**UNIVERSITY OF SPLIT**

**SCHOOL OF MEDICINE**

**Ivan Adamović**

# NEW HOSPITAL ENVIRONMENT AND PATIENT SAFETY

**DISSERTATION thesis**

**Split, 2026**

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The doctoral dissertation was carried out as part of a research projects „Measuring the Overall Development of Patient Safety in a New Hospital Using Trigger Tools“ and “ The importance of using multiple safety evaluation systems in hospitals: A comparison of Critical Incident Reporting System (CIRS), Assurance of Quality in Surgery (AQC) and The Global Trigger Tool (GTT)” headed by Prof. Dr. med. Johannes Brachmann. The first study was conducted at Sana Clinic Lichtenfels in Bavaria, Germany, and the second at ASANA Hospital Leuggern in Switzerland. The papers are connected by their shared focus on improving patient safety through the use of the Global Trigger Tool (GTT). While the first study uses the GTT to assess safety changes during a hospital relocation, the second study compares the GTT's effectiveness with other established systems, such as the AQC and CIRS.

**Mentor:**

**Prof. Dr. med. Johannes Brachmann**

Managing Director of Sana Medical School, Primary Responsible

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**TABLE OF CONTENTS**

## LIST OF ABBREVIATIONS / ACRONYMS

Academic and Professional Titles

- CV: Curriculum Vitae
- Dr. med.: Doctor Medicinae (Doctor of Medicine)
- PhD: Doctor of Philosophy
- Prof.: Professor

Administrative and Technical Terms

- AQC: Assurance of Quality in Surgery (Swiss surgical registry)
- DRG: Diagnosis-Related Group
- ICD-10: International Classification of Diseases, 10th Revision
- IT: Information Technology
- PACS: Picture Archiving and Communication System
- PDMS: Patient Data Management System

Medical and Clinical Abbreviations

- AEs: Adverse Events
- BUN: Blood Urea Nitrogen
- CIRS: Critical Incident Reporting System
- DVT: Deep Vein Thrombosis
- ENT (HNO): Ear, Nose, and Throat (Hals-Nasen-Ohren)
- HDU: High Dependency Unit
- ICU: Intensive Care Unit
- INR: International Normalised Ratio
- LOS: Length of Stay
- OR: Operating Room
- SSI: Surgical Site Infection

- VRE: Vancomycin-Resistant Enterococci

Research and Statistical Terms

- GTT: Global Trigger Tool
- IHI: Institute for Healthcare Improvement
- MERP: Medication Error Reporting Program
- NCC MERP: National Coordinating Council for Medication Error Reporting and Prevention
- SD: Standard Deviation
- SE: Standard Error

# 1. INTRODUCTION

Conventional approaches to monitoring adverse events (AEs) within the German healthcare sector have historically relied on voluntary reporting systems, such as error-tracking mechanisms and the Critical Incident Reporting System (CIRS). The data captured via CIRS includes comprehensive details regarding the nature of the event, preventive strategies, and contributing environmental factors. Employees submit these disclosures voluntarily, using a secure internal intranet platform. To address the inherent sensitivity of disclosing clinical errors, medical institutions guarantee absolute anonymity. This protection encourages a transparent "speak-up" institutional culture, which is vital for cultivating open communication and optimizing reporting volumes. Consequently, these insights are crucial for diagnosing systemic weaknesses and fostering continuous advancements in patient safety. Nonetheless, epidemiological and public health data indicate that just 10% to 20% of clinical errors are ever formally documented via these channels[1].

While local voluntary AE reporting frameworks are universally implemented across German clinical facilities to facilitate the documentation and analysis of critical incidents, their diagnostic sensitivity remains limited. On the other hand, an extensive body of European and American literature has successfully quantified patient harm through the application of specific "trigger tools" or the Global Trigger Tool (GTT)[3,4,5,6,7,8]. Empirical evidence demonstrates that voluntary self-reporting mechanisms fail to capture more than 90% of adverse events occurring within inpatient populations[1]. Consequently, an exclusive reliance on voluntary metrics and standard patient safety indicators may yield highly inaccurate conclusions regarding the actual safety profile of German hospital care. Originally engineered by the Institute for Healthcare Improvement (IHI) in the United States, the GTT serves as a widely accepted methodology for the retrospective evaluation of randomized patient charts, utilizing distinct clinical "triggers" or markers to uncover latent AEs[1].

Systematic evaluations have repeatedly demonstrated that the GTT exhibits superior diagnostic efficacy compared to traditional incident-reporting frameworks in detecting adverse events[9,10,11,12]. Although the GTT features a proven methodological superiority over standard CIRS frameworks, peer-reviewed data regarding its practical application remains unrecorded in the published literature of Germany. As highlighted in the publication ‘The application of the Global Trigger Tool: a systematic review’, formal studies utilizing this particular tracking methodology have been documented in 16 countries worldwide[13].

Canadian empirical data indicated that the inauguration of a modernized clinical environment promoted significantly more positive staff perceptions alongside a broad-based expansion in

overall occupational satisfaction among the workforce[14]. Though the sustained, retrospective benefits of hospital modernization for patients and healthcare workers are established in the literature, studies capturing their longitudinal perspectives across both the preparatory and operational phases are noticeably limited[15]. This investigation seeks to determine how ‘safe’ or ‘secure’ the new hospital or department upon its initial launch.

The above-mentioned fact prompted us to conduct a unique experiment: to observe changes in the initial rate of AEs in a new hospital in Lichtenfels, Upper Franconia (Bavaria, Germany), using GTT, as this has never been described. The SANA Hospital in Lichtenfels is the largest acute care clinic in the district of Lichtenfels, with 251 beds. The SANA Klinikum Lichtenfels functions as a highly structured regional medical center, integrating advanced diagnostic and therapeutic technologies to deliver secondary-level healthcare services across a substantial portion of Upper Franconia, Bavaria. The hospital’s operational scope incorporates a comprehensive array of specialties, including internal medicine (subdivided into cardiology, gastroenterology, diabetology, nephrology, and dialysis), general and abdominal surgeries, traumatology, and orthopedic surgery. Additionally, the facility maintains dedicated departments for neurosurgery, gynecology and obstetrics, anesthesiology, radiology and interventional radiology, otorhinolaryngology, palliative care, interdisciplinary pain management, and acute emergency medicine. Notably, the hospital’s operational scope excludes pediatric, rehabilitative, and psychiatric departments.

In mid-July 2018, operations transitioned to the newly constructed "Green Hospital" facility, situated directly opposite the legacy site. As a pioneering pilot project, "Green Hospital Lichtenfels" serves as a benchmark for German healthcare institutions aiming to optimize ecological sustainability. The infrastructure represents Germany’s most environmentally sustainable clinical facility and marks the first Bavarian hospital engineered to passive house standards. Although all clinical divisions relocated without alterations to bed capacity, staffing volume, or departmental architecture, the physical transition prompted significant organizational workflow adjustments. In contrast to the multi-bed layout (three to four patients per room) of the former facility, the new configuration implements an exclusive single-occupancy rooming model, which subsequently increased the spatial distribution of the wards. Furthermore, previously decentralized units of the same department - which were occasionally isolated across multiple floors in the old building - were consolidated onto unified floors to facilitate staff co-location. The emergency department underwent a substantial spatial expansion, incorporating additional clinical rooms alongside advanced diagnostic and

therapeutic modalities, including a newly integrated ambulatory surgical unit. However, this decentralized, expanded template on the ground floor significantly increased travel distances between operational zones. While certain legacy medical technologies were retained, a considerable portion was modernized. Crucially, while IT and documentation architectures remained constant, administrative admission protocols were modified to capture significantly higher volumes of patient metrics, particularly through newly structured triage workflows. This contrasted with the compact legacy admission framework, where a smaller emergency team routinely rotated between triage, elective admissions, and acute treatment zones.

Operating as a public acute-care regional facility within the Swiss healthcare network, the Asana Spital Leuggern maintains a baseline capacity of 60 inpatient beds. In accordance with federal legislation, all medical institutions across Switzerland are under a strict statutory mandate to systematically implement comprehensive quality assurance protocols. The Asana Spital Leuggern is a well-maintained public regional hospital, situated in a quiet, idyllic landscape with a view of the Klingnau reservoir, not far from the towns of Baden and Brugg (northern Switzerland). With an extensive range of services, the hospital ensures high-quality basic medical care in the region and its surroundings. The hospital has a long-standing attending physician system that ensures patients are cared for by their trusted family doctors before, during, and after their hospital stay. Until August 2022, the hospital consisted of an internal medicine department, while all other specialties – including general surgery, traumatology, orthopedics, gynecology, obstetrics, ENT (HNO), plastic and hand surgery, urology, and angiology—operated under the attending physician system. Since August 2022, in an effort to improve quality and safety and to expand its services, the hospital established its own surgical department alongside the existing attending physician system. Since its inception, the safety protocols of the newly established surgical department had not been formally investigated. However, the hospital itself maintains a long-standing tradition of utilizing a Critical Incident Reporting System (CIRS) and fostering a 'Speak Up' culture. The CIRS serves as a voluntary, anonymous reporting platform, allowing all staff members to report near-misses or safety concerns without fear of retribution. This is reinforced by a 'Speak Up' culture—an organizational environment that empowers healthcare professionals across all hierarchical levels to voice concerns regarding potential errors or patient risks in real time.

After an initial 16-month stabilization period that began in August 2022 with the appointment of the Head of the Surgical Department and a Senior Physician (Oberarzt) for the Interdisciplinary Emergency Department, the department reached full staffing capacity in

autumn 2023. The medical team was finalized with the appointment of a Lead Physician (Leitender Arzt) specializing in general, visceral, and proctological surgery, a Senior Physician (Oberarzt) specializing in traumatology, and two residents (Assistenzärzte). With the department fully operational and staffing complete, we were positioned to conduct a comprehensive safety evaluation throughout 2024. As a critical prerequisite for this assessment, the hospital officially joined the Swiss 'Assurance of Quality in Surgery' (AQC) registry on January 1, 2024. This membership provided a standardized, external framework for monitoring surgical outcomes and complications, serving as a vital benchmark for our safety analysis and enabling a multi-system comparison of patient harm detection. This new department focuses specifically on visceral surgery, common traumatology, complex wound management, proctology, and incontinence surgery.

In accordance with Swiss federal legislation, medical institutions are legally bound to maintain rigorous quality monitoring frameworks. Enhancing safety systems remains an indispensable component of highly specialized healthcare delivery, particularly within the demanding environment of acute care hospitals. Safety concepts are directly linked to error reporting, reductions in adverse events, and lower mortality[16].

Surgical Quality Assurance Protocols (AQC) is a leading Swiss working group and registry dedicated to the standardized documentation and evaluation of surgical procedures and outcomes. A significant majority of surgical clinics across Switzerland are active members, contributing to a centralized national database that monitors clinical performance and produces comparative annual statistics. The AQC operates under an established, rigorous protocol that uses standardized procedure lists and monitoring criteria. By systematically recording surgical interventions, complications, and patient outcomes, the registry enables hospitals to benchmark their performance against national averages. Regular, disciplined use of this database is a cornerstone of quality assurance in Swiss surgery, ensuring that departments maintain high standards of perioperative care and transparency[17].

In alignment with these national standards, our surgical unit at Asana Spital Leuggern officially joined the AQC on January 1, 2024. This membership was a strategic step to integrate our new department into the Swiss quality landscape, providing the data infrastructure needed to validate our surgical safety and compare our complication rates with established national benchmarks. In this study, data collection was limited to inpatient visceral surgical, proctological, and wound cases; patients admitted for traumatological or orthopedic procedures were excluded from the analysis. Outpatient (ambulatory) surgical cases were also excluded

from the study scope. Additionally, Visiting Physicians were not participating members of the surgical department during the 2024 study period, ensuring a consistent and unified medical team throughout the evaluation.

It is imperative to underscore the distinct novelty of this secondary investigation. Following an exhaustive evaluation of the current literature, there is to the best of our knowledge no documented equivalent study comparing the Global Trigger Tool (GTT) with the Assurance of Quality in Surgery (AQC) registry. This omission constitutes a pronounced void within contemporary patient safety research, as no prior study has empirically measured the comparative diagnostic sensitivity of these two systems in a Swiss clinical setting.

