

## RECOMMENDATION



# Requirements on Clinical Risk Management Systems in Hospitals

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### Clinical Risk Management

Clinical risk management in hospitals and rehabilitation clinics comprises the totality of the strategies, structures, processes, methods, instruments and activities used in prevention, diagnosis, therapy and nursing care, that support staff at all levels, functions and professions in recognising, analysing, assessing and handling risks in patient care, so that the safety of patients, of those involved in their care and the organisation itself is increased.

### Safety Culture

Safety culture, in the context of clinical risk management in hospitals and rehabilitation clinics, describes the manner in which safety is organised in the context of patient care and thus reflects the attitudes, convictions, perceptions, values and conduct of management and other staff with respect to the safety of patients, staff and the organisation itself. Safety culture can be developed and is subject to a constant learning process.

## Foreword

The management of clinical risks in hospitals and rehabilitation clinics reveals increasing importance within recent years. Based on the findings of research conducted in the field of critical error avoidance, risk management has been established as a core task of management in securing the continued existence of organisations.

Besides business risk management policies in healthcare facilities, which are widespread as they are based on statutory provisions, the systematic and comprehensive preoccupation with clinical risks via clinical risk management is gaining importance in the health care system.

The Federal Joint Committee (G-BA) has been commissioned with the task of specifying minimum standards for clinical risk management systems in hospitals. However, so far, it is unclear which preventive measures must be included in the minimum requirements placed on such a system.

The German Coalition for Patient Safety (Aktionsbündnis Patientensicherheit—APS) set up a working group on this topic to recommend minimum requirements for clinical risk management systems in hospitals and rehabilitation clinics.

This recommendation is meant to enable administrative, medical and nursing management staff, risk managers and risk owners/persons responsible for the risk to adapt already existing or emerging risk management systems according to need.

This recommendation takes a meta-level approach and consequently contains no detailed roadmap of measures or individual checklists, as the conception of the management system has to be adapted to the specific context of the individual facility or institution.

This recommendation was read and commented on prior to publication by numerous experts and practitioners from various professional fields. We wish to thank all of the commentators for their most valuable contributions.

Your German Coalition for Patient Safety  
(Aktionsbündnis Patientensicherheit)

## Risk Management Principles



Clinical risk management in hospitals and rehabilitation clinics:

1. aims to increase the safety of patients, persons involved in their care and the organisation itself, thereby creating and protecting value,
2. serves, together with quality management, for the organisation's development,
3. is part of the decision-making process in the context of providing care for patients,
4. addresses clinical risks in connection with prevention, diagnosis, treatment and nursing care,
5. is systematic, structured, prioritised and tailored to the needs of the individual organisation,
6. is based on the best available information, figures, data, facts and scientific findings,
7. fosters inter-professional and inter-disciplinary communication,
8. takes into account the patient's social, cultural and individual environment and that of persons involved in their care,
9. creates target group oriented transparency,
10. reacts to developments in medicine and nursing care, as well as to health-related economic and demographic changes.

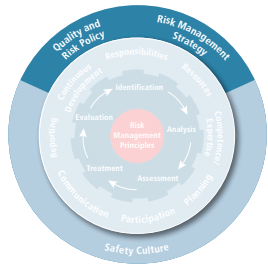
## Clinical Risk Management System

The administrative, medical and nursing top management in hospitals and rehabilitation clinics ensures the setting up and maintenance of a clinical risk management system (CRMS) by:

- a) drawing up and communicating a risk policy and risk management strategy,
- b) defining goals for the CRMS,
- c) providing the necessary resources for CRMS,
- d) planning the CRMS,
- e) specifying responsibilities within the CRMS,
- f) designing a measurement system to determine the efficacy of the CRMS, and
- g) creating a safety culture built on the CRMS.

The administrative, medical and nursing top management in hospitals and rehabilitation clinics ensures that the CRMS is coordinated and compatible with the quality management system, other management systems, as well as with the organisation's policies and strategies.

The top management assures that the relevant statutory and sub-statutory requirements are fulfilled by the organisation.



## Risk Policy and Risk Management Strategy

Organisations supplement their policies with input from clinical risk management (CRM) and use this input to draw up a risk management strategy.

