Research Paper: Risk Assessment of Surgical Procedures in a Referral Hospital

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ABSTRACT

Background: Adverse Events (AEs) due to failure in healthcare procedures are common. These procedures are often evaluated independently. The objectives of this study are to investigate the nature of the failures in healthcare procedures of the surgical patients, assessing the frequency of these failures and preventability, and exploring their consequences, underlying causes, and prevention strategies in a referral hospital in the center of Iran.

Materials and Methods: This study is a prospective quantitative and qualitative research. Focus Group Discussion (FGD) meetings have been conducted to understand potential failures, their consequences, causes, and prevention strategies. Afterwards, the frequencies of these concepts have been determined separately in predefined subcategories in each step of the process.

Results: The first phase of the patient care process was the most risk-prone phase. Temporary or permanent disability at the time of discharge (final impacts), inflammation/infection (injuries), the rule-based behavior associated with coordination (causes), information and communication, preventability more than 50 were the most frequent failures and had achieved the highest score.

Conclusion: Failures of healthcare processes are preventable to a high degree, although patients injure frequently. Interventions to mitigate these failures will enhance the reliability of surgical procedures.

1. Introduction

Patient safety and health services quality have become the most critical priority in the modern surgical care [1]. Complex environments in which multiple processes carried out by large multidisciplinary teams are uncertain [2]. The surgical ward has been required to avoid care failures and Adverse Events (AEs) by increasing communication and synchronization with other wards [3]. Failures at various steps in patient journey could occur despite all efforts of the healthcare professionals. Process failures

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would cause serious injuries, increase the length of hospital stay and waste resources [4].

Despite this, the rate of AEs (14%) associated with surgical procedures is high [5]. Sukumar, et al. have demonstrated that 12.9% of inpatients undergoing major oncological procedures were exposed to unintended hospital-acquired AEs by using Patient Safety Indicators (PSI) [6, 7]. However, 37.9% of them are considered potentially preventable surgical AEs [8]. On the other hand, although there has been a great attempt to understand contributory factors in the operating room (OR) prospectively to develop evidence-based interventions, [9, 10] main studies which investigate surgical AEs are retrospective reports. However, recorded review and prospective incident-based report which can not be compared are limited by voluntary reporting bias [11, 12].

Significant improvements depend profoundly on an understanding of surgical AEs comprehensively. Improvement of patient safety should identify the most significant causes of preventable harms to the patient, and consequences of AEs [8, 13]. Also, focusing exclusively on the frequency of AEs and neglecting healthcare processes that underlie them has been criticized [14]. Since a single AE may have multiple causes, consequences and defensive barriers (preventability) in each phase of the healthcare procedures [9]. For example, clinical audit often assesses individual healthcare procedures, and as a result, fewer process failures is demonstrated regarding their frequency, relative risk, and cumulative effect on the surgical patient [4].The purpose of this study was to investigate the frequency and nature of failures in the healthcare procedures of the surgical patient journey for elective surgical patients. Additionally, final impacts and injuries, causes, preventability, and prevention strategies were also determined.

2. Materials and Methods

This study is a prospective quantitative and qualitative research in a referral hospital in the center of Iran. Regarding qualitative research, the most vulnerable and essential process that has potentiality caused AEs were determined. This achieved by the agreements of Focus Group Discussion (FGD) members during initial meetings. FGD Members consisted of a multidisciplinary team with the involvement of responsible deeply experienced individuals and critical informant leaders in the ward. Inclusion criteria for this group were considered at least 20 years of experience and seniority. Therefore, the FGD Members were head nurses of surgical ward, anesthesia and recovery care teams and subordinate personnel, physicians and experts of clinical governance and accreditation units who were responsible for hospital risk assessment.

