



# **Patient Safety and Quality Management**

## **A German Perspective**

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# The German Coalition for Patient Safety (I)

- established as a non-profit organization in 2005 by health care professionals, institutions and patient organizations to improve patient safety in Germany
- supported by the German Ministry of Health
- headed by an executive committee which consists of nine members who are elected for a two years term of office by the general assembly
- the committee is assisted by an advisory council and a board of trustees
- the general meeting decides on projects and initiatives
- a platform for safe health care in Germany
- expert groups work on practical safety projects
- multi-disciplinary working groups hold regular meetings and results are published as recommendations



# The German Coalition for Patient Safety (II)

## ➤ Initiating members





## The German Coalition for Patient Safety (III)

- Working groups
- Results are summarized in recommendations which are published periodically and are provided to all institutions and organizations in German healthcare free of charge.
- Recommendation for preventing wrong site surgery
- Recommendation for establishing critical incident reporting system (CIRS) in hospitals
- Checklist for medication safety in hospitals
- Medication list for patients
- Working groups also organize presentations and conferences on special patient safety topics.



# Cooperation for Transparency and Quality in Healthcare

## KTQ



## Shareholders of KTQ-GmbH

- The Umbrella Associations of the Statutory Health Insurers
- The German Medical Association
- The German Hospital Federation
- The German Nursing Council
- The Association of Physicians in Germany





## Overview: KTQ-Certificates

**2002**

Hospitals

**2007**

Ambulant Nursing Services  
Nursing Homes and Hospices

**2004**

Doctor's Practices and Medical  
Centers

**2011**

Emergency Rescue Services

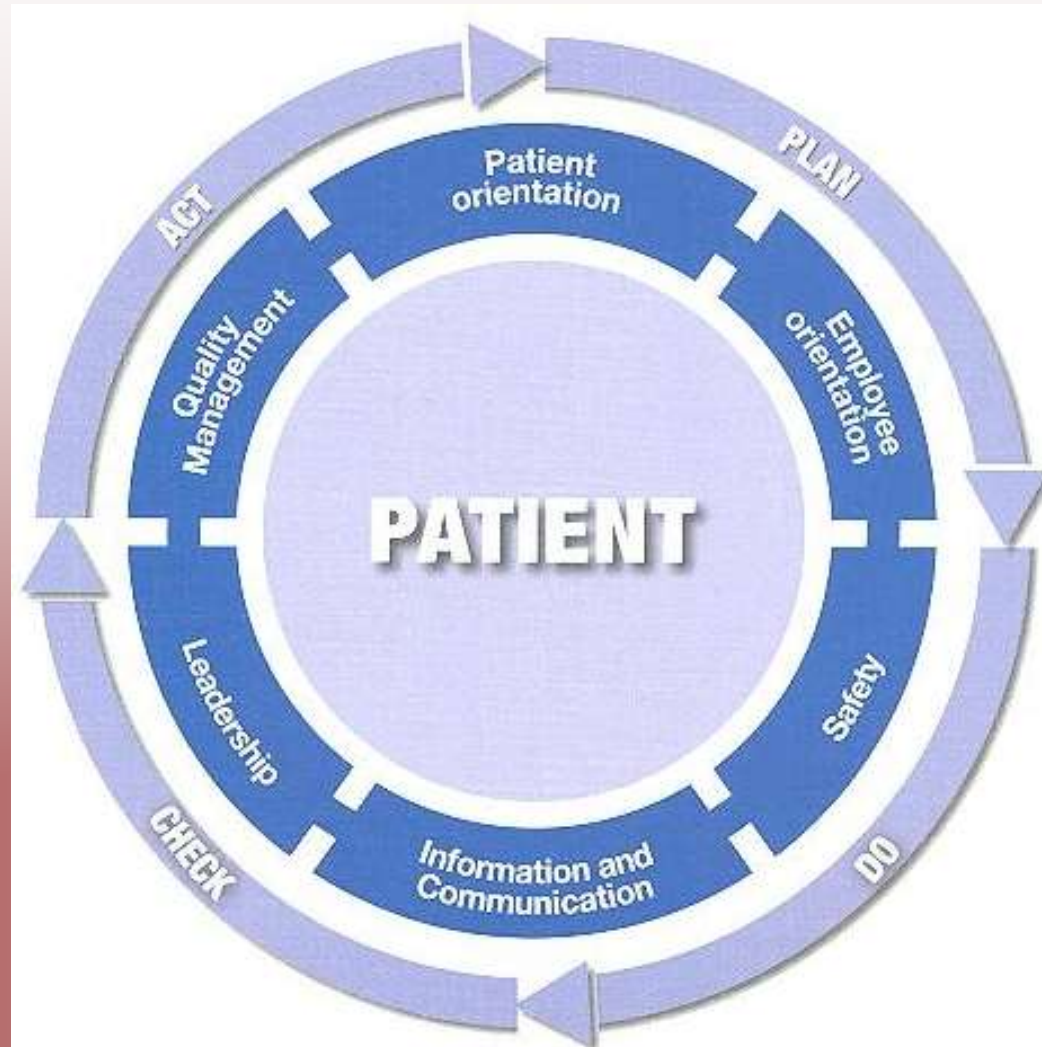
**2005**

Rehabilitation Clinics

- Specific certification procedures for different healthcare practice
- Certification of hospitals



