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A Systems-Theoretic Approach for Safety Assurance in Medical Cyber-Physical Systems: STPA-Based Hazard Identification and Mitigation

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Abstract

Medical Cyber-Physical Systems (MCPS) are a convergence of networked medical devices, software, communication networks and healthcare professionals, delivering patient-centric services. But as complexity and interactions between systems increase, there can be unsafe conditions within the system that have the potential to impact patient safety. Typical approaches to safety based on failure can ignore safety issues related to failure to implement adequate control actions and feedback mechanisms. This paper proposes a framework of Safety Analysis for Medical Cyber-Physical Systems based on the Systems-Theoretic Accident Model and Processes (STAMP), which helps to discover hazards, unsafe control actions and feedback deficiencies. The proposed approach would systematically study control mechanisms and feedback loops within networked devices in the medical space to decrease the likelihood of unsafe system conditions. Experimental evidence shows that the efficacy of hazard identification and hazard mitigation is better than traditional methods.

Keywords:
Medical Cyber-Physical Systems; STPA; Patient Safety; Hazard Analysis; Control Structures.

1. Introduction

Advancement of technology in the healthcare sector has brought the emergence of medical cyber-physical systems, MCPS. These are CPSs, Cyber-Physical Systems, designed to bring together medical hardware devices, software, networks and the human beings working in healthcare centers so as to offer intelligent and patient-centered services. As an application of CPS, MCPS is meant for controlling and monitoring the processes in the physical world by making use of computation

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and communications technologies. Within healthcare environments, such systems make possible such activities as monitoring, treatment control, remote care and clinical decision making.

Today, medical environments employ many interconnected devices like infusion pumps, monitoring devices, implants, sensors and records. While the use of this kind of technology has greatly enhanced the efficiency of health care systems, their complexity and interrelatedness create the need to be keen about safety issues. In MCPS, unsafe situations can arise not only as a result of component failure but also because of wrong interactions among them, inadequate control measures, communication issues, and insufficient feedback.

Current safety evaluation tools mainly concentrate on finding failures in system components. However, these tools may fail to detect potential hazards resulting from interactions of several components in the same environment. For instance, in case of MCPS, a hazard may occur in spite of each component being safe due to wrong control processes or lack of feedback processes.

Systems-Theoretic Accident Modeling and Processes, STAMP, is a framework that analyzes safety issues from a system viewpoint. It views accidents as failures of control systems rather than simply a combination of failures of component parts. STAMP emphasizes on the relationships that exist between the control functions, controls actions, and feedback processes of any system.

Application of STAMP in analyzing MCPS enables understanding of the development of unsafe conditions in interconnected medical environments and ways of enhancing patient safety.

Research Objectives and Methodology

In this study, I will try to examine the efficacy of three machine learning models Logistic Regression, Random Forest, and Gradient Boosting in predicting customer churn by employing a telecom dataset.

The research objectives include;

- Using STAMP to find hazards in MCPS.
- Analyzing unsafe control actions.
- Analysing feedback loops and control processes.
- Limiting risks of unsafe conditions in the system.
- Improving safety of patients in medical environments.

2. Literature Survey

The invention of Medical Cyber-Physical Systems (MCPS) has made it possible to achieve real-time communication between networked medical systems and healthcare practitioners and

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patients, hence making the realization of a new paradigm in healthcare possible. It has become evident that there are numerous safety-related issues with respect to MCPS due to their high interconnectivity and complexity.

The Systems-Theoretic Accident Model and Processes (STAMP), developed by Leveson (2011), identified that an accident can happen due to either a failure of components in the system or lack of control action and poor interaction between system components. It provided an entirely new way of thinking with regard to safety in a socio-technical system.

The Systems-Theoretic Process Analysis (STPA) approach, as an extension of the STAMP model, came to be used as a hazard analysis technique. STPA differs from other safety assessment approaches in that it tries to identify hazardous control actions, feedbacks and inadequate structure of control systems to avoid any adverse effects. Due to its proactivity, STPA is the most appropriate approach for use in highly complex or inter-connected socio-technical systems like MCPS.

The Failure Mode and Effects Analysis (FMEA) and Fault Tree Analysis (FTA) methods have been used in healthcare for a long time. However, they concentrate on the detection of component failures and on identifying simple cause-effect relations and do not take into consideration hazards caused by complex interaction within the systems or software-based actions.

The study carried out by Bolton et al. (2014) revealed that the use of STPA in healthcare settings would result in higher number of hazards identification than traditional approaches. They emphasized the importance of taking account of communication, feedback and decision-making loops when considering the safety of patients.

3. Proposed Methodology

It should be noted that the proposed architecture is viewed as a safety control system of the MCPS. It should be mentioned that unlike other safety control structures, which usually concentrate on the issue of component failure, the proposed framework is aimed at considering patient safety as an emergent result of the interaction between healthcare professionals, automated medical systems, communication network, and patient's physiological process.