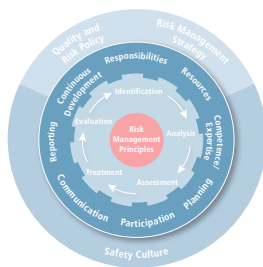
The risk management strategy lays down specifications regarding the following aspects:

- linkage of the organisation's goals, particularly economic and safety-related goals,
- provision of the resources necessary to implement the risk management system (persons, budget, necessary equipment),
- risk-related responsibilities in organising both the setting up and the running of the system,
- the way in which the evaluation is conducted to determine the efficacy of the CRMS,
- the way in which the findings of the efficacy evaluation are reported,
- evaluation and further development of the risk policy and risk management strategy, including frequency, content and evaluation criteria.

In order to incorporate the principles specified in the risk policy into a risk management strategy, the context that is relevant to the CRMS needs to be analysed. This includes:

- the demand for healthcare,
- the state of the art and development trends in medicine, nursing and technology,
- clinical risks related to the particular location,
- the economic situation,
- health policy as well as statutory and sub-statutory requirements that affect the CRM,
- the status, expectations and values of current and future personnel,
- the values, approaches and interests of the cross sectoral partners in care provision,
- the approaches of suppliers and other service providers.

The risk policy and risk management strategy are communicated appropriately.



## Responsibilities

Hospitals and rehabilitation clinics expand the existing initial organisation by adding CRM aspects. A member of the top management has full responsibility for the development, implementation and maintenance of the CRM. This includes, in particular, responsibility for ensuring that the clinical risks

are regularly identified, analysed, assessed, treated, evaluated and reported.

Furthermore:

- At least one qualified risk manager must be appointed,
- Persons responsible for the risk must be designated.

## Resources

Hospitals and rehabilitation clinics provide sufficient resources (personnel and equipment), to achieve the goals laid down in the risk management strategy.

To this end, in particular:

- The risk manager and the persons responsible for the risk must have to be qualified,
- Training programs must be implemented within the framework of the statutory and sub-statutory requirements,
- Resources must also be made available to conduct measures to treat risks.

## Competence/Expertise

Hospitals and rehabilitation clinics possess the competence to select and use suitable methods for the identification, analysis, assessment, treatment and evaluation of risks.

This comprises the competence to define the internal and external sources of information that are relevant to the CRM and to

aggregate and analyse the information gleaned from these sources within a reasonable timeframe.

If necessary, suitable internal and external experts will be consulted.

## Planning

Based on the risk policy and risk management strategy, hospitals and rehabilitation clinics integrate:

- the risk management process into existing management processes and, where necessary, into additional management processes that are to be defined,
- effective and appropriate prevention measures in all of the performance and supporting processes relevant to the CRM.

To this end, a risk management plan will be drawn up, and will be an integral component of the organisation's entire planning process.

Based on the risk management plan, the following steps will be taken at specified intervals:

- risk analyses will be conducted,
- the policy, goals and strategies will be analysed with a view to minimising risk,
- the material/immaterial resources, as well as the existing knowledge will be assessed in relation to risk,

- d) the information systems, information flow and decision-making processes will be assessed in relation to risk,
- e) the safety culture will be evaluated from the perspective of the patient, those involved in providing care and any other executive staff,
- f) the implementation of external guidelines, requirements and models will be assessed for resulting internal risks,
- g) existing cooperation schemes and the services they produce will be examined for clinical risks; the same goes for services that the facility itself provides for third parties within the framework of cooperation schemes.

## Participation

Hospitals and rehabilitation clinics will inform and train those involved in providing care to patients regarding the need for a CRMS and the necessary methods and instruments that have been introduced for this purpose.

For different target groups, educational interventions/training that is appropriate—timewise, as well as in terms of content and language skills—are to be planned and conducted. This training is to be repeated if necessary and adapted to possible changes in the system.

A key element of educational interventions/training is making employees aware of the

need for their active involvement in CRMS, whether in the form of the notification of critical events, collaboration in the analysis of potential causes, or the implementation of preventive measures.

In the process, employees have a key role to play in the identification of clinical risks, both in their role as individuals and in their function as members of professional and interdisciplinary teams of care.

## Communication

Hospitals and rehabilitation clinics inform everyone who is involved in patient care on the status and results of the CRMS and the resulting changes, on a regular basis and using content that is appropriate to the target group.