# KTQ-Model





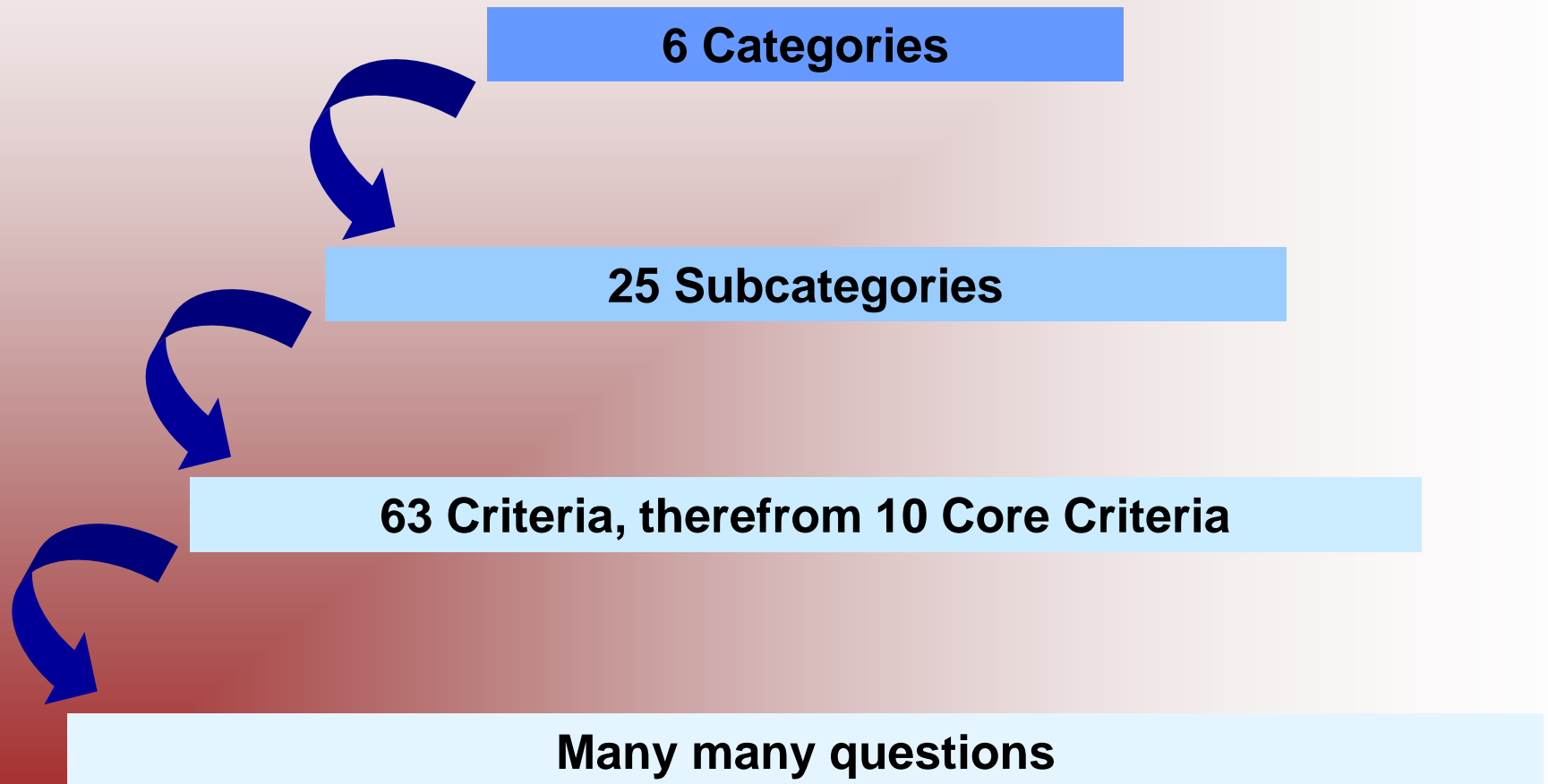


# KTQ-Categories

- 1 Patient-orientation**
- 2 Securing Employee-orientation**
- 3 Safety**
- 4 Information and Communication**
- 5 Leadership**
- 6 Quality management**



# Category, Subcategory, Criterion, Questions





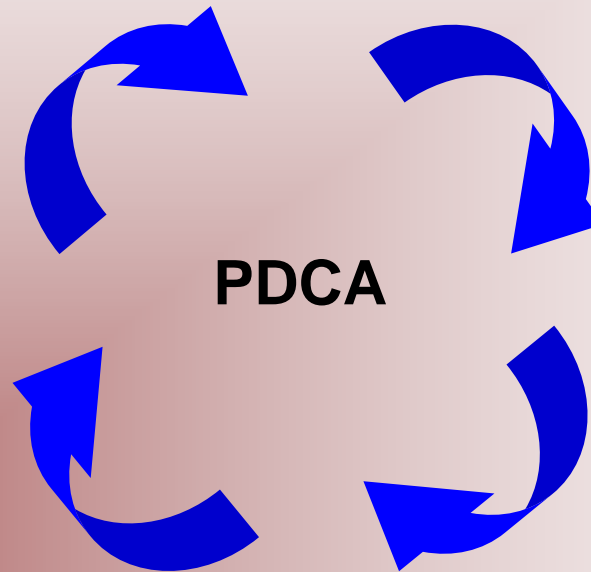
# PDCA Cycle

## Act

Recommendations for improvements based on the results of the "Check" step

## Plan

Target and process planning, responsibilities



## Check

Assessment and review of the processes describes under "Do"

## Do

Transformation into practice, „current status“



# PDCA Cycle

## 3 Safety

### 3.2 Patient Safety

#### 3.2.3 Hygiene Management



### Plan

0 1 2 3

■ Describe the planning of processes/the target state, to which the criterion refers, as well as the defined responsibilities in your institution. Please include the following topics, amongst others, as far as applicable:

- ▶ The regulation of the responsibilities with regard to hygiene in all areas of the hospital
- ▶ The planned information channels and the form of communication if a lack of hygiene occurs or a malpractice in terms of hygiene is determined
- ▶ The instructions and procedures (e.g. hygiene plans), as well as their regular updating, documenting and filing
- ▶ The regulation that the guidelines and recommendations with regard to the hospital hygiene are observed by and known to the staff
- ▶ The regulation of the batch documentation in the central department of sterile material supply
- ▶ The planning with respect to the HACCP concept for the entire meals supply