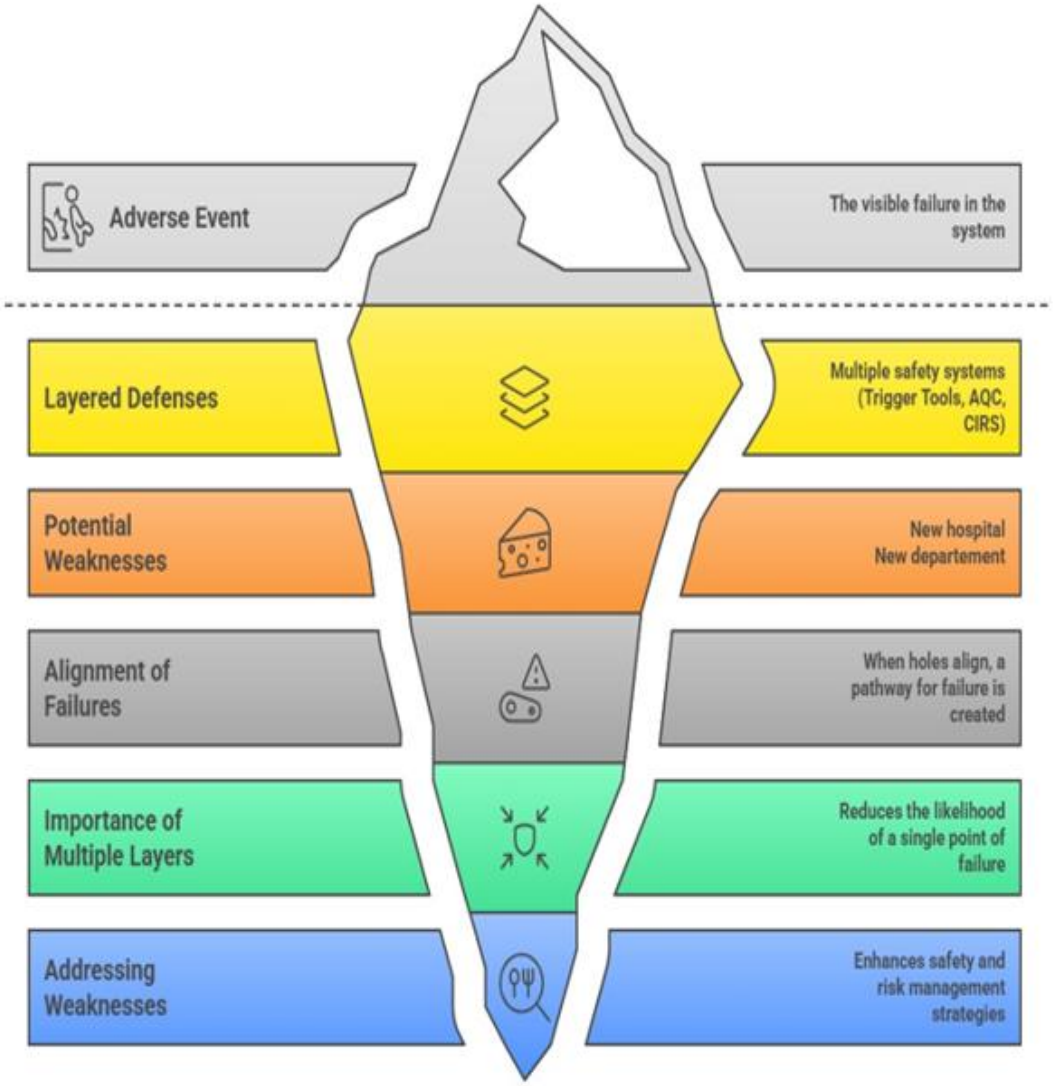
**The Swiss Cheese Model**

Within the domain of patient safety, the paradigm shift from individual culpability to systemic analysis is quintessentially exemplified by James Reason's "Swiss Cheese Model" of organizational failure[18]. Traditionally, medicine viewed errors through the "person approach," focusing on "unsafe acts" - slips, lapses, and procedural violations by frontline staff. In contrast, modern safety science and the framework adopted in this study utilize a "systems approach." This theoretical lens operates on the premise that human error is inevitable, acknowledging that mistakes will manifest even within highly optimized clinical settings.

The Swiss Cheese Model likens a hospital's safety layers to multiple slices of Swiss cheese, arranged side-by-side. In an ideal system, each slice - representing a defense, barrier, or safeguard - would be solid, preventing any hazard from reaching the patient. These defenses include administrative controls (standard operating procedures), technological safeguards (electronic prescribing systems), and human checks (the "four-eyes" principle or surgical patients)[18].

**Figure 1.** Swiss Cheese Model: Unveiling Hidden System Failures.

Source: Prepared by the author (2026)




The Swiss Cheese Model is particularly dynamic during significant transitions in a healthcare system, such as relocating an entire facility or establishing a new clinical department. In these scenarios, the "slices" of defense are not merely shifted. They are often entirely replaced or redesigned. At Sana Clinic Lichtenfels, the move to the "Green Hospital" represented a fundamental change in the physical and organizational "slices" of the cheese.

In a new environment, staff members are initially unfamiliar with the location and nature of the "holes" in the system's defenses. For instance, the transition from traditional four-patient rooms to single-patient or two-patient rooms in Lichtenfels modernized the "Physical Barrier" slice, offering superior infection control and patient privacy. However, this same change created a new "latent condition": reduced direct visual surveillance. In the old, compact wards, nursing staff could monitor multiple patients simultaneously; in the new, more spread-out architecture,

a patient’s clinical deterioration or a fall might go unobserved for longer periods. This represents a new "hole" for which staff had not yet developed "workarounds" or subconscious checks to cover.

Similarly, at Asana Spital Leuggern, the foundation of a new surgical department in 2022 introduced a new "Human and Team-Based" slice. Even after a complete team of highly specialized surgeons and residents was finalized by autumn 2023, the "holes" in communication, hierarchical dynamics, and interdisciplinary coordination - often referred to as "team-based latent conditions" - were not yet fully mapped. During this 16-month stabilization period, the department was essentially learning where its systemic weaknesses lay.

The danger during such transitions is the "alignment of the unfamiliar." When staff are navigating a new physical space (Lichtenfels, Germany) or new collaborative protocols (Leuggern, Switzerland), their cognitive load increases. This higher mental demand makes them more susceptible to "active failures" (slips and lapses). If these active failures coincide with new, unidentified "latent holes" in the hospital's architecture or workflow, the trajectory toward an Adverse Event (AE) becomes much shorter.

My research posits that traditional safety systems like CIRS may struggle during these periods of change, as staff may be too overwhelmed by the new environment to report every "near-accident." This dynamic justifies the deployment of the Global Trigger Tool (GTT) as a retrospective surveillance mechanism capable of auditing newly configured operational layers. By doing so, the GTT identifies incipient systemic vulnerabilities in the institutional defensive barriers - before they culminate in a catastrophic organizational failure.

# 2. OBJECTIVES

The overarching objective of this research was to examine the influence of healthcare facility reconstruction on patient safety outcomes alongside the newly established institutional and departmental environments. More specifically, this study aimed to evaluate the correlation, distribution, and statistical significance of identified triggers, detected adverse events, and corresponding degrees of patient harm within the reconfigured hospital and department frameworks.

We hypothesize that patient safety decreases at the beginning of a new hospital or department, despite modern facilities and conditions.

# 3. MATERIALS AND METHODS

# 3.1. Materials and Methods of the German Study

### 3.1.1. Ethical considerations

In accordance with institutional and regional policies governing Upper Franconia/Bavaria, the European Union, and Switzerland, the activities executed herein satisfy the criteria for operational quality improvement initiatives and are consequently exempt from formal ethical review. Strict confidentiality protocols were maintained, ensuring that no patient metrics were disclosed or published. Because no identifiers capable of exposing individual patient identities were obtained, the dataset remains entirely anonymized.

### 3.1.2. Patient and public involvement

In both the German (Lichtenfels) and Swiss (Leuggern) investigations, there was no active patient or public involvement in the conceptual design, cohort recruitment, or operational execution of the research. The findings were not directly disseminated to the patient cohorts.

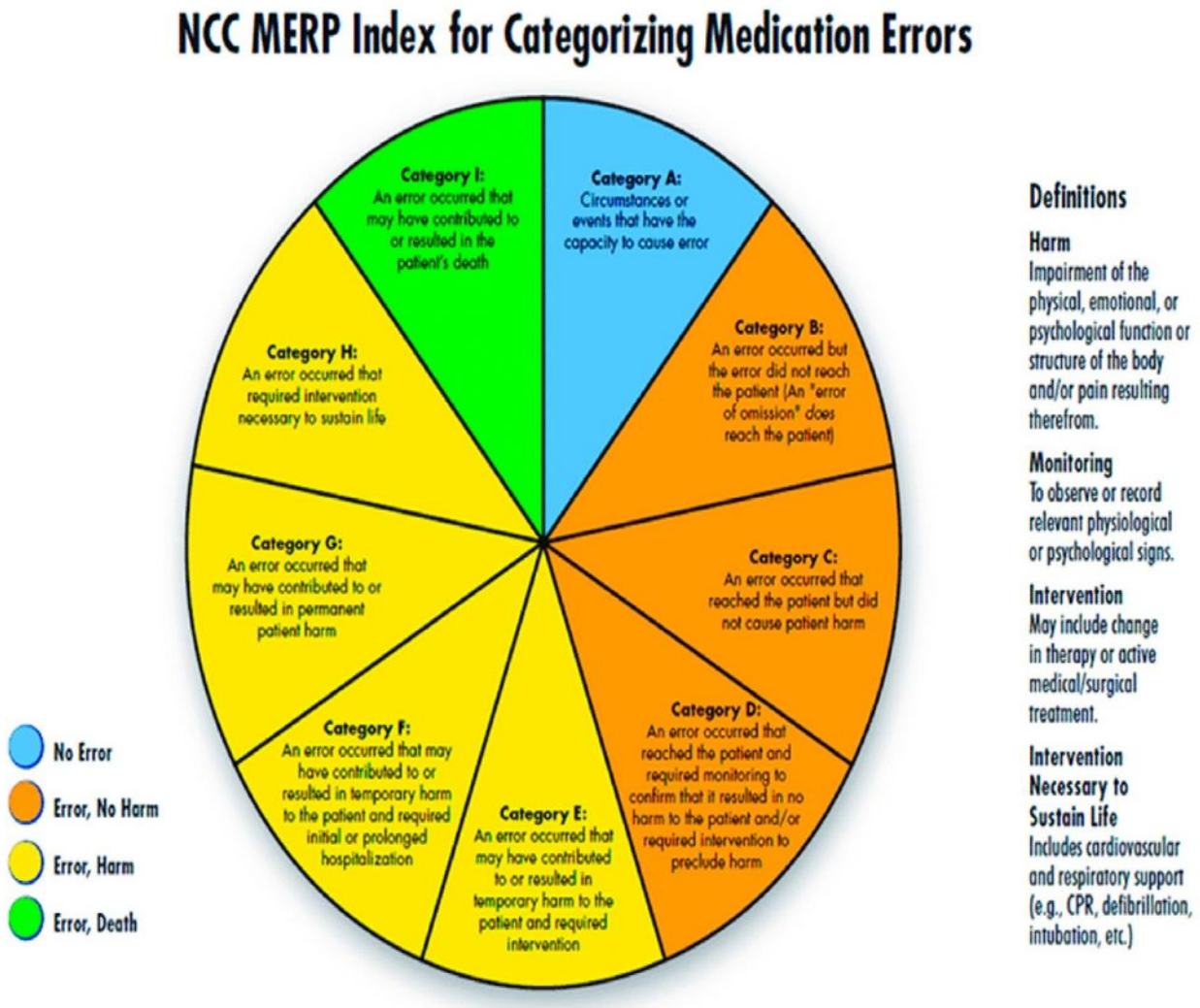
**Table 1.** Categories identifying adverse events in the German Study. Adapted from Ivan Adamovic et al., 2024 (14), based on frameworks developed by the IHI, reference 1, reproduced under the Creative Commons CC-BY-NC license.

| **Cares Module Triggers** | | **Medication Module Triggers** | |
|---|---|---|---|
| C1 | Transfusion or use blood products | M1 | Clostridium difficile + stool |
| C2 | Code/arrest/rapid response team | M2 | Partial thromboplastin time greater than 100 seconds |
| C3 | Acute dialysis | M3 | INR ratio greater than 6 |
| C4 | Positive blood culture | M4 | Glucose less than 50 mg/dl |
| C5 | X-Ray or Doppler for emboli or DVT | M5 | Rising BUN or serum creatinine greater 2 time |
| C6 | Decrease greater than 25% in hemoglobin | M6 | Vitamin K administration |
| C7 | Patient fall | M7 | Dyphenhydramine use |
| C8 | Pressure ulcers | M8 | Flumazenil use |
| C9 | Readmission within 30 days | M9 | Naloxone use |
| C10 | Restraint use | M10 | Anti-emetic use |
| C11 | Healthcare-associated infection | M11 | Over-Sedation/hypotension |
| C12 | In-hospital stroke | M12 | Abrupt medication stop |
| C13 | Transfer to higher level of care | M13 | Other |
| C14 | Any procedure complication | | |