Except conducting discussion meetings, interviews with each FGD members were also considered in this study. FGD Members were responsible for predicting failure modes and related AEs. In this study, we reviewed the literature and offered FGD Members to express final impacts, injuries, causes, prevention strategies, and preventability of each predicted failure modes in a single format with predefined themes from previous studies. They accepted and also included their implications. Thus, following categories applied as a guide in this study:

Final impact

Death as a result of an AE, prolonged hospital (surgical ward) stay, extra treatment (extra intervention), readmission to the hospital (surgical ward), temporary or permanent disability at the time of discharge (after surgery), suboptimal care, physical injury, mental injury, inconvenience [11, 15], Lack of treatment audit before starting procedures, misidentification, exceeded workload, legal liability, and unidentified.

Injury

Inflammation/infection, bleeding/hematoma, injury by mechanical/physical or chemical cause, other functional disorders, accumulation/leakage of body fluids, symptoms without diagnosis, abnormal wound healing, fistula formation, shock, necrosis/infarction, thrombosis/embolism, ischemia/heart failure, pressure ulcers, rejection/allergy/other immunological reactions and other/non-specified categories.

Causes

The categories of the Eindhoven Classification Model (PRISMA-Medical version) was utilized in this study [16, 17] (Appendix A).

Preventability

The degree of preventability of AEs was measured on a six-point scale including according to Zegers et al. study: “Virtually no evidence of preventability, Slight to modest evidence of preventability, preventability not very likely, less than 50 close call, preventability more than likely, more than 50 close call, strong evidence of preventability” [18].

Preventive strategies

Merten et al. purposed ten categories for possible strategies to prevent AEs as following: "quality assurance/peer review, training, evaluation, procedures, motivation, information and communication, technology/equipment, personnel, scaling up, financial investment and others" [19].

Regarding quantitative research, we were going to seek the frequency of predicted sub-categories at each step of the process. Therefore, we would be able to anticipate the critical points of the process in the future to turn the attention of hospital management. Consequences (final impact and injuries), causes, and prevention strategies were analyzed using descriptive statistics and frequency tables and figures. Means of scores given by five key informant members of the team were considered for preventability levels. Ethical approval has been granted by the medical board of the Hospital that is affiliated to Isfahan University of medical sciences in Isfahan-Iran.

3. Results

Five steps of the patient journey in surgical wards were developed by FGD Members. For this process 85 potential failure modes were found. The most failures (about 36.4%) were anticipated to occur in phase one named "Required actions before entering the surgical ward" and the least (about 8.2%) in the phase fifth named "Transfer of patient from recovery bay to Intensive Care Unit (ICU) or related ward". It's important to know that as a failure is passing through coherent steps without any detection, the consequences would be worse. Therefore, FGD members confirmed and emphasized the prevention of failures before starting surgical procedures.

Table 1. Final impacts frequency in each five sub-process phase of the patient journey

Patient Journey Processes / Final Impacts	1. Required Actions Before Entering the Surgical Ward	2. Patient's Admission Before Entering the Holding Area of Surgical Ward	3-1. Patient Flow From the Holding Area to the Operating Room	3-2. Delivery of Patient to Anesthesia Team	4. Delivery of Patient to Recovery Ward	5. Transfer of Patient From Recovery Bay to ICU or Related Ward	Total
Prolonged hospital (surgical ward) stay	23	3	4	5	8	2	45(8.2%)
Extra treatment (Extra intervention)	28	8	2	10	0	1	49(8.9%)
Readmission to the hospital (surgical ward)	14	4	3	1	0	3	25(4.5%)
Temporary or permanent disability at discharge (after surgery)	42	26	25	28	14	7	142(25.9%)
Death as a result of an AE	7	1	1	2	0	0	11(2%)
Suboptimal care	40	4	19	22	15	3	103(18.8%)
Physical injury	5	2	1	1	0	1	10(1.8%)
Mental injury	6	2	2	2	2	1	15(2.7%)
Inconvenience	17	9	1	0	4	3	34(6.2%)
Lack of treatment audit before starting procedures	22	7	6	22	8	0	65(11.8%)
Misidentification	3	0	0	3	0	0	6(1.1%)
Exceeded work load	3	1	2	0	0	0	6(1.1%)
Legal liability	3	7	5	1	2	4	22(4.1%)
Unknown	6	2	2	3	1	0	14(2.5%)
Total	219(40.1%)	76(13.8%)	73(13.3%)	100(18.2%)	54(9.8%)	25(4.5%)	547(100%)

