The 36th International Conference of the System Dynamics Society
Reykjavík, Iceland, August 6-10, 2018

Model-Based Risk Assessment to Clinical Risk Management Policies

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Abstract

Errors and adverse events occur even under the most efficient circumstances. On the one hand, clinical errors reduce patient's safety level and can even sometimes cause patient's death; on the other hand, weak management of clinical risks harms staff and hospital's reputation and can be quite costly for the health system of any country. That is why a clinical risk management system, as a systematic tool for minimizing errors and preventing systematic errors, plays an important role. According to World Health Organization statistics, medical errors are the eighth cause of death worldwide. Consequently, due to the significance of patient safety in the health system, the present study focuses on the identification and simulation of the factors influencing the occurrence of clinical errors using system dynamics approach. System dynamics provides a quantitative mathematical model which makes it possible to generate different scenarios and then, simulate the results of the implementation them on the model. The purpose of simulating clinical risk management is to identify policies that help prevent and minimize clinical errors. In Iran's health system, despite the growth of technology and health infrastructure, medical errors have an increasing trend, and this has become one of the major challenges of policymakers in healthcare section. The results showed that development and improvement of the performance indicators defined in the Ministry of Health and Medical Education, e.g. increasing human resources, improving equipment and facilities, increasing the number of healthcare-associated graduates, increasing the number of hospital beds, and so forth will not reduce the level of clinical errors. For this reason, here different policies regarding electronic health records, patient safety culture, and clinical governance have been implemented on the model and their simulation results have been examined. While all three policies have played a significant role in reducing the errors, the results of the policy related to patient safety culture has the greatest impact on clinical errors.

Keywords: *Clinical Risk Management, Clinical Governance, Electronic Health Record, System Dynamics*

I. INTRODUCTION

Errors and adverse events occur even under the most efficient circumstances. On the one hand, clinical errors reduce patient's safety level and can even sometimes cause patient's death; on the other hand, weak management of clinical risks harms staff and hospital's reputation and can be quite costly for the health system of any country. That is why a clinical risk management system, as a systematic tool for minimizing errors and preventing systematic errors, plays an important role.

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Clinical risk management is a specific form of risk management, focusing on direct and indirect clinical and patient-related processes, physicians and staff, hospitals, and healthcare institutions. The three main dimensions and main variables of clinical risk management are the reductions of risks for patients, physicians, and the organization [1].In the past, most of the errors were attributed to a person or an individual mistake, and the person was rebuked; but today, various studies, such as the Swiss Cheese Model, have shown that there are deficiencies in each system, each of which alone may not lead to an error, but the error occurs when these defects in the various parts of the system occur unexpectedly and simultaneously, and a chain of these defects leads to the emergence of an incident. There are various causes leading to clinical errors; e.g. inconsistencies between health care staff, the effects of bad physical conditions of work, fatigue, lack of concentration, physician distress, lack of awareness among patients about their illnesses and problems, congestion in treatment centers and pharmacies, communication problems, unsuitable information flow and knowledge management, unusual presentation of disease, inapt recruitment patterns, lack of policies and procedures, lack of proper care, lack of accountability, inadequate skills and knowledge, misidentification of the disease or misdiagnosis, wrong prescription, mistakes in surgical procedures or use of equipment, wrong interpretation of experimental data [2-5]. As previously stated, the effects of medical error are threefold. The first and most important consequence is the risk to the patient's health. According to World Health Organization statistics, medical mistakes in the world are the eighth cause of death worldwide [6]. In Palestine, one in seven is somehow injured in hospitals, which means a rate of 14.2% of errors, of which 59.3% are preventable and 70.4% of these errors lead to temporary damage and prolongation of hospitalization [7]. This challenge is also found in developed countries, as the medical error in hospitals is the third leading cause of death in the United States [8]. In Australia, medical errors have led to 18,000 unnecessary deaths; plus, more than 50,000 disability cases each year [9]. In Canada, on average, 1 out of every 18 hospitalized patients is injured. According to studies conducted in 20 hospitals in Canada, the rate of injury to the patient was 7.5%. This rate is 8.3% in Australia, 8.4% in Spain, and 13.5% in the United States. These clinical errors have occurred in various departments and within different services of the therapeutic process. 7.6% of these errors happen during surgery, 6.2% medication errors, 4.2% to women and delivery and 1% to newborns [10]. The second consequence of a clinical error is the threat faced by physicians, nurses, pharmacists and other healthcare providers, which endangers their social and future professional lives. The third consequence of a clinical error is its economic impact on the system. According to Iran’s Ministry of Health and Medical Education statistics, billions of dollars are spent annually on preservation and care of patients in hospitals due to medication errors and subsequent complications due to prolonged hospital stay [11]. In the United Kingdom, it is estimated that 850,000 medical errors occur each year at a cost of over £2 billion [12].