### 3.1.3. The GTT method

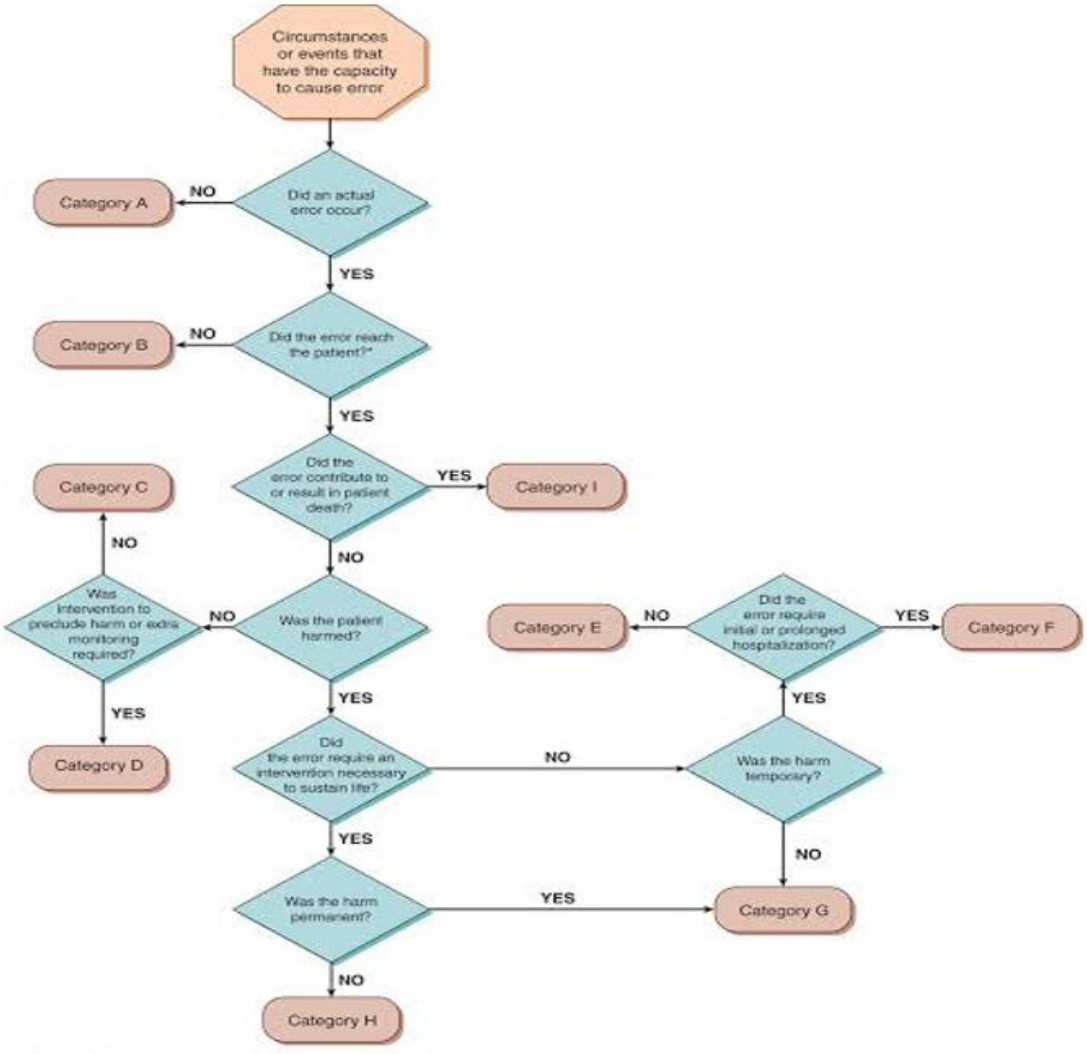
We used the IHI GTT definition for AEs: unintended physical injury resulting from or contributing to medical care, which required additional monitoring, treatment, or hospitalization, or which resulted in death[1]. Step I in the GTT is the identification of triggers. The identified triggers were stratified into 27 distinct categories in accordance with the Institute for Healthcare Improvement (IHI) GTT guidelines (Table 2). Subsequently, the clinical documentation was evaluated to determine the occurrence of adverse events (AEs), which were quantified using standardized metrics: AEs per 1,000 patient days, AEs per 100 admissions, and the overall proportion of admissions featuring at least one AE. Confirmed AEs were then aggregated into nine primary severity classifications. (Fig. 2)

**Figure 2.** Severity categories of adverse events. Adapted from Ivan Adamovic et al., 2024 (19), based on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index (1), reproduced under the Creative Commons CC-BY-NC license.



To evaluate identified triggers - defined as clinical circumstances or adverse events with the potential to inflict harm, medication errors were systematically classified utilizing the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index algorithm (Fig. 3).

**Figure 3.** NCC MERP index algorithm for categorizing medication errors. Adapted from Ivan Adamovic et al., 2024 (19), based on the original algorithm by the National Coordinating Council for Medication Error Reporting and Prevention NCC MERP (1), reproduced under the Creative Commons CC-BY-NC license.




### 3.1.4. Review team

Under a modified approach, a three-member clinical team managed the review process. This included a primary reviewer who was an experienced physician with substantial hospital-care expertise and at least five years of clinical experience. Rather than conducting independent

record evaluations, the second and third highly experienced physicians functioned to audit and formally authenticate the findings generated by the primary reviewer.

### 3.1.5. How to do a training as a reviewer for Global trigger tools

The IHI Global Trigger Tool for Measuring Adverse Events is best used when personnel have been trained as reviewers for this methodology. IHI provides five sample patient records for reviewer training. These training records can be accessed on IHI's website[1]. Phase one of the training methodology involved auditing authentic, deidentified patient charts selected by the IHI to emphasize core competencies required for the Global Trigger Tool. Expert-validated reference keys were provided for each chart. Given that chart reviews are subject to individual reviewer interpretation, the provided answers represent the most common consensus findings. This methodology prioritizes a balanced sampling strategy designed to capture adverse events with high dependability during brief review intervals, rather than detecting every potential incident. Compliance with all training guidelines was rigorously maintained. We began by completing five cases from IHI's official website, which provided a foundational understanding of the methodology.

Following this initial phase, we randomly selected 20 of our own patient records from 2017 to further our training and ensure practical application. This comprehensive training and calibration process took approximately one month to complete, allowing us to thoroughly familiarize ourselves with the Global Trigger Tool methodology and ensure consistent application. After the records were reviewed independently, interactive discussions were held. This process optimizes understanding and improves the team's skills.

### 3.1.6. Sampling patient records - data collection

Institutional relocation did not fundamentally alter patient volume. The total number of individuals treated remained comparable across both the legacy and newly constructed facilities. This stability ensured consistency in both sample size and patient case-mix across the pre- and post-relocation cohorts, thereby moderating potential influences on baseline adverse event (AE) risks. While the standard Institute for Healthcare Improvement (IHI) GTT guidelines recommend sampling 10 discharged adult patient records biweekly, this study elected to deploy a larger sample size of 40 records per month. Consequently, 40 randomly selected inpatient records (representing adults aged 18 or older with a minimum length of stay

of 24 hours) spanning all hospital departments were reviewed each month retrospectively over a six-month pre-move baseline period (1 January to 30 June 2018). Following the physical relocation on 16 July 2018, an identical retrospective sampling strategy of 40 adult records per month was executed from 1 August to 31 January 2019. To accommodate relocation workflows and allow for initial operational stabilization, chart reviews were intentionally suspended for a two-week window immediately preceding and following the moving date.

### 3.1.7. Guidelines for selecting the records

Comprehensive inpatient admission lists were collected monthly throughout the study period, which encompassed the six months prior to and the six months following the hospital relocation. Each patient had a unique patient identification number. We used only the identification numbers, without any other patient data, such as names, birthdays, and addresses. After that, we selected every 30th record for review. Selection criteria according to GTT rules are as follows:

(1) Eligible medical charts were required to be formally finalized upon patient discharge.

(2) A minimum hospitalization duration of 24 hours was established.

(3) Eligible individuals were restricted to adult patients aged 18 years or older.

(4) Psychiatric and rehabilitation patient populations were entirely excluded from the study

Excluding these two patient groups aligns with IHI GTT recommendations.

Any initially sampled records failing to meet the predefined inclusion criteria were excluded and systematically replaced with a chart from a pre-selected pool of ten reserve records. The review panel strictly capped each monthly audit at 40 records. The reserve pool was utilized only on an as-needed basis. Within this framework, the identification of a "positive trigger" indicated solely the presence of a target indicator and did not inherently confirm the occurrence of an adverse event[1].

### 3.1.8. Review process

A 20-minute time constraint per patient record was established for the post-training auditing process. The research team met biweekly to review training charts and standardize data collection protocols. Leveraging the facility's digital framework, all relevant clinical data were retrieved and evaluated in an electronic format.

Order of Reviewing:

(1) Hospital discharge codes, specifically DRG and ICD-10 classifications

(2) Text-based clinical discharge summaries

(3) Text-based medication records and pharmacological documentation

(4) Documented laboratory results and diagnostic values

(5) Electronic prescriber orders documented within the ORBIS healthcare platform

(6) Operative registries and anesthesia charts

(7) Narrative nursing documentation and progress notes

(8) Qualitative physician observations in unstructured progress note format

(9) Clinical consultations, emergency department entries, and free-text documentation

### 3.1.9. Comparing data

To evaluate differences across the two study periods - pre- and post-relocation - a chi-square test of independence was utilized for each distinct category of adverse event.

### 3.1.10. Forming harm measurements

In accordance with the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) taxonomy, three distinct metrics were established based on the MERP Index categorization framework: the total number of AEs per 1000 patient days, the total number of AEs per 100 admissions, and the percentage of admissions with AEs. We have used the Global Trigger Tool to measure the Adverse Review Summary Sheet 1.

**Global Trigger Tool for Measuring Adverse Review Summary Sheet 1**

Measure ***1: Adverse events per 1,000 patient days**
Total number od adverse events/Total length of stay (LOS) for all records reviewed x 1, 000 = _____ Adverse events per 1,000 patient days.
Events_____/ Total LOS for all records reviewed_____x 1,000=_____

Measure ***2: Adverse events per 100 admissions**
Total number of adverse events/Total records reviewed x 100=Adverse events per 100 admissions Events_____/ Total records reviewed_____x 100=Adverse events per 100 admissions.

Measure ***3: Percent of addmisions with an adverse event**
The number of admissions with at least one adverse event
Total number of records with at least one event/Total records reviewed x 100=Percent of admissions with an adverse event. Records with at least one adverse event_____/ Total records reviewed_____ x 100=_____

Several secondary metrics were also defined, including the aggregate of non-harming events (NCC MERP categories B–D) and harming events (NCC MERP categories E–I). Furthermore, an exploratory patient metric was constructed to mirror the traditional aggregate rate of adverse events per 1,000 patient-days. This was operationalized for individual participants by dividing the total number of adverse events by the patient's specific length of stay and multiplying the product by 1,000. Finally, these latter two metrics were partitioned to reflect the respective sums of nursing care errors and medical errors.

## 3.2. Materials and Methods of the Swiss Study

### 3.2.1. Ethical considerations

In accordance with Swiss and European regulatory frameworks governing human subjects research, this project qualified as an operational quality improvement initiative and was consequently exempt from formal institutional ethics review. Absolute data confidentiality was maintained, as no patient-specific identifiers or personal identification numbers were collected or recorded within any database. Because all data acquisition procedures completely omitted identifiable information, the final dataset remains strictly anonymous.

### 3.2.2. Patient and public involvement

There was no patient involvement in the design, recruitment, or conduct of this research. Because the study utilized fully anonymized data that precluded the disclosure or publication of identifying details, patient notification was not required, and study results were not disseminated to individual participants.

### 3.2.3. Review team

The review team consisted of three people (modified approach used), including one primary reviewer who was an experienced physician with very good knowledge of care in the hospital and had long firsthand experience there (for at least 10 years). The second and third clinicians were senior physicians who did not perform direct chart extractions but instead served as expert adjudicators to authenticate the findings of the primary reviewer.

### 3.2.4. CIRS method

Voluntary CIRS reports capture adverse event details, preventative measures, and surrounding clinical contexts via a secure intranet infrastructure. To encourage comprehensive incident reporting without fear of negative repercussions, the platform supports entirely anonymous submissions. Cultivating this transparent communication environment ensures a

higher volume of valuable reports, which are essential for uncovering systemic vulnerabilities and enhancing patient safety protocols.

### 3.2.5. The GTT method

Phase I of the Global Trigger Tool (GTT) methodology involves primary trigger identification. In this study, detected triggers were classified into 32 distinct categories (Table 2) according to the Institute for Healthcare Improvement (IHI) GTT - UK Version. The selection of the UK variant was justified by its established utility in surgical safety research, validated by prior institutional experience utilizing the GTT framework in a German pilot study[19].

While the original IHI GTT framework uses 27 categories, the UK Version expands to 32. These additional triggers are not only more numerous but also significantly more sensitive to specific surgical outcomes.

For instance, the UK Version incorporates enhanced triggers for post-operative monitoring, enabling the identification of complications such as respiratory distress or pulmonary embolism that might otherwise go undetected in a general review. Regarding wound care and infection control, the tool provides more detailed indicators for detecting Surgical Site Infections (SSIs), which are frequently overlooked by the broader, more generic 'infection' triggers in the original US version.

Furthermore, the UK adaptation includes specific triggers for post-surgical neurological deficits—a critical addition for traumatology and neurosurgical contexts. Methodologically, the triggers based on laboratory results (such as creatinine levels or white blood cell counts) are aligned with European measurement standards, ensuring greater clinical relevance in a Swiss setting.

Finally, the UK Version refines the criteria for one of the most reliable indicators of surgical harm: the 'Unplanned Return to the Operating Room.' By providing more precise definitions of what constitutes a 'trigger' for reoperation, the UK Version effectively reduces the rate of 'false positives' while ensuring that serious technical complications are captured during the audit process.

The updated table (Table 2) is tailored to reflect our transition to the Swiss clinical setting at Asana Spital Leuggern. It is designed to show examiners why the methodology in your second study was an "upgrade" over previous research.