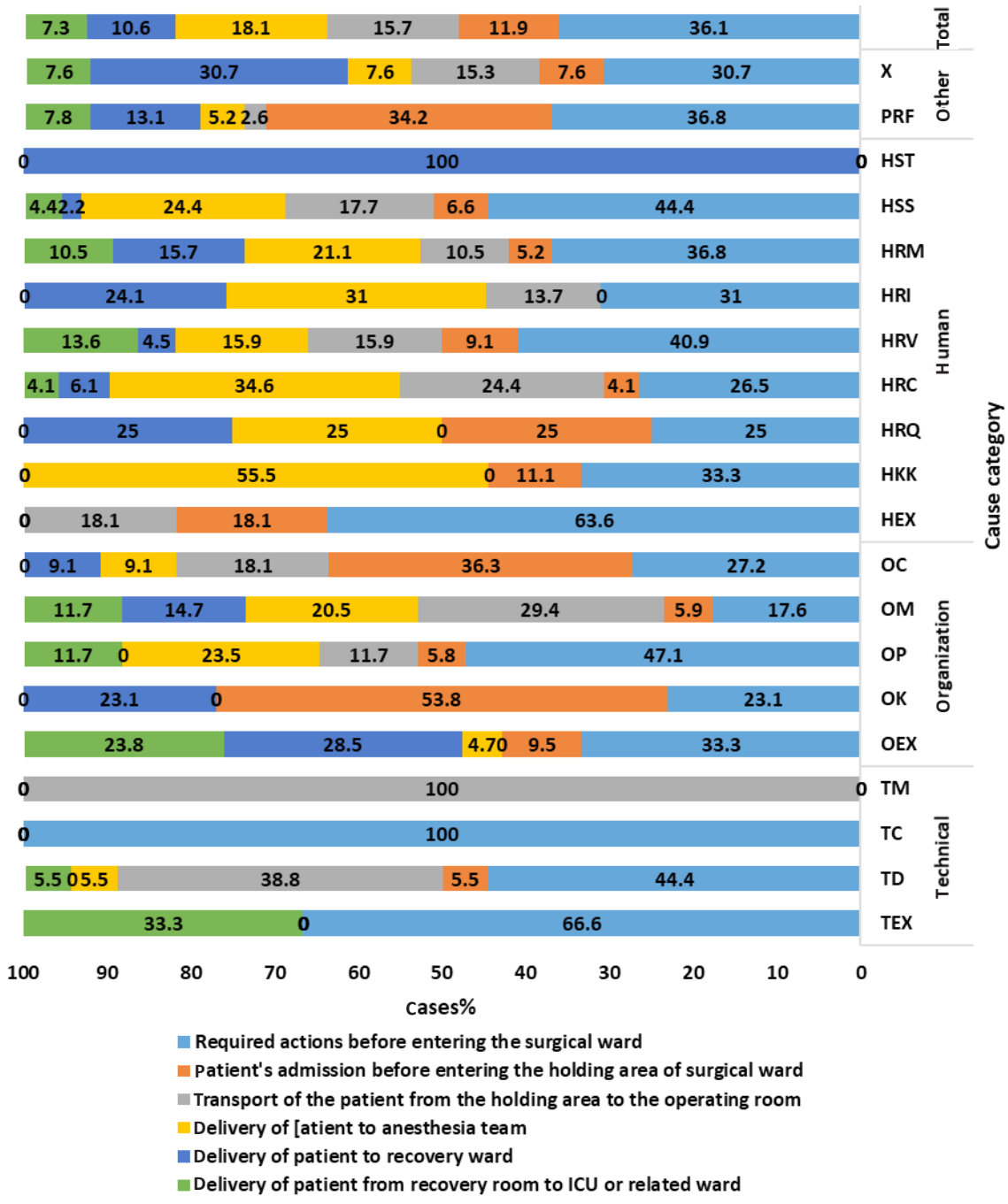

Figure 1. ECM categories and subcategories percentage

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This suggests that before phase three which is divided into two parts: "1. Patient flow from the holding area to the OR; and 2. Delivery of patient to anesthesia care team". However, we decided to investigate descriptive statistics of potential failures claimed by FGD members in the following aspect: final impacts, injuries, causes, preventability and prevention strategies which were predicted. These elements were defined separately for each step of the process (Tables 1 and 2, Figures 1, 2, and 3). Table 1 describes final impacts categories as a subset of the clinical AEs consequences. Temporary or permanent disability at the time of discharge (after surgery) is shown to be the most frequent final impact (25.9%). This table also demonstrated that phase one failures were more susceptible to have these ultimate consequences (40%). The least final consequence was in phase five as this was predicted correctly by FGD

Table 2. Injuries frequency in each five sub-process phase of the patient journey

Patient journey Processes / Injuries	Required Actions Before Entering the Surgical Ward	Patient's Admission Before Entering the Holding Area of Surgical Ward	Patient Flow From the Holding Area to the Operating Room	Delivery of Patient to Anesthesia Team	Delivery of Patient to Recovery Ward	Transfer of Patient From Recovery Bay to ICU or Related Ward	Total
Inflammation/ infection	51	9	15	14	8	1	98(15.2%)
Bleeding/ hematoma	26	3	2	12	3	3	49(7.6%)
Injury by mechanical/ physical or chemical cause	17	4	25	12	4	4	66(10.12%)
Other functional disorder	8	1	8	8	3	5	33(5.1%)
Accumulation/ leakage of body fluids	10	2	1	3	4	0	20(3.1%)
Abnormal wound healing	6	5	3	2	3	0	19(2.9%)
Symptoms without diagnosis	9	3	0	1	3	0	13(2.01%)