### Do

0 1 2 3 4 5 6 7 8 9

■ Describe the actual state or the implementation of the processes, to which the criterion refers. Please include the following topics, amongst others, as far as applicable:

- ▶ The safeguarding that the employees have access to the instructions and procedures
- ▶ The regular meetings of the hygiene commission according to the requirements of the Robert Koch Institute or the hygiene regulations of the German federal states
- ▶ The journal of the meetings of the hygiene commission and the implementation of the resolutions in the form of e.g. internal guidelines
- ▶ The safeguarding that the hygiene guidelines are observed
- ▶ The implementation of the HACCP concept in the entire meals supply
- ▶ The processes with respect to the conditioning of medicinal products (e.g. endoscopes)



# PDCA Cycle

## 3 Safety

### 3.2 Patient Safety

#### 3.2.3 Hygiene Management



### Check

0 1 2 3

- Describe the metrics, measurements and methods you use to revise and assess the requirements, actions and processes set forth in Plan and Do in a regular and comprehensible way:

- ▶ The checking whether the instructions and procedures are observed (e.g. hygiene plans)
- ▶ The checking whether the hygiene ordinance of the federal states, as well as the guidelines of the Robert Koch Institute and other institutions are observed
- ▶ The checking of the proper management of sterile goods as well their correct handling and storage
- ▶ The comparison of the results with other departments or facilities

### Act

0 1 2 3

- Describe the improvement measures you derived from the Check results:

- ▶ The defined improvement measures, which have been derived from previous certification processes



# PDCA Cycle

## ASSESSMENT

PDCA-Step	Maximum achievable score for (P) and (A)	Attainment level (A)	Penetration level (P)	Result
Plan	3	A:	P:	$\frac{1}{2} (A + P):$
Do	9	A:	P:	$\frac{1}{2} (A + P):$
Check	3	A:	P:	$\frac{1}{2} (A + P):$
Act	3	A:	P:	$\frac{1}{2} (A + P):$
<b>Total</b>	<b>18</b>			
<b>Final score</b>	<b>max. 18</b>			



# Category, Subcategories

## 3. Safety

### 3.1 Safety and security systems

3.1.1 Occupational safety

3.1.2 Fire protection

3.1.3 Environmental protection

3.1.4 Disaster management

3.1.5 Non-medical emergency situations

### 3.2 Patient safety

3.2.1 Protection of patients against the endangerment to self or others

3.2.2 Management of medical emergencies

3.2.3 Hygiene management

3.2.4 Hygiene-relevant data

3.2.5 Management of infections

3.2.6 Drugs

3.2.7 Blood components and plasma derivatives

3.2.8 Medical devices

5.5.1 Structure and development of a risk management system

Core criteria



# 3 Safety

## 3.1 Safety and security systems

### 3.1.4 Disaster management



#### Plan

0 1 2 3

■ Describe the planning of processes/the target state, to which the criterion refers, as well as the defined responsibilities in your institution. Please include the following topics, amongst others, as far as applicable:

- ▶ The integration of the hospital in the disaster management pursuant to the German federal state law
- ▶ The defined responsibilities
- ▶ The obligation of the hospital to admit emergency patients in case of major disaster

#### Do

0 1 2 3 4 5 6 7 8 9

■ Describe the actual state or the implementation of the processes, to which the criterion refers. Please include the following topics, amongst others, as far as applicable:

- ▶ The implementation of instructions (e.g. operational command, hotline)
- ▶ The regular updating and corresponding communication of the disaster management plan
- ▶ The offer of and participation in regular instructions and training seminars in respect of disaster management for the employees

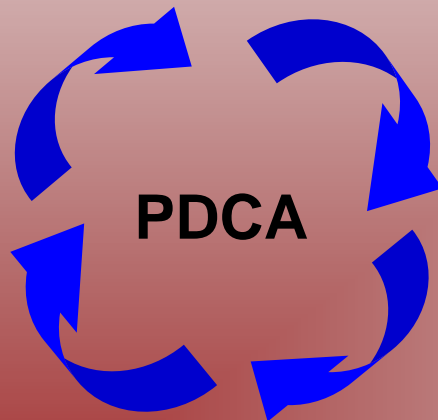




# 3 Safety

## 3.1 Safety and security systems

### 3.1.4 Disaster management



#### Check

0 1 2 3

■ Describe the metrics, measurements and methods you use to revise and assess the requirements, actions and processes set forth in Plan and Do in a regular and comprehensible way:

- ▶ The latest disaster management exercise (e.g. date, improvement potentials)
- ▶ The number of further education seminars for employees in the previous year
- ▶ The comparison of the results with other departments or facilities

#### Act

0 1 2 3

■ Describe the improvement measures you derived from the Check results:

- ▶ The defined improvement measures, which have been derived from previous certification processes
- ▶ The consequences from the latest disaster management exercise



# 3 Safety

## 3.2 Patient safety

### 3.2.2 Management of medical emergencies



#### Plan

0 1 2 3

■ Describe the planning of processes/the target state, to which the criterion refers, as well as the defined responsibilities in your institution. Please include the following topics, amongst others, as far as applicable:

- ▶ The planning of the emergency management for internal medical emergency cases, incl. internal emergency transport (e.g. a standardised procedure for CPR emergency calls)
- ▶ The planning with respect to the availability of standardised emergency equipment on the wards and in the functional areas
- ▶ The qualification of the staff

#### Do

0 1 2 3 4 5 6 7 8 9

■ Describe the actual state or the implementation of the processes, to which the criterion refers. Please include the following topics, amongst others, as far as applicable:

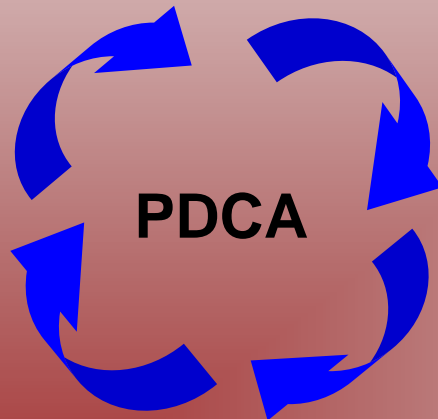
- ▶ The safeguarding of the access to the emergency equipment and emergency medication at all times
- ▶ The safeguarding that qualified staff are immediately available to perform medical emergency care at all times
- ▶ The offer of and the participation in regular instructions and training seminars with respect to emergency management and practical CPR exercises for the employees



# 3 Safety

## 3.2 Patient safety

### 3.2.2 Management of medical emergencies



## Check

0 1 2 3

■ Describe the metrics, measurements and methods you use to revise and assess the requirements, actions and processes set forth in Plan and Do in a regular and comprehensible way:

- ▶ The regular checking of the standard emergency equipment on the wards and in the functional areas
- ▶ The checking and documentation of the participation in further education seminars and the qualification of the staff
- ▶ The analysis of performed actions in the medical emergency management and the qualification of the staff
- ▶ The comparison of the results with other departments or facilities

## Act

0 1 2 3

■ Describe the improvement measures you derived from the Check results:

- ▶ The defined improvement measures, which have been derived from previous certification processes



# 3 Safety

## 3.2 Patient safety

### 3.2.4 Hygiene-relevant data



### Plan

0 1 2 3

■ Describe the planning of processes/the target state, to which the criterion refers, as well as the defined responsibilities in your institution. Please include the following topics, amongst others, as far as applicable:

- ▶ The planning of measures to ensure hygiene (e.g. Infection Protection Act, hospital infections)
- ▶ The requirements with respect to the management of patients infected with special infectious agents (especially MRSA, VRE, HIV, hepatitis, TB)
- ▶ The safeguarding that the planning in respect of the management of such infected patients distinguishes between the organisational and the functional processes and describes the same in detail
- ▶ The concept for the use of personal protection equipments for the employees
- ▶ The planning of infection management in case of acute viral infections (e.g. Novovirus)
- ▶ The planning of measures to improve hand disinfection (e.g. furnishing with disinfectant dispenser, employee compliance, "clean hands" campaign)
- ▶ The planning of screening procedures (e.g. MRSA)
- ▶ The conception to prevent infections through water supply (e.g. Legionella)

### Do

0 1 2 3 4 5 6 7 8 9

■ Describe the actual state or the implementation of the processes, to which the criterion refers. Please include the following topics, amongst others, as far as applicable:

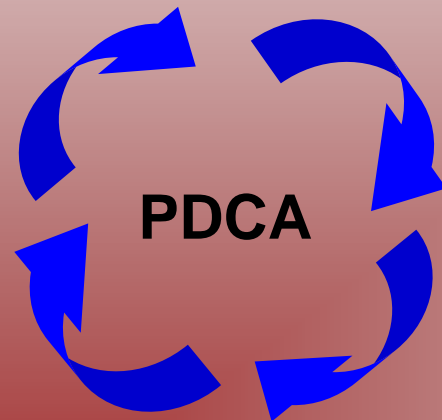
- ▶ The offer of and the participation in regular instructions and training seminars in respect of the management of special infectious agents
- ▶ The prophylaxis to identify an infectiological episode in the accident and emergency unit
- ▶ The infection management in case of acute viral infections
- ▶ The measures to improve the hand disinfection (e.g. furnishing of disinfectant dispensers, employee compliance, „clean hands“ campaign)
- ▶ The use of screening procedures (e.g. MRSA)
- ▶ The avoidance of infections through the water supply (e.g. Legionella)



### 3 Safety

#### 3.2 Patient safety

##### 3.2.4 Hygiene-relevant data



### Check

0 1 2 3

■ Describe the metrics, measurements and methods you use to revise and assess the requirements, actions and processes set forth in Plan and Do in a regular and comprehensible way:

- ▶ The analysis of statistics on infections with regard to cause and originator (e.g. surgery room)
- ▶ The regular checking of statistics on germinal resistance with regard to listed antibiotics and used disinfectants (e.g. by the German Drug and Hygiene Commission)
- ▶ The regular checking of statistics on germinal resistance with regard to the hospital-internal therapy guidelines (e.g. antibiotics therapy)
- ▶ The complete internal and external forwarding of information related to reportable infections
- ▶ The comparison of the results with other departments or facilities

### Act

0 1 2 3

■ Describe the improvement measures you derived from the Check results:

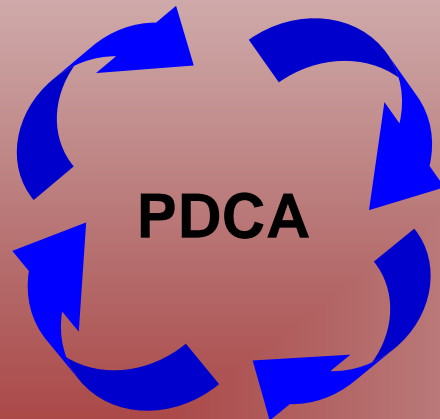
- ▶ The defined improvement measures, which have been derived from previous certification processes
- ▶ The interdisciplinary and inter-professional discussion and documentation of the statistical results
- ▶ The integration of all employees in these discussions
- ▶ The deduction and re-checking of the improvement measures from the statistical results
- ▶ The measures in case of abnormalities