Furthermore, the degree and frequency with which communication on clinical risks is to take place—and with which interest groups—will be specified. This includes, in particular, the intersectoral interfaces.

Within their crisis management framework, hospitals and rehabilitation clinics have written regulations on how to communicate in a crisis situation. The persons designated in the communication plan are to be instructed with respect to their roles.

## Reporting

Hospitals and rehabilitation clinics are called upon, within the framework of statutory-official requirements, to inform internal and external agencies regarding the status, modifications to and the efficacy of the CRMS.

If appropriate hospitals and rehabilitation clinics will aggregate comparable individual risks from several areas, or from different methods and instruments, to arrive at an overall assessment of the specific risk to which the hospital is exposed.

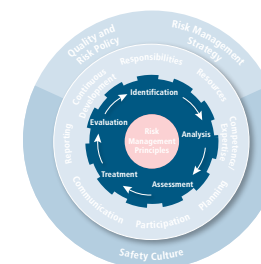
As a confidence building measure, hospitals and rehabilitation clinics will report on their management of clinical risks. The recipients of this information will be especially: patients, relatives and inter-sectoral partners in healthcare provision. The information is to be prepared in such a way as to be target-group oriented and, where necessary, will be examined to ensure comprehensibility.

## Continuous Development

The administrative, medical and nursing top management in hospitals and rehabilitation clinics assess the clinical risk management system systematically and regularly, according to the organisation's needs.

The results will serve as a basis for taking decisions on how the risk policy, the risk man-

agement strategy and the risk management plan are to be further developed.



## The Risk Management Process

The risk management process generically describes the procedure for handling risk and is broken down into the following steps: identification, analysis, assessment, treatment and evaluation.

## Risk Identification

Hospitals and rehabilitation clinics identify the risks that have the potential to harm patients, those persons involved in providing patient care or the organisation itself.

Risk identification is conducted taking into account the context that is relevant for the CRMS. In this process, special consideration is to be given to patient's perspective.

The risk identification takes into account:

- a) notifications from reporting and learning systems, especially the Critical Incident Reporting System (CIRS),
- b) events that have caused harm to patients,
- c) liability cases,
- d) occupational accidents,
- e) complaints,

- f) external risks or instances of harm that have been made public,
- g) national and international recommendations for action on patient safety,
- h) survey results,
- i) statistics on complications,
- j) results of audits and inspections.

All relevant identified risks are to be documented and assigned to the person responsible for the risk.

### Risk Analysis

The goal of the risk analysis is to determine the causes of risks and factors that favour errors, the likelihood that such errors will occur, as well as their effect on the safety of patients, persons involved in providing healthcare and the organisation itself.

If sufficient information cannot be gathered with one method of risk analysis, it might become necessary to apply additional methods of analysis or to consult additional experts.

### Risk Assessment

Within the context of risk assessment, decision-makers determine, on the basis of identified and analysed risks, which risks are treated with what intensity and priority.

### Risk Treatment

Risk treatment includes all of the measures agreed upon for treating identified, analysed and assessed risks. The following options are available for handling risk:

- Avoiding the risk by terminating the activities in question,
- Reducing the risk by means of preventive measures and/or
- Transferring the risk until an acceptable level of residual risk is achieved,
- Accepting the risk with supervision, and
- Accepting the risk without additional supervision.

Risk handling is conducted on the basis of the PDCA Cycle and must take statutory and sub-statutory requirements, including recommendations for action by external experts, into account.

### Evaluation

Within the framework of the evaluation, it will be ascertained whether the procedure stipulated for risk handling achieved the desired goal. If the desired goal was not reached, alternative options for treating risk must be taken into consideration.