Finally, cumulative adverse event metrics were operationalized as the number of AEs per 1,000 patient-days, AEs per 100 admissions, and the percentage of total admissions with an AE. The identified AEs were then grouped into nine major severity categories (Fig. 2).

**Table 2.** Categories identifying adverse events (AEs). Adapted from Ivan Adamovic et al., 2026 (27), based on the tracking methodology developed by the IHI (1), reproduced under the Creative Commons CC-BY-NC license.

**IHI Global Trigger Tool (UK version)**

Category E: contributed to or resulted in temporary harm to the patient & required intervention
Category F: contributed to or resulted in temporary harm to patients& required initial or prolonged hospitalisation
Category G: contributed to or resulted in permanent patient harm
Category H: required intervention to sustain life
Category I: contributed to the patient's death

| Trigger | | + | Event Description and Severity E-I |
|---|---|---|---|
| | **General care module** | | |
| G 1 | Lack of early warning score or early warning score requiring response | | |
| G 2 | Any patient fall | | |
| G 3 | Decubiti | | |
| G 4 | Readmission to hospital within 30 days | | |
| G 5 | Shock or cardiac arrest | | |
| G 6 | DVT/PE following admission evidenced by imaging +/or D dimmers | | |
| G7 | Complication of procedure or treatment | | |
| G8 | Transfer to higher level of care | | |
| | **Surgical care module** | | |
| S 1 | Return to theatre | | |
| S 2 | Change in planned procedure | | |
| S3 | Removal/Injury or repair of organ | | |
| | **Intensive care module** | | |
| I 1 | Readmission to ICU or HDU | | |
| I 2 | Unplanned transfer to ICU or HDU | | |
| | Patient identifier | | |
| | Total events | | |
| | Total length of stay | | |

| Trigger | | + | Event Description and Severity E-I |
|---|---|---|---|
| | **Medication module** | | |
| M 1 | Vitamin K | | |
| M 2 | Naloxone | | |
| M 3 | Flumazenil | | |
| M 4 | Glucagon or 50% glucose | | |
| M5 | Abrupt medication stop | | |
| | **Lab test module** | | |
| | **Haematology** | | |
| L1 | High INR (>5) | | |
| L 2 | Transfusion | | |
| L3 | **Abrupt drop in Hb or Hct (>25%)** | | |
| | **Biochemistry** | | |
| L4 | Rising urea or creatinine (>2x baseline) | | |
| L5 | Electrolyte abnormalities $Na^+$ <120 or >160 | | |
| L6 | $K^+$ <2.5 or >6.5 | | |
| L7 | Hypoglycaemia (<3mmol/l) | | |
| L8 | Raised Troponin (>1.5 ng/ml) | | |
| | **Microbiology** | | |
| :L9 | MRSA bacteraemia | | |
| L10 | C. difficile | | |
| L11 | VRE | | |
| L12 | Wound infection | | |
| L13 | Nosocomial pneumonia | | |
| L14 | Positive blood culture | | |

### 3.2.6. Sampling patient records—data collection

In accordance with the Institute for Healthcare Improvement (IHI) GTT recommendations, the sampling protocol dictates the selection of 10 adult patient records (aged 18 years and older) from the total discharged population every two weeks. Adhering to this framework, a total of 20 complete medical records were randomly selected and retrospectively reviewed each month over a 12-month period (January 1 to December 31, 2024). Eligible charts included adult inpatients with a minimum length of stay of 24 hours admitted to the general surgical department, while orthopedic admissions were explicitly excluded.

### 3.2.7. Guidelines for selecting the records

Monthly administrative registries of all admitted inpatients were generated independently throughout the 12-month study period. To keep patient confidentiality, individuals were represented solely by their unique institutional identification numbers. All direct identifiers, including names, birthdates, and residential addresses, were completely omitted from data collection. Randomization was subsequently achieved by applying a random number generator to these identification codes to select the final charts for review.

### 3.2.8. Review process and reviewing order

To ensure efficiency and standardize the audit process, a strict 20-minute time was allocated for the review of each medical record. The reviewing team convened on a weekly basis to examine findings, resolve discrepancies, and ensure inter-rater consistency. Given the advanced digital infrastructure of the institution, all relevant clinical data were accessed and analyzed in a fully integrated electronic health record (EHR) format.

<u>Order of Reviewing:</u>

(1) Hospital discharge codes, specifically DRG and ICD-10 classifications
(2) Text-based clinical discharge summaries
(3) Text-based medication records and pharmacological documentation
(4) Documented laboratory results and diagnostic values
(5) Electronic prescriber orders documented within the ORBIS healthcare platform
(6) Operative registries and anesthesia charts
(7) Narrative nursing documentation and progress notes
(8) Qualitative physician observations in unstructured progress note format
(9) Clinical consultations, emergency department entries, and free-text documentation

### 3.2.9. AQC method

The AQC platform supports two primary modalities for data acquisition: direct manual entry into highly structured clinical questionnaires - featuring diverse input fields, integrated codings, automated calculations, and validation checks - or automated transmission from an institutional clinical information system. At the time of this study, our institution utilized the Medical Clinical Information System (MKIS), which lacked a direct data-transfer interface with the AQC platform. Consequently, data for all surgical patients, excluding those undergoing orthopedic procedures, required manual entry. The primary operating surgeon was responsible for individual patient data input. Notably, all interface tools utilize responsive design frameworks to ensure device and browser compatibility[17]. The inputs were controlled weekly by the first and second authors.

The AQC recommends follow-ups within the first 30 days. We conducted at least one postoperative consultation on every patient, assessing patients 25-30 days postoperatively. The study population extracted from the AQC system was restricted to hospitalized surgical inpatients, rather than a comprehensive census of all patients admitted in 2024. Orthopedic surgical cases were explicitly excluded from this cohort. This specific sample selection was intentionally targeted to capture a high-risk patient population deemed most appropriate for the study's safety objectives. Non-operative inpatients are systematically excluded from the AQC database registry. Quality assurance protocols dictated that the final verification of all AQC entries was completed by the first author two months post-discharge and subsequently authenticated by the third author. To ensure absolute data anonymity, the data entry workflow relied exclusively on institutional patient identification numbers, precluding any direct personal identifiers.

Following the collection, finalization, and formal administrative closure of the AQC dataset, an audited summary of the aggregated data was provided by the AQC service vendor in March 2025. Data extraction was strictly confined to adverse event parameters. These identified adverse events were subsequently stratified and aggregated into nine primary severity categories (Fig. 2).

### 3.2.10. Comparative Analysis of GTT Triggers: Original vs. UK Version

The updated table (Table 3) is tailored to reflect our transition to the Swiss clinical setting at Asana Spital Leuggern. It is designed to show examiners why the methodology in your second study was an "upgrade" over previous research.

**Table 3**. Comparative Analysis of GTT Triggers: Original vs. UK Version

| **Feature** | **IHI GTT (Original / German Study)** | **IHI GTT - UK Version (Used in Switzerland)** | **Advantage for Surgical Research** |
|---|---|---|---|
| **Total Trigger Categories** | **27 Categories** | **32 Categories** | Increased sensitivity; identifies a broader spectrum of "hidden" patient harm. |
| **Surgical Focus** | General "Surgical Module" focused on major errors. | Specialized for Perioperative Care and stabilization. | Better at identifying complications during the department's 16-month growth phase. |
| **Laboratory Thresholds** | Based on US/General standards. | Aligned with Swiss/European laboratory measurement units. | Reduces "false positives" and aligns with local clinical protocols. |
| **Rescue Medications** | Focused on high-alert drugs (Insulin, Warfarin). | Expanded list including Antidotes and Reversal Agents used in Switzerland. | Effectively catches over-sedation or postoperative respiratory depression. |
| **Infection Detection** | Broad "Antibiotic use" trigger. | Specific triggers for Surgical Site Infections (SSI) and wound care. | Directly monitors the quality of the new visceral and proctological unit. |
| **Procedural Triggers** | Focus on ICU transfer. | Includes "Unplanned Return to OR" and specialized wound treatments. | Highlights technical surgical outcomes and successful complex wound management. |

# 4. RESULTS

## 4.1. Results of German Study

In the preceding German pilot study, the inter-rater reliability achieved a high level of consensus, with an overall agreement exceeding 95%.

Mean differences across all proposed measurements between the pre-move and post-move periods were evaluated using independent-samples $t$-tests (Table 4).

**Table 4.** Descriptive statistics with statistical significance testing applied to assess variations between the baseline (pre-move) and post-move phases. Adapted from Adamovic et al., 2024 (19), reproduced under the Creative Commons CC-BY-NC license

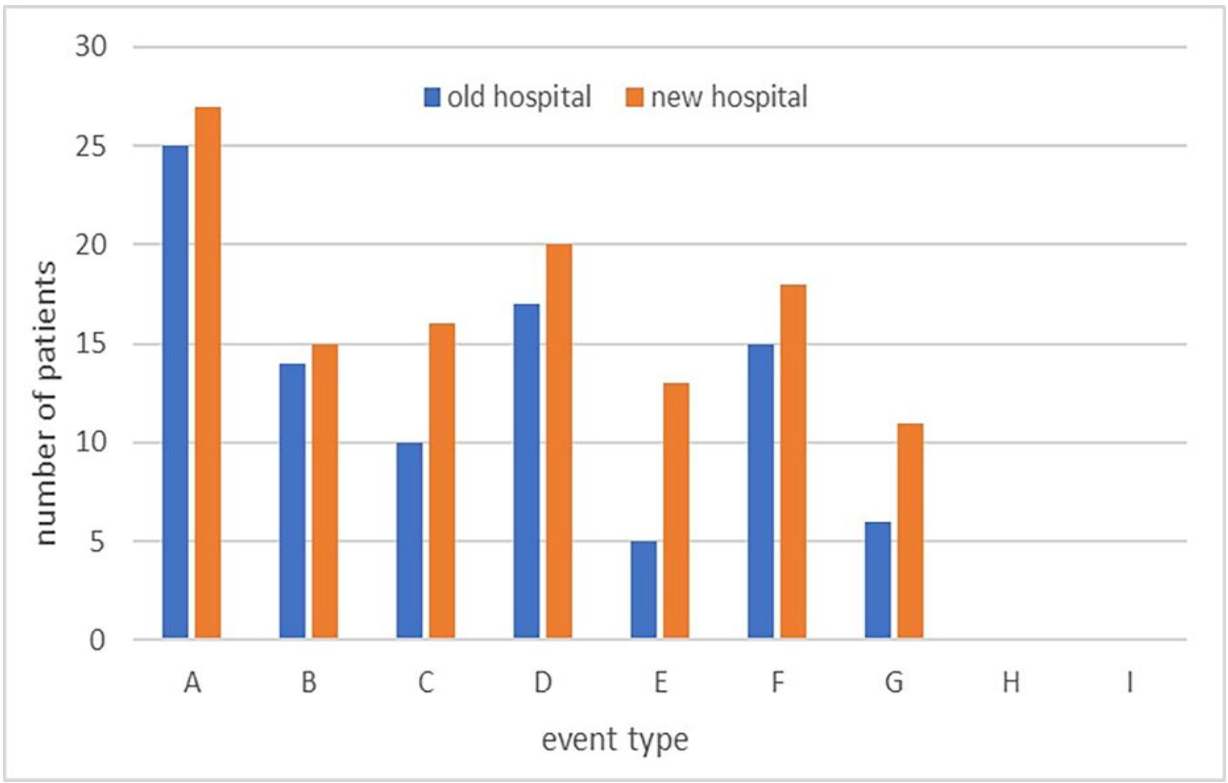
| N=40 | Period | Mean | Sd | SE | t | df | p |
|---|---|---|---|---|---|---|---|
| Sum of no-harm events (MERP B-D) | before move | .17 | .38 | .02 | -1.16 | 474.72 | .247 |
| | after move to a new hospital | .21 | .41 | .023 | | | |
| Sum of harm events (MERP E-I) | before move | .10 | .31 | .02 | -2.10 | 459.92 | .036 |
| | after move to a new hospital | .17 | .38 | .02 | | | |
| MERP_trial | before move | 50.98 | 85.62 | 5.53 | -2.69 | 450.72 | .007 |
| | after move to a new hospital | 75.15 | 110.07 | 7.11 | | | |
| AEs per 1.000 pat days | before move | 51.63 | 65.62 | 4.24 | -3.27 | 473.45 | .001 |
| | after move to a new hospital | 72.25 | 72.40 | 4.67 | | | |
| AEs per 100 admissions | before move | 38.33 | 48.72 | 3.14 | -2.59 | 477.63 | .010 |
| | after move to a new hospital | 50.00 | 50.10 | 3.23 | | | |
| Percentage of admissions with at least 1 AE | before move | 38.33 | 48.72 | 3.14 | -2.59 | 477.63 | .010 |
| | after move to a new hospital | 50.00 | 50.10 | 3.23 | | | |
| Sum of care errors (C1-C14) | before move | .54 | 1.157 | .074 | -1.68 | 478 | .094 |
| | after move to a new hospital | .72 | 1.23 | .080 | | | |
| Sum of medical errors (M1-M13) | before move | .24 | .49 | .03 | -1.21 | 469.19 | .229 |
| | after move to a new hospital | .30 | .57 | .037 | | | |

For statistical significance, we used alpha = 0.05. The analysis showed a significant increase in the sum of AEs after moving to a new hospital [sum of harm events (MERP E–I), MERP trial, AEs per 1000 patient days, AEs per 100 admissions, and percent of admissions with at least 1 AE]. Measures such as the sum of no-harm events, the sum of care errors, and the sum of medical errors did not show significant differences between the two periods. None of the

individual AEs showed significant differences in occurrence between the two periods. The results are provided in Supplement 1 (supplementary statistics on harm distribution).