Considering the important role of patient safety in health systems, the present study focuses on the identification and simulation of factors influencing the occurrence of clinical errors using system dynamics approach. The goal of clinical risk management simulation is to identify policies that can be effective in preventing and minimizing errors. The proposed policies in this research include implementation of the electronic health record, promoting a patient safety culture, and implementation of clinical governance. The Electronic Health Record is a collection of all the information about the health of every citizen that is stored electronically and is used at the right time. All the features and innovations of electronic health, such as health cards, medical records, etc., are directly related to these cases. Safety culture is a quality that looks at safety as a communal responsibility. It is up to the top executives to carry out safety measures and reward safety to motivate staff. Employees should be assured that they will be supported by managers for decisions that are safe for the benefit [13]. Clinical governance is the framework by which healthcare insurance organizations are responsible for continuously improving the quality of healthcare services and maintaining high standards of care by creating an environment in which excellence in clinical care flourishes [14]. This framework has a number of key elements e.g. clinical effectiveness, clinical audit, risk management, patient and community engagement, human resources and staff management, education, and use of information and also has several bases e.g. system awareness, teamwork, communication, ownership, and supervision. The effect of all these elements and bases are considered in the developed model [14-16].

Many studies have been conducted to investigate this problem. Using system dynamics, Valentina, Ceresia [17] examined the promotion of safety culture in an organization as a safety improvement tool. Using simulation, they investigated the effect of creating a safety culture on reducing the

occurrence of unfavorable events. Ceresia and Montemaggiore [1] using a system dynamics method, carried out a multidimensional study on hospital's complicated operation management system. For this purpose, they modeled clinical risk management in three different hospitals and then compared the results. Guo [3] studied the diagnostic errors in three phases of medical therapy using system dynamics modeling. [9], Soheilinia and Sepehry [18]examined error management in the operating room processes with the help of Improved Failure mode and effect analysis.

II. METHOD

Research methodology followed by this paper is based on the general stages of system dynamics methodology. This method is an appropriate tool for analyzing and understanding the causes of dynamic behavior in complex systems in which the productive structure of problematic behavior is modeled using system thinking. The model development process in system dynamics involves the following steps: 1) detailed problem statement and ambiguity expression; 2) reference Modes; 3) dynamic hypothesis; 4) system structure mapping; 5) mapping of the stock and flow structure; 6) mathematical formulation of the model; 7) model validation; 8) leverage points identification 9) scenario design; 10) simulation of scenarios implementation [26]. Applying system dynamics approach to solving healthcare problems are increasing. There is very cases of applying system dynamics approach in healthcare contexts [19-25]. Also, this approach applied with a combination of other approaches such as neural network [27], multiple response surfaces [28-30]. In addition, it is an appropriate approach for modeling all complex systems [31-40]. To develop a mathematical model for the research problem, a methodology similar to figure 1 is designed.