## Glossary of Clinical Risk Management

<b>Risk</b>	In the context of clinical risk management, risk is defined as an uncertainty in the provision of patient care that, with a projected likelihood of occurrence and a projected impact, is capable of causing harm to patients, to the persons involved in their care and/or to the organisation itself.
<b>Clinical Risk Management</b>	Clinical risk management in hospitals and rehabilitation clinics comprises the totality of strategies, structures, processes, instruments and activities in the fields of prevention, diagnostics, treatment and nursing care that support staff members at all levels, in all functions and in all professional groups in recognising, analysing, assessing and handling risks in the provision of care, thereby increasing the safety of patients, those who care for them and the organisation itself.
<b>Risk Policy</b>	Risk policy formulates principles or guidelines for basic handling, not only of risks but also of opportunities. It forms the external framework for the implementation of a risk management system and is the foundation of a risk management strategy.
<b>Risk Management Strategy</b>	Risk management strategy describes the implementation of principles specified in the risk policy. To this end, the components, methods and tools of risk management come into play.
<b>Risk Management System</b>	A risk management system is described as the entirety of components, methods and tools that are related or linked to each other in such a way that the organisation is placed in a position to identify and permanently reduce the relevant clinical risks with a view to enhancing patient safety.
<b>Person responsible for the risk (= risk owner)</b>	Every risk is clearly assigned to a so-called “person responsible for the risk” who has the responsibility and authority to take action with respect to this specific risk. The person responsible for the risk makes an assessment of identified risk on a regular basis, identifies potential risk minimisation measures and ensures that they are effectively implemented.

<b>Risk Manager</b>	Risk manager is responsible for and has the methodical expertise to coordinate the clinical risk management system. This means especially observing and assessing the planning and implementation of measures.
<b>Management Assessment</b>	Assessment of the clinical risk management system according to the requirements laid down in DIN EN ISO 9001 [1].
<b>Safety Culture</b>	Safety culture, in the context of clinical risk management in hospitals and rehabilitation clinics, describes the manner in which safety is organised in the context of patient care and thus reflects the attitudes, convictions, perceptions, values and conduct of management and other staff with respect to the safety of patients, staff and the organisation itself. Safety culture can be developed and is subject to a constant learning process [in line with 2].
<b>Risk Management Plan</b>	The risk management plan, as a part of the CRMS, emerges from the risk management strategy as an annual plan. It describes the facility's activities and goals for the given period in relation to the CRMS and is coordinated with other management plans.
<b>Risk Matrix</b>	The risk matrix is a graphic representation in which risks are classified on a scale according to impact and likelihood and/or frequency [3].
<b>Risk Appraisal</b>	Risk appraisal covers: risk identification, risk analysis and risk assessment.
<b>Indicators</b>	An indicator is a quantitative measure that can be used to monitor and appraise important process-related, executive, management and support functions [4].

## Methods and Tools for Risk Management

Clinical risk management methods are systematic, reproducible procedures that are suitable for identifying, analysing and assessing risks and generating measures to treat these risks. Tools, on the other hand, support parts of the risk management process.

A distinction is made between proactive and reactive methods and tools. Proactive meth-

ods and tools can be used in the absence of a certain event, whereas reactive methods and tools must always be preceded by an event if they are to be applied.

What all methods have in common is the fact that they can only be fully effective within the organisation if they are based on an effective measures management system.

### Proactive methods

#### Peer Review Procedure

Peer review is a continuous, systematic and critical reflection of personal performance and experience by experts involved in patient care. The open and direct exchange of information on aspects of good patient care, among expert colleagues from different fields as equals, serves to promote mutual learning with the aim of achieving continuous improvements in patient care.

Peer review was originally conceived as a proactive method. However, it can also be used as a reactive method, in response to a certain event (for example, in the case of a suspicious quality indicator).

#### Audits

An audit is a systematic, independent and documented process to gather (audit) evidence; following the latter's objective evaluation, it serves to determine the extent to which the audit criteria have been fulfilled [5].

#### Process Oriented Risk Analysis (PORA)

PORA provides a systemic analysis of incidents or close calls based on the analysis of patient care procedures. PORA is based on the following approaches: the Failure Mode and Effect Analysis (FMEA), the Root Cause Analysis (RCA) and the London Protocol [6].

<b>Fault Tree Analysis (FTA)</b>	The Fault Tree Analysis (FTA) establishes a graphic connection between an incident that could potentially have resulted in harm to the patient and the corresponding sources and causes of failure.
<b>Failure Mode and Effect Analysis (FMEA)</b>	The FMEA serves to analyse and apprais risks involved in complex systems of processes and is based on a consideration of all individual subsystems or process steps (further information: [7]).
<b>Scenario Analysis</b>	A scenario analysis is a pictorial description of complex risks with respect to their causes, frequency of occurrence and possible effects based on a hazard list. The risks are depicted in a risk matrix based on defined risk criteria. In the context of risk management, the 'credible worst-case' scenario is applied [8] for this purpose.
<b>Systematic data collection</b>	Systematic data collection serves as a proactive method for identifying risks and deriving preventive measures. This could be, for example, the results of surveys, harm registers or complication statistics.
<b>Surveys</b>	Surveys are systematic feedback from patients, employees and third parties, with the aim not only to increase satisfaction of the respondents and optimise procedures, but also to improve patient safety.
<b>Crew Resource Management</b>	Crew Resource Management is a set of training procedures especially the non-technical abilities of an institution's staff to empower them to handle critical situations through the optimum use of all resources and information. Examples from field of medicine are: labour ward or trauma room training (further information: [9,10]).