Fistula forming	7	2	8	29	8	0	54(8.3%)
Shock	55	15	8	7	4	1	90(13.9%)
Necrosis/ infarction	39	8	13	15	2	3	80(12.4%)
Thrombosis/ embolism	2	1	2	0	0	0	5(0.7%)
Ischemia/ heart failure	9	10	7	10	10	3	49(7.6%)
Pressure ulcers	10	4	7	9	3	1	34(5.21%)
Rejection/ allergy/ other immunological reaction	15	9	3	6	1	0	34(5.2%)
Total	264(40.9%)	76(11.8%)	102(15.8%)	128(19.8%)	53(8.2%)	21(3.2%)	644(100%)

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members. Misidentification and exceeded workload were the final impacts of few failures.

Table 2 describes injuries categories as the second subset of the clinical AEs consequences. Inflammation/infection is shown to be the most frequent injury (15.2%). Again, failures of phase one were more susceptible to have these injuries (40.9%). The least injures were anticipated to occur in phase five as the most preventable point in the process, and susceptibility to failures would decrease after phase 3. Thrombosis and Embolism were the least injuries that would be caused by anticipated failures.

Eindhoven Classification Model (ECM) categories and subcategories percentage are shown in Figure 1. The highest score (36.1%) was accrued to phase one as the most causes of failure modes originated from not implementing required actions before entering the surgical ward. For example, not reserving the ICU beds, lack of coordination between surgery and anesthesia care teams, missing blood sample tags, not determining which part of the patient's body needs surgery in HIS, etc. About 7.3% of causes were accrued to phase five showing the least causes of failures rooted in this phase. HRC (Rule-based behavior associated with Coordination) became the most frequent cause of failures (12.4%). TM (Technical-materials latent conditions) and HST (Skill-based behavior -Tripping active human errors) categories were included the lowest number of causes of failures.