Category E events approached statistical significance, suggesting an upward trend in the post-relocation period. Conversely, the cumulative frequency of harm-inducing events achieved statistical significance ($\chi$ 2 = 6.62; df = 1; P < .05; Cramer's V = 0.12), demonstrating that the new environment was associated with a higher proportion of potential errors than the legacy environment (50% vs. 38.33%). To evaluate and compare the predictive strength of the proposed metrics, a binary logistic regression model with forward stepwise elimination was constructed, utilizing the study period (pre- vs. post-move) as the dependent variable. Predictor variables were iteratively added based on statistical significance. The final model yielded a significant predictive capacity ($\chi$ 2 = 10.54; df = 1; P < .01) with a 75% and retained a single sufficient predictor. The rate of adverse events (AEs) per 1,000 patient-days emerged as the strongest predictor (Table 3). Based on the calculated odds ratio, an increase of one AE per 1,000 patient-days corresponded to a 1.004 - fold increase in the odds of the patient being admitted post-relocation. Furthermore, descriptive distribution analysis revealed an increased prevalence of harm across NCC MERP categories A through G following the transition to the new facility (Fig. 4).

**Figure 4.** Distribution of harm by category. Adapted from Adamovic et al., 2024 (19), reproduced under the Creative Commons CC-BY-NC license



## 4.2. Results of Swiss Study

CIRS evaluation

Analysis of the 2024 CIRS data indicated that only one adverse event was voluntarily reported within the surgical department (Table 5).

**Table 5.** Total CIRS reports registered Leuggern Hospital during the 2024 study period. Adapted from Adamovic et al., 2026 (27), reproduced under the Creative Commons CC-BY-NC license

| **Month** | **All reports** | **Surgical department** |
|---|---|---|
| January | 6 | 0 |
| February | 2 | 0 |
| March | 2 | 0 |
| April | 7 | 1 |
| May | 13 | 0 |
| June | 2 | 0 |
| July | 3 | 0 |
| August | 3 | 0 |
| September | 1 | 0 |
| October | 4 | 0 |
| November | 5 | 0 |
| December | 0 | 0 |
| ∑ | **48** | **1** |

AQC evaluation

Within the surgical department, a total of 283 inpatient operative procedures were performed, yielding 17 postoperative complications (comprising both surgical and non-surgical events). This corresponds to an overall complication rate of 6.01% among all surgical cases (Table 6). Of these events, six were classified as non-surgical complications, consisting of myocardial infarction (n = 1), pneumonia (n = 2), confirmed pulmonary embolism (n = 1), gastrointestinal hemorrhage (n = 1), and acute renal insufficiency (n = 1).

**Table 6.** AQC Annual Reporting Metrics (2024). Adapted from Adamovic et al., 2026 (27), reproduced under the Creative Commons CC-BY-NC license

| **Complication related to the case. Severity level** | **Number** | **Percentage** | **Percentage (B)** |
|---|---|---|---|
| No complications | 266 | 93.99 | 93.02 |
| Complication with conservative treatment | 10 | 3.53 | 5.58 |
| Complication with operative treatment | 6 | 2.12 | 1.04 |
| Complication with long-term damage with conservative treatment | 1 | 0.35 | 0.03 |
| Complication with long-term damage with operative treatment | | | 0.03 |
| Fatal complication | | | 0.30 |
| **Total** | **283** | **100.00** | **100.00** |

GTT evaluation

During the 2024 study period, the non-orthopedic surgical inpatient cohort comprised 596 patients. Among these, 58 individuals (9.73%) presented with at least one trigger according to the Institute for Healthcare Improvement (IHI) Global Trigger Tool methodology, revealing an aggregate total of 101 identified triggers. The most prevalent trigger occurred within the General Care module, specifically item G8 (transfer to a higher level of care), which was detected 29 times.

Subsequent analysis of the 58 trigger-positive patients revealed that 29 individuals met the criteria for the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) severity categories E through I. Because these specific categories denote patient harm resulting from an adverse event or complication, this indicates that approximately 4.87% of the total inpatient population (excluding orthopedic cases) experienced identifiable harm during hospitalization.

Conversely, the remaining 29 patients - revising the previously stated figure of 34 out of the 58 total trigger-positive individuals - did not exhibit any discernible harm upon clinical review. This finding underscores that while trigger tools serve as highly sensitive screening indicators,

they do not invariably correlate with verifiable patient injury, thereby necessitating secondary clinical adjudication to precisely assess the clinical significance of each flagged event.

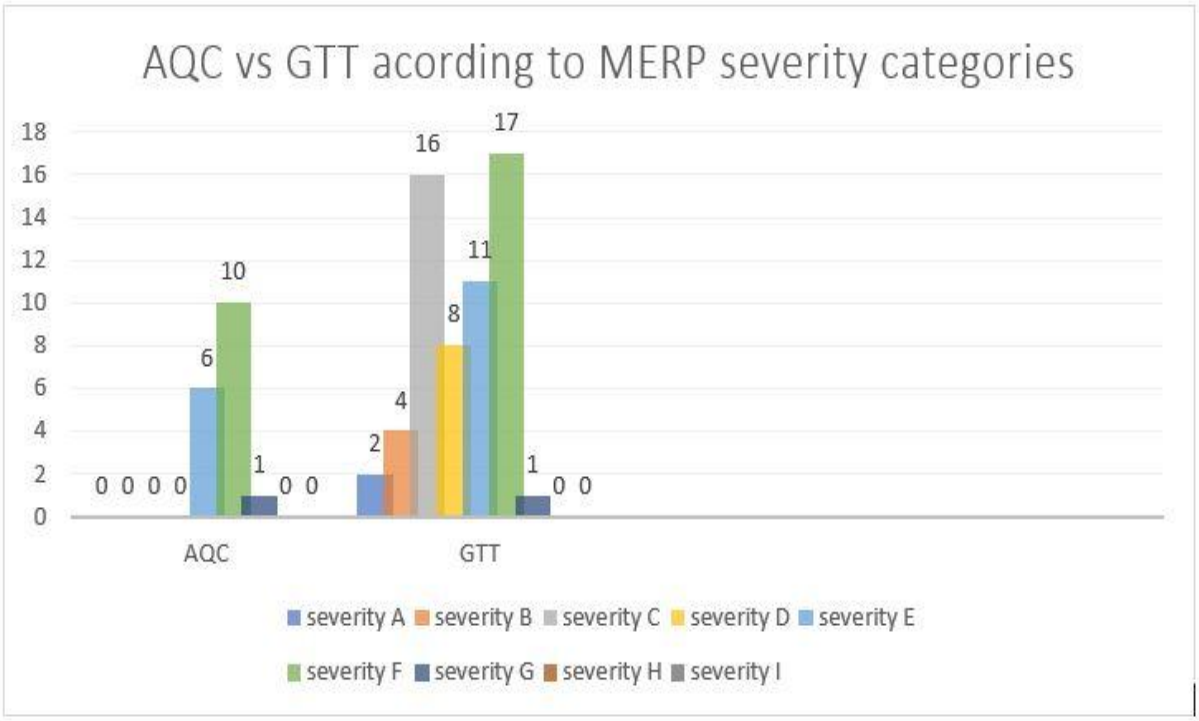
Distribution of harm by category comparing AQC and Global Trigger Tools

Following the analysis of AQC-identified complications and their subsequent classification via a modified National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index, all documented events fell exclusively within severity categories E through I. Consequently, based on the clinical registry data and this specific severity framework, none of the recorded complications were classified as having negligible or low potential for harm (categories A–D).

These findings from the AQC database were subsequently compared with the results obtained from the prior application of the IHI Global Trigger Tool. To visually synthesize the comparative data between these two quality assessment modalities, Figure 5 illustrates the frequency and severity distribution of events captured by each system, thereby facilitating a direct evaluation of their respective sensitivity in identifying patient harm.

**Figure 5.**

Visual comparison of the two quality assessment systems, AQC vs GTT, according to MERP severity categories. Adapted from Adamovic et al., 2026 (27), reproduced under the Creative Commons CC-BY-NC license



# 5. DISCUSSION

### 5.1. Statement of principal findings in the German study

While statistical analysis revealed no significant differences among individual adverse event (AE) types, a significant cumulative increase in total AEs was observed following the relocation to the new facility. The overall frequency of harm-inducing events similarly reached statistical significance, suggesting that the novel clinical environment was associated with an elevated rate of potential errors. Crucially, within the context of the Global Trigger Tool framework, a positive trigger serves merely as an index of a potential deviation in care rather than a definitive confirmation of injury. No documented events in either study cohort escalated to severity category H (requiring life-sustaining intervention) or category I (contributing to patient death). However, category E events - denoting temporary harm requiring intervention - approached statistical significance. It is hypothesized that the proliferation of post-relocation AEs is primarily attributable to modified organizational modalities and the redistribution of clinical responsibilities within the new facility. Administrative burdens and operational objectives intensified across several domains, inflating individual workloads. Concurrent adaptations to novel workflows, unfamiliar equipment, and altered organizational structures likely disrupted established clinical algorithms. Consequently, these findings suggest that institutional digitalization and modernization may expand administrative workloads independently of patient volume, thereby requiring a protracted transition period to overcome early systemic challenges.

### 5.2. Statement of principal findings in Swiss study

The Critical Incident Reporting System (CIRS) documented only a single entry during the study period. Subsequent root-cause analysis determined that this incident did not involve an adverse event or patient harm, but was instead entirely attributable to systemic organizational vulnerabilities.

Both alternative surveillance instruments (AQC and GTT) demonstrated a comparable distribution pattern, with the majority of identified events mapping to the higher tiers of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) severity index (categories E and F). Within the AQC dataset, the highest frequency of events clustered in severity category F (n = 10), followed by category E (n = 6). Similarly, the GTT framework captured the highest volume of events within severity category F (n = 17), followed by categories C (n = 16) and E (n = 11). Notably, the architectural parameters of the AQC clinical registry omit data collection for severity categories A through D.

The AQC registry appears less sensitive in detecting events situated within the lower severity strata (categories A–D). The GTT framework demonstrates a more comprehensive capture spectrum across the full continuum of the NCC MERP severity index. Comparative analysis of both surveillance modalities revealed a complete absence of the most critical patient safety events, specifically those indexed under severity categories H and I.

Conclusively, the GTT framework proves more sensitive than the AQC system within this specific evaluative context, identifying adverse events across a more comprehensive range of MERP severity levels. These observed proportions provide crucial insight into the clinical diagnostic threshold and the relative visibility of safety events within specific patient cohorts. Our objective was not to conduct a direct statistical head-to-head comparison of rates, but to illustrate how detection sensitivity varies when moving from a specialty procedural registry (AQC) to a broad surveillance tool (GTT).

This variance in diagnostic sensitivity is partly attributable to the divergent inclusion criteria of the two instruments: the GTT framework encompasses both operative and non-operative patient cohorts, whereas the AQC registry restricts its scope exclusively to patients undergoing surgical intervention within this clinical context.

The "Methodological Justification":

A foundational methodological premise of this investigation posits that patient safety cannot be adequately operationalized through a singular 'gold standard' metric. Instead, safety is conceptualized as a multidimensional construct, wherein disparate surveillance modalities offer distinct analytical windows into the manifestations of patient harm:

1. CIRS (Voluntary Reporting Framework): Serves as an indicator of organizational safety culture, quantifying the voluntary inclination of staff to document systemic anomalies and clinical variations.

2. The AQC Registry (Specialty-Specific Modality): Assesses the incidence of clinical complications within a predefined, high-risk procedural cohort, focusing on surgical outcomes.

3. GTT (Retrospective Active Surveillance Framework): Quantifies documented, evidence-based adverse events by systematically auditing the comprehensive inpatient clinical pathway.

While these systems utilize different denominators and definitions, comparing them through the MERP severity scale reveals where their detection capabilities overlap and where blind spots remain. We contend that the lack of overlap is not a methodological flaw, but a key finding

that demonstrates the necessity of combining multiple, heterogeneous systems to establish a complete safety profile.

### 5.3. Strengths and limitations in the German study

This investigation represents the first European study to evaluate variations in patient safety following a major hospital relocation, and it contributes to a limited body of international literature examining the impact of new healthcare infrastructure on clinical outcomes. By critically analyzing current practices and identifying innovative solutions, these findings can foster global awareness of institutional safety risks, ultimately driving environmental and structural modifications designed to mitigate such hazards. Furthermore, the insights generated from this research are highly generalizable to other acute care settings. A significant methodological strength of this study lies in the composition of its expert review panel, which consisted of three senior physicians whose consistent involvement throughout the entire study period minimized inter-rater variability and ensured rigorous data continuity.

