on after paralyzing the patient during an orthopaedic operation. She tried to signal the surgeon, but was unable to because she was paralyzed. She subsequently sued the anaesthesiologists [8].

According to a report by the Institute of Medicine (IOM) that quoted estimates from two major studies, between 44,000 and 98,000 preventable medical deaths occur in healthcare facilities in the United States each year [9]. A study published by Health Grades in March 2011 found that from 2007 through 2009, 52,127 Medicare inpatients developed hospital-acquired infections, and 8,114 of them did not survive their hospitalization. The study also reported that in the same period there were 79, 670 patient deaths among patients who experienced one or more adverse events [10]. According to World Health Organization report, 1 in 10 individuals receiving medical care will suffer preventable harm [11]. A study by the IOM found that 1.5 million Americans are injured by a medication error every year [12]. According to the Centers for Disease Control, there are 2 million acquired infections in hospitals in the United States every year. It is estimated that medical errors cost between $17 billion and $29 billion annually. Clearly, this is not acceptable and has to be improved [13].

In a recent article published in the *New England Journal of Medicine,* researchers report that there was no significant improvement in patient safety in the 10 years since the IOM published its report *To Err Is Human*. The researchers studied 10 hospitals in North Carolina from 2002 to 2007 and found that medical harms remain common, with little evidence of widespread improvement. They also found there was no significant improvement in patient safety from year to year. They concluded, "Further efforts are needed to translate effective safety interventions into routine practice and to monitor healthcare safety over time [14]".

By using checklists and quality tools and by collecting data on the various processes in healthcare facilities, healthcare providers can improve the processes to reduce errors [15].

Impact of adverse events includes suffering of the patients due to pain, disability, psychological trauma and failure of treatment & betrayal of trust. Staff suffers from shame, guilt, depression, litigations and complains [15]. Economic cost or

loss from adverse events per annum includes lost bed days consequent to prolonged stay. Lost working time and expenditure for disability benefits should be added. So must lost income, lost household production [15, 16].

Studies which were carried out in various countries have shown that dealing with adverse events is expensive. Some countries such as USA, UK spend a huge sum of money on them. More over the insurance companies quote a high price for medical provider coverage. This has resulted in narrowing down the range of treatment offered to patients by providers [17].

Instilling patient safety culture in health care system is one of the best methods to overcome these grievances and economical burdens. Having a reliable system to overcome unpredictable adverse events makes institutions trust worthy for patients and pleasure to work for staff [18, 19].

1.4. Justification

Healthcare Quality and Safety is an evolving category in the history of Sri Lankan Healthcare system. There is no much study done to find out the factors that affect the patient safety programmes. Sri Lanka is a developing country and the healthcare system has shown dramatic improvement in the development. Nearly 90% of the Sri Lankan population is getting inward treatment from government hospitals. Therefore, assessment of quality and safety associated factors from a government hospitals carries a great value which will help the Sri Lankan government to improve the system of healthcare quality and safety in future.

Therefore the objective of this study is to describe the factors affecting patient safety programme in government hospitals of Sri Lanka.

1.5. Ethical Clearance

Informed written consent was taken from each participant before administering the questionnaire. They were given reassurance that their identities would not be revealed and also that the data would not be processed in terms of individuals, but as groups. Ethical review was sought and obtained from the Faculty of Medicine, University of Colombo. Permission was taken from the Ministry of Health and relevant hospital authorities.

The questionnaires were stored at the workplace of the principle investigator. Except the investigators no one else had access to data. The computerized data was protected with password and is only available to the investigators.

2. Methods

This was a hospital based cross sectional descriptive study. The hospitals in Sri Lanka are either administered directly by the Line Ministry or Provincial Ministry. All the Tertiary Care Hospitals and selected secondary care hospitals functions come under Line Ministry (n = 42) and all other hospitals, usually Base Hospitals and Divisional Hospitals come under Provincial Ministry. (n = 1002). In the year 2014,

out of 42 hospitals, in 16 hospitals functional Quality Management Units (QMUs) were established. Therefore for this study, the hospitals where Quality Management Units were established (16 line ministry hospitals) were selected. The study population was the administrative and clinical staff at these hospitals who had been employed at the hospital for at least 6 months and they should be working on a permanent basis.

The included categories were:
- Medical Doctors (Medical Administrators, Consultant doctors and Medical Officers);
- Nursing Category Staff (Special Grade Nursing Officers, Nursing Sisters, Nursing Officers and Midwives); and
- Professionals supplementary to Medicine (PSM) category (Pharmacists, Medical Laboratory Technicians, Physiotherapists, Radiologists and Occupational Therapists).

There were no previous studies done in Sri Lanka to evaluate the factors affecting patient safety programme in government hospitals of Sri Lanka. Hence using standard formula to collect sample size was used and it was found to be 384. A non-response rate of 10% was assumed and further 38 were added to the minimum sample and the sample size was determined to be 422 in this study. Stratified sampling method was used to select the participants from the sampling population for this study both for hospitals and for the three staff categories.