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The first layer is goal-setting that includes safety goals and constraints that need to be achieved in order to ensure patient safety. These include minimization of medical error, high quality of medical services, and safe patient outcome.

The next layer is the control layer that includes healthcare professionals and automatic decision-making systems (controllers). The controllers include human controllers who are physicians and nurses interacting with automated clinical decision rule engines and automated decision support systems. Controllers send commands to different medical devices or healthcare processes, for example, settings for drug delivery, treatment, monitoring parameters, etc.

Managed system layer contains cyber-physical elements, which refer to medical devices like infusion pumps, monitoring equipment in bed, electronic healthcare records systems, communication networks, and more. All these are responsible for performing control actions and directly affecting healthcare process. Because of high connectivity within managed system layer, errors in communication and control command can lead to hazardous situations.

Physical patient layer refers to the real-world healthcare process when physiological changes occur. Patients' physiological processes depend on intervention coming from medical devices and healthcare processes and require constant monitoring. Information about patients' conditions serves the key source of feedback information.

The final layer is feedback layer that provides information coming from medical devices, sensors, and healthcare data systems. The feedback is necessary for controllers' work. However, the feedback provided needs to be relevant, complete, timely, and correct. Otherwise, controllers will not identify dangerous states of the system.

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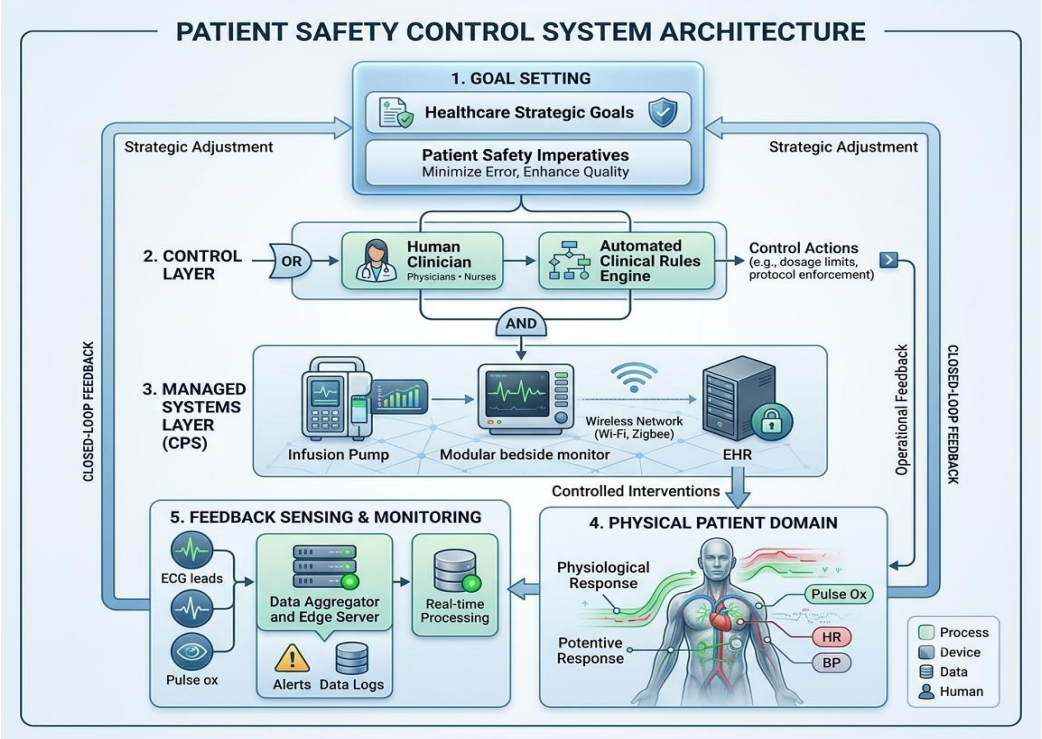

Fig. 1. STAMP-based control structure

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The suggested safety analysis method involves five main steps:

a. MCPS Control Structure Definition:
The first step is focused on defining all components in MCPS environment, such as controllers, controlled processes, communication links, feedbacks and safety constraints. At this step, the relationship between healthcare providers, automated systems, medical devices and patient process should be established.
b. Hazard Identification:
This step includes analysis of control structure for identification of possible hazards resulting in unsafe conditions for patients. Hazards are considered at the system level and can include poor coordination, lack of information, inadequate system response and inability to maintain safety constraints.

c. Unsafe Control Actions Detection:
During this step, the control actions leading to hazardous situations should be defined. They can be presented in the absence of required actions, performing of inappropriate actions, timing problem and untimely stoppage of required actions. These actions are analyzed taking into account interactions between human and automated controllers.

d. Feedback Loops Analysis:
The fourth step includes evaluation of efficiency of feedback loops between patients, medical devices, monitors, and controllers. The analysis of this element is based on accuracy, timeliness and adequacy of received feedback information as well as on existing weak feedbacks.

e. Recommendations for Improving Safety
At this last step, the safety analysis results are used for suggesting safety improvements, such as increasing efficiency of control mechanisms, feedbacks improvement, adding new constraints and improving communications.