Certain geographic and statistical constraints restrict the scope of these findings. Geographically, the sample cohort is confined to Upper Franconia, meaning these outcomes may not perfectly reflect national trends across Germany. However, Bavaria's substantial capital investment in healthcare digitalization and modernization represents a unique regional context that heavily supports patient safety initiatives. Methodologically, because this study utilizes an exploratory design with a constrained sample size, it lacks the statistical power required to draw definitive conclusions. Thus, any statistical discrepancies reported herein must be evaluated conservatively until broader confirmatory data become available. Third, the study is single-center, which is also a limitation. Fourth, the exact reasons behind the investigated phenomenon are not entirely clear. To better characterize these transitional trends, subsequent research is essential. Structurally, although this study utilizes a highly robust methodological framework, its scope is constrained to acute care environments, rendering the conclusions inapplicable to non-acute settings like psychiatric or rehabilitation hospitals. Lastly, the lack of reviewer blinding regarding the timeline represents a potential source of bias. Despite rigorous standardized training and the achievement of a high inter-rater reliability coefficient, the reviewers' explicit knowledge of whether a record belonged to the pre- or post-move cohort could theoretically compromise objectivity and introduce assessment bias.

### 5.4. Strengths and limitations in the Swiss study

By delineating the respective strengths, constraints, and operational utility of CIRS, GTT, and the AQC system, this study provides an essential contribution to patient safety publications. To the authors' knowledge, this work constitutes the first direct comparison of GTT and AQC performance metrics within a European clinical setting. Previously, a critical gap persisted in the literature regarding the concurrent application and mutual evaluation of these two prominent quality assurance frameworks in Europe.

The findings generated from this investigation carry significant operational implications for peer acute care institutions. Crucially, this study underscores the necessity of implementing two or more complementary surveillance systems within hospital infrastructure, as relying on a singular modality inevitably yields an incomplete assessment of the institutional safety landscape. Furthermore, a major methodological strength of this research lies in the composition and stability of the expert review panel. The team comprised three senior physicians whose diverse clinical specialties and comprehensive expertise significantly enhanced the rigor, precision, and internal validity of the adverse event identification process.

Several limitations of this study warrant consideration. First, the data derived from the AQC registry are restricted exclusively to in-hospital outcomes for surgical patients, omitting post-discharge tracking and non-operative cohorts. Second, the analysis is fundamentally dependent on the primary documentation completed by the operating physicians; because these source records were not externally validated, the potential for reporting or documentation bias cannot be entirely discounted. Third, the investigation was conducted as a single-center study, which may limit the external validity of the findings to other clinical environments. Fourth, the review panel was not blinded to the study periods during the GTT assessment, introducing a theoretical risk of detection bias. Finally, due to the absence of automated data interoperability within the hospital's clinical information system during the study timeframe, AQC metrics required manual validation by the surgical team to verify data integrity.

### 5.5. Interpretation within the context of the wider literature of German study

Prior research indicates that although sample size does not govern the distribution or severity of identified categories, a standard audit volume is sufficient to capture representative event rates, with the review of greater than 40 records per month offering negligible additional

benefit. While an initial appraisal might suggest that a cohort of 40 records monthly is insufficient to capture true variations in patient safety, this volume is consistent with established trigger tool protocols. Ultimately, the primary advantage of trigger-based frameworks over conventional adverse-event tracking modalities lies in this ability to generate actionable, high-yield safety data from an optimized, streamlined sample size[1]. Consistent with standard practice in most trigger tool studies, we employed a larger sample size of 40 records per month, compared to the usual sample size of 20 records[21].

Methodological guidelines for the standard trigger tool recommend a tri-partite review process consisting of two primary reviewers and a secondary adjudicator. While most published cohorts utilize specialized nurses as primary reviewers, alternative implementations have demonstrated the efficacy of a modified protocol featuring a single primary reviewer paired with one or two secondary reviewers. In this study, a similar modified approach was implemented to optimize resource allocation. The evaluation framework benefited from a dedicated, unchanging review team across the entire study timeframe. The extensive experience and long-term consistency of these identical reviewers served as an important mechanism to maintain uniform interpretive criteria during chart analysis[21].

Our findings align with a prior study indicating that the hospital length of stay (LOS) was twofold higher among patients who experienced adverse events (AEs)[22]. While not formally evaluated in this study, these unmeasured factors could substantially escalate expenditure at the new hospital site. The modernization and restructuring of a healthcare facility is a prolonged undertaking involving extensive alterations to the physical environment. Literature indicates that this period of transformation introduces significant operational stress for clinical staff, who face the dual challenge of maintaining rigorous patient safety standards while navigating infrastructure-related activities[23]. A comparative Australian study indicated that while patients reacted favorably to the transition to a modern facility, overall patient experience scores experienced a significant, transient decline during the immediate post-reopening months relative to baseline. The investigation identified four core themes mediating this transition: change uncertainty, communication effectiveness, staffing adequacy, and personnel resilience. Ultimately, despite initial operational disruptions, there was no evidence of a sustained, long-term negative impact on the overarching patient experience[24]. One study demonstrated that while clinical personnel initially experienced a sense of enthusiasm regarding the opening of the new hospital infrastructure, this sentiment was rapidly superseded by disappointment among certain cohorts upon entering the post-relocation phase[25].

### 5.6. Interpretation within the context of the wider literature of Swiss study

Previous research indicates that the number of AEs identified by the GTT was 8.3 times higher than in CIRS[13]. To understand how safety culture influences event reduction, it is essential to acknowledge the limitations of voluntary systems. A systematic review found that incident reporting systems captured only 7.0% of the AEs detected by the GTT, representing a tenfold gap in detection[13]. The current study confirms this discrepancy and reports an even larger reporting gap. This variation likely reflects the specific reporting culture within each institution. When a non-punitive 'speak-up' culture is not fully established, employees may hesitate to report incidents due to fear of reprisal or the sensitive nature of the events, even when anonymous platforms are available. Consequently, a large volume of adverse events and harm remains 'invisible' to traditional reporting methods.

Recent psychometric research, including the validation of the RoCAES scale by Ferorelli et al. (2025) and the foundational framework established by Wilson et al. (2008), emphasizes that the prevailing reporting climate serves as a critical determinant of adverse event capture efficacy. Specifically, dimensions of organizational culture, perceived blame, and procedural clarity heavily modulate workforce reporting behaviors[25,26]. The pronounced detection gap identified in the present study likely reflects these localized reporting climate challenges within the institutional setting. These data demonstrate that even well-established anonymous platforms cannot fully mitigate the psychological barriers inherent to voluntary disclosure - vulnerabilities that structured, active surveillance instruments like the AQC and GTT are systematically designed to bypass.

By deploying the GTT in tandem with specialized registries such as the AQC, healthcare institutions can transcend the inherent limitations of voluntary disclosure. This multi-modal approach facilitates the systematic identification of adverse events through objective, record-based surveillance, thereby constructing a more robust, transparent, and comprehensive institutional safety profile.

The foundational Global Trigger Tool methodology prescribes a review framework comprising two primary reviewers - predominantly experienced nursing professionals within the literature - and one secondary reviewer[7]. Subsequent investigations, however, have successfully adapted this paradigm, demonstrating the efficacy of a modified protocol that utilizes a single primary reviewer in conjunction with one or two secondary reviewers[3,13].

Extant literature evaluating the Global Trigger Tool (GTT) demonstrates its superior diagnostic sensitivity in identifying adverse events (AEs) compared to traditional incident-reporting systems[9,10,11]. However, while automated or manual triggers serve as efficient screening indicators, they do not universally correlate with actual patient harm. Secondary clinical adjudication is required to determine the structural significance of each identified event. Crucially, the GTT is not designed for exhaustive harm detection. Rather, consistent, longitudinal sampling provides a reliable baseline rate of harm, serving as a data-rich metric to reveal systemic opportunities for quality improvement. Because distinct detection modalities fundamentally capture non-overlapping cohorts of AEs, these findings underscore the necessity of methodological complementarity.

The IHI Surgical Trigger Tool provides a reliable mechanism for both estimating institutional adverse event rates and assessing the direct impact of patient safety interventions within surgical departments[22].

These results correspond with a broader body of literature advocating for the integration of heterogeneous surveillance methodologies to optimize patient safety monitoring and drive internal quality improvement initiatives[9].

### 5.7. Implications for policy, practice, and research of the German study

Decreasing AE rates in new hospitals or departments requires continuous staff education focused on electronic medical interfaces and patient safety. Although reducing administrative bureaucracy in Germany would be advantageous, it is not a realistic short-term solution. Therefore, mandating higher staffing levels in new facilities is a crucial alternative measure. Future research should investigate the exact timeframes required for a new clinical site to reach or surpass its pre-relocation safety levels. Additionally, future studies should focus on specific high-risk patient groups and utilize blinded record reviews to strengthen the methodology and eliminate observer bias.

Ultimately, the acute post-relocation period reveals that transitioning to a new facility generates distinct operational vulnerabilities that can compromise patient safety. Addressing them requires a multi-pronged approach that includes dedicated education, a long-term vision for administrative simplification, mandatory strategic staffing increases during transitions, and rigorous, targeted future research to refine our understanding and guide effective interventions.

The GTT, as demonstrated in our study, remains an indispensable tool for illuminating these critical safety landscapes.

### 5.8. Implications for policy, practice, and research of the Swiss study

From a policy perspective, regulatory bodies should establish guidelines or financial incentives encouraging healthcare institutions to deploy at least two complementary patient safety surveillance modalities, such as pairing voluntary incident reporting (CIRS) with active chart surveillance (GTT or AQC). Compliance with these multi-modal frameworks could be integrated directly into institutional accreditation standards or state funding models. Furthermore, governmental agencies should provide strategic resources for the development of interoperable healthcare information technology architectures that facilitate seamless data integration across disparate safety systems. Such infrastructure would optimize the operational efficiency and clinical utility of automated data extraction tools within registries like the AQC. Finally, the implementation of standardized training curricula for clinical reviewers - including specialized physicians and nursing personnel - is imperative to secure inter-rater reliability, data consistency, and overall review quality.

### 5.9. Navigating institutional change and detection sensitivity in European Healthcare

Evolution of a surgical department, whether through physical relocation or the creation of a new unit, fundamentally alters the "slices" of a hospital's defensive architecture. Following James Reason's Swiss Cheese Model, these transitions introduce new latent conditions. In the German study, the "Green Hospital" transition modernized the physical environment but inadvertently created "holes" in patient surveillance due to increased ward spread and the use of single-room isolation. Similarly, the Swiss study highlighted that a new department requires a lengthy "stabilization period" (16 months) before staffing and organizational processes mature.

A common finding across both studies is that institutional change acts as an error trigger. In Germany, moving to a new building led to a statistically significant increase in the total number of harms. This suggests that digitalization and modernization, while beneficial in the long term, initially undermine learned clinical algorithms and increase the cognitive workload of medical staff.

A central theme of this research is the stark discrepancy between voluntary reporting and objective detection. In the Swiss cohort, the Critical Incident Reporting System (CIRS) captured only one organizational issue, leaving a "tenfold gap" between what was reported and what occurred. A comparative analysis of the Assurance of Quality in Surgery (AQC) registry and the Global Trigger Tool (GTT) underscores that patient safety constitutes a inherently multidimensional construct requiring diverse evaluative frameworks. While the AQC secures a vital window into specialty-specific procedural complications (primarily Category F harms), the GTT serves as a broad-spectrum "safety scanner." Using the UK version of the GTT—which employs 32 categories rather than the standard 27—the study identified a higher volume of "hidden" harm, particularly in MERP categories E and F. This confirms that specialty registries like the AQC are excellent for procedural tracking, but they must be supplemented by active record-review tools like the GTT to achieve a comprehensive safety profile.

Both the German and Swiss investigations found no catastrophic "Never Events" (Severity H and I). Instead, the data show that the primary threat to patient safety during transitions is Severity Categories E and F. These categories represent harms that require intervention or prolong the hospital stay. This common finding suggests that while European acute hospitals have robust defenses against death, they are vulnerable to process-related errors that arise when organizational modalities are in flux.

Synthesizing these two studies demonstrates that patient safety cannot be captured by any single "gold standard" metric. The methodological justification for this research relies entirely on the necessity of utilizing heterogeneous systems:

1. CIRS for measure safety culture.
2. AQC or similar systems or registers to measure procedural quality.
3. GTT to quantify objective, record-based adverse events

For policy and practice, this implies that hospital redevelopments or new departmental foundations must be accompanied by mandatory staffing increases and at least dual-system surveillance, ideally 3-system surveillance. Governments and accrediting bodies should incentivize the implementation of at least two complementary systems. Relying on a single registry or a voluntary reporting platform creates a dangerous "illusion of safety," masking the latent vulnerabilities that naturally arise during the modernization of European healthcare.

# 6. CONCLUSION

Our research conducted in Germany reveals that newly opened or relocated hospitals face a temporary but sharp increase in Adverse Events (AEs) and patient harm. This trend is particularly prominent during the first six months of operation, indicating a phase of operational instability right after the transition. Although the aggregate volume of AEs and injuries was substantially higher, individual subcategories of harm (evaluated using the NCC MERP index) showed no significant differences. These results highlight that close, uninterrupted monitoring of patient safety risks is essential immediately following any hospital relocation.

