

Hygiene Policies in European Health Care Facilities - How to Harmonize the Discrepancies in Europe-

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2.1 Regulatory Organization of Hospital Hygiene and Infection Prevention in Germany

Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz - IfSG)

IfSG

Infection Prevention Act, last amendment Febr. 2020

→ legality valid document for whole Germany

→ § 23: Nosocomial Infections ; Antibiotic resistance; Regulations in Federal States of Germany

§ 23 Abs. 1 and 2 IfSG

- Establishing the Commission for Hospital Hygiene and Infection prevention (KRINKO)
- Establishing the Commission of Antiinfectives; Resistance and Therapy (ART)

at the German Federal Robert Koch Institute (RKI), which has to organize the Commissions



www.rki.de

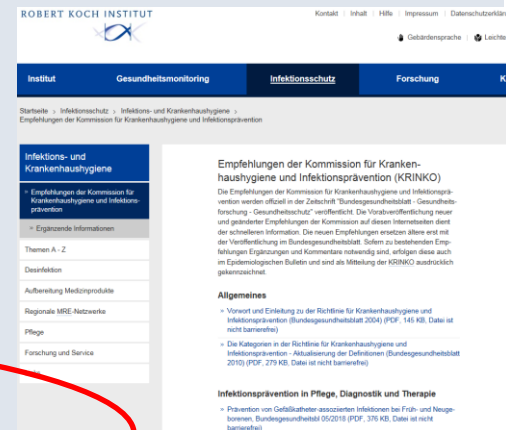
KRINKO is mandated by German law

The task of KRINKO is to work on guidelines

- to prevent nosocomial infections and give recommendations for
- organizational and operative measures
- constructional and functional measures

in hospitals and other health care facilities

The guidelines/recommendations represent
the state of the scientific and technical knowledge



Topics are available at www.rki.de

- Basic hygiene to prevent and minimize transmission of pathogens:
 - hand hygiene, reprocessing of surfaces and medical products/ devices, endoscopy, dealings with infectious patients, clothes, waste, food, water, ...
- Prevention of device-associated nosocomial infections and post-operative surgical sites infections,
- Hygiene for special groups such as newborns, immunocompromised patients, ..
- Hygiene regarding multidrug resistant organisms (MRSA, VRE, MRGN (multidrug resistant gramnegative bacteria) and infection prevention of C. diffile
- Recommendations for hygiene organization and data for hygiene personnel...

2.1: Are there sanctions for non-compliance ?

- Public health authorities are obliged by law for infection control of medical institutions and facilities; they can charge fines or hand out a punishment for not obeying the KRINKO recommendations
- Fines often cheaper for hospitals than implementation of standards by law
- Civil law acts take KRINKO-recommendations as basis for state of scientific and technical knowledge in legal disputes between patient and hospital in case of a nosocomial infection
- For the hospital is imminent:
 - possible damages for patients pain and suffering,
 - loss of image,
 - scandal

2.2. Training and further education

Licensing Regulations for Physicians (Approbationsordnung) → *legality in whole Germany, but*

- “Hygiene” is listed together only with Microbiology and Virology, Especially there is no subject “Hospital hygiene and infection prevention”
 - Faculties of Medicine determine the extent of hours for Hygiene for themselves
- Great differences between the universities and the education of medical students

2.2. Training and further education

- Hospital hygiene and infection prevention for its own is not a binding examination subject at medical faculties or in medical schools when training nursing staff.
 - Throughout the later career of doctors and nurses they receive further education and training in the fields of hospital hygiene and infection prevention in line with KRINKO guidelines and by law regulations of Federal States of Germany (different extent).
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2.3 Use of Antibiotics in Germany

For the outpatient treatment of community-acquired infections **antibiotics are available on prescription only**

Mandatory regulations on the use of antibiotics:

- Infection Prevention Act § 23 (3): The Commission of Antiinfectives; Resistance and Therapy (ART) has to work on recommendations for the use of antibiotics → **no recommendation till now**
- Infection Prevention Act (IfsG) § 23 (4): Hospitals have to perform a surveillance of the specific consumption of antibiotics
- Guidelines from the scientific societies
- There is a national antibiotic stewardship program → DART (German Antibiotic-resistance strategy)

2.5 Staffing: What is the patient/nursing staff ratio in your country?

Regulation to
this topic →

Verordnung
zur Festlegung von Pflegepersonaluntergrenzen in pflegesensitiven Bereichen in Krankenhäusern
(Pflegepersonaluntergrenzen-Verordnung – PpUGV)

Vom 28. Oktober 2019

It determines the lower limit of nursing staff,
in the first instance for special units, in future there will be a fixed total
number of nursing staff for the entire hospital.

patient-nursing staff-ratio for medical units with complex and elaborate care

	Intensiv care	Geriatrics	Trauma surgery	Cardio-surgery	Cardiology	Neurology	Stroke Unit	Early Neurology Rehabilitation
Day shift	2.5 to 1	10 to 1	10 to 1	7 to 1	12 to 1	10 to 1	3 to 1	5 to 1
Night shift	3.5 to 1	20 to 1	20 to 1	15 to 1	24 to 1	20 to 1	5 to 1	12 to 1

2.7 Cleaning, Disinfection, Sterilisation

For cleaning, disinfection and sterilisation of medical devices hospitals and other medical facilities have to adhere to this law in Germany:

- Medical Devices Act (MPG)
- Ordinance on Medical Devices (MPV)
- Ordinance on Installing, Operating and Using Medical Devices (Medical Devices Operator Ordinance (MPBetreibV))
- Medical Devices Safety Plan Ordinance (MPSV)



