Z. Evid. Fortbild. Qual. Gesundh. wesen (ZEFQ) 184 (2024) 18–25

Contents lists available at ScienceDirect

Z. Evid. Fortbild. Qual. Gesundh. wesen (ZEFQ)

journal homepage: http://www.elsevier.com/locate/zefq

Qualität und Sicherheit in der Gesundheitsversorgung / Quality and Safety in Health Care

Implementation of a comprehensive clinical risk management system in a university hospital

Implementierung eines umfassenden klinischen Risikomanagementsystems in einem Universitätsklinikum

Wolfgang Buchberger [a,*], Marten Schmied [b], Michael Schomaker [c,d], Anca del Rio [e], Uwe Siebert [a,f,g]

[a] *UMIT TIROL- University for Health Sciences and Technology, Institute of Public Health, Medical Decision Making and HTA, Hall in Tirol, Austria*
[b] *UMIT TIROL- University for Health Sciences and Technology, Institute of Nursing Science, Hall in Tirol, Austria*
[c] *Ludwig-Maximilians-Universität München, Department of Statistics, Munich, Germany*
[d] *University of Cape Town, Centre of Infectious Disease Epidemiology and Research, Cape Town, South Africa*
[e] *Strategy and Global Development Advisor, EIT Health Germany-Switzerland, Munich, Germany*
[f] *Harvard T.H. Chan School of Public Health, Center for Health Decision Science and Departments of Epidemiology and Health Policy & Management, Boston, MA, USA*
[g] *Massachusetts General Hospital, Harvard Medical School, Institute for Technology Assessment and Department of Radiology, Boston, MA, USA*

ARTICLE INFO

Article History:
Received: 5 February 2023
Received in revised form: 20 November 2023
Accepted: 22 November 2023
Available online: 10 January 2024

Keywords:
Patient safety
Clinical risk management
Risk assessment
Adverse events
Incident reporting

ABSTRACT

Background: Adverse events during hospital treatment are common and can lead to serious harm. This study reports the implementation of a comprehensive clinical risk management system in a university hospital and assesses the impact of clinical risk management on patient harms.
Methods: The clinical risk management system was rolled out over a period of eight years and consisted of a training of interdisciplinary risk management teams, external and internal risk audits, and the implementation of a critical incident reporting system (CIRS). The risks identified during the audits were analyzed according to the type, severity, and implementation of preventive measures. Other key figures of the risk management system were obtained from the annual risk reports. The number of liability cases was used as primary outcome measurement.
Results: Of the 1,104 risks identified during the risk audits, 56.2 % were related to organization, 21.3 % to documentation, 15.3 % to treatment, and 7.2 % to patient information and consent. The highest proportion of serious risks was found in the category organization (22.7 %), the lowest in the category documentation (13.6 %). Critical incident reporting identified between 241 and 370 critical incidents per year, for which in 79.5 % to 83% preventive measures were implemented within twelve months. The frequency of incident reports per department correlated with the number of active risk managers and risk team meetings.

Compared with the years prior to the introduction of the clinical risk management system, an average annual reduction of harms by 60.1 % (95% CI: 57.1; 63.1) was observed two years after the implementation was completed. On average, the rate of harms dropped by 5 % per year for each 10 % increase in roll-out of the clinical risk management system (incidence rate ratio: 0.95; 95% CI: 0.93; 0.97) .
Conclusion: The results of this project demonstrate the effectiveness of clinical risk management in detecting treatment-related risks and in reducing harm to patients.

ARTIKEL INFO

Artikel-Historie:
Eingegangen: 5. Februar 2023
Revision eingegangen: 20. November 2023

ZUSAMMENFASSUNG

Hintergrund: Unerwünschte Ereignisse während einer Krankenhausbehandlung sind häufig und können zu schweren Schäden führen. Diese Studie berichtet über die Einführung eines umfassenden klinischen Risikomanagements in einem Universitätsklinikum und untersucht die Auswirkungen auf die aufgetretenen Patientenschäden.

* Corresponding author. Priv.-Doz. Dr. med. Wolfgang Buchberger, M.Sc. UMIT TIROL- University for Health Sciences and Technology, Institute of Public Health, Medical Decision Making und HTA, Research Unit for Quality and Efficiency in Medicine, Eduard Wallnoefer-Zentrum 1, 6060 Hall in Tirol, Austria.
E-Mail: wolfgang.buchberger@umit-tirol.at (W. Buchberger).

https://doi.org/10.1016/j.zefq.2023.11.008
1865-9217/

Akzeptiert: 22. November 2023
Online gestellt: 10. Januar 2024

Schlüsselwörter:
Patientensicherheit
Klinisches Risikomanagement
Risikoassessment
Unerwünschte Ereignisse
Fehlermeldesysteme

Methoden: Das klinische Risikomanagement wurde über einen Zeitraum von acht Jahren eingeführt und umfasste die Schulung interdisziplinärer Risikomanagementteams, externe und interne Risikoaudits sowie die Einführung eines Critical-Incident-Reporting-Systems (CIRS). Die im Rahmen der Audits festgestellten Risiken wurden nach Art, Schweregrad und Umsetzung von Präventionsmaßnahmen analysiert. Weitere Kennzahlen des Risikomanagementsystems wurden den jährlichen Risikoberichten entnommen. Die Anzahl der Schadensfälle pro Jahr wurde als primärer Outcomeparameter verwendet.
Ergebnisse: Von den 1.104 bei den Risikoaudits festgestellten Risiken betrafen 56,2 % die Organisation, 21,3 % die Dokumentation, 15,3 % die Behandlung und 7,2 % die Patientenaufklärung. Der höchste Anteil an schwerwiegenden Risiken wurde in der Kategorie Organisation (22,7 %) festgestellt, der niedrigste in der Kategorie Dokumentation (13,6 %). Im CIRS wurden zwischen 241 und 370 kritische Ereignisse pro Jahr gemeldet, bei denen in 79,5 % bis 83 % der Fälle innerhalb von zwölf Monaten Präventivmaßnahmen etabliert wurden. Die Häufigkeit der CIRS-Meldungen pro Abteilung korrelierte signifikant mit der Anzahl der aktiven Risikomanager und der Anzahl der Risikoteamsitzungen.