2.1. Data Collection Instrument

A self-administered questionnaire was used to obtain data for this study. This instrument had been developed and used by Davies et al (2007) and Mary Dixon-Woods (2012) to measure quality improvement in the United Kingdom. Focus group discussions were held to adapt the questionnaire to the Sri Lankan context. The Medical Officer of the relevant Quality Management Unit had given an initial introduction to the questionnaire followed by the administration of self-administered questionnaire.

The questionnaire consisted of two parts; the first part dealt with the perception on patient safety programme in government hospitals of Sri Lanka. This part consisted patient safety programme as the dependent variable and five independent variables (Organizational Safety Culture, Leadership, Communication, Team Structure and Work Environment) with 45 questions. The second part comprised six questions on socio-economic characteristics. Five point Likert scale of agreement ('strongly agree' to 'strongly disagree') was used in this study. Pre-testing of the questionnaire was done at the District General Hospital, Kilinochchi, Sri Lanka, while data collection was done at the hospitals where Quality Management Units were established.

The self-administered questionnaire was submitted and filled by staff individually. To ascertain the test re-test reliability, the same instrument was administered again to the staff member after three weeks. Serial numbers were used to pair the responses to compare repeatability. The second of the responses

were used when there was any discrepancy of the responses.

2.2. Analysis

Internal consistency reliability was estimated with the Cronbach ∝ coefficient. The ∝ coefficient ranges from 0 to 1: values greater than 0.70 are generally considered acceptable for a group comparison has been recommended. Where important decisions about the fate of individual is made on the basis of test scores reliability should be at least 0.90, preferably 0.95 or better (Nunnally, 1978). Upon completion of data collection, statistical analyses were completed using the Statistical Package for the Social Sciences (SPSS 16.0) computer program to determine and measure frequencies and central tendencies. Before analysis, the computer base screening was done to avoid possible data entry errors. Analysis of the data carried out manually as well as with the aid of computer. Operational Variables are illustrated in supplementary material. Statistical associations between categories were evaluated by the Chi-square test with Yate's correction or fisher exact test.

3. Results

Test-Retest Reliability revealed that the significance level for paired sample correlation and paired samples test is more than 0.05 for all the variables. In this study Cronbach's α coefficient is 0.904, and therefore, this questionnaire can be regarded as reliable.

This study was conducted in 16 line ministry hospital and total of 327 members participated in this study.

Out of that, 242(74%) were female, 74(22.6%) were male and 11(3.4%) didn't mention the gender. The majority of the participants (28.4%) were between the age of 31-40 years and minority of them (12.8%) was below 30 years. When we analyzed the educational level, 163(49.8%) of them had completed Diploma, 69(21.1%) of them were basic degree holders, 46(14.1%) of them passed Advanced level and 31(9.6%) of them had done postgraduate studies. Regarding current designation, 211(64.5%) of them were Nursing

Officers, 69(21.1%) of them were Medical Officers and 13(4%) of them were medical Consultants. 76(23.2%) of them had >21 years of working experience in Health department, 65(19.9%) of them had 4-8 years of experience and 46(14.1%) of them had < 4 years of experience.

The mean and standard deviation of patient safety programme and factors affecting patient safety programme are given below in Table 1.

Table 1. Mean and standard deviation of patient safety programme.

	Mean	Std. Deviation	N
Patient Safety Program	3.8338	0.53005	325
Organizational Safety Culture	3.2080	0.64079	327
Leadership	3.6483	0.91100	327
Communication	3.2577	0.80452	326
Team Structure	3.2669	0.80724	326
Work Environment	3.5215	0.79101	326

*Positive attitudes were defined as having mean of scale scores ≥3.5, the equivalent of somewhat agree or agree or strongly agree on the Likert scale used for the response options.

Of the independent variables, leadership has the highest mean value followed by the work environment in Government Hospitals. The high value of standard deviation from the above table infers that there are variations of responses.

Correlation between patient safety programme and factors affecting patient safety programme were calculated using Pearson correlation. All the correlations between independent and dependent variables were significant. Patient safety programme shows highest correlation with team structure (0.255), and lowest with work environment (0.200). Organizational safety culture has the correlation of 0.253 with patient safety programme which is an important factor next to Team structure. Communication has the correlation of 0.231 and Leadership has the value of 0.221, and both have significant correlation with patient safety programme.

Table 2 describes the correlation coefficient between patient safety programme and factors affecting patient safety programme in government hospitals of Sri Lanka.

Table 2. Correlation coefficient between patient safety programme and factors affecting patient safety programme.

Correlations							
		Patient Safety Program	Organizational Safety Culture	Leadership	Communication	Team Structure	Work Environment
Patient Safety Program	Pearson Correlation	1	0.253[**]	0.221[**]	0.231[**]	0.255[**]	0.200[**]
	Sig. (2-tailed)		0.000	0.000	0.000	0.000	0.000
	N	325	325	325	325	325	325

**. Correlation is significant at the 0.01 level (2-tailed).

Table 3 summarizes the multiple regression models for factors affecting patient safety programme in Government Hospitals.