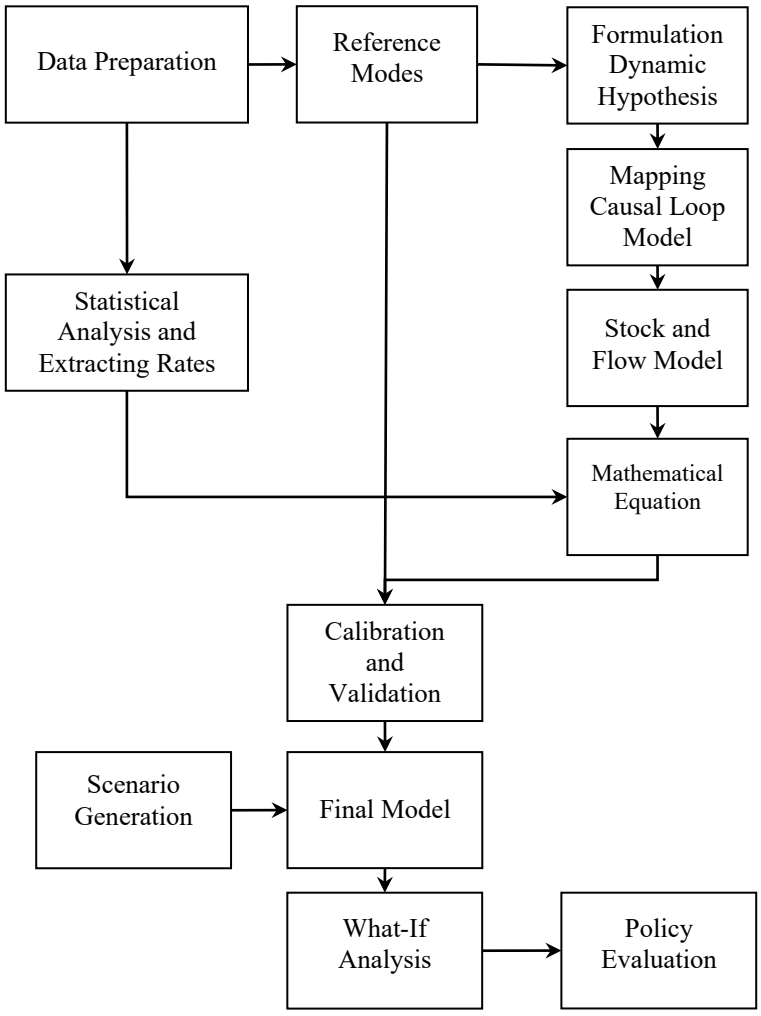

Figure 1. The process of the proposed approach

A. *Problem Statement and its ambiguity*

Patient safety is one of the basic pillars of quality in health care. Today, treatment with minimal risk and maximum safety for all patients is desirable and expected. However, the rate of injury can never be as low as zero, so identifying the factors influencing the occurrence of clinical errors is quite important. According to researches and studies carried out in this field, one of the most effective factors in the occurrence of errors is the heavy workload of medical staff. The workload is affected by the shortage of workforce in hospitals and medical centers. Figure 2 shows the growth in the workforce in Iran's healthcare system. The number, which includes physicians and nurses, has a significant increasing trend.

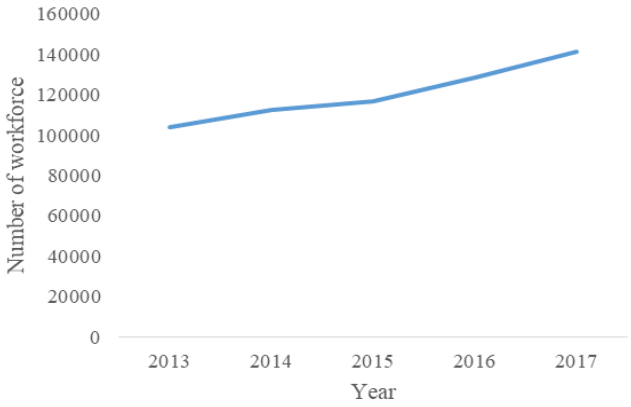

Figure 2. Health System Workforce in Iran's healthcare system

Additionally, in Iran during the last two decades, many measures have been taken to improve the quality of treatment and healthcare services. Health and treatment evaluations in Iran are carried out using indicators defined for eight areas, e.g. health and prevention, treatment and care, medicine and food, medical education, medical research, management and resources development, public relations, and medical equipment. There has been a growth in these areas between 2005 and 2009, including 5% increase in active hospitals and 13% increase in the number of hospital beds, and by increasing access to health care, the general health condition of the society accompanied with the workload of medical staff have improved. Other performance indicators in the field of medical education indicate that the total number of admission to medical science majors has increased by 24%. As a result, potential human resources that have a significant role in reducing clinical errors, have been growing well. Regarding the impact of skill and knowledge on error rates, the number of admissions in continuous educational programs has increased by 30%, and admissions in continuous educational programs in medical sciences have doubled, while occupational training programs for managers has had a 3.4% increase in capacity. Furthermore, regarding the importance of medicine-related or prescriptive errors, keeping a record of side effects of drugs can have a significant influence on reducing this type of error. Between 2005 and 2009, the number of hospitals with a system capable of recording drugs side effects has increased dramatically by 166 times, with 3.2% increase in their reports.