Im Vergleich zu den Jahren vor der Einführung wurde zwei Jahre nach der vollständigen Implementierung des klinischen Risikomanagements ein durchschnittlicher jährlicher Rückgang der Schäden um 60,1 % (95%-CI: 57,1; 63,1) festgestellt. Im Durchschnitt sank die Schadensrate um 5 % pro Jahr pro 10 % Erhöhung des Ausrollungsgrades des klinischen Risikomanagements (Inzidenzratenverhältnis: 0,95; 95%-CI: 0,93; 0,97).
Schlussfolgerung: Die Ergebnisse dieses Projekts belegen die Wirksamkeit des klinischen Risikomanagements für die Erkennung behandlungsbedingter Risiken und die Verringerung von Patientenschäden.

Introduction

Since the two Institute of Medicine reports "To Err is Human" and "Crossing the Quality Chasm" from 1999 and 2001, patient safety has become a priority issue for health care institutions [1,2]. Subsequent studies using chart review methods confirmed that adverse events are frequent and often have serious consequences for patients [3–8]. A systematic review showed that, in a total of 74,485 hospital patients, at least one adverse event occurred in 3.8% to 12.9% of cases (median: 9.2%). 7.0% of the events resulted in permanent disability, and 7.4% were lethal [9]. In surgical patients, the rate of adverse events was even higher at 11.7% to 23.2% [10]. Of particular significance is that 37.9% to 43.5% of adverse events were considered potentially preventable [9,10].

In order to reduce the number of preventable harms, extensive efforts have been made in many countries to increase patient safety, both at the level of national health systems and individual health care organizations. A systematic approach to increasing patient safety is clinical risk management, which comprises the clinical and administrative systems, processes, and instruments employed to detect, monitor, assess, mitigate, and prevent treatment-related risks [11].

While risk management primarily aims to prevent adverse events, quality management has a broader focus and aims to achieve defined requirements in all areas of a company's activities. In recent quality frameworks, patient safety is usually regarded as one of six quality dimensions in patient care, along with effectiveness, responsiveness (alignment with patients' needs), timeliness, appropriateness, coordination and continuity [2,12]. The revised International Organization for Standardization (IOS) standard for implementing a quality management system (DIN EN ISO 9001:2015) incorporated the principles of systematic identification and management of risks associated with a company's activities [13]. Accordingly, clinical risk management is regarded as a core element of effective quality management in healthcare organizations [14].

On the other hand, risk management uses many tools from quality management, such as process management, the introduction of standards and standard operating procedures (SOP), observations, surveys and quality measurements. Risk management should therefore ideally be integrated into an existing quality management system to be able to manage improvement projects using the PDCA cycle (Plan-Do-Check-Act) [15]. In any case, a strict separation of quality and risk management and their respective effects and mutual interactions is neither possible nor reasonable.

Although various elements of clinical risk management have been introduced in many hospitals, there are few reports on its systematic implementation and effectiveness [16,17]. The purpose of this study was to report on the implementation and outcomes of a comprehensive clinical risk management system in a tertiary care hospital.

Methods

Study design and setting

We performed a retrospective analysis of the clinical risk management system at a University Hospital in Tyrol, Austria. The hospital is a tertiary medical center serving a population of about eight hundred thousand inhabitants. It has 35 clinical departments with a total of 1,530 beds and 5,095 employees (full-time equivalents).

The study was approved by the institutional review board of UMIT TIROL. Data protection issues were regulated in a data protection agreement with the hospital organization Tirol Kliniken.

Intervention

Following the decision to implement a clinical risk management system, a risk strategy and an implementation plan were developed. The risk strategy included the definition of the objectives, structures, processes and responsibilities and described the integration of the clinical risk management into the organization's management systems. The rollout of the clinical risk management was centrally coordinated by hospital management, while its operation was the responsibility of the respective clinical departments.

The risk management system consisted of the following three components:

1. Training and assignment of multi-professional risk teams: Training of clinical risk managers was carried out in accordance with the ONR 49003/ISO 31000 standard in three- to six-day in-house training courses. In each department, the risk management team included at least one physician and one nurse or medical technical-staff member. The risk managers were appointed by the hospital management and were responsible for the operation of the risk management together with the head of the department. Some departments, especially those with an existing quality management system, had trained quality managers. When risk man-

agement was implemented, care was taken to integrate risk management into the quality management system and, if possible, to assign quality managers to risk management as well. At the level of the hospital management, a central coordination office for quality and risk management was established.

2. External risk audits: Risk analyses were performed at all departments by means of one- or two-day audits by two experienced external auditors. The two auditors had a professional background as registered nurses with long-standing experience in healthcare organizations and were certified quality and risk managers and risk assessors. The audits included semi-structured interviews, a review of medical records and other relevant documents and participatory observation by the auditors. All risks were categorized according to their severity and probability of occurrence and presented in a risk matrix using riskala™ software (GRB - Gesellschaft für Risiko-Beratung mbH, Detmold, Germany). Together with the auditors, the risk managers developed preventive measures for all observed risks. In a repeat audit after 12 to 18 months, the implementation of these measures was evaluated and the severity of the existing risks were reassessed.