After analyzing the data, we've concluded that the difference in AEs at the new hospital likely stems from changes in structural configurations and the redistribution of individual obligations inherent to a unfamiliar setting. Moving to a new facility isn't just about changing buildings. It often involves new workflows, altered communication pathways, unfamiliar equipment locations, and potentially revised roles or reporting structures. Even proficient personnel can encounter a formidable adjustment period when acclimating to novel operational workflows and structural configurations. These shifts can create conditions where errors are more likely, leading to an increase in identified AEs.

This study further underscores the Global Trigger Tool's (GTT) value for understanding the specific issues that arise during transitional periods. The GTT's systematic, retrospective review process, which relies on predefined "triggers," enables precise identification and measurement of AEs that might otherwise go undetected by traditional reporting systems. Our findings should serve as a compelling reason for more German hospitals to adopt the GTT methodology. Its implementation offers an effective way to measure patient harm, learn from adverse events, and enhance patient safety, particularly during critical phases of organizational change, such as a new hospital opening.

The Swiss study at Asana Spital Leuggern highlighted a profound "detection gap" between voluntary and active surveillance systems. While the CIRS is essential for fostering a 'Speak Up' culture, it often fails to capture the full spectrum of patient harm, particularly in newly established departments where staff may be overwhelmed by high cognitive loads. The GTT proved to be a significantly more sensitive "safety scanner," detecting a broader range of adverse events across all severity levels than both CIRS and the specialty-focused AQC registry. This lack of overlap between systems is not a methodological failure but confirmation that no single "gold standard" can capture every aspect of patient safety.

The findings from both studies suggest that relying on a single safety system provides an incomplete and potentially misleading picture of the safety landscape. To manage risks during periods of change - whether moving into a new building or establishing a new surgical unit - hospitals must adopt a proactive, multi-pronged approach:

- Mandatory Multi-System Monitoring: Implement at least two complementary surveillance systems (e.g., CIRS alongside GTT) to ensure that technical complications and systemic vulnerabilities are captured.
- Strategic Staffing and Training: Recognizing that digitalization and modernization increase administrative workloads, hospitals should prioritize mandatory staffing increases and targeted IT training during transition periods.
- Active Safety Culture: Beyond anonymous platforms, hospitals must address the psychological barriers to reporting by fostering a mature reporting climate that moves beyond the "person approach" toward system-wide analysis.

In conclusion, while modern environments offer the potential for enhanced care, they do not inherently guarantee safety during the critical "stabilization phase." The Global Trigger Tool remains an indispensable active tool for illuminating hidden risks. To establish a more thorough, transparent, and adaptive safety infrastructure in acute care settings, future operational strategies must endorse the synthesis of heterogeneous patient safety systems.

# 7. SUMMARY

The framework of this dissertation consists of two complementary studies that utilize the Global Trigger Tool (GTT) to evaluate and systematically optimize patient safety protocols. The research highlights the risks associated with hospital or departmental transitions - whether moving to a new building or establishing a new department - and the need for multiple safety monitoring systems.

Objective :

The primary objective of this doctoral research is to investigate whether patient safety diminishes during the launch of a new hospital or department, even when operating within modern facilities and conditions. Additionally, this research evaluates the diagnostic sensitivity of the IHI Global Trigger Tool (GTT) in uncovering adverse events, using the AQC registry and the voluntary CIRS as benchmarks for comparison.

Materials and methods :

Treatment-related adverse events (AEs) were incorporated into the analysis to assess the aggregate incidence of complications stemming from both clinical interventions and pharmaceutical therapies. Following IHI Global Trigger Tool (GTT) guidelines, eligible cases required completed documentation, a minimum hospital stay of 24 hours, and formal inpatient admission. The detected adverse events were then sorted into the 27 IHI GTT categories. Forty medical charts were chosen at random every month, spanning an observation window of six months prior to and six months following the relocation to the new facility.

We conducted a retrospective review covering the full calendar year of 2024 (January 1 to December 31). Data were evaluated across three surveillance channels: first, a comprehensive review of all voluntary submissions via the Critical Incident Reporting System (CIRS). Second, an evaluation of 20 randomly chosen monthly medical records for surgical inpatients utilizing the GTT (restricted to adults aged 18+ with stays over 24 hours, excluding orthopedic patients). Third, manual data entry and thorough quality verification for all operated surgical inpatients via the Assurance of Quality in Surgery (AQC) registry, excluding orthopedic cases. The outcomes from all three methods were subsequently compared.

Results:

While individual types of AEs showed no statistically significant differences upon analysis, the aggregate number of adverse events was significantly greater in the period succeeding the hospital relocation. Overall harm counts showed a statistically significant difference ($\chi$ 2 = 6.62; df = 1; P < .05; Cramer's V = 0.12). Specifically, new settings generated a significantly greater share of potential errors at (50%) compared to (38.33%) in older settings Reviewing the 2024 CIRS records yielded just one reported case for the surgical department. Meanwhile, the AQC database documented 283 inpatient surgeries, with complications arising in 17 instances (6.01%). Of the 596 stationary patients managed in 2024, the GTT flagged 58 individuals (9.73%) as having experienced one or more adverse events. An intersection of the GTT and AQC datasets identified an overlap of exactly 14 adverse event entries..

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Conclusion :

Based on our data, the newly established medical facility exhibits a degree of systemic vulnerability during the initial six months post-opening.

Although the AQC provides substantial value for surgical cohorts, the GTT yields broader clinical applicability. Its strength is derived from a systematic record review process that encompasses both operated and non-operated patients to capture adverse events. Given that voluntary reporting alone proves insufficient for detailed harm detection, hospitals should deploy an additional, structured safety tool to reinforce current CIRS reporting channels.

# 8. LAY SUMMARY

We often think that moving into a brand - new hospital building with state-of-the-art facilities automatically makes patients safer. However, any big transition - like moving to a new building or opening a new department - can actually create new problems that put patient safety at risk. This study investigated whether a modern environment really leads to fewer medical errors and which "monitoring tools" are best at catching those errors.

Objective: What We Wanted to Find Out:

The research had two main objectives:

1. Safety Check: To see if patient safety deteriorates during the first few months in a new hospital building.
2. To test which method is best at finding "Adverse Events" (medical mistakes or harms). We compared three systems:
    - The Global Trigger Tool (GTT): A deep-dive review of patient records.
    - AQC: A specialized database for tracking surgical quality.
    - CIRS: A system where staff voluntarily report mistakes they notice.

What We Did (Materials and Methods):

To track patient safety during the move, we conducted a retrospective study throughout 2018, comparing data from the six months before and six months after the transition to the new building. We identified treatment-related errors and medication issues by performing a "deep-dive" review of 40 randomly selected patient records each month, specifically targeting adult patients who stayed at least 24 hours. These events were then categorized using a standardized 27-point safety checklist.

This detailed record review was cross-referenced with two other sources in a new study in 2024: the voluntary reports submitted by hospital staff through an incident reporting system and specialized surgical data that we manually entered and double-checked for accuracy. By combining these three different monitoring methods, we were able to compare how effectively each system found errors during the hospital's transition period.

What We Found (Results):

The results of the study showed that while individual types of medical errors didn't change much, the total number of errors and patient harms significantly increased after the move. In

the old hospital, the rate of potential errors was around 38%, but this increased to 50% in the new building.

When we compared our three tracking methods for 2024, the differences were striking. The voluntary reporting system used by staff was the least effective, catching only one case all year. In contrast, the specialized surgical database recorded complications in 17 out of 283 surgeries (about 6%). However, the most thorough method - the record "deep-search" - found that nearly 10% of all patients (58 out of 596) experienced at least one medical error. Interestingly, the different systems rarely caught the same mistakes, with only 14 cases overlapping between the surgical database and the record reviews

What This Means (Conclusion):

Our findings suggest that a new hospital building may actually be slightly less safe during its first six months as the staff and systems adjust. While the surgical database (AQC) is excellent for tracking patients who have operations, the "deep-search" record review (GTT) is even more powerful because it catches errors for all types of patients, whether they had surgery or not.

The most important lesson is that waiting for staff to voluntarily report their own mistakes is not enough to keep patients safe. We strongly recommend that hospitals use a more proactive, systematic review process to catch the errors that voluntary reporting often misses.

# 9. CROATIAN SUMMARY

# Novo bolničko okruženje i sigurnost pacijenata

Ova doktorska disertacija sastoji se od dvije međusobno povezane studije koje procjenjuju i unapređuju sigurnost pacijenata koristeći metodu Global Trigger Tool (GTT). Istraživanje naglašava rizike povezane s bolničkim ili odjelnim tranzicijama – bilo da se radi o preseljenju u novu zgradu ili osnivanju novog odjela – te ukazuje na potrebu za višestrukim sustavima nadzora sigurnosti.

Cilj:

Prvi cilj je utvrditi opada li razina sigurnosti na početku rada nove bolnice ili odjela, unatoč modernom okruženju i uvjetima. Drugi cilj ove teze je procijeniti osjetljivost metode GTT (Instituta za unapređenje zdravstvene zaštite - IHI) u otkrivanju štetnih događaja u usporedbi s kirurškom bazom podataka AQC (Assurance of Quality in Surgery) i sustavom dobrovoljne prijave incidenata CIRS (Critical Incident Reporting System).

Metode:

Uključeni su štetni događaji (AE) povezani s liječenjem kako bi se procijenio ukupan broj štetnih događaja proizašlih iz medicinske skrbi i primjene lijekova. Medicinska dokumentacija morala je biti zaključena i potpuna, duljina boravka najmanje 24 sata, a pacijent formalno primljen u bolnicu (prema preporuci IHI GTT-a). Identificirani štetni događaji grupirani su u 27 kategorija IHI GTT-a. Nasumično smo pregledali 40 povijesti bolesti mjesečno, tijekom 6 mjeseci prije i 6 mjeseci nakon preseljenja u novu bolnicu.

Provedena je retrospektivna analiza tijekom 12 mjeseci, od 1. siječnja do 31. prosinca 2024. Analizirani su podaci iz tri metode nadzora:

1. Pregledani su svi incidenti prijavljeni putem sustava dobrovoljne prijave (CIRS).
2. Za metodu GTT nasumično je odabrano 20 mjesečnih zapisa kirurških pacijenata (dob 18+, boravak min. 24 sata, isključujući ortopediju).
3. Podaci AQC baze ručno su uneseni za sve operirane kirurške pacijente (isključujući ortopediju), uz strogu provjeru kvalitete od strane autora. Nalazi ovih sustava su potom uspoređeni.

Rezultati :

Statistička analiza nije pokazala značajne razlike u pojedinačnim štetnim događajima. Ukupan zbroj štetnih događaja bio je statistički veći nakon preseljenja u novu bolnicu. Ukupan broj nanesenih šteta dosegao je statističku značajnost ($\chi$ 2 = 6.62; df = 1; P < .05; Cramer's V = 0.12), što ukazuje na to da nova okruženja "aktiviraju" značajno više potencijalnih pogrešaka (50%) u usporedbi sa starim okruženjima (38,33%).

Evaluacija CIRS-a za 2024. godinu otkrila je samo jedan prijavljeni slučaj na kirurškom odjelu. Istovremeno, statistika AQC-a pokazala je 283 obavljena kirurška zahvata, od kojih je 17 (6,01%) rezultiralo komplikacijama (kirurškim i nekirurškim). Nadalje, među 596 stacionarnih pacijenata liječenih u 2024. godini, GTT je identificirao 58 pacijenata (9,73%) s barem jednim štetnim događajem. Broj preklapajućih slučajeva između GTT-a i AQC sustava izvješćivanja bio je 14.

Zaključak :

Prema našim nalazima, nova bolnica čini se blago nesigurnom u prvih 6 mjeseci nakon otvaranja

# 10. CROATIAN LAY SUMMARY

# Novo bolničko okruženje i sigurnost pacijenata

Često mislimo da preseljenje u potpuno novu bolničku zgradu s najsuvremenijom opremom automatski znači veću sigurnost za pacijente. Međutim, svaka velika tranzicija – poput selidbe u novu zgradu ili otvaranja novog odjela - zapravo može stvoriti nove probleme koji ugrožavaju sigurnost pacijenata. Ovo istraživanje ispitalo je vodi li moderno okruženje doista do manjeg broja medicinskih pogrešaka i koji su „alati za nadzor“ najbolji u otkrivanju tih pogrešaka.

Cilj - Što smo željeli saznati :

Istraživanje je imalo dva glavna cilja:

1. Provjera sigurnosti**:** Utvrditi pogoršava li se sigurnost pacijenata tijekom prvih nekoliko mjeseci u novoj bolničkoj zgradi.
2. Usporedba alata: Testirati koja je metoda najbolja u pronalaženju „štetnih događaja“ (medicinskih pogrešaka ili šteta). Uspoređili smo tri sustava:
    - Global Trigger Tool (GTT): Dubinska analiza medicinske dokumentacije pacijenata.
    - AQC: Specijalizirana baza podataka za praćenje kvalitete kirurških zahvata.
    - CIRS: Sustav putem kojeg osoblje dobrovoljno prijavljuje pogreške koje uoči.