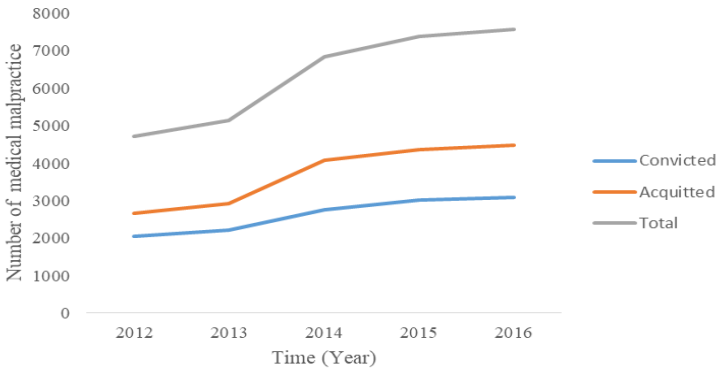

Figure 3. Trend of medical malpractice that references to forensic

Following the growth of various indicators, one would expect to see a meaningful growth in quality of healthcare and patient safety, and a decrease in medical errors. However, according to the statistics, the number of legal claims and also convictions related to medical errors have had a positive trend from 2012 to 2016. Understanding the productive structure of adverse behaviors which leads to the occurrence of clinical errors is the main issue of the present research.

B. Dynamic Hypothesis and Causal Structure

As the population increases, access to treatment and healthcare faces shortage; this process can lead to a decline in the society's general health level. The more patients there are, the more treatments are needed in hospitals, which requires more workload for a limited workforce. This would increase the chance of medical errors and adverse events, and in consequence, more injured patients are referred back to hospitals for further treatment, and the loop is repeats itself.

On the other hand, the increase in the number of patients in hospitals and healthcare centers would increase the patients' waiting time to receive health care services; in other words, this would cause problems in patients and staff communication. Prolongation of the patients' hospitalization and their fatigue, leads to an inappropriate communication between the physician and the patient. In some cases, as the perceived temporary noises are heightened, even misdiagnosis may occur. Also, the incorrect prescription of drugs for the patients adds to the number of clinical errors, and as a result, more patients are going to come back to hospitals, which intensifies the defective loop. Although, misdiagnosis is not always the result of communication problems between the patient and the doctor, and in some cases, the complexity of the disease, and even medical knowledge limits, can lead to misdiagnosis of a disease. Plus, drug-related errors are not confined to misdiagnosis. In some cases, despite the correct diagnosis, prescription of an inappropriate dose of a drug or drugs adverse interactions causes problems for the patient. Failure to use electronic prescriptions and the use of paper copies poses problems in delivering medicines to patients at pharmacies, and this also adds to the chance of making errors. In addition, the inappropriate physical environment is also effective in increasing the workload of the medical staff and error rate.

Clinical errors rise in a health system is followed by a system response. An increase in error forces the system to develop clinical risk management policies. A reasonable response would be the increase of the share of research and development in healthcare budget and overcome medical knowledge limits by emphasizing on training the medical staff. By emphasizing the role of clinical risk management, the role of supervision, teamwork, accountability, and equipment improvement would be highlighted as they act as the limiting mechanisms in the occurrence of errors. Some of the clinical errors occur in critical situations that medical personnel is experiencing for the first time and require appropriate decision being made in the shortest time possible to control the harm to the patient.