3. Critical Incident Reporting System (CIRS): After completion of the risk assessment process, an intranet-based system for voluntary and anonymous reporting of critical incidents was implemented in all departments. Reported incidents were regularly discussed at meetings attended by the risk managers, departmental management, and representatives of the various professional groups.

To ensure the sustainability of the system, the risk managers prepared annual summaries of the critical incidents reported and the measures taken to reduce risks. These reports were supplemented by other data, such as patient surveys, evaluations of patient complaints, infection statistics, fall statistics, and morbidity and mortality conferences. Based on these data, hospital management annually defined hospital-wide projects and explicit measures to increase patient safety. In addition, an external re-audit was carried out at the various departments five years after the initial implementation of the clinical risk management.

Data collection

Information on the number, type and severity of risks detected in the risk audits and the implementation of appropriate measures was taken from the audit reports. During the re-audits, the degree of implementation of risk-reducing measures was assessed for each risk by the auditors on a four-level scale (25%, 50%, 75%, and 100%). In order to estimate the global degree of risk control, mean values per department and risk category were calculated. Other information, such as the time of implementation of clinical risk management in the individual departments, the number of CIRS reports per department and year, as well as the number of active risk managers and the number of meetings of the risk management teams per year was obtained from the annual risk management reports.

The annual number of patient harms reported to the liability insurance was used as the primary outcome parameter. The occurrence of these events was analyzed at the level of individual departments and the hospital as a whole. The adverse events were classified in regard to their severity according to the categories of the National Coordination Council for Medication Error Reporting and Prevention Index (NCC MERP) [18].

Data analysis

Statistical data analysis was performed using IBM SPSS Statistics for Windows Version 27 and R 4.2 for Windows. Descriptive statistics included frequency tables with averages, minima, maxima, and standard deviations (SD) and 95% confidence intervals (CI). The Wilcoxon signed-rank test was used for comparisons of dependent, non-normally distributed variables. Correlations between key figures of clinical risk management at the individual hospital departments and the extent of harm reduction were analyzed using the Spearman rank correlation coefficient. A P value of <0.05 was considered significant.

In order to adjust for the different number of inpatient admissions in the various hospital departments, the degree of rollout of the clinical risk management was calculated as the number of inpatient admissions in departments with established risk management as a percentage of the total number of inpatient admissions to the entire hospital in the respective year. The relationship between risk management rollout and harms was visualized in a scatter plot and summarized with a Locally Weighted Scatterplot Smoothing (LOESS). We used quasi-Poisson regression, with absolute number of admissions per year as an offset, to quantify the association between the degree of the rollout and the number of harms. The effect of the risk management implementation was expressed as relative reduction of incident harms per year per 10% increase in rollout with a 95% confidence interval.

Time-dependent variations in the occurrence of harms were analyzed for three periods, that is, 2001 to 2010 (baseline), 2011 to 2018 (implementation phase), and 2019- 2020 (post-implementation phase) using control charts. The year 2021 was not included in the analysis to avoid underestimating patient harms due to delayed reporting. Since the measured value under investigation (i.e., the number of harms per year) was a discrete variable from a relatively constant population (i.e., the number of inpatient admissions per year), the selected type of control chart was a C chart [19]. Identification of special cause variation was based on established criteria [19,20]. The calculation was performed with the software package QI Chart Version 2.0.23 for Microsoft Excel (Process Improvement Products, Austin, Texas).

Results

Risk analysis

A total of 1,104 risks were identified during the risk audits. The number of risks per department varied between four and 90 (mean: 30.4; SD: 22.9). 620 risks (56.2%) were related to the organization of clinical care, 235 (21.3%) to documentation, 169 (15.3%) to patient treatment and 80 (7.2%) to patient information and consent. Overall, 208 risks (18.8%) were assessed as serious, 831 (75.3%) as moderate and 65 (5.9%) as low. The highest proportion of serious risks was found in the category organization (141/620, 22.7%), and the lowest in the category documentation (23/169, 13.6%). A summary of the detected risks and the associated severity levels is shown in Table 1.

At the time of the re-evaluation audit, the average degree of implementation of risk-reducing measures at the individual departments was 83.4% for risks associated with patient information, 71.8% for risks associated with treatment, 69.7% for risks associated with organization and 68.4% for risks associated with documentation.

Rollout of the clinical risk management

The clinical risk management system was gradually rolled out in the years 2011 to 2019. At the time of evaluation by the end of 2020, the system was active in the individual departments between 14 and 108 months. Depending on the size of the departments, two to eight trained risk managers per department (127 in

Table 1
Risks identified in the risk audits by type and severity.