Što smo radili (materijali i metode):

Kako bismo pratili sigurnost pacijenata tijekom preseljenja, proveli smo retrospektivnu studiju tijekom 2018. godine, uspoređujući podatke iz šest mjeseci prije i šest mjeseci nakon prijelaza u novu zgradu. Pogreške povezane s liječenjem i problemima s lijekovima identificirali smo provodeći „dubinsku analizu“ 40 nasumično odabranih povijesti bolesti mjesečno, ciljajući odrasle pacijente koji su u bolnici boravili najmanje 24 sata. Ti su događaji potom kategorizirani pomoću standardizirane liste od 27 sigurnosnih točaka.

Ovaj detaljan pregled dokumentacije uspoređen je s dva druga izvora u novoj studiji iz 2024. godine: dobrovoljnim prijavama bolničkog osoblja kroz sustav za izvješćivanje o incidentima i specijaliziranim kirurškim podacima koje smo ručno unijeli i dvostruko provjerili. Kombiniranjem ove tri različite metode nadzora, mogli smo usporediti koliko je učinkovito svaki sustav pronalazio pogreške tijekom razdoblja tranzicije.

Što smo pronašli (rezultati):

Rezultati studije pokazali su da, iako se pojedinačne vrste medicinskih pogrešaka nisu bitno promijenile, ukupni broj pogrešaka i šteta nanesenih pacijentima značajno se povećao nakon preseljenja. U staroj bolnici stopa potencijalnih pogrešaka bila je oko 38%, dok se u novoj zgradi taj broj popeo na 50%.

Kada smo usporedili naše tri metode praćenja za 2024. godinu, razlike su bile zapanjujuće. Sustav dobrovoljne prijave (CIRS) bio je najmanje učinkovit, zabilježivši samo jedan slučaj tijekom cijele godine. Nasuprot tome, specijalizirana kirurška baza (AQC) zabilježila je komplikacije u 17 od 283 operacije (oko 6%). Međutim, najiscrpnija metoda – „dubinska analiza“ dokumentacije (GTT) – otkrila je da je gotovo 10% svih pacijenata (58 od 596) doživjelo barem jednu medicinsku pogrešku. Zanimljivo je da su različiti sustavi rijetko hvatali iste pogreške; samo se 14 slučajeva preklapalo između kirurške baze podataka i pregleda dokumentacije.

Što to znači (zaključak):

Naši nalazi sugeriraju da nova bolnička zgrada zapravo može biti malo manje sigurna tijekom prvih šest mjeseci, dok se osoblje i sustavi ne prilagode. Iako je kirurška baza podataka (AQC) izvrsna za praćenje pacijenata koji idu na operaciju, dubinska analiza dokumentacije (GTT) još je moćnija jer otkriva pogreške kod svih vrsta pacijenata, bez obzira na to jesu li operirani ili ne.

Najvažnija lekcija je da čekanje da osoblje dobrovoljno prijavi vlastite pogreške nije dovoljno za sigurnost pacijenata. Snažno preporučujemo bolnicama korištenje aktivnijeg, sustavnog procesa pregleda kako bi se otkrile pogreške koje dobrovoljno izvješćivanje često propušta.

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# 12. CURRICULUM VITAE

## Curriculum Vitae | Ivan Adamovic

### Personal details

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### Education

| | |
|---|---|
| 16th March 2024 | FEBS Coloproctology (exam), Munich, Germany |
| 14th February 2023 | Fellow EAFWH post-graduate education |
| 30th July 2021 | Wound-expert doctor ICW (exam), Duisburg, DE |
| 22nd October 2020 | Visceral-surgery surgeon (exam), Munich, Germany |
| 24th March 2020 | Subspecialty Proctology (exam), Jena, Germany |
| 11th July 2016 | General surgeon (exam), Munich, Germany |
| 1st Dec 2014 | Emergency medicine doctor (exam), Munich, DE |
| 14th Jan 2013 | State exam Germany, Munich, Germany |
| 31st May 2005 | State exam Serbia, Belgrade, Serbia |
| October 1997-March 2004 | Medical School, Belgrade University, Serbia |

### Ongoing Education

PhD in Evidence-based Medicine, Medical School Split University, Croatia

### Clinical and Work Experience

IN SWITZERLAND:

**September 2023 – today**
Surgical department in Leuggern hospital, Kommendeweg 12, 5316 Leuggern, CH

Job title: Senior specialist (Leitender Arzt) - Deputy Chief of Surgery

Job description and main tasks:

- Development and leadership of the outpatient surgery department

- Development and leadership of the proctology and incontinence center
- Development and leadership of the wound center
- Organization and co-leadership of the surgical department with the Chief of Surger

IN GERMANY:

**Feb 2012 - Nov 2018**
• The department of General and abdominal surgical, General hospital Lichtenfels, Prof.-Arneth-St. 2, Lichtenfels, Germany

Job title: Surgical Resident: July 2012 - July 2016; General Surgeon: August 2016 -November 2018

**Dez 2018 - Mar 2020**
• General, abdominal, and proctology surgical department in General Hospital Sonneberg, Neustadter St. 61, Sonneberg, Germany

Job title: General surgeon, proctologist

**June 2020 – Aug 2023**
• General and abdominal surgical department in Sozialstiftung Bamberg hospital & MVZ Bamberg, Buger St. 80, Bamberg, Germany

Job title: General and visceral surgeon, proctologist, Wound-expert

Job description and main tasks:
- Development and leadership of the outpatient surgery department
- Development and leadership of wound management and proctology
- Development of the pelvic floor center and sacral neuromodulation for fecal incontinence

**Secondary position / Part – time**

**Feb 2015 – Aug 2023**
• Region Oberfranken, Bavaria, Germany

Job description: Emergency physician, Part-time: After-hours and weekends, 48 hours/month; Honorary position

**April 2017-Nov 2020**
• Medical School for Nurses, Prof.-Arneth Straße 5, Lichtenfels, Germany

Job description: Teacher of Surgery; Provided theoretical and practical surgical education to nursing staff

IN SERBIA:

**June 2007 - Feb 2012**
• The Surgical department in The General hospital of Pozarevac, Bratstva i Jedinstva St. no.109, Pozarevac, Serbia, and Clinical Center of Serbia, Pasterova St. no. 2, Belgrade, Serbia

Job title: General surgery resident
**April 2005 - Aug 2005 & June 2006 - May 2007**
• The Emergency department in The General Hospital in Pozarevac, Bratstva i Jedinstva St. no.109, Pozarevac, Serbia

Job title: Medical doctor in the emergency department

Job description: Triage, treatment, and admission of patients in the Emergency Department

**April 2004 - April 2005**
• Health Center Pozarevac, Jovana Serbanovica St. No. 10-12, Pozarevac, Serbia

Job title: Medical Doctor, Internship Year

Job description: Clinical Experience in: Internal Medicine, Surgery, General Medicine, Epidemiology, Pediatrics, Gynecology, Otorhinolaryngology, Ophthalmology, Neurology, Psychiatry, Infectious Diseases, Dermatology, Physical Medicine, Forensic Medicine

**Secondary position / Part – time**

**Sep 2004-August 2005**
• Medical School for Nurses Pozarevac, Lole Ribara St. No. 6-8, Pozarevac, Serbia

Job description: **Anatomy and Pathology Teacher -** Provided theoretical and practical surgical

**Publications**

1. Adamovic I, Mäder HD, Golowan A, Michael K, Sivakumar T, Lucian J, Krähenbühl L. The use of intact fish skin grafts in the treatment of acute complicated bite wounds: a case report. J Surg Case Rep. **2026 Mar**;2026(3):rjag197. doi: 10.1093/jscr/rjag197. - 1. Author

2. Adamović I, Krähenbühl L, Brachmann J. The Importance of Using Multiple Safety Evaluation Systems in Hospitals: A Comparison of Critical Incident Reporting System (CIRS), Assurance of Quality in Surgery (AQC), and the Global Trigger Tool (GTT). J Patient Saf. **Feb 2026.** - 1. Author

3. Necessity of Surgery for Cystic Duct Remnant Syndrome; Journal of Clinical Case Reports, **November 2024**, DOI: 10.37421/2165-7920.2024.14.1622; - 1. Author

4. Measuring the overall development of patient safety in a new hospital using trigger tools; International Journal for Quality in Health Care, **July 2024**, 36(3), mzae064; DOI: https://doi.org/10.1093/intqhc/mzae064; - 1. Author

5. Vaccination Attitudes and Impact of the Second Covid -19 Lockdown on Mood, Mental State, and Exercise Habits in Germany, A Cross-Sectional-Study – 3. Author **Sep 2021**

6. Regional treatment-analysis about colorectal cancer, Forum, official newspaper of German Cancer Society, v90 - 1. Author **Feb 2017**

7. Loop colostomy vs Hartmann procedure and primary resection and anastomosis in the management of obstructing cancer of the left colon-advantages in mortality rate and postoperative complications rate." 13th World Congress on Gastrointestinal Cancer, Barcelona, Spain; Annals of Oncology 22, v27–v133, 2011 - 1. Author **June 2011**

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## Languages

- Mother tongue: Serbian, Croatian, Bosnian

| • Other languages | Reading Skills | Writing Skills | Verbal Skills |
|---|---|---|---|
| • GERMAN | Excellent | Excellent | Excellent |
| • ENGLISH | Excellent | Excellent | Excellent |
| • RUSSIAN | Good | Good | Good |

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## Hobbies

- Sport (basketball, swimming, football, table tennis)
- Traveling
- Chess (master candidate)
- Reading and writing books

## Technical skills

- Excellent in Word, Excel, PowerPoint

- Orbis, Medico, PACS, PDMS
- PubMed, UpToDat

**References**

- Prof. Lukas Krähenbühl, Chief of Surgery, Hospital Leuggern, Switzerland
- Prof. Johannes Brachmann, Dean of Medical School Regiomed-Split, Germany / Croatia
- Prof. Georg Pistorius, Chief of Surgery, Sozialstiftung Bamberg Hospital, Germany
- Dr. Johannes Jongen, surgeon & proctologist, co-owner of Proctology Center Kiel, Germany
- Dr. Matthias Eichhorn, Chief of Surgery, Sonneberg Hospital, Germany
- Dr. Reinhard Ruppert, Chief of Surgery, Neuperlach Hospital, Germany – retired
- Prof. Emiilio Dominguez, Chief of Surgery, Lichtenfels Hospital, Germany
- Prof. Bernhard Greger, Chief of Surgery, Lichtenfels Hospital, Germany – retired
- Dr. Friedrich W. Müller, Chief of Orthopedic/Trauma, Lichtenfels, Germany – retired
- Dr. Christoph Sommer, Chief of Anesthesiology, Klinikum Königsberg, Germany
- Dr. Christian Müller-Osten, chief-emergency service, reg. Lichtenfels, DE
- Dr. Nenad Veljkovic, Chief of Surgery, General Hospital Pozarevac, Serbia – retired
- Prof. Dr. sci med. Zivan Maksimovic, Medical Faculty, Belgrade, Serbia – retired
- Dr. Milance Vuckovic, chief of Emergency Department, Hospital Pozarevac, Serbia

# 13. SUPLEMENT

## Supplement I

### Harm distribution

We have compared two periods, before and after the move, on each type of adverse events by Chi-square test. None of the individual adverse events did not show significantly different appearance in two periods. Category E are close to statistical significance level, indicating higher appearance in a period after the move.

| event type | period | No | Yes | Total | $\chi^2$ | df | p |
|---|---|---|---|---|---|---|---|
| A | before move | 215 | 25 | 240 | .086 | 1 | .769 |
| | after move to a new hospital | 213 | 27 | 240 | | | |
| | Total | 428 | 52 | 480 | | | |
| B | before move | 226 | 14 | 240 | .037 | 1 | .848 |
| | after move to a new hospital | 225 | 15 | 240 | | | |
| | Total | 451 | 29 | 480 | | | |
| C | before move | 230 | 10 | 240 | 1.464 | 1 | .226 |
| | after move to a new hospital | 224 | 16 | 240 | | | |
| | Total | 454 | 26 | 480 | | | |
| D | before move | 223 | 17 | 240 | .264 | 1 | .608 |
| | after move to a new hospital | 220 | 20 | 240 | | | |
| | Total | 443 | 37 | 480 | | | |
| E | before move | 235 | 5 | 240 | 3.694 | 1 | .055 |
| | after move to a new hospital | 227 | 13 | 240 | | | |
| | Total | 462 | 18 | 480 | | | |
| F | before move | 225 | 15 | 240 | .293 | 1 | .588 |
| | after move to a new hospital | 222 | 18 | 240 | | | |
| | Total | 447 | 33 | 480 | | | |
| G | before move | 234 | 6 | 240 | 1.525 | 1 | .217 |
| | after move to a new hospital | 229 | 11 | 240 | | | |
| | Total | 463 | 17 | 480 | | | |
| H | before move | 240 | 0 | 240 | - | - | - |
| | after move to a new hospital | 240 | 0 | 240 | | | |
| | Total | 480 | 0 | 480 | | | |
| I | before move | 240 | 0 | 240 | - | - | - |
| | after move to a new hospital | 240 | 0 | 240 | | | |
| | Total | 480 | 0 | 480 | | | |