# 3 Safety

## 3.2 Patient safety

### 3.2.5 Management of infections



### Plan

0 1 2 3

■ Describe the planning of processes/the target state, to which the criterion refers, as well as the defined responsibilities in your institution. Please include the following topics, amongst others, as far as applicable:

- ▶ The planning of measures to ensure hygiene (e.g. Infection Protection Act, hospital infections)
- ▶ The requirements with respect to the management of patients infected with special infectious agents (especially MRSA, VRE, HIV, hepatitis, TB)
- ▶ The safeguarding that the planning in respect of the management of such infected patients distinguishes between the organisational and the functional processes and describes the same in detail
- ▶ The concept for the use of personal protection equipments for the employees
- ▶ The planning of infection management in case of acute viral infections (e.g. Novovirus)
- ▶ The planning of measures to improve hand disinfection (e.g. furnishing with disinfectant dispenser, employee compliance, "clean hands" campaign)
- ▶ The planning of screening procedures (e.g. MRSA)
- ▶ The conception to prevent infections through water supply (e.g. Legionella)

### Do

0 1 2 3 4 5 6 7 8 9

■ Describe the actual state or the implementation of the processes, to which the criterion refers. Please include the following topics, amongst others, as far as applicable:

- ▶ The offer of and the participation in regular instructions and training seminars in respect of the management of special infectious agents
- ▶ The prophylaxis to identify an infectiological episode in the accident and emergency unit
- ▶ The infection management in case of acute viral infections
- ▶ The measures to improve the hand disinfection (e.g. furnishing of disinfectant dispensers, employee compliance, „clean hands" campaign)
- ▶ The use of screening procedures (e.g. MRSA)
- ▶ The avoidance of infections through the water supply (e.g. Legionella)



### 3 Safety

#### 3.2 Patient safety

##### 3.2.5 Management of infections



### Check

0 1 2 3

■ Describe the metrics, measurements and methods you use to revise and assess the requirements, actions and processes set forth in Plan and Do in a regular and comprehensible way:

- ▶ The inspection of ward and risk areas by specialist or hygiene officers in the previous year (especially ICU, sterile areas, surgery room areas, kitchen, pathology)
- ▶ The analysis of the disinfectant consumption per ward
- ▶ The observation of employee compliance
- ▶ The analysis of infection rates (e.g. MRSA, device-associated infections)
- ▶ The training of employees with respect to the use of personal protection equipment
- ▶ The comparison of the results with other departments or facilities

### Act

0 1 2 3

■ Describe the improvement measures you derived from the Check results:

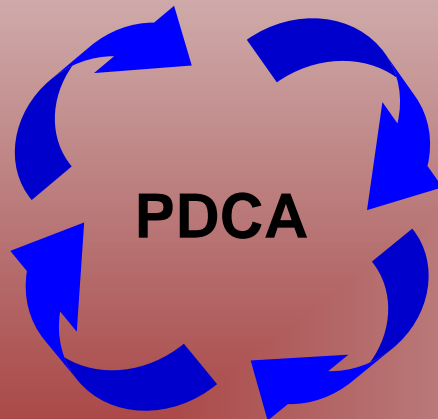
- ▶ The defined improvement measures, which have been derived from previous certification processes



# 3 Safety

## 3.2 Patient safety

### 3.2.6 Drugs



### Plan

0 1 2 3

■ Describe the planning of processes/the target state, to which the criterion refers, as well as the defined responsibilities in your institution. Please include the following topics, amongst others, as far as applicable:

- ▶ The planning to provide drugs, as well as the planning to prevent risks and mistakes in the supply and use of drugs (e.g. „adverse drug reactions“ [www.akdae.de](http://www.akdae.de))
- ▶ The regulations defining the process of purchasing
- ▶ The work of the drug commission and the implementation of the resolutions
- ▶ The regulation for the supply of drugs to patients in need of drugs not held in stock
- ▶ The short-term supply of enteral special compound, e.g. for patients with renal or liver insufficiency
- ▶ The description of the regulation:
  - With respect to the supply and storage of drugs
  - With respect to the handling of cytostatics and the preparation of aseptic solutions
  - With respect to the handling of narcotics
- ▶ The structured procedure to prevent complications during drug therapy, e.g. side effects and drug interactions, incompatibilities, overdosing

### Do

0 1 2 3 4 5 6 7 8 9

■ Describe the actual state or the implementation of the processes, to which the criterion refers. Please include the following topics, amongst others, as far as applicable:

- ▶ The safeguarding that the regulations for the process of purchasing are known to every employee in his/her operational area (e.g. purchasing)
- ▶ The safeguarding that user-specific requirements are considered in the purchasing process
- ▶ The provision of supplying suitable means for work (e.g. by participation of the employees in the preparation of the list of drugs)
- ▶ The safeguarding of a timely, structured and complete drug anamnesis upon admission of the patients by the physician or the hospital pharmacist (e.g. adverse drug reactions as cause of hospitalisation, drug dosage according to renal function, safe change over to drugs held in stock)
- ▶ The safeguarding of the aseptic preparation (e.g. solutions for total parenteral nutrition, opiates, cytostatics, antibiotics), which fall under the responsibility of the pharmacist

*Continuation of 3.2.6 ▶*

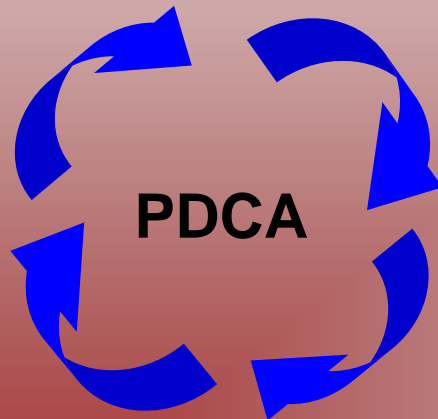




# 3 Safety

## 3.2 Patient safety

### 3.2.6 Drugs



### Check

0 1 2 3

■ Describe the metrics, measurements and methods you use to revise and assess the requirements, actions and processes set forth in Plan and Do in a regular and comprehensible way:

- ▶ The checking of the observance of the regulations by means of ward inspections (e.g. stock shortfall, expiration date)
- ▶ The filing of incidents and near-incidents related to the application of drugs
- ▶ The comparison of the results with other departments or facilities

### Act

0 1 2 3

■ Describe the improvement measures you derived from the Check results:

- ▶ The defined improvement measures, which have been derived from previous certification processes



# 3 Safety

## 3.2 Patient safety

### 3.2.6 Drugs



### Plan

0 1 2 3

■ Describe the planning of processes/the target state, to which the criterion refers, as well as the defined responsibilities in your institution. Please include the following topics, amongst others, as far as applicable:

#### *Continuation of 3.2.6*

- ▶ The hospital-internal reporting channels for adverse drug reactions, incidents and near-incidents (e.g. dosing mistakes, wrong use or confusion of drugs)
- ▶ The planning of a comprehensive and timely education
- ▶ The safeguarding that patients who receive a study medication are sufficiently supplied and will continue to receive this medication in an emergency situation

### Do

0 1 2 3 4 5 6 7 8 9

■ Describe the actual state or the implementation of the processes, to which the criterion refers. Please include the following topics, amongst others, as far as applicable:

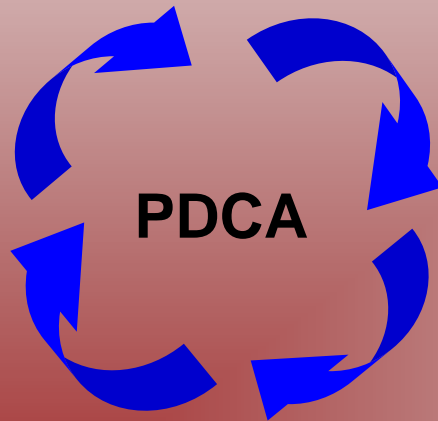
- ▶ The guarantee of a short-term availability of high-quality information with respect to adverse effects of drug therapies (e.g. interactions, compatibility of infusions, treatment of patients with renal insufficiency)
- ▶ Avoidance of mistakes (e.g. typing error, reading error, transcription error) with regard to the prescription and documentation of the drug therapy
- ▶ The safeguarding of drug supply at all times



## 3 Safety

### 3.2 Patient safety

#### 3.2.6 Drugs



### Check

0 1 2 3

■ Describe the metrics, measurements and methods you use to revise and assess the requirements, actions and processes set forth in Plan and Do in a regular and comprehensible way:

### Act

0 1 2 3

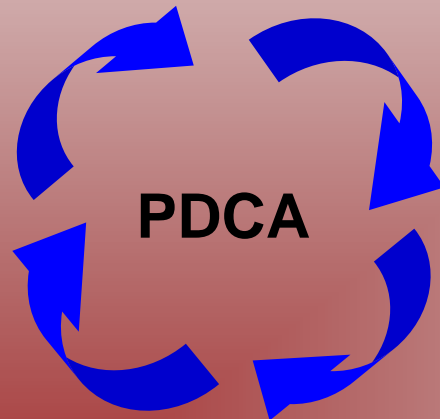
■ Describe the improvement measures you derived from the Check results:



# 3 Safety

## 3.2 Patient safety

### 3.2.7 Blood components and plasma derivatives



#### Plan

0 1 2 3

■ Describe the planning of processes/the target state, to which the criterion refers, as well as the defined responsibilities in your institution. Please include the following topics, amongst others, as far as applicable:

- ▶ The description of the quality management system with respect to the handling of blood components and plasma derivatives (e.g. in consideration of cross-guidelines of the German Medical Association)
- ▶ The description of the regulation in respect of the use of autologous and allogeneic blood

#### Do

0 1 2 3 4 5 6 7 8 9

■ Describe the actual state or the implementation of the processes, to which the criterion refers. Please include the following topics, amongst others, as far as applicable:

- ▶ The hospital-internal reporting channel for incidents and near-incidents with blood components and plasma derivatives
- ▶ To which extent there is a batch-related documentation of blood components and plasma derivatives in addition to a patient-related documentation
- ▶ The offer of and participation in regular instructions and training seminars in respect of the handling of blood components and plasma derivatives



### 3 Safety

#### 3.2 Patient safety

##### 3.2.7 Blood components and plasma derivatives



### Check

0 1 2 3

■ Describe the metrics, measurements and methods you use to revise and assess the requirements, actions and processes set forth in Plan and Do in a regular and comprehensible way:

- ▶ The internal audits with respect to the handling of blood components and plasma derivatives
- ▶ The checking of completeness of the batch-related documentation of blood components and plasma derivatives
- ▶ The checking whether the regulation of the QM system is known to the respective users in the departments
- ▶ The expiration rates of supplied and used blood components and plasma derivatives
- ▶ The comparison of the results with other departments or facilities

### Act

0 1 2 3

■ Describe the improvement measures you derived from the Check results:

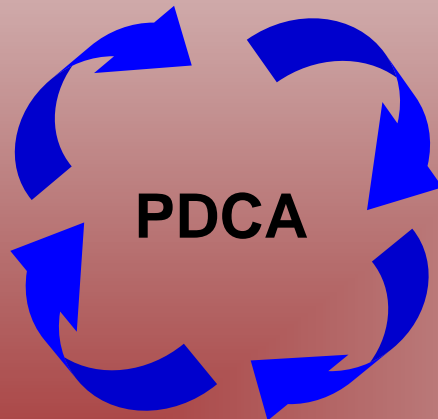
- ▶ The defined improvement measures, which have been derived from previous certification processes