Risk Categories	Risk areas	Number of Risks Detected by Severity Grade		
		Low	Moderate	Serious
Treatment	Diagnostics and treatment planning	2	10	3
	Pain management	3	1	0
	Emergencies	0	16	9
	Treatment guidelines and SOPs	9	72	14
	Decubitus and fall prophylaxis, wound management	4	26	0
	TOTAL	**18**	**125**	**26**
Documentation	Emergency admissions	0	9	0
	Anesthesia documentation	0	3	2
	OP documentation	0	13	1
	Documentation in the hospital ward	17	135	16
	Physiotherapy, logotherapy, ergotherapy	2	20	2
	Functional areas (endoscopy, delivery room, catheter laboratory, etc.)	1	12	2
	TOTAL	**20**	**192**	**23**
Patient information and consent	Patient information in the emergency department	0	3	3
	General standards (risks and complications requiring disclosure, documentation of informed consent, information material, etc.)	1	41	13
	Pre-operative patient information	1	2	2
	Patient information in functional areas	0	14	0
	TOTAL	**2**	**60**	**18**
Organization	Organization in the emergency department	1	20	10
	Organization in the outpatient clinic	1	47	10
	OP planning and coordination	2	58	11
	Patient transport to the operation room, identification of the patient and the surgical site	1	36	21
	OP organization(anesthesia and wake-up room, handling of implants and prostheses, sterile goods processing, handling of tissue samples, outpatient surgery)	2	58	19
	Organization in the intensive care unit	1	9	6
	Organization in other functional areas (endoscopy, therapy, delivery room, etc.)	9	82	30
	Intra-hospital emergency management (resuscitation team, alarm system, emergency equipment, staff training)	1	10	7
	Medication safety	0	51	11
	Workforce planning and training	5	15	1
	Safety of medical devices	0	5	0
	Other organizational issues (communication, patient transport, infrastructure, hospital hygiene, etc.)	2	63	15
	TOTAL	**25**	**454**	**141**
All risks		**65**	**831**	**208**

total) were active. The number of meetings of the risk management teams in the various departments varied between four and 14 per year. The number of reported critical incidents per year increased from 241 in 2016 to 290 in 2017, 350 in 2018 and 370 in 2019, and was 336 in 2020. On average, 14.7 (1 to 46) CIRS reports were recorded per department and year. The percentage of completely processed risk notifications remained largely constant in the years under review and ranged between 79.5% and 83%. The average number of CIRS reports at each department showed a positive correlation with the number of active clinical risk managers ($r = 0.764$; $P < 0.001$) and the number of meetings of the risk management team ($r = 0.575$; $P < 0.002$).

Development of patient harms

In the ten years prior to the introduction of clinical risk management (2001 to 2010), a total of 911 treatment-related harms were registered, that is, 79 to 106 harms per year (mean: 91.1; SD: 9.6). In 2020, two years after complete rollout of the clinical risk management, 36 harms were recorded for the entire hospital. Compared to the years prior to the introduction of the clinical risk management, this is a relative reduction between 54.4% and 66.0% (mean: 60.1%; 95% CI: 57.1, 63.1).

Table 2 shows the number and severity grades of adverse events before and after the implementation of the clinical risk management. The number of significant harms, i.e. categories G (event causing permanent harm), H (event requiring life-saving intervention) and I (event contributing to patient death) was lower in 2020 compared to 2010 (12 vs. 21).

Table 2
Comparison of the number and severity of adverse events 2010 (before introduction of clinical risk management) and 2020 (after introduction of clinical risk management).

Severity Grade[1)]	N adverse events (%) 2010	N adverse events (%) 2020
C	1 (1.1)	
D	7 (8.0)	1 (2.8)
E	21 (23.9)	11 (30.6)
F	38 (43.2)	12 (33.3)
G	13 (14.8)	6 (16.7)
H	6 (6.8)	5 (13.9)
I	2 (2.3)	1 (2.8)
Total	**88 (100)**	**36 (100)**

[1)] Classification according to the National Coordination Council for Medication Error Reporting and Prevention Index (NCC MERP):
Category C: Error that reached the patient but did not cause patient harm.
Category D: Error that reached the patient and required monitoring and/or required intervention to preclude harm.
Category E: Error that may have contributed to or resulted in temporary harm and required intervention.
Category F: Error that may have contributed to or resulted in temporary harm and required initial or prolonged hospitalization.
Category G: Error that may have contributed to or resulted in permanent harm.
Category H: Error that required intervention necessary to sustain life.
Category I: Error that may have contributed to or resulted in the patient's death.

Table 3 shows the implementation date of the clinical risk management in each department and the mean number of adverse events per year and per department before and after the implementation. All departments showed a decrease in the number of adverse events in the post-intervention phase. However, neither the time since the implementation of the clinical risk management

Table 3
Implementation date of clinical risk management per department and mean number of adverse events per year before and after implementation.

Department	Year and month of implementation of CRM	Mean number of AE p.a. before implementation of CRM (range; SD)	Mean number of AE p.a. after implementation of CRM (range; SD)
Gynecology and Obstetrics	12-2011	8.27 (2–23; 6.48)	4.56 (1–8; 2.35)
Trauma Surgery	3-2012	22.50 (14–35; 6.20)	13.50 (6–18; 4.38)
Plastic Surgery	5-2012	5.33 (1–10; 2.43)	2.50 (0–7;2.45)
Visceral, Transplant and Thoracic Surgery	10-2012	17.08 (12–21; 3.15)	9.63 (6–15; 3.29)
Anesthesiology and Intensive Care	10-2012	4.27 (1–11; 3.17)	2.38 (0–4; 1.30)
ENT	12-2012	4.92 (1–15; 4.27)	1.88 (1–4;1.25)
Pediatrics	12-2012	5.08 (1–10; 2.81)	2.13 (0–4; 1.36)
Ophthalmology	6-2013	2.38 (0–4; 1.19)	1.71 (0–3; 1.11)
Orthopedics	12-2013	16.77 (9–22; 3.88)	6.17 (4–8; 1.47)
Oral and Maxillofacial Surgery	10-2014	6.14 (2–12; 3.09)	2.86 (1–8; 2.48)
Neurology	4-2014	2.71 (0–7; 2.16)	0.83 (0–3; 1.17)
Neurosurgery	5-2014	8.93 (5–15; 2.81)	4.33 (2–10; 3.20)
Dermatology	7-2015	1.87 (0–5; 1.36)	1.00 (0–2; 1.00)
Radiology	3-2017	10.88 (0–45; 13.46)	1.67 (1–3; 1.16)
Psychiatry	9-2017	1.08 (0–3; 1.04)	0.86 (0–2; 0.69)
Urology	3-2019	3.53 (1–6; 1.47)	1.00 (1–1; 1.00)
Internal Medicine	10-2019	9.25 (5–14; 2.79)	4.33 (2–6; 2.08)