Figure 2 contains prevention strategies percentage per phase. As the most causes and clinical consequences are related to correct patients admission in phase one, it is clear that prevention strategies should be performed more than others in the first phase. Information and communication determined the most appropriate strategy to be employed in our surgical ward. The need

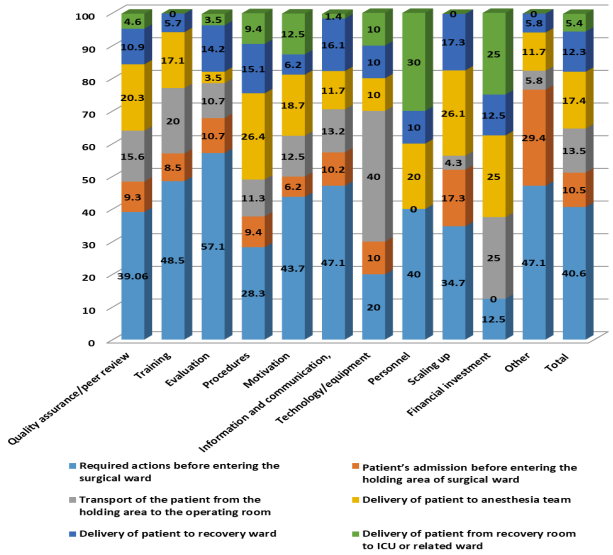

Figure 2. prevention strategies percentage per phase

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for prevention strategies complies with the following order: Information and communication, quality assurance/peer review, procedures, training, evaluation, scaling up, motivation, technology/equipment, personnel and financial investment.

Figure 3 demonstrates the preventability of failures based on FGD member experience. Preventability more than 50 had given the highest score (32.4%). Just a few of failures had no evidence of preventability (11.1%). Failures in the first phase had more evidence of preventability.

4. Discussion

During FGD meetings, decision makers, invited professionals, and representatives of other hospital wards or units emphasized focusing on prevention strategies precisely before starting the operation which means before patient flow from the holding area to the OR (Phase 3). They apparently disagreed with the representatives of the surgical department who considered the first phases of the process to be more significant in prevention. This means, required actions before entering the surgical ward and patient admission before entering the holding area. In the last meeting, results of their previous discussion about final impacts, injuries, causes, prevention strategies, and preventability of failures were unveiled, and they were surprised as the results showed that possible final impacts, injuries, causes, prevention strategies and preventability of failures are more frequent in phase one. We conducted this study to extract significant themes declared about potentially patient's failures in surgical

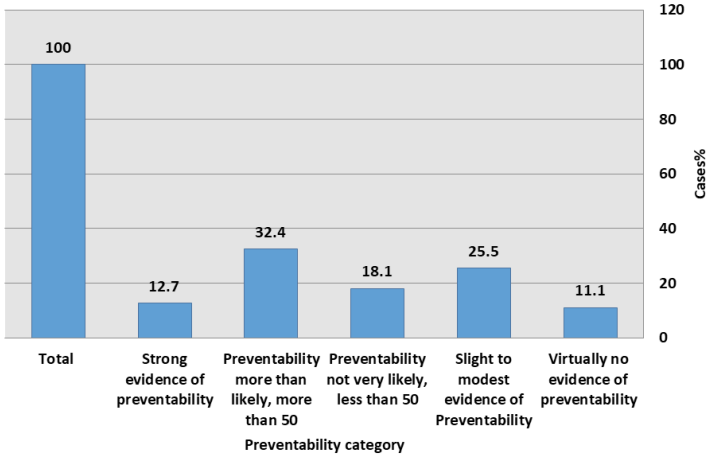

Figure 3. the preventability of failures based on (FGD) member experience

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process and quantifying the consequences, causes and preventability of surgical AEs. We also analyzed proposed prevention strategies to overcome failures that have an effect on patient safety in surgical procedures.