# 3 Safety

## 3.2 Patient safety

### 3.2.8 Medical devices



## Plan

0 1 2 3

■ Describe the planning of processes/the target state, to which the criterion refers, as well as the defined responsibilities in your institution. Please include the following topics, amongst others, as far as applicable:

- ▶ The description of the procedures and instructions with respect to the handling of medical devices (MD)
- ▶ The regulation with respect to the conditioning of medical devices
- ▶ The regulation with respect to the handling of sterile materials (e.g. storage, expiration date)
- ▶ The naming of persons to receive instructions on medical devices, e.g. pursuant to the German Medical Device Operator Ordinance (MPBetreibV)
- ▶ The planning that the persons commissioned by the operator are known to the users
- ▶ The regulation with respect to the instruction of the users of medical devices, e.g. pursuant to annex 1 of the German Medical Device Operator Ordinance (MPBetreibV)
- ▶ The planning with respect to the documentation of the employee instruction
- ▶ The determination of the need to instruct
- ▶ The regulation for the supply of medical devices

## Do

0 1 2 3 4 5 6 7 8 9

■ Describe the actual state or the implementation of the processes, to which the criterion refers. Please include the following topics, amongst others, as far as applicable:

- ▶ The definition of the operator-interfaces between medicine and technology
- ▶ The accessibility of the medical device log for the using employees
- ▶ The safeguarding that the internal incidents and near-incidents with medical devices are documented and forwarded (e.g. German Federal Institute for Drugs and Medical Devices [BfArM])
- ▶ The existence of the following documentations:
  - Inspections by way of measurement technique
  - Safety engineering inspections
  - Inspections of electrical systems and equipment
- ▶ The existence of the inventory of medical devices
- ▶ The possibility of testing medical devices
- ▶ The safeguarding that user-specific requirements are considered in the purchasing process
- ▶ The safeguarding that the requirements in terms of hygiene and ecology, as well as occupational safety aspects are considered in the purchasing process



### 3 Safety

#### 3.2 Patient safety

##### 3.2.8 Medical devices



### Check

0 1 2 3

■ Describe the metrics, measurements and methods you use to revise and assess the requirements, actions and processes set forth in Plan and Do in a regular and comprehensible way:

- ▶ The collection, reporting and analysis of incidents and near-incidents during the use of medical devices
- ▶ The continuous checking and improvement of the procedure and instructions
- ▶ The checking to ensure that the maintenance of the medical devices is performed by qualified staff
- ▶ The checking that in case of and after repairs only repaired medical devices are used on the ward
- ▶ The comparison of the results with other departments or facilities

### Act

0 1 2 3

■ Describe the improvement measures you derived from the Check results:

- ▶ The defined improvement measures, which have been derived from previous certification processes



# Core elements of the KTQ procedure (I)

## Step 1: Self-assessment



An overview of the practice based on the requirements described in the KTQ catalogue.