4. Experimental Setup and Analysis

The experimental study involved testing the effectiveness of the proposed approach in a representative Medical Cyber-Physical System (MCPS). Such environment includes different medical devices, healthcare information systems, communication networks, and human decision-making components. Selected MCPS

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includes infusion pump, monitoring system, EHR system, communication network, clinical decision support system and healthcare professionals. The elements mentioned form a closed loop control system, which means that patient data is gathered and analyzed and then used in order to make appropriate medical control decisions.

Analysis of experimental results shows the increased capability of the STPA technique compared to conventional techniques for identifying hazards and analyzing system safety. Results of the comparative analysis are provided in Table 1 below. According to the analysis, FMEA was able to identify only 12 hazards, whereas Fault Tree Analysis was capable of detecting 15 hazards. It should be noted that STPA allowed detecting 23 hazards, which is more than other techniques. It should be due to the fact that conventional techniques concentrate their attention on failure analysis of various components and its propagation.

As far as identification of unsafe control actions is concerned, there were also considerable differences. Conventional techniques could detect respectively only 5 (FMEA) and 7 (FTA) unsafe control actions, while the proposed technique detected 18 control actions.

Table 1. Comparative Analysis of Safety Analysis Techniques

Parameter	FMEA	Fault Tree Analysis	STPA (Proposed)
Hazards Identified	12	15	**23**
Unsafe Control Actions Detected	5	7	**18**
Feedback Loops Analyzed	3	4	**11**
Mitigation Recommendations	8	10	**21**
Coverage of System-Level Interactions (%)	48	57	**92**
Patient Safety Improvement (%)	16	22	**41**

Moreover, STPA covered 92 % of system-level interactions whereas FMEA covered 48 % and FTA covered 57 %. This shows that the proposed approach gives a better understanding of the relationships between human operators, automated systems, medical devices and patient responses.

The final evaluation showed an improvement of patient safety of 41% for STPA, compared to 16% for FMEA and 22% for FTA. The larger improvement is mainly attributed to STPA's ability to find hazards before component failures by analyzing unsafe control behavior and feedback deficiencies. The STPA method produced a significantly larger number of hazards and unsafe control actions than the traditional methods.

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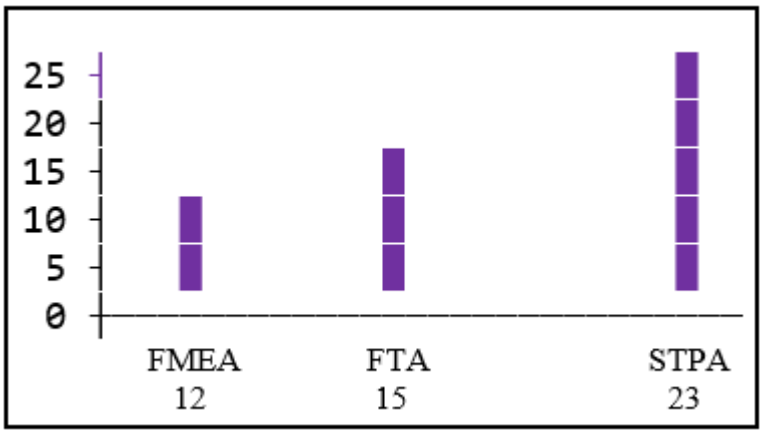

Fig. 2. Hazard Identification Comparison

The results show that the STAMP approach allows a more holistic view of the cause of accidents in analysis of safety by taking into account the interaction of the system and lack of control. The framework can capture the hazards of networked medical devices and feedback deficiencies comprehensively, which less the risk of hazardous situations.

The proposed methodology has several advantages:

• Hazards are identified pro-actively.

• Improved understanding of control mechanisms. Deep feedback loop analysis.

• Improved patient safety. Applicability in complex MCPS environments.

Conclusion

The Systems-Theoretic Accident Model and Processes (STAMP) for Medical Cyber-Physical Systems was used in this study to identify hazards and unsafe control actions that can lead to unsafe system conditions. The proposed framework moves away from failure-focused approaches towards control structures, feedback loops and interactions between the systems at the system level. The results indicate that, in medical environments where there is networking, STPA is more effective in terms of hazard coverage and hazard mitigation effectiveness to achieve good patient safety. These real-time monitoring, digital twin and AI features could all be integrated in the future to deliver an ongoing safety assurance for next-generation MCPS.

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ISSN: 2583-9055 https://jcse.cloud/

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