Note: The pre-implementation period was defined as the period from 2001 up to and including the year of implementation, and the post-implementation period was defined as the first full year after implementation through 2020. The Departments of Orthopedics and Trauma Surgery were merged in 2019; to ensure comparability with previous years, the adverse events in 2020 were assigned on the basis of medical focus. Departments with a mean number of adverse events of less than one are not listed. AE = adverse event; CRM = clinical risk management; SD = standard deviation.

nor the number of CIRS reports, the number of active risk managers nor the number of meetings of the risk team showed a statistically significant correlation with the extent to which harms were reduced (r = 0.12 to 0.26; all $P > 0.05$).

Figure 1 shows the continuous decrease in harms with the progress of the rollout of the clinical risk management. The estimation with the quasi-Poisson model showed that the relative incidence rate was 0.95 per 10% increase in rollout (95% CI: 0.93, 0.97), or in other words, with each 10% of rollout, the incidence rate dropped by relative 5%.

The temporal relationships between the implementation of the clinical risk management and the development of treatment-related harms were investigated using a statistical process control chart (C chart). The period from 2001 to 2010 was chosen as the baseline for this analysis. In 2014, two consecutive points were below the lower control limit (Figure 2a). According to established evaluation rules, this indicates a special cause variation. The temporal correlation with the rollout of risk management under otherwise constant conditions suggests that this change was caused by the implementation of the clinical risk management system. After adjustment of the mean value and standard deviations, the number of adverse events from 2014 onwards showed no indication of a special cause variation, which indicates a stable process (Figure 2b).

Discussion

Statement of principal findings

Our retrospective study showed a significant and persistent reduction of patient harms following the introduction of a comprehensive clinical risk management system. The effect was visible in all hospital departments as well as on the level of the entire hospital. Despite the difficulties in measuring relatively infrequent events, such as treatment-related harms, the data support an association between intervention and outcome.

Interpretation within the context of the wider literature

There are very few previous reports on the outcome of clinical risk management projects in hospitals. Cropper et al. reported on the implementation of a safety program in a large healthcare organization, which included some elements of clinical risk management, such as multi-professional risk management teams, a critical incident reporting system, safety critical policies and safety training [21]. The authors reported a continuous decrease in the number of serious safety events after the introduction of the program. Ramirez et al. reported on the introduction of an incident reporting system at a university hospital and evaluated the effectiveness of the resulting improvement actions through prospective real-time observations [17]. The authors found a significant reduction of patient safety incidents for 63.15% of the implemented safety measures. In contrast, a retrospective patient record review study at a department for cardiovascular surgery reported an increase in the rate of adverse events from 21.1 to 42.8 events per 1,000 patient days three years after the implementation of clinical risk management [22].

We classified the detected risks according to type and severity in order to get an overview of the hospital's risk profile. We could not find comparable data on risk profiles from other projects. Several studies reported on the number and type of adverse events detected by medical record review [4,6,23,24]. However, the methods and classifications used are heterogeneous and not readily transferable to prospectively detected risks. Among the risks identified in this project, risks due to organizational deficiencies were the most common (56.2%), with the highest proportion of serious risks (22.7%). This seems to be in contrast with a patient record study at 21 Dutch hospitals, which found that the majority of adverse events (61%) were caused by human factors, followed by patient-related factors with 39% and organizational factors with 14% [23]. However, active failures by persons who are in direct contact with the patients often only lead to damage in combination with latent conditions, that is, weaknesses in the organization. Unlike active failures, whose specific forms are hard to predict,

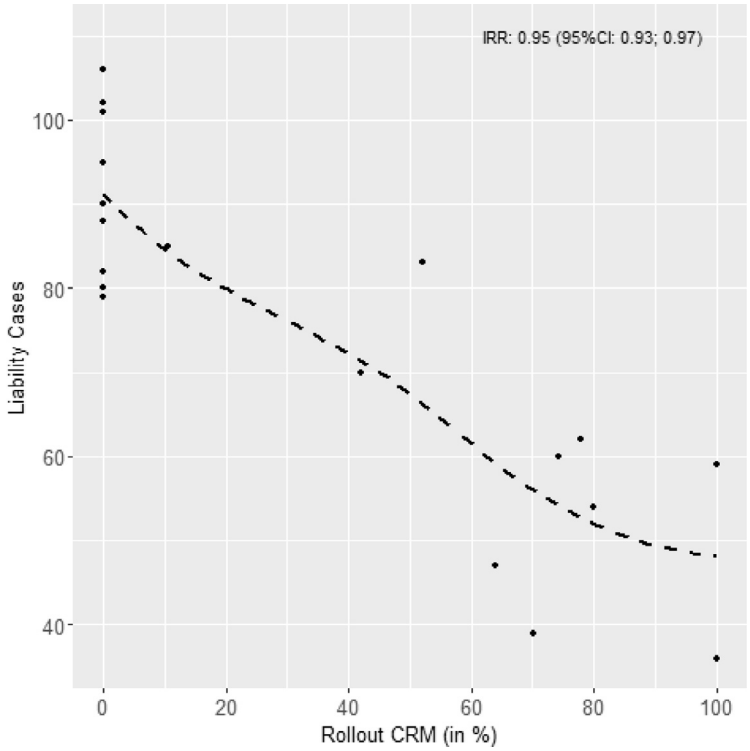

Figure 1. Relationship between rollout of clinical risk management (CRM) and liability cases, with absolute number of admissions per year as offset, summarized with Locally Weighted Scatterplot Smoothing (LOESS). IRR: Relative incidence rate of harms; 95% CI: 95% confidence interval.