## Proactive tools

<b>Poka Yoke</b>	This Japanese term describes a procedure that, by means of technical precautions, is intended to identify and prevent failure proactively. For example, wall-mounted connections for oxygen and compressed air are standardised in such a way as to prevent mix-ups [11].
<b>Recommendations</b>	Recommendations are national and international guidelines, drawn up by organisations, professional societies and healthcare organisations with the aim of setting standards for safe patient care. One such example is the APS' recommendations.
<b>Directives</b>	Directives are statutory and sub-statutory, normative requirements, a deviation from which can lead to direct sanctions. Examples are the Protection against Infection Act and the Medical Devices Act.

## Reactive methods

### DAMAGE EVENT ANALYSIS

<b>Mortality and Morbidity Conference (M&amp;M Conference)</b>	A Mortality and Morbidity Conference is a regularly held, structured oral presentation and analysis of selected deaths or serious pathogeneses, the aim of which is to improve future patient treatment and make it safer (further information:[12-14]).
<b>London Protocol</b>	The London Protocol is a systematic investigative technique used to analyse serious harm. It was developed based on the Organisational Accident Causation Model and aims to achieve a comprehensive identification of both systemic aspects as well as individual causes (further information:[15]).
<b>Error and Risk Analysis (ERA)</b>	The purpose of ERA is the systemic analysis of incidents or close calls and is based primarily on the London Protocol (further information:[16, 17]).



## ANALYSIS OF CRITICAL EVENTS

**Complaints Management** Complaints management is defined as a system in which complaints, praise and criticism are understood as welcome information and analysed for risks might present to patient care. This aims not only increasing client satisfaction and optimising processes, but also improving patient safety.

**CIRS (reporting and learning systems)** Critical Incident Reporting Systems are based on notification of critical events, which are systematically analysed and assessed. If necessary, measures to improve patient safety are derived. Similarly, third parties are meant to benefit and learn from the anonymized notifications and the measures resulting therefrom.

## Reactive tools

**Additional reporting systems** Additional reporting systems exist alongside CIRS in the field of clinical risk management. These include compulsory reporting systems such as that of the Federal Institute for Drugs and Medical Devices (BfArM) or the Federal Institute for Vaccines and Biomedicines (PEI). These reporting systems primarily serve the purpose of risk identification.

**Root Cause Analysis (RCA)** The RCA is a set of various methods that endeavour to identify the root causes of a specific event. One prominent example is the Ishikawa Diagram.

## List of abbreviations used

APS	Aktionsbündnis Patientensicherheit (German Coalition for Patient Safety (GCPS))
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)
CIRS	Critical Incident Reporting System
DIN	Deutsches Institut für Normung (German Institute for Standardization)
EN	Europäische Norm (European Standard)
ERA	Error and Risk Analysis
FMEA	Failure Mode and Effects Analysis
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
ISO	International Organization for Standardization
CRM	Clinical Risk Management
CRMS	Clinical Risk Management System
ONR	ON Rule
PDCA	Plan-Do-Check-Act
PEI	Paul-Ehrlich-Institut (Federal Institute for Vaccines and Biomedicines)
PORA	Process Oriented Risk Analysis
RCA	Root Cause Analysis

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## Feedback

APS Recommendations are tools for improving patient safety. These tools require continuous further development and adaptation. The APS therefore expressly welcomes every form of feedback. Should you, in perusing or using this Recommendation, discover inconsistencies, ambiguities or errors, we would appreciate if you would point these out and render suggestions for improvement.

Furthermore, you may feel free to address questions, which have not been dealt with in this recommendation, directly to the APS.

### Note:

Normally, the recommendation is to be revised after a period of three years by the publisher.

Please address all of your questions, suggestions and feedback to:  
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