Table 3. Multiple regression models for factors affecting patient safety programme.

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
1	0.430[a]	0.409	0.405	0.50430	1.657

a. Predictors: (Constant), Work Environment, Organizational Safety Culture, Leadership, Communication, Team Structure

b. Dependent Variable: Patient Safety Program

4. Discussion

The simplest definition of patient safety is the prevention of errors and adverse effects to patients associated with health care. Patient safety is a crucial element in healthcare Quality. Unexpected and unwanted events can take place in any setting where health care is delivered. Every 10th patient in Europe experiences preventable harm or adverse events in hospital, causing suffering and loss for the patient, their families and health care providers, and taking a high financial toll on health care systems [18].

In multiple regression for the patient safety programme R^2 of 0.430 indicates that 43.0% of the variables can be explained by this model. It indicates some other important variables should be included in this model. However, R Square tends to somewhat over-estimate the success of the model when applied to the real world, so an Adjusted R Square value is calculated which takes into account the number of variables in the model and the number of observations (participants) our model is based on. This Adjusted R Square value gives the most useful measure of the success of our model. The Durbin-Watson statistic is always between 0 and 4. A value of 2 means that there is no autocorrelation in the sample. Values approaching 0 indicate positive autocorrelation and values toward 4 indicate negative autocorrelation. Hence there is a positive autocorrelation between the factors affecting patient safety programme and the dependent variables [19].

Overall in this study, leadership has the highest mean (3.64) when compared with the other independent variables. Its correlation with the patient safety programme is 0.221 and it is statistically significant. This indicates that the leadership should involve actively in the quality improvement. Ensuring patient safety has always been important for critical care teams. Since team and leadership skills are increasingly recognized as important for the patient's safety, a body of literature on leadership in critical care has emerged [20].

Organizational safety culture has the mean value of 3.208 and the correlation with patient safety programme is 0.253 and is statically significant which shows that organizational safety culture has an important role in patient safety programme. A study says that, safety culture change is currently being tracked as part of several large scale patient safety programs. Baseline culture measures have been taken in the US Veterans Health Administration and periodic assessments are planned in the future as part of an ambitious patient safety program that includes a patient safety reporting and analysis system, technology usability assessments, and methodologies for prioritizing safety related actions [21].

Communication in patient safety programme has the mean value of 3.257 and the correlation with patient safety programme is 0.231 which is statically significant. Several studies have been done to assess the importance of communication for patient safety programme [21, 22, 23]. A study in Australia showed that, Communication breakdown is a factor contributing to most cases of patient harm, and this harm continues to occur at unacceptable levels. Responding to this evidence, the Metro South District of Queensland Health (Australia) has developed a communication skills training programme titled 'Communication and Patient Safety' [22].

Team structure has the mean value of 3.2669 and the correlation is 0.255 in our study which had the highest correlation out of all independent variables. Therefore team structure is an important factor which decides the patient safety programme. Research has found that 70% of all medical errors can be attributed to breakdowns in healthcare team interactions. Patient safety experts agree that communication and other teamwork skills are critical in the prevention and mitigation of medical errors, and that teamwork is essential in achieving high reliability in healthcare organizations [24]. Teams make fewer mistakes than do individuals, especially when each team member knows his or her responsibilities, as well as those of other team members. However, simply installing a team structure does not automatically ensure it will operate effectively [23, 24]. In healthcare system it mainly depends on the willingness of the individuals.

Work environment has the mean value of 3.5215 and the correlation is 0.200 in this study. Out of all five independent variables, work environment has the less correlation with patient safety programme but, still it is statically significant. The study results support other research findings indicating that a positive practice environment enhances patient safety outcomes [19, 20, 25]. Specifically at ward level, factors such as the ward practice environment and the proportion of nurses with degrees were found to significantly impact safety outcomes [25].

Unit increase in organizational safety culture standardizes to other variables. It increases the coefficient of patient safety programme by 0.181 (p value 0.001). Leadership (p value 0.357), Communication (p value 0.470), Team structure (p value 0.102) and Work environment (p value 0.719) were not standardizing to other variables.

limitations

This study was conducted after doing several literature reviews. Still there are few limitations to this study. Those are,

1. The study was carried out only in sixteen Line Ministry Hospitals. Hence, the study cannot be generalized.
2. The study was carried out only among medical doctors, nursing category and PSM category staff. Other categories of staff were not included. Therefore, generalization of the findings of this study may not be possible.
3. District Hospitals, Peripheral Units and Rural Hospitals are not included in this study. Therefore, factors affecting patient safety programme in these hospitals are not identified.

5. Conclusion

According to our study results, all assessed independent variables such as Team structure, Organizational safety

culture, Leadership, Communication and work environment significantly affect the patient safety programme. Team structure and Organizational safety culture have the highest correlation with patient safety programme. Therefor these two factors should be given priority when we implement a patient safety programme in government hospitals of Sri Lanka.

Acknowledgments

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