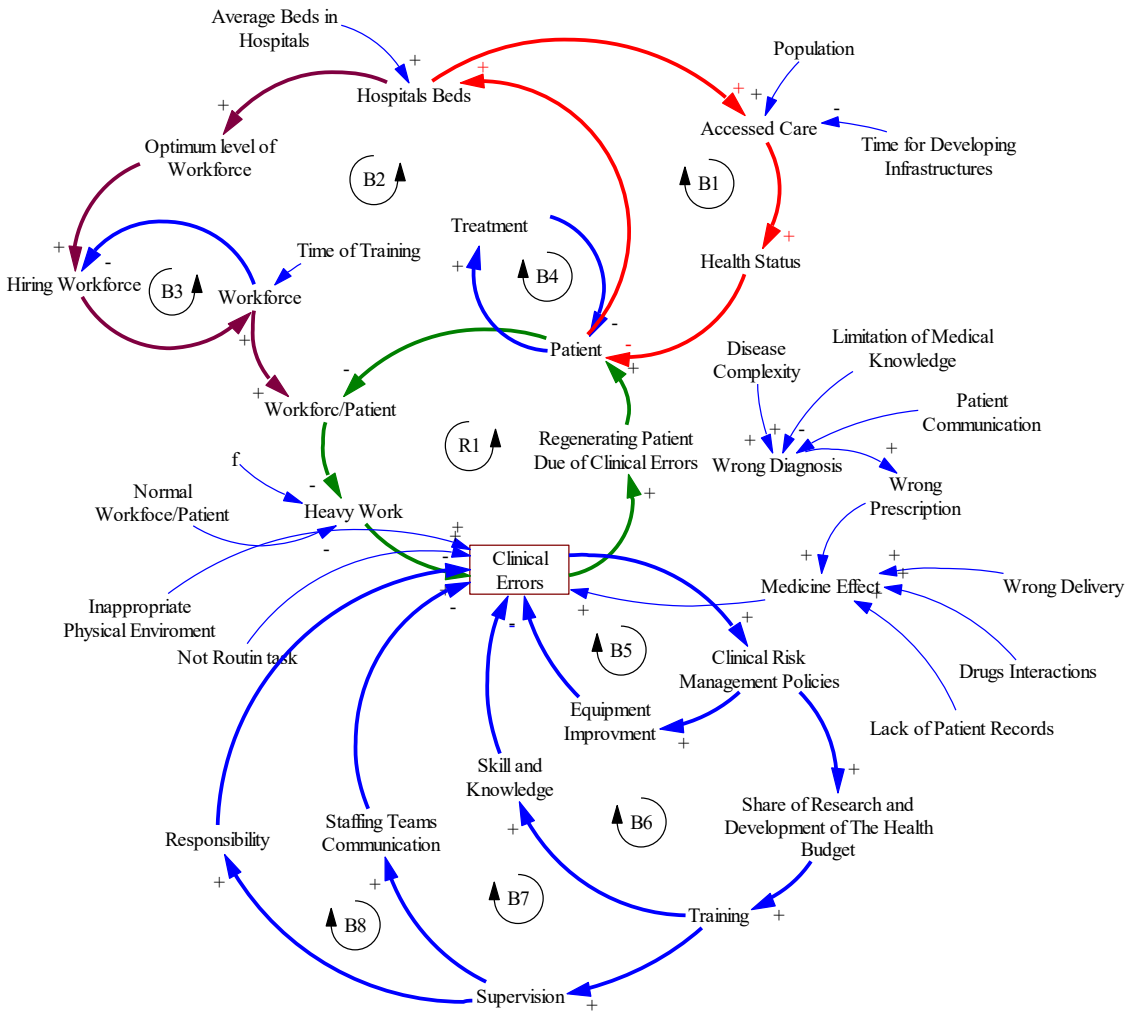

Figure 4. Causal loop diagram

C. Stock and Flow Model

After providing a dynamic hypothesis of the problem structure, in order to construct a quantitative model and simulate the results, the stock and flow model was developed and the mathematical equations were formulated.