## Step 2: External assessment / visitation

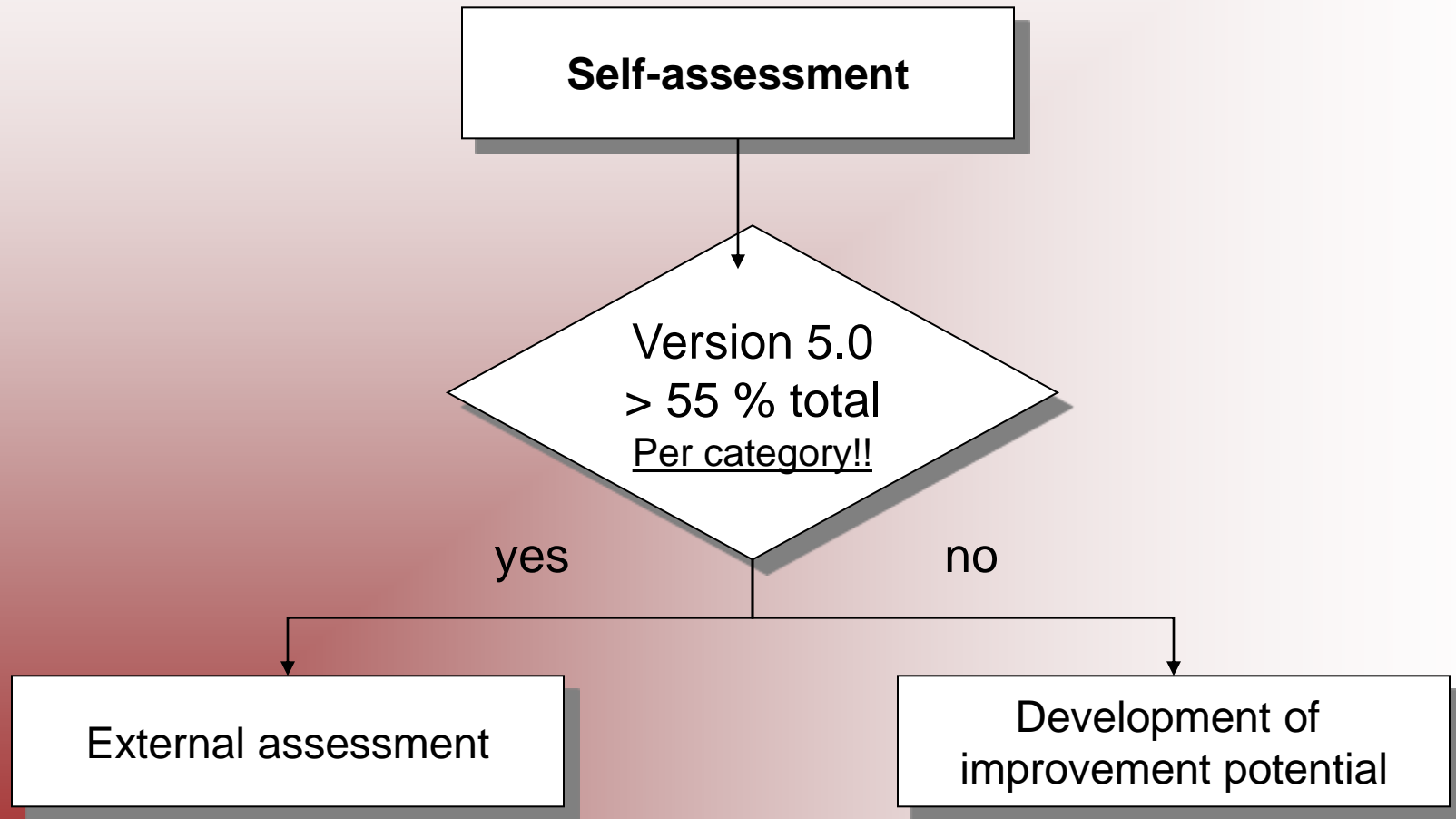


Following self-assessment, the practice **may** choose to apply via a KTQ certification agency for an external KTQ assessment.





# Self-assessment





## Core elements of the KTQ procedure (II)

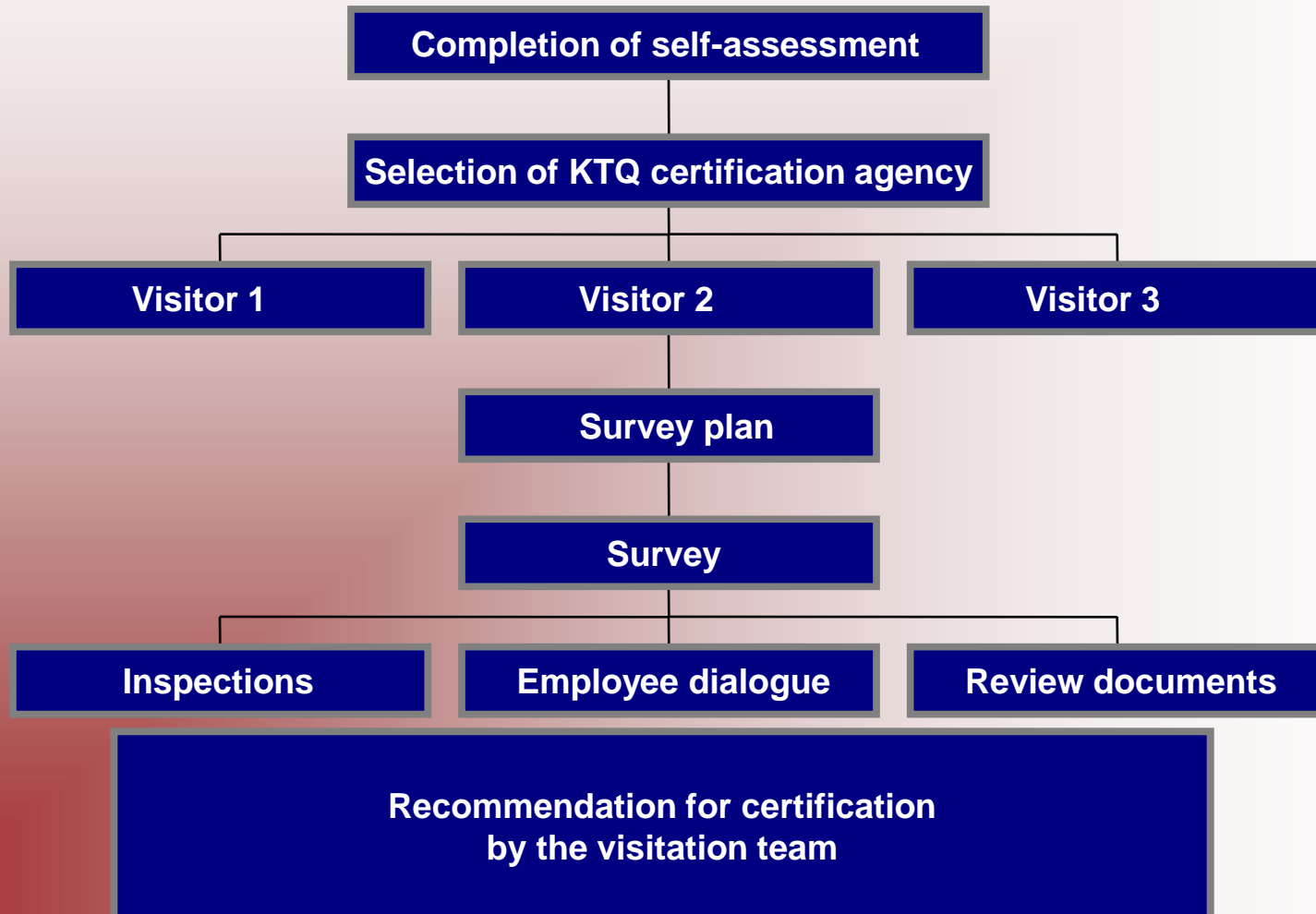


Step 3: Publication of the  
KTQ-Quality Report

The KTQ-Quality report describes the specific performance of the hospital and makes it transparent to the public.



# The KTQ Visitation Procedure



# KTQ-Certificate

- Recommended by the KTQ-Visitors
- Awarded by the KTQ-GmbH
- Valid for 3 years
- **Remark**
  - certified since:  
XX.XX.XXXX





# THANK YOU

**for your Interest and your Attention.**