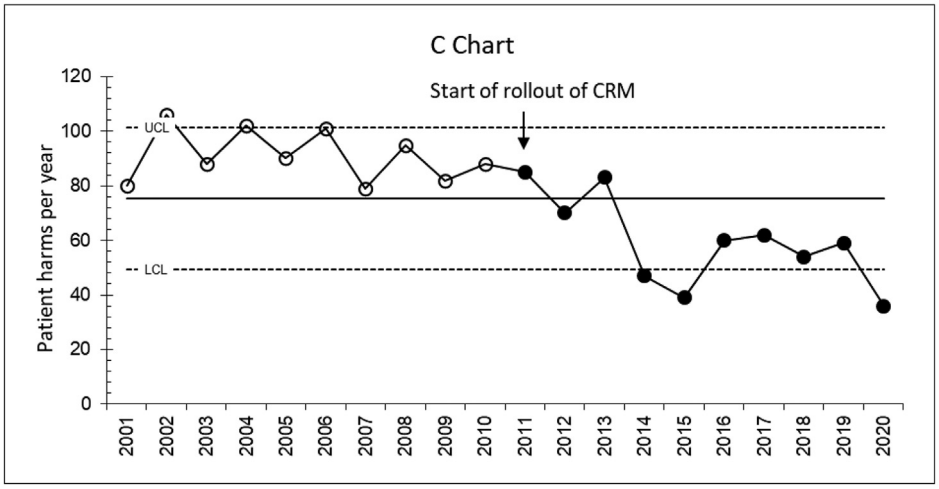

Figure 2a. Statistical process control chart (C chart) of treatment-related harms per year. A special cause variation (two consecutive data points below the lower control limit) is evident three years after the start of rollout of clinical risk management. UCL: upper control limit; LCL: lower control limit.

latent conditions can be identified and remedied before an adverse event occurs [25].

Implications for research, policy and practice

Although the essential components of comprehensive clinical risk management are well defined, previous reports show that the extent and maturity of its implementation vary considerably between hospitals. A cross-sectional study of 138 Swiss hospitals identified the implementation of central coordination, established communication structures in and between the individual hospital facilities and the existence of a risk management strategy and strategic goals as key enablers for clinical risk management [26,27]. In contrast, a survey of 572 German hospitals in 2015 revealed that, depending on the type of hospital, only 33% to 54% had systematically implemented a risk management strategy and in only 38% of hospitals the top management was involved in the project [28]. Only 13% of hospitals reported systematic use of information from the analysis of critical incidents, and only 14% reported the use of prospective risk analysis methods, although the vast majority had implemented a CIRS [28,29].

Unlike many other projects to improve patient safety, this project took a comprehensive and systematic approach to clinical risk management, as suggested by the German Patient Safety Coalition

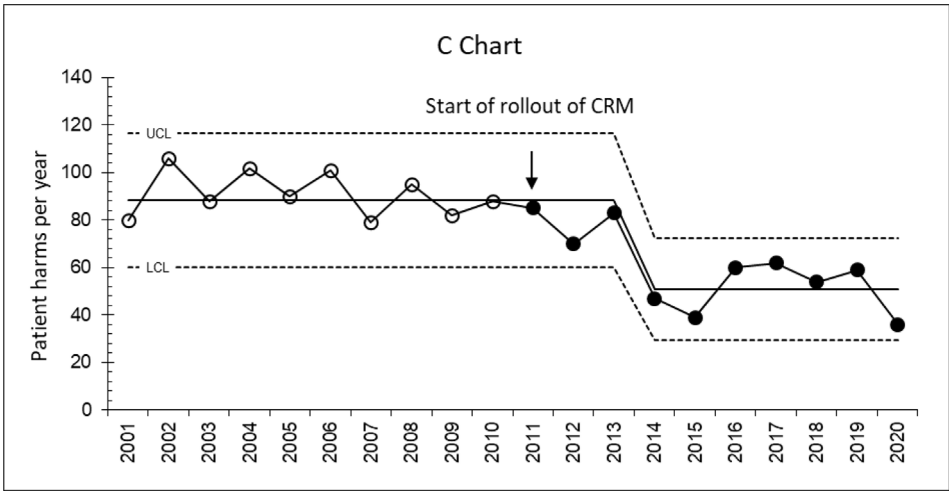

Figure 2b. Statistical process control chart (C chart) of treatment-related harms per year with recalculation of mean, upper and lower control limit after the occurrence of a special cause variation. The further course of the curve indicates a stable process. UCL: upper control limit; LCL: lower control limit.

[11]. The risk policy and risk strategy were integral parts of the corporate strategy, and the risk management processes were integrated into the management processes at corporate and hospital level. The development of expertise in the management of clinical risks was achieved by training a sufficiently large number of risk managers, and multi-professional risk management teams ensured a broad participation of all professional groups.