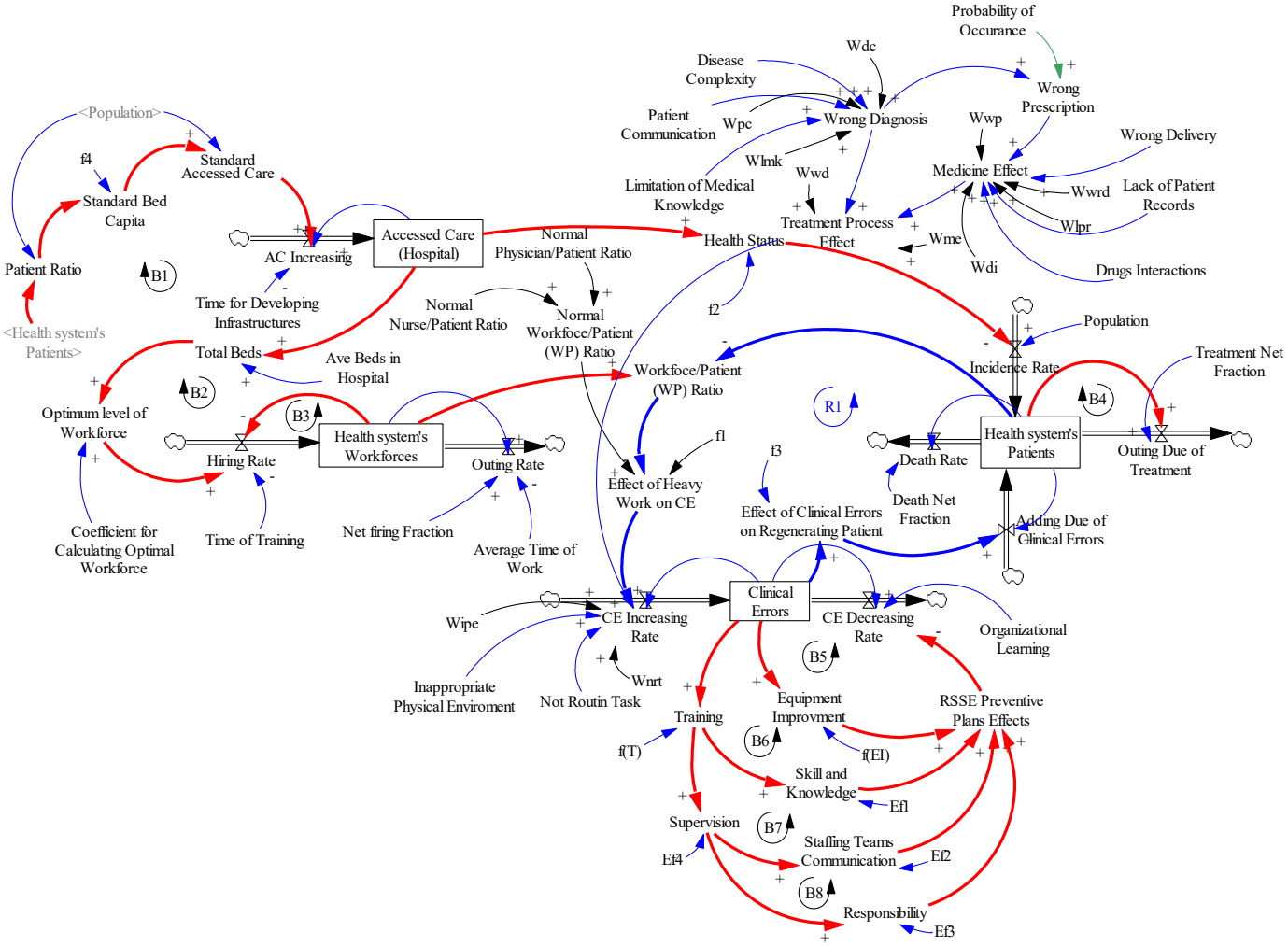

Figure 5. Stock and Flow Diagram

D. Model Validation

After developing the model and before scenario generation and analysis of results, it is necessary to verify the reliability and validity of the model under different conditions, which is done through some validation tests on the model. To validate the model, several tests such as historical behavior reproduction test, Extreme Condition Test, Boundary Adequacy for Structure Test, Model Equations Logic Test and Dimensions Consistency Test have been performed. In general, the accuracy of the model was assured via these tests.

In historical behavior reproduction test, we used the reproduction test and also the MAPE (Mean Absolute Percent Error) index. Its value for the clinical error variable was 1.76% and for health system's workforce was on 4.54 %.

E. Leverage Points Identification

Considering the structure of the problem and considering the modeling done for it, the most important leverage points of the system are the following variables. 1) Factors related to inaccurate diagnosis, 2) drug-induced effects, and 3) RSSEI (Responsibility, Skill and knowledge, Supervision, Equipment improvement, Staffing team communication) agent which indicates the impact of factors of responsibility, skill, and knowledge, supervision, equipment improvement, teamwork collaboration.

Table 1. Leverage Points

Row	Leverage Point	Variable
1	Inaccurate Diagnosis	Wrong Diagnosis
2	Drug-Induced Effects	Medicine Effect
3	RSSEI	RSSEI Variables

F. Scenario Generation

1) Scenario 1: Continuing with of Existing Situation

According to this scenario, no changes are made in the values and parameters or structure of the proposed model. The purpose of this statement is to show that if the status quo continues, what are the consequences on the behavior of key variables and clinical errors.