These aims were partly achieved because of insufficient data about near miss reports. Oliver Anderson and colleagues [8] distinguished between surgical AEs and preventable surgical AEs. Distinct categories of consequences were introduced for each of them. Clinical injuries considered as consequences of AEs included number of surgical records, wound problems, bleeding, sepsis (including abscess), cardiovascular, cerebrovascular and respiratory for preventable AEs. Number of surgical records, wound problems, genitourinary, cardiovascular, gastrointestinal, respiratory, anesthesia, fluid/electrolytes/renal, medication, anastomotic leak, intraoperative, bleeding, sepsis (including abscess), thromboembolic and cerebrovascular for AEs. This study also distinguished between consequences and outcomes of AEs. Outcomes were measured by severity degrees of fatal, severe, moderate, and minor.

Outcomes are equivalent to the concept of final impacts in our study. We predicted preventability of each AE because the FGD members believed that there would be some degree of preventability for most failures and then statistics showed that just 11% of failures had virtually no evidence of preventability. Symons and colleagues [4] concluded that clear, unambiguous processes, such as prescribing and administration of medication, have a high degree of preventability. Therefore, this could be implied that fewer incidents were due to unexpected and unpreventable events and more failures occurred in routine procedures. About 89% of failures were regarded as potentially preventable in this study, and this was estimated from 37.9% to 85% in other studies [4, 8, 20-22].

Inflammation and infection were more frequent as a minor harm than the others. This was also demonstrated in Vincent study as wound problems and most frequent potential consequence of surgical AEs [23]. Death as a result of AEs, misidentification and exceeded workload had a lower percentage. Similar results in fatal and minor outcomes were demonstrated in Anderson's study [8]. However, Extra treatment and extra intervention such as required ICU care or (re)admission ranged from 1.1% to 37.2% in other studies [24]. Causative types of surgical AEs proposed in previous studies as the most common categories included: number of surgical records, error in surgical technique/operative management, all nonoperative management failures, monitoring error, unreliable or delayed treatment, diagnostic failures/delay, medication error, anesthesia error, and error in judgment/outside expertise [8, 20, 23].

In the present study rule-based behavior associated with coordination as the nonoperative management causes were more frequent than technical-based and skilled-based behavior which corresponds to Kable and Vincent study. Coordination problems included causes such as not performing anesthesia consultation before admission, not prioritizing patients who should be operated, not informing critical laboratory values and not cross-checking patient's documents at the time of admission by inpatient ward nurse and surgical ward nurse.

Clear intercommunication procedures of treatment team have been shown applicable strategies to improve patient safety and consistent delivery of care as more than half of AEs were caused by either delays or lack of communication [4, 25]. Although we demonstrated communication and information related strategies as a possible defensive barriers; we focused more on communication between surgical /anesthesia teams and patients (and also their family) and interdepartmental information exchange through predefined procedures. Some examples of related failures are lack of explanation about the satisfaction forms to the patient, not informing other personnel about patient bedsore and not monitoring patient's data in HIS system.

In the referral hospital used in this investigation, WHO surgical safety checklist [26] was used as a prevention strategy. However, this was not filled out by all involved participants in the patient journey. In fact filling out the checklist was the duty of anesthesia technicians and other personnel would not crosscheck this. We recommend Surgical Patient Safety System (SURPASS) checklist, a patient-center multidisciplinary list that covers the entire surgical patient pathway [27]. As most of the incidents would occur in the period before a surgical procedure and following a surgical procedure, intercepting incidents by only using a single checklist in the OR is under question [28].

The location of surgical AEs was described in detail in this study. The most frequent potential failures, causes, and preventability existed in phase one. Also, other researchers confirmed that preventable surgical fatalities in the ward or intensive care unit are 53% of all 47% fatalities related to surgery. That is the result of significant number of AEs occurred in monitoring patients following a surgical operation and daily care of them [29, 30]. This result emphasizes that more improvement efforts at the ward and other areas within the hospital are required.