As a result of the present evaluation study and the experience with the operation of the clinical risk management in practice, some changes were made to the system after the roll-out was completed:

To ensure the sustainability and continuous development of the clinical risk management, internal risk assessments are now performed every two years by the risk teams of the respective departments. The assessment is based on hospital-wide defined focus areas and an evaluation of the action plans of the previous period. Reports from the hospital's internal CIRS, public reporting systems, and analysis of liability cases, patient complaints and patient surveys are used to determine the focus areas. External experts are involved in the process.

In order to promote the desired integration of quality management and clinical risk management, experts from a university of applied sciences (FH Gesundheit, Innsbruck, Austria) developed an integrated training program for quality and clinical risk managers, which has been implemented in the form of six-day in-house training courses.

Limitations

Our study has several limitations. One limitation it shares with many retrospective observational analyses is that the described intervention was carried out without the evaluation having been considered at the planning stage. The evaluation was therefore done retrospectively and had to be limited to the available data. For this reason, important aspects of complex multiple interventions, such as effects on patient safety culture, could not be evaluated [30,31].

Another limitation is that liability cases were used as outcome measure. This approach has some advantages and disadvantages. An advantage is the relatively high reliability of the data, since manifest damages are usually reliably recorded. A retrospective review of 206 cases of medico-legal litigation showed that only 20% of adverse events were not reported to the hospital management [32]. Furthermore, liability cases mostly concern serious adverse events with temporary or permanent damage or even fatal consequences, while up to 56% of adverse events detected with medical record review have no or only minimal consequences for patients [9]. A drawback of restricting the analysis to liability cases, is that they represent only a small proportion of the actual patient damage [29]. However, the effect of safety improvement measures on the reduction of litigation claims has been proven before, which suggests that liability cases can be used as a surrogate parameter for patient safety [17].

Third, our study design was observational, and therefore, outcomes may not only be affected by the intervention itself, but also by other confounding factors leading to a biased estimation of the interventioń s effect [33,34]. In our study, the relationship between clinical risk management rollout and harms could be adjusted for the number of inpatient admissions, age and gender distribution, but not for other potential confounders, such as patient case mix and cultural factors.

In addition, it can be assumed that other quality improvement measures also had an effect on the observed outcome. Hospital-wide quality projects running at the same time were the systematic implementation of treatment standards, optimization of clinical and supportive processes (process management) and the continuous collection of quality indicators (Austrian Inpatient Quality Indicators, A-IQI). Due to the close integration of quality management and clinical risk management, it is ultimately not possible to differentiate what contribution these individual components made to the overall result.

Finally, implementing a system as comprehensive as clinical risk management is by definition a complex multiple intervention. Complex interventions are usually described as interventions that contain several interacting components and target numerous groups or organizational levels, resulting in a high number of specific behaviors required by those delivering or receiving the intervention. Accordingly, the evaluation should include both measurements of relevant outcomes and an examination of the underlying processes, for example, through interviews, ethnographic observations, or documentary analysis [35,36]. However, although several process indicators, such as the degree of implementation of risk-reducing measures, the number of CIRS reports and risk team activities per department, were collected, our study did not use qualitative methods.

Conclusions

This study demonstrates that systematic implementation of a clinical risk management system in a large tertiary care hospital is feasible. Despite some methodical limitations, the results suggest that clinical risk management can reduce patient harm. In contrast to the majority of other reports, this project met all requirements for a comprehensive quality management system, so that a sustained effectiveness of the intervention can be expected.

Acknowledgement

The authors thank the University Hospital Innsbruck and Tirol Kliniken GmbH for providing the data and other valuable information for this research project.

The authors would like to thank Mag. Inge Pokorny for reviewing and editing the paper.

Conflict of interest

The Research Unit for Quality and Efficiency in Medicine is financially supported by Tirol Kliniken GmbH.

CRediT author statement

Wolfgang Buchberger: Writing – original draft, Methodology, Conceptualization. Marten Schmied: Investigation. Michael Schomaker: Formal analysis. Anca del Rio: Resources, Investigation. Uwe Siebert: Writing – review & editing.