2) Scenario 2: Developing Electronic Health Record

In this scenario, the impact of implementing this technology on ease of access to integrated information, as inpatient records, drug interactions records, and the use of electronic prescriptions, is examined.

3) Scenario 3: Creating a Safety Culture

A safety culture is a way to ensure safety as a communal responsibility. In this approach, employees must be assured that they will be supported by managers for decisions that are in benefit of safety. By creating this culture, the punitive response to the error is laid away and the first result is an increase in the number of reports of errors, which can make the organization learn about the root causes of errors and better learn how to deal with them. On the other hand, the creation of a safety culture will have a positive impact on the staff's accountability and their collaboration, as well as a supportive supervision on the work that will result in increased quality of care.

4) Scenario 4: Implementing Clinical Governance Principles

These principles present a framework for continuous improvement of the quality of healthcare. Using clinical audit, risk management on leadership foundations, education and training pillars on the systems awareness foundations, patient and community engagement based on communication, and human resources foundation based on teamwork, a healthcare system can manage to reduce the number of errors as staff's knowledge and skills, patient and staff communication, and also teamwork are all improved.

Table 2. The implications and the affected variables of each scenario

Scenario	Description	Affected Variables		
		Name	Old Value	New Value
1	Continuing with of Existing Situation	-	-	-
2	Developing Electronic Health Record	Drugs Interactions	0.4	0.2
		Lack of Patient Records	0.8	0
		Wrong Delivery	0.3	0
3	Creating a Safety Culture	Organizational Learning	0	0.2
4	Implementing Clinical Governance Principles	Patient Communication	0.3	0.2
		Skill and Knowledge	0.6	0.7
		Staffing Teams Communication	0.3	0.4
		Supervision	0.1	0.3

III. RESULTS

With the implementation of the first scenario, more clinical errors with rising rates are expected to occur in the future. However, the balancing feedback loops related to the error reduction are active and in effect, but their impact is less than error reinforcing feedback loops. This increasing trend in clinical errors is a threat in eyes of policymakers. The health system is evaluated only by a few performance indicators in the areas of hygiene and prevention, treatment and care, medicine and food, medical education, medical research, and medical equipment; and while the indicators show a positive growth in these areas, the outcome of this scenario shows that improvement of functional indicators does not necessarily mean the reduction of clinical errors of the system.

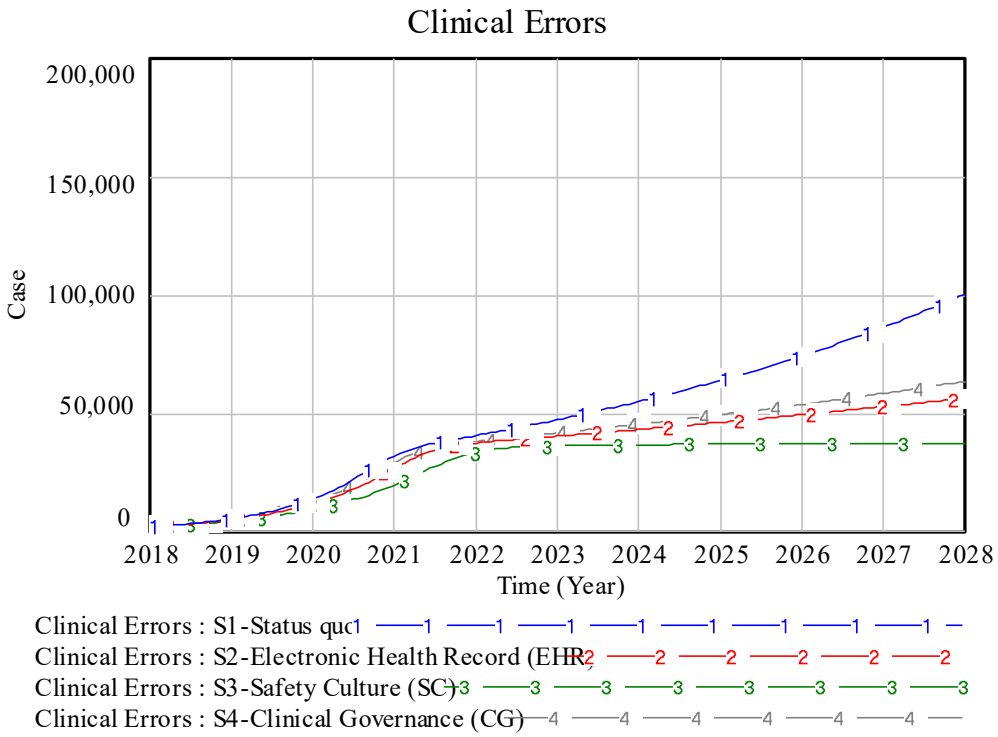

Figure 7- The impact of implementing different scenarios on the number of clinical errors.