Ordinance on Installing, Operating and Using Medical Devices (Medical Devices Operator Ordinance (MPBetreibV))

→ KRINKO/BfArM Guideline determines the process and is revised e.g. when law changes

Hygiene Requirements for the Reprocessing of Medical Devices

Bundesgesundheitsbl 2012 · 55:1244–1310
DOI 10.1007/s00103-012-1548-6
© Springer-Verlag 2012

Epidemiologisches Bulletin

8. Februar 2018 / Nr. 6 AKTUELLE DATEN UND INFORMATIONEN ZU INFIZIÖSEN KRANKHEITEN UND PUBLIC HEALTH

Ergänzung zur Empfehlung „Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten“ der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte (BfArM)

Diese Woche 6/2018

Ergänzung zur Empfehlung Anforderungen an die Krankenhaushygiene

Validation according to EN 15883 is demanded, further controls are recommended to ensure the efficacy of the process

→ **quality management**



Cleaning and disinfection of surfaces

KRINKO guideline “Hygiene Requirements on the Cleaning and Disinfection of Surfaces”, Bundesgesundheitsbl 47 (2004): 51-61

English translation by the German Society of Hospital Hygiene (DGKH),
www.krankenhaushygiene.de/english-information/

Amongst other issues, it defines

- risk areas, disinfection intervals,
- the targeted spectrum of activity,
- addresses the correct dosage of disinfectants,
- makes demands on training and supervision of cleaning staff,
- gives advices for storage of cleaning and disinfection utensils
- and defines the durability of furniture and equipment.

Controls of surface disinfection are recommended to ensure the efficacy of the process
→ Quality control

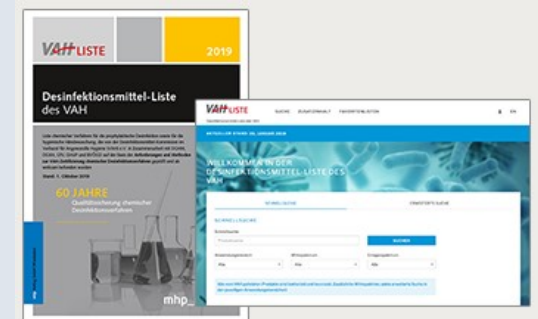


Disinfectant lists: VAH list,

The German Disinfectant Commission of the Association of Applied Hygiene (VAH) is an independent expert panel.

Its tasks include the development of guidelines and standards for efficacy tests, and all valid European standards are integrated in the VAH test methods.

The VAH Disinfectant Commission compiles a list of effective disinfectants tested according to the VAH-Standard Methods.



01.01.2018

> Ab 1.1.2018: Kostenfreier OPEN-ACCESS-Service für die VAH-Liste Online

www.vah-online.de

RKI list

Bekanntmachungen – Amtliche Mitteilungen

Bundesgesundheitsbl 2017 - 60:1274-1297
<https://doi.org/10.1007/s00103-017-2634-6>
 © Springer-Verlag GmbH Deutschland 2017

Bekanntmachung des Robert Koch-Institutes

Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und -verfahren

Stand: 31. Oktober 2017 (17. Ausgabe)

www.rki.de

→ used for disinfection with special pathogens (e.g. virucidal efficacy)
or by order of public health authorities

2.8 Hygienic-Microbiological Environmental Tests

- There are different methods to check the success of cleaning and disinfection with e.g. visual control, measurement of ATP and so on.

Only hygienic-microbiological tests allow a counting and to detect special bacteria, fungi, and spores.

- There is an old recommendation from KRINKO for hygienic-microbiological environmental tests but without guide values. This is in state of revision.
- There are some topics with boundary or guide values for cleaned and disinfected area e.g. for air conditioning systems or surfaces in food industry. They are not mandated by law.
- If there is evidence for a lack of cleaning/disinfection efficacy
 - hospital hygiene staff has to check the whole process together with cleaning staff.
 - the cause of contamination has to be detected.

2.9 Structural-Functional Criteria in Germany

- This topic has to be contained in guidelines of KRINKO (mandated by law)
 - Most scientific professional societies cover it in their Guidelines
 - In some Federal States of Germany there are guidelines from the ministry of health for hospitals which want to get subsidies
 - Most regulations for hospital hygiene in Federal States of Germany contain demands on structural-functional configuration
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2.9 Structural-Functional Criteria in Germany

There are specific recommendations for the construction of

- o surgical units
- o intensive care units
- o haemato-oncological wards
- o neonatal intensive care units
- o neurological early rehabilitation facilities
- o normal wards

Are there recommendations on the number of beds / rooms?	yes
Are there recommendations for water supply and sewage systems?	yes
Are there any recommendations for sanitary facilities?	Yes

→ but not all mandated by law or by KRINKO recommendation

3. Causes, Deficit Analysis and Need for Optimisation

The most important problem regarding nosocomial infections in our opinion is the

→ **lack of implementation of these regulations and guidelines in practice** because of

- lack of education for doctors and nursing staff in hospital hygiene and infection prevention
- lack of nursing staff
- lack of experts specialized on hospital hygiene
- insufficient hospital cleaning and disinfection
- not enough antibiotic stewardship (hospital and ambulatory setting)
- too many therapies in hospitals instead of ambulatory?

We have to ensure compliance with standards and principles

- Standards for assessing compliance with guidelines should be established (conformity assessment)
- Offences and deliberate infringements should be punished in a more powerful way

The EU (Directives) or other European institutions could help to achieve these targets