References

[1] Kohn LT, Corrigan JL, Donaldson MS. To err is human: building a safer health system. Washington, DC: National Academy Press; 2000.
[2] Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academy Press; 2001.
[3] Zegers M, de Bruijne MC, Wagner C, Hoonhout LH, Waaijman R, Smits M, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. Qual Saf Health Care 2009;18(4):297–302.
[4] Soop M, Fryksmark U, Koster M, Haglund B. The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. Int J Qual Health Care 2009;21(4):285–91.
[5] Rafter N, Hickey A, Conroy RM, Condell S, O'Connor P, Vaughan D, et al. The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals-a retrospective record review study. BMJ Qual Saf 2017;26(2):111–9.
[6] Sari AB, Sheldon TA, Cracknell A, Turnbull A, Dobson Y, Grant C, et al. Extent, nature and consequences of adverse events: results of a retrospective casenote review in a large NHS hospital. Qual Saf Health Care 2007;16(6):434–9.
[7] Classen DC, Resar RK. The burden of harm. Jt Comm J Qual Patient Saf 2013;39(7):291. https://doi.org/10.1016/s1553-7250(13)39040-0.
[8] Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med 2010;363(22):2124–34.
[9] De Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health Care 2008;17(3):216–23.
[10] Anderson O, Davis R, Hanna GB, Vincent CA. Surgical adverse events: a systematic review. Am J Surg 2013;206(2):253–62.
[11] Aktionsbündnis Patientensicherheit. Anforderung an klinische Risikomanagementsysteme im Krankenhaus 2016. https://www.aps-ev.de/wp-content/uploads/2016/08/HE_Risikomanagement-1.pdf (assessed 5. 2023).
[12] Institut für Qualitätssicherung und Transparenz im Gesundheitswesen (IQTIG): Methodische Grundagen Version 2.0. Berlin (2022). https://iqtig.org/downloads/berichte-2/meg/IQTIG_Methodische-Grundlagen_Version-2.0_2022-04-27_barrierefrei.pdf (accessed 11. 11. 2023)
[13] International Organization for Standardization (ed): Quality management systems- requirements. ISO 9001:2015- 6.1 (actions to address risks and opportunities). https://www.risk-technologies.com/filehandler.ashx?file=15829 (accessed 17. 11. 2023).
[14] Suprin M, Chow A, Pillwein M, Rowe J, Ryan M, Rygiel-Zbikowska B, et al. Quality risk management framework: guidance for successful implementation of risk management in clinical development. Ther Innov Regul Sci 2019;53(1):36–44.
[15] Bartz HJ. Development of clinical risk management in German hospitals. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2022;65(3):293–301.
[16] Sendlhofer G, Brunner G, Tax C, Falzberger G, Smolle J, Leitgeb K, et al. Systematic implementation of clinical risk management in a large university hospital: the impact of risk managers. Wien Klin Wochenschr 2015;127(1–2):1–11.
[17] Ramirez E, Martin A, Villan Y, Lorente M, Ojeda J, Moro M, et al. Effectiveness and limitations of an incident-reporting system analyzed by local clinical safety leaders in a tertiary hospital: Prospective evaluation through real-time observations of patient safety incidents. Medicine (Baltimore) 2018;97(38):e12509.
[18] National Coordination Council for Medication Error Reporting and Prevention. Taxonomy of Medication Errors. http://www.NCCMERP.org (assessed 11. 5. 2022).
[19] Mohammed MA, Worthington P, Woodall WH. Plotting basic control charts: tutorial notes for healthcare practitioners. Qual Saf Health Care 2008;17(2):137–45.
[20] Benneyan JC, Lloyd RC, Plsek PE. Statistical process control as a tool for research and healthcare improvement. Qual Saf Health Care 2003;12(6):458–64.
[21] Cropper DP, Harb NH, Said PA, Lemke JH, Shammas NW. Implementation of a patient safety program at a tertiary health system: A longitudinal analysis of interventions and serious safety events. J Healthc Risk Manag 2018;37(4):17–24.
[22] Hoffmann-Völkl G, Kästenbauer T, Mück U, Zottl M, Huf W, Ettl B. Detection of adverse events using IHI Global Trigger Tool during the adoption of a risk management system: a retrospective study over three years at a department for cardiovascular surgery in Vienna. Z Evid Fortbild Qual Gesundhwes 2018;131–132:38–45.
[23] Smits M, Zegers M, Groenewegen PP, Timmermans DR, Zwaan L, van der Wal G, et al. Exploring the causes of adverse events in hospitals and potential prevention strategies. Qual Saf Health Care 2010;19(5):e5. https://doi.org/10.1136/qshc.2008.030726.
[24] Albolino S, Tartaglia R, Bellandi T, Bianchini E, Fabbro G, Forni S, et al. Variability of adverse events in the public health-care service of the Tuscany region. Intern Emerg Med 2017;12(7):1033–42.
[25] Reason J. Human error: models and management. BMJ 2000;320(7237):768–70.
[26] Briner M, Manser T, Kessler O. Clinical risk management in hospitals: strategy, central coordination and dialogue as key enablers. J Eval Clin Pract 2013;19(2):363–9.
[27] Briner M, Kessler O, Pfeiffer Y, Wehner T, Manser T. Assessing hospitals' clinical risk management: development of a monitoring instrument. BMC Health Serv Res 2010;10:337. https://doi.org/10.1186/1472-6963-10-337.
[28] Manser T, Frings J, Heuser G, Mc DF. The German clinical risk management survey for hospitals: implementation levels and areas for improvement in 2015. Z Evid Fortbild Qual Gesundhwes 2016;114:28–38.
[29] Manser T, Imhof M, Lessing C, Briner M. A cross-national comparison of incident reporting systems implemented in German and Swiss hospitals. Int J Qual Health Care 2017;29(3):349–59.
[30] Euteneier A. Culture of safety and clinical risk management. Unfallchirurg 2020;123(1):22–8.
[31] Weaver SJ, Lubomksi LH, Wilson RF, Pfoh ER, Martinez KA, Dy SM. Promoting a culture of safety as a patient safety strategy: a systematic review. Ann Intern Med 2013;158(5 Pt 2):369–74.
[32] Bolcato M, Fassina G, Rodriguez D, Russo M, Aprile A. The contribution of legal medicine in clinical risk management. BMC Health Serv Res 2019;19(1):85. https://doi.org/10.1186/s12913-018-3846-7.
[33] Thomas EJ, Petersen LA. Measuring errors and adverse events in health care. J Gen Intern Med 2003;18(1):61–7.
[34] Johnson ML, Crown W, Martin BC, Dormuth CR, Siebert U. Good research practices for comparative effectiveness research: analytic methods to improve causal inference from nonrandomized studies of treatment effects using secondary data sources: the ISPOR Good Research Practices for Retrospective Database Analysis Task Force Report-Part III. Value Health 2009;12(8):1062–73.
[35] Craig P, Dieppe P, Mcintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions. The new Medical Research Council guidance. BMJ 2008;337:. https://doi.org/10.1136/bmj.a1655a1655.
[36] Portela MC, Pronovost PJ, Woodcock T, Carter P, Dixon-Woods M. How to study improvement interventions: a brief overview of possible study types. BMJ Qual Saf 2015;24:325–36.