There was some overlap between ECM categories identified in the present study. For example, not informing the surgical ward head nurse about the exact number and types of surgical procedures would lead to lack of coordination with inpatient ward or Coronary Care Unit (CCU) and ICU. This kind of failure could be placed into two categories: first, HRC, because the head nurse of the selected referral hospital claimed that physicians wouldn't persuade to inform the ward about the number and types of the surgeries in advanced. Second, O-ex, systematic failures would expose them to numerous unpredictable patients. The causes of failures might be in emergency patients, day clinic admission, economic incentives (by the physicians or the hospital), and the role of a referral hospital. To overcome this limitation, FGD members tried to make an agreement for one category or both. Also, subjective judgments made to estimate preventability.

5. Conclusion

Improvement efforts of the surgical AEs have been demonstrated that patient safety should not only focus on causes of failures in surgical techniques but also focus on coordination of all hospital wards and management procedures. Azari Rad recommends scheduling the surgeons weekly based on the patients' length of stay is required to manage perioperative procedures [31]. We recommend that future studies will document both AEs and near miss (close call) events, experiences of critical stakeholders, critical reporting forms, and report the frequency, severity, and preventability of events.

These data will identify and prioritize surgical patient safety improvement efforts. Also, the involvement of professionals in multidisciplinary focus discussions is the main prerequisite in conducting effective medical reviews. Also, a physician-center program might be a more acceptable in contrast to nursing-led initiatives in other settings [32]. We have used a prospective approach to review the investigation of surgical AEs, but methods of medical record were more frequent in previous studies. Medical record reviews might lead to an underestimation of AEs. The quality of the medical records is often unreliable as incomplete information was documented [24].

However, we need both prospective and retrospective approaches to enhance the validity of results. Observational studies have also been recommended to identify the underlying causes of process failures and AEs. Understanding the origins of failure more profoundly leads us to apply quality improvement strategies appropriately and uncover changes in healthcare process and failure patterns before and after interventions [4].

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Conflict of Interest

The authors declared no conflicts of interest.

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Appendix A. The categories of the Eindhoven Classification Model

Main Category	Subcategory (Code)	Description
		Latent Conditions
Technical	External (T-ex)	Technical failures beyond the control and responsibility of the investigating organization
	Design (TD)	Failures due to poor design of equipment, software, labels or forms
	Construction (TC)	Correct design, but not appropriately constructed or set up in inaccessible areas
	Materials (TM)	Material defects not classified under TD or TC
Organizational	External (O-ex)	Failures at an organizational level beyond the control and responsibility of the investigating organization, such as in another department or area (address by collaborative systems)
	Knowledge (OK)	Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff
	protocols (OP)	Failures relating to the quality and availability of protocols within the department (too complicated, inaccurate, unrealistic, absent or poorly presented)
	Management priorities (OM)	Internal management decisions in which safety is relegated to an inferior position when faced with conflicting demands or objectives. This is a conflict between production needs and safety. Example: decisions made about staffing levels
	Culture (OC)	Failures resulting from collective approach and its attendant modes of behavior to risk in the investigating organization
	External (H-ex)	Human failures are originating beyond the control and responsibility of the investigating organization. This could apply to individuals in another department
Knowledge based behavior	Knowledge-based behavior (HKK)	The inability of an individual to apply his or her existing knowledge to a novel situation
Rule based behavior	Qualifications (HRQ)	The incorrect fit between an individual's training or education and a particular task
	Coordination (HRC)	Lack of task coordination within a healthcare team in an organization
	Verification (HRV)	Correct and complete assessment of a situation including related conditions of the patient and materials to be used before starting the intervention
	Intervention (HRI)	Failures that result from faulty task planning and execution
	Monitoring (HRM)	Monitoring a process or patient status
Skill based behavior	Slips (HSS)	Failures in the performance of highly developed skills
	Tripping (HST)	Failures in whole-body movements. These errors are often referred to as "slipping, tripping or falling"
Patient related	Patient related factor (PRF)	Failures related to patient characteristics or conditions, which are beyond the control of staff and influence treatment
	Unclassifiable (X)	Failures that cannot be classified in any other category