The second scenario shows that with the implementation of the electronic health record, the upward trend of clinical errors will be controlled. The greatest impact of this scenario is on reducing the effect of lack of patient records, drugs adverse interactions, as well as drug delivery mistakes in pharmacies. In the third scenario, by creating a safety culture, we see that the clinical error variable becomes decreasing. In other words, this scenario acted better than other scenarios and errors drop rate was the greatest for this scenario. As the number of reports on errors increases, organizational learning and continuous improvement of the system becomes possible. The communications openness and feedback in this scheme have an effective role in reducing errors. As the safety culture in the internal system is improved, teamwork is facilitated in hospital units, and staff is much assured that they are supported by the hospital management, and they are not going to be punished for making an error for the first time.

The fourth scenario, which involves the establishment of clinical governance, also reduced the trend of the clinical error variable, but the rate of decrease was less than the third scenario. Although since this project is considered as one of the performance measurement methods in hospitals, it can play a key role in increasing the quality of care services. Within this framework, care providers will be accountable for quality sustainability, and high standards are established for service through the creation of an environment which follows the excellence of clinical services.

IV. DISCUSSION AND CONCLUSION

In the present study, the behavior structure of clinical errors including the effective factors and relations among them are presented. Health systems work to improve the health and well-being of the community, but the risks in some cases cause irreparable damage to the system that prevents the system from achieving its goals. In the event of an incident, the staff was accused of committing an offense, which would cause the person to make mistakes and exacerbate the subsequent errors, but in view of the non-intrusiveness of the error and the notion that the error is not always the fault of one person, and in many cases, other factors that are in line, cause the incidents, the chance of future errors would decrease, after they are being reported by the staff. This is a systematic approach to the problem of medical error that is very helpful in understanding the problem correctly and providing a solution for it.

In this paper, the system's reproductive behavior was identified and its stock and flow model was developed to express the system's performance. Then, four scenarios which indicated the policies and methods proposed for solving the problem were presented on the model and their results were simulated.

Table 3-Summary of Scenario Results

Scenario		Results	Conclusion
S1	**Continuing with status quo**	The error is still increasing; although the error-balancing loops had their effect, their power was less than the error strengthening loops.	Although investments on the performance indicators of the Ministry of Health, Medicine and Medical Education are very helpful, without risk management programs, these indicators cannot reduce the error rate.
S2	**Developing Electronic Health Record**	The error rate has been reduced but still has a very small increase.	The effects of implementing this policy quickly show themselves. Initial effects significantly decrease the error rate, and in the long run, it still continues to decrease errors.
S3	**Creating a Safety Culture**	The error was decreased with the highest rate.	This scenario is the best executive scenario and the decreasing rate of errors is more than other scenarios. It has been ignored in Iran for many years.
S4	**Clinical Governance**	This scenario reduces the error rate to a great extent. But its rate is less than the third scenario.	This scenario is effective in reducing the error and as a performance measurement tool for hospitals, it can play a significant role in increasing the quality of care services. It was first implemented in England in 1998 as a strategy and produced very good results.

The result of the research showed that the best scenario is creating a safety culture, which means creating an integrated safety management system that puts safety at the forefront of all employees. In this risk management system, a positive reward will be considered for safety awareness and compliance with it. After each action and decision, targeted safety operations will be considered and the persons responsible for its implementation, and the employees are convinced that their decisions in benefit of safety get management support. This environment encourages all individuals to identify, report, and modify safety issues, as a result of organizational learning from error, which is a central focus of the learning process.

In this study, there was a limitation on separating probable errors in different diseases. Also, there exist some limits on determining the boundaries of the model and taking into account all endogenous and exogenous variables. Therefore, for future studies, it is recommended that clinical risk management models be simulated for specific diseases and the effects of different scenarios on them